

Studie 091
(CTN: 20124/ADE 091)

Studienbericht

FCE 20124/706 i

REBOXETINE	CLINICAL STUDY REPORT
FCE 20124	CTN:20124/ADE 091

COVER PAGE

TITLE:

Phase II Placebo-Controlled Clinical Study with Reboxetine in Major Depressions

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DATE: November 17, 1993

NUMBER OF PAGES: 1577

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REBOXETINE	CLINICAL STUDY REPORT
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TITLE: PHASE II PLACEBO-CONTROLLED
CLINICAL STUDY WITH REBOXETINE IN
MAJOR DEPRESSIONS

PRODUCT: REBOXETINE

CTN.: 20124/ADE 091

PHASE OF STUDY: II

REPORT STATUS: FINAL

REPORT DATE: November 17, 1993

START DATE: April 1989

COMPLETION DATE: November 1990

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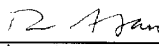
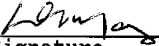
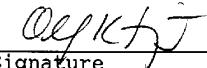
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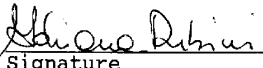
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Product: REBOXETINE
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REBOXETINE - PROTOCOL ADE 091

SYNOPSIS

Name of Company: Pharmacia	Individual study Table referring to part IV of the dossier	(For national authority use only)
Name of finished product:	Ref.:	
Name of active ingredient(s): Reboxetine	Vol.:	
	Page:	
Title of the study:	Phase II Placebo-Controlled Clinical Study with Reboxetine in Major Depressions	
Investigators:	Dr. Guy Chouinard, Dr. Mohamed Amin, Dr. Marcio Versiani	
Study centres:	no. 3 centres involved, from Montreal, Pointe Claire, Rio de Janeiro: Clinical Pharmacology Unit, Allan Memorial Institute, Montreal, Canada Lakeshore General Hospital, Pointe Claire, Canada Instituto de Psiquiatria, Rio de Janeiro, Brazil	
Publication (reference):		
Study period:	Dec 1989 -Nov 1990	Clinical Phase: II
Objectives:	To test the hypothesis that RBX in a daily dose of 6 to 10 mg is a therapeutically superior to placebo, well-tolerated and safe drug in major depressions, as well as to identify the time of onset of therapeutic effects; to identify therapeutically responsive subform(s) within major depressive disorders; to provide further evidence of tolerability of Reboxetine in the daily dose from 6 to 10 mg over a period of 42 days.	
Methodology:	The study was a multinational, multi-center double-blind parallel group, placebo controlled clinical trial, in which patients were randomly assigned to one of the treatment groups. The patients had to fulfill DSM-III-R criteria of major depression. The total score of the HAMD Scale (21 items) had to be of 20 or above. After a seven-day single blind placebo washout period patients were treated either with RBX on the basis of a fixed changing dosage regime and divided dosage scheme, or PBO for 42 days. Each patient was evaluated at regular intervals by 1 of the 4 assessor. Every patient was looked after the same assessor, who, on the basis of the results of the examination completed a battery of tests providing specific information on therapeutic efficacy, tolerability, safety, benefit/risk ratio and indirect indications of efficacy at termination and follow-up.	
Number of subject (total and for each treatment):	A total of 56 patients were recruited, 44 in Brazil and 12 in Canada: 28 patients were allocated to RBX and 28 to PBO	
Diagnosis and criteria for inclusion:	Subjects recruited in the two countries were affected by a major depressive episode according DSM-III-R criteria. The age was between 18 and 65. The HAMD score had to be of 20 or above at day 0 assessment. Absence of pregnancy, presence and/or history of Schizophrenia, Schizophreniform Disorder, Delusional Disorder, or Psychotic Disorder NOSS (not otherwise specified), substance abuse according to DSM-III-R. The patients included were not to be affected by severe medical illness, medical disorders requiring a chronic pharmacological treatment and/or interfering with pharmacokinetics of RBX.	
Test product:	Capsules containing 2 mg of reboxetine (free base) as methanesulphonate salt.	

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<p>Daily dose: 6-10mg of reboxetine. Day 1 6mg/day of reboxetine or placebo: 1 capsule in the morning and 2 capsules in the evening. Day 2: 8 mg /day of reboxetine or placebo: 2 capsules in the morning and 2 capsules in the evening. Day 3-42 10 mg/day of reboxetine or placebo: 2 capsules in the morning and 3 capsules in the evening. Medication administered in the morning at 10.00 am and in the evening at 8.00 pm.</p> <p>mode of administration: by oral route.</p> <p>batch no.: SF898, SF967</p>
<p>Duration of treatment: 42 days</p>
<p>Reference therapy: placebo (excipients alone) indistinguishable capsules administered b.i.d</p> <p>mode of administration: by oral route.</p> <p>batch no.: SF897,SF1039</p>
<p>Criteria for evaluation:</p> <p>efficacy criteria: Study end-points: reduction of HAMD Total Score at subsequent assessments; frequency of clinically significant treatment response defined as 50% reduction in the HAMD Total Score over the course of the clinical trial. Secondary efficacy criteria: CGI, ZUNG-SRDS changes.</p> <p>safety criteria: Vital signs, ECG, EEG, laboratory tests were monitored and adverse events were collected by NOSS schedule (Newly Observed Signs and Symptoms).Frequencies of blood pressure values outside the normal range (systolic below 100 or above 140 Hgmm) and of systolic postural drops were calculated as well as frequencies of heart rate acceleration > 10% vs baseline. Frequencies of abnormal laboratory values were calculated.</p>
<p>Statistical methods: Efficacy analyses were primarily based on covariance analyses, repeated measures analyses of variance and chi-square comparison; tolerability and safety analyses were primarily based on descriptive statistics. In all analyses the SPSS-X/SPSS-PC+ statistical package was employed.</p>
<p>Summary- Conclusions : Of the 28 patients admitted to each of the two treatment groups, 27 and 25 were considered evaluable for efficacy in the reboxetine and placebo groups, respectively. Of these, 23 and 9 cases completed the study, respectively (3 and 15, respectively, dropped for lack of response; 1 per group for adverse effects, i.e. hypomania in the reboxetine and agitation in the placebo group). Primary and secondary efficacy assessments as well as tolerability evaluations showed that in this six-week, double-blind, placebo-controlled clinical trial in patients with the DSM-III-R Axis I diagnosis of major depression, RBX in the daily dose range from 6 mg to 10 mg was a therapeutically effective, well-tolerated and safe drug. Onset of therapeutic effects, based on the assessments (judgments) of external assessors (observers), were detectable by the 10th day of treatment and, based on the experienced patients, by the 14th day. The primary effect of RBX was on depressed mood, the nuclear symptom of depression: alleviation of depressed mood preceded the alleviation of the arousal manifestations, such as insomnia and activities, and other affective manifestations, such as anxiety and somatic symptoms, of depressive illness.</p>

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1. DISCUSSION AND SUMMARY

1.1 A Phase II placebo-controlled clinical study with reboxetine (RBX) in major depression was conducted with the participation of three centers: two in Canada and one in Brazil.

1.2 The material used in the clinical study consisted of capsules of either 2 mg RBX with excipients or excipients only supplied by Farmitalia Carlo Erba Galenic Department.

1.3 The purpose of the clinical study was to test the hypothesis that RBX in the daily dosage of 6 to 10 mg is a therapeutically effective, well-tolerated and safe drug in major depression, as well as to identify the time of onset of therapeutic effects.

1.4 The study was a multinational, multi-center clinical trial which followed a double-blind, placebo-controlled, parallel group design in which patients fulfilling DSM-III-R criteria of major depression, with a total score of 20 or above on the 21-item HAMD, were randomly assigned to one of two groups and after a seven-day placebo washout were treated with either RBX or placebo (PBO) for 42 days on the basis of a fixed increasing dosage regime and divided dosage schedule.

1.5 Each patient included in the clinical trial was evaluated at regular intervals from the time of the screening to the time of the follow-up examination by 1 of the 4 assessors, with the same assessor assessing the same patient throughout the clinical trial; and on the basis of these evaluations a specially devised battery of tests was completed providing information on therapeutic efficacy, tolerability, safety, benefit/risk ratio and indirect indications of efficacy at termination and follow-up.

1.6 A total of 56 patients were recruited to participate in the study: 44 patients in Brazil and 12 patients in Canada.

1.7 The populations recruited in the two countries were comparable in all but five variables: the number of prior depressive episodes was higher and the presence of precipitating factor, insidious onset and psychotic features was more frequent in the Canadian population, whereas the presence of single (first) episode was more frequent in the Brazilian population.

1.8 The two treatment groups -- RBX and PBO, 28 patients each -- in the total recruited population were comparable in term of personal and physical characteristics, as well as in terms of the characteristics of their depressive illness.

1.9 From the total recruited population of 56 patients, 4 patients were non included in the analytic cohort: 2 patients (1 each from RBX and PBO groups) because of missing information relevant to thyroid functions, 1 patient (from the PBO group) because of refusal to continue with treatment and another (from the PBO group) because of severe worsening of depression during the first week of treatment.

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1.10 No patient was excluded from the analytic cohort of the total recruited population because of a 20 percent or greater decrease in HAMD total scores during the pretreatment washout; and 1 patient from the RBX group was retained in spite of a greater than 20 percent increase of HAMD Total Score during the first 14 days of treatment.

1.11 The two treatment groups -- RBX: 27 patients and PBO: 25 patients -- of the analytic cohort were comparable in terms of personal and physical characteristics, as well as in terms of the characteristics of their depressive illness.

1.12 Of the 52 patients of the analytic cohort, 32 (61.5%) completed the clinical trial with significantly ($p < .001$) more completers from the RBX (23 patients) than from the PBO (9 patients) group.

1.13 Of the 20 (38.5%) prematurely terminated patients 2 (10%) were discontinued for adverse effects -- 1 patient from the RBX and 1 patient from the PBO group -- and 18 (90%) were discontinued for lack of therapeutic response -- 3 from RBX and 15 from the PBO group.

1.14 Of the 2 patients discontinued for adverse effects, 1 patient from the RBX group was taken off the clinical trial because of the development of hypomania and 1 patient from the PBO group was taken off the clinical trial because of the development of agitation.

1.15 In 2 completing patients from the RBX group the dosage of medication was transiently decreased because of adverse effects (tremor and insomnia in 1 patient , vomiting in the other).

1.16 All patients in the analytic cohort complied with taking the study medication as prescribed.

1.17 Evaluation of therapeutic efficacy, including the onset and profile of therapeutic activity was based on the analyses of data recorded on the HAMD , ZUNG and the SI and GI components of the CGI.

1.18 There was a significantly ($p < .001$) greater increase (improvement) in mean total scores of the HAMD from Day 0 to Day 42 in the RBX- (from 35.7 to 12.6) than in PBO- (from 35.1 to 30.6) treated group.

1.19 Significantly ($p < .001$) more patients attained a 50 % of greater decrease (improvement) in the mean total scores of HAMD in the RBX- (20 patients; 74.1%) than in the PBO- (5 patients; 20.0%) treated group.

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1.20 By the time of the Day 10 assessment the decrease (improvement) of mean total scores of the HAMD was significantly ($p=0.006$) greater in the RBX- than in the PBO- treated group, indicating an onset of therapeutic activity for RBX within 10 days of commencement of treatment.

1.21 There was a significantly ($p=0.044$) greater decrease (improvement) of depressed mood by Day 10, insomnia ($p=0.006$) and activities ($p=0.003$) by Day 14 and anxiety ($p<0.001$) and somatic symptoms ($p<0.001$) by Day 21 in the RBX- than in the PBO- treated group, indicating that the primary effect of RBX is on the nuclear symptom (depressed mood) of depressive illness, and that the alleviation of depressed mood precedes the favorable changes on accessory symptoms related to arousal (insomnia and activities) and other affective (anxiety and somatic symptoms) parameters.

1.22 There was a significantly ($p=0.001$) greater decrease (improvement) in mean total scores of the ZUNG from Day 0 to Day 42 in the RBX- (from 66.3 to 42.8) than in the PBO (from 65.2 to 58.6) treated group.

1.23 By the time of the Day 14 assessment the decrease (improvement) of ZUNG total scores was significantly ($p=0.035$) greater in the RBX- than in the PBO-treated group, indicating that the onset of therapeutic activity for RBX in patient's experience is within 14 days of commencement of treatment.

1.24 There was a significantly ($p=0.001$) greater decrease (improvement) in mean scores of the CGI-SI from Day 0 to Day 42 in the RBX- (from 57.6 to 2.07) than in the PBO-treated group (from 5.40 to 4.24).

1.25 By the time of the Day 14 assessment the decrease (improvement) of mean CGI-SI was significantly ($p=0.025$) greater in the RBX- (from 5.74 to 3.78) than in the PBO (from 5.40 to 4.56) treated group.

1.26 Global improvement, as measured by the CGI-GI, was significantly ($p<0.001$) greater at the time of termination of treatment in terms of mean CGI-SI scores (RBX: 1.56 and PBO: 3.40) and in terms of number of patients showing much to very much improvement in the RBX- (22 patients) than in PBO- (7 patients) treated group.

1.27 By the time of the Day 14 assessment, global improvement, as measured by the CGI-GI, was significantly ($p<0.001$) greater in terms of mean CGI-GI scores (RBX: 2.41 and PBO: 3.32) in terms of number of patients showing very much and much improvement in the RBX - (15 patients) than in the PBO- (5 patients) treated group.

1.28 Therapeutic effects of RBX (as measured by a significantly greater improvement with the drug than with an inactive placebo) began by Day 10 of treatment by favorable changes in the depressed mood and in the HAMD total scores; and was followed by Day14 of treatment

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by favorable changes in ZUNG total scores, composite scores of insomnia and activities, and CGI scores of SI ad GI; and by Day 21 of treatment by favorable changes in composite scores of anxiety and somatic symptoms.

1.29 Improvement with RBX, detectable by external assessor (HAMD Total Score) preceded improvement experienced by the patient by approximately four days.

1.30 Six of the 21 newly observed signs and symptoms (i.e., dizziness, headache, insomnia, constipation, agitation and sexual disturbances) which were reported in the course of the clinical trial were encountered in 4 patients -- 3 to be treated with PBO and 1 to be treated with RBX-- already prior to commencement of treatment on Day 0 after the pretreatment washout period.

1.31 Of the 21 newly observed signs and symptoms encountered in 37 patients from Day 4 to Day 42 of the clinical trial, 18 were encountered in 24 patients in the RBX group; 13 were encountered in 13 patients in the PBO group; and 10 were encountered in 35 patients in both treatment groups (i.e., RBX: 22 patients and PBO: 13 patients).

1.32 Eight newly observed signs and symptoms (i.e., insomnia, urinary retention, sweating, cold extremities, hypotension, decrease appetite, pruritus and hypomania) were encountered only in the RBX- treated group, whereas three newly observed sign and symptoms (i.e., urinary incontinence, diarrhea and lassitude) were encountered only in the PBO-treated group.

1.33 In both treatment groups spontaneously reported newly observed signs and symptoms outnumbered newly observed signs and symptoms elicited by inquiry (RBX: 143 vs 69 patients); PBO: 39 vs 15 patients.

1.34 The onset of all but two (i.e., pruritus and hypomania) newly observed signs and symptoms in the majority of patients in the RBX-treated group was within the first 10 days of treatment, although the onset of sexual disturbance in 1 patient was as late as the 35 day and the onset of blurred vision in 1 patient was as late as 28th day of treatment.

1.35 With the exception of blurred vision at Day14, the onset of all newly observed signs and symptoms in the PBO-treated group was within the first seven days of treatment.

1.36 The mean number of days newly observed signs and symptoms were present in the 24 RBX- treated patients with newly observed signs and symptoms was significantly ($p<.001$) longer (mean 10.22 +/- 7.66 days) than the mean number of days newly observed signs and symptoms were present in the 13 PBO-treated patients with newly observed signs and symptoms (mean 2.72 +/-2.86 days).

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1.37 Duration of the 18 newly observed signs and symptoms ranged from 1 to 39 days in individual patients in the RBX group and the duration of 13 newly observed signs and symptoms ranged from 1 to 11 days in individual patients in the PBO group.

1.38 The mean number of days the 18 different newly observed sign and symptoms were displayed in the RBX-treated group ranged from 1 (cold extremities) to 17.2 (sexual disturbances) days and the mean number of days the 13 newly observed signs and symptoms displayed in the PBO-treated group ranged from 1 (blurred vision) to 6.13 (dry mouth).

1.39 Severity of the 216 reports of newly observed signs and symptoms was significantly ($p=.038$) more frequently reported as "severe" in the RBX- (13 patients; 6.0%) than in the PBO- (1 patient; 1.85%) treated group.

1.40 Counteractive measures --regardless of their nature-- were recorded in a similar proportion of the reports of newly observed signs and symptoms in the RBX- (103 reports; 47.7%) treated group and in the reports of newly observed signs and symptoms in the PBO- (26 reports; 47.3%) treated group.

1.41 The number of patients discontinued for adverse effects was the same in the RBX- (1 patients) and in the PBO- (1 patient) treated groups.

1.42 To counteract newly observed signs and symptoms, i.e., agitation, headache, insomnia, urinary retention and constipation in 4 RBX treated patients, chloral hydrate, acetaminophen, diazepam, urecholine, and/or surfak was given. And to counteract headache in 1 PBO- treated patient, acetaminophen was administered.

1.43 In 1 RBX- treated patient three newly signs and symptoms, i.e., sweating, decreased appetite and sexual disturbance, persisted after discontinuation of treatment for three, five and three days, respectively.

1.44 Of the 271 reports of newly observed signs and symptoms 165 (61.1%) were attributed definitely (certain) to the treatment with a significantly ($p<.001$) greater number of newly observed signs and symptoms attributed to treatment with RBX (145 reports; 67.1%) than with PBO (20 reports; 37.7%).

1.45 The number of patients with blood pressure (lying and standing) readings outside the normal range were comparable in the two treatment groups within the first days of treatment.

1.46 A decrease of systolic pressure from lying to standing was encountered consistently in more patients in the RBX- than in the PBO- treated group during the first four days of treatment, but in none of these patients was the drop of systolic pressure clinically significant or sufficiently prominent to be considered an adverse effect.

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1.47 The number of patients with acceleration of heart rate from lying to standing were comparable within the first four days of treatment in the two treatment groups.

1.48 There was a significantly ($p=.036$) greater decrease of standing systolic blood pressure (but not of lying systolic or diastolic blood pressure) from Day 0 to Day 42 in the RBX- (from 121.3 Hgmm to 116.8 Hgmm) than in the PBO- (from 118.7 Hgmm to 118.0 Hgmm) treated group, but only in 3 RBX treated patients was hypotension sufficiently prominent to be reported as in adverse effect.

1.49 There was no significant difference in heart rate changes between the two treatment groups in the course of the clinical trial.

1.50 There was no significant difference in weight changes between the two treatment groups in the course of the clinical trial.

1.51 The percent of patients with out-of-range values in the 10 tests subsumed under hematology increased similarly in the RBX- and PBO-treated group from pretreatment to termination of treatment. None out-of-range values in any of the patients was of clinical significance.

1.52 The percent of patients with out-of-range values in 22 tests subsumed under blood chemistry increased in the RBX-treated group in 6 cases (Ca⁺⁺, blood sugar, alkaline phosphatase, creatinine, cholesterol, tryglicerides) and in the PBO-treated group in 4 cases (blood sugar, creatinine, total bilirubin and triglycerides) from pretreatment to termination of treatment. None of the out-of-range values in any of the patients was clinical significance.

1.53 The number of patients with out-of-range urinalysis values were comparable in the two treatment groups; none of the out-of-range values in any of the patients was of clinical significance.

1.54 The number of patients with abnormal ECG tracing remained the same from pretreatment to termination of the clinical trial in both treatment groups.

1.55 By the time of termination of treatment, a significantly ($p=.023$) greater number and higher proportion of patients were discharged from the RBX- (13 patients; 48.1%) than from the PBO- (4 patients; 14.8%) treated group.

1.56 After discontinuation of the clinical trial a significantly ($p=.002$) greater number and higher proportion of patients were prescribed pharmacologic treatment in the PBO- (19 patients; 70.4%) than in the RBX- (7 patients; 26.9%) treated group.

1.57 Abrupt discontinuation of treatment with RBX was safe and did not yield withdrawal effects.

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1.58 One month after discontinuation of the clinical trial, twice as many PBO- (4 patients) than RBX-(2 patients) treated patients were still hospitalized.

1.59 One month after discontinuation of the clinical trial, a significantly ($p < .001$) greater number and higher proportion of patients were still on one or another antidepressant medication (imipramine, amitriptyline or desipramine) from the PBO- (19 patients; 73.1%) than from the RBX- (6 patients; 23.1%) treated group.

1.60 Investigator choice to continue with the treatment the patients was receiving during the 42 days of drug administration after termination of the clinical trial was "definitely yes" in a significantly ($p = .001$) greater number and higher proportion of patients from the RBX- (19 patients; 76.0%) than from the PBO- (4 patients; 16.7%) treated group.

1.61 CONCLUSIONS In a six-week, double-blind, placebo-controlled clinical trial in patients with the DSM-III-R Axis I diagnosis of major depression, RBX in the daily dose range from 6 mg to 10 mg was found to be a therapeutically effective, well-tolerated and safe drug. Onset of therapeutic effects, based on the assessments (judgments) of external assessors (observers), were detectable by the 10th day of treatment and, based on the experienced patients, by the 14th day. The primary effect of RBX was on depressed mood, the nuclear symptom of depression: alleviation of depressed mood preceded the alleviation of the arousal manifestations, such as insomnia and activities, and other affective manifestations, such as anxiety and somatic symptoms, of depressive illness.

2. REPORT COMPOSITION

The study was carried out using traditional assessment instruments as well as a non traditional diagnostic system newly developed (CODE-DD). The present report includes the results of the study related to the traditional assessments, while the CODE-DD data will be provided in an "ad hoc" report, edited as an Addendum to the present report.

3. IDENTITY OF THE TEST MATERIAL

The drug supply consisted of capsules containing either 2 mg of RBX plus excipients (batch nos. SF898, SF967) or excipients only (placebo batch. Nos. SF 897, SF 1039), manufactured by the Galenic Department of Farmitalia Carlo Erba. Certificates of analyses for batches SF898 (FCE 20124 hard gelatin capsules, with each capsule containing 2 mg of the active substance), SF897 (placebo for FCE20124 capsules), SF967 (FCE20124 hard gelatin capsules, with each capsules containing 2 mg of the active substance) and SF1039 (placebo for FCE20124 capsules), dated 22 June 1987, 22 June 1987, 27 September 1988 and 6 July 1988, respectively, are presented in Enclosure 1. Capsules of RBX and PBO were identical in appearance and indistinguishable by sight or smell.

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4. INTRODUCTION

Reboxetine or RBX, (2RS,αRS)-2-[α-(2ethoxyphenoxy)benzyl] morpholine is a new chemical entity which shares pharmacological properties, such as reserpine antagonism and norepinephrine reuptake inhibition, with the standard antidepressants. In animal pharmacological studies a single oral dose of RBX was shown to inhibit clonidine-induced hypothermia. In contrast, multiple doses of standard antidepressants were required to inhibit clonidine-induced hypothermia and other clonidine-induced effects. It was on the basis of this observation, that the possibility was raised that RBX may have a faster onset of therapeutic action than standard antidepressants.

Early pharmacokinetic studies -- conducted in healthy volunteers-- revealed that after the administration of a single dose of 2 mg ¹⁴C-reboxetine the unchanged substance accounted for the majority (73% in terms of the area under the curve) of the radioactivity in the circulating plasma. In the same studies, plasma half-life was estimated as 13.2 hours.

Analyses of plasma samples obtained from patients receiving RBX in different doses chronically yielded findings on the basis of which it was suggested that RBX has linear pharmacokinetics with steady state levels attained within three days

In phase I studies carried out in healthy volunteers, RBX was well tolerated in single oral doses below 5 mg. Administration of 5 mg resulted in orthostatic hypotension associated with tachycardia and other symptoms consistent with disturbance of circulatory regulation.

In a dose determination study conducted in patients with the diagnosis of Major Depressive Disorders, RBX was found to be well tolerated in doses up to 10 mg per day for a period of 28 days. The clinical improvement observed during this period appeared to be dose related. On the basis of findings in this study, it was suggested that the therapeutic daily dose of RBX is from 6 to 10 mg per day. Patients who were given 12mg per day of RBX did not tolerate the drug well.

5. STUDY OBJECTIVE

The purpose of this study was to evaluate treatment with RBX in patients with Major Depressive Disorders and, more specifically:

- a. to test the hypothesis that RBX in the daily dosage of 6 to 10 mg is superior in therapeutic effects to an inactive placebo within a period of 42 days;

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- b. to identify the time of onset of therapeutic effects;
- c. to identify therapeutically responsive subform(s) within major depressive disorders; and
- d. to provide further evidence of tolerability of RBX in the daily dosage from 6 to 10 mg over a period of 42 days.

6. INVESTIGATION PLAN

The original investigational plan is described in the study protocol (see Enclosure 2). It should be noted, however, that the original investigational plan was modified -- without being amended -- by terminating recruitment in one center without a single patient being enrolled (London, Canada) and in two centers after the enrollment of 8 patients (Pointe Claire, Canada) and 4 patients (Montreal, Canada), respectively; and by continuing recruitment in one center (Rio de Janeiro, Brazil) until 44 patients were enrolled. This decision was taken on the basis of the very slow recruitment rate in the Canadian centers and with the objective of reaching the sample size compatible with the analysis foreseen by the protocol on the first 60 admitted patients (Enclosure 2, page 3). Another modification -- without amendment -- was related to vital signs (blood pressure and heart rate) which were taken only eight times during the first four days of treatment instead of 12 times as specified in the protocol.

6.1 Experimental Design

The study was a multinational, multicenter clinical trial. It followed a double-blind, placebo-controlled parallel group design in which patients were stratified according to sex and randomly assigned -- on the basis of a prepared randomization code (see Enclosure 3) -- to the two treatment groups (RBX and PBO) at each center separately. Drugs were administered on the basis of a fixed changing (increasing) dosage regime and divided (b.i.d., administration at 10 a.m. and 8 p.m.) dosage schedule for a well-defined time period (42 days). Each patient was assessed by the same assessor at regular time intervals employing the same battery of tests.

6.2 Study Centers

All patients in the study were recruited and treated in one of the three investigational centers by 1 of 4 assessors. Of the three investigational centers, two centers were in Canada, one in Montreal (1 Investigator and 1 Assessor) and one in Pointe Claire (1 Investigator and 2 Assessors), and one center was in Rio de Janeiro, Brazil (1 Investigator and 1 Assessor).

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The three centers as well as the education and experience of each Investigator and Assessor was characterized in the "Statement of Investigator", Enclosure 4.

6.3 Study Population

Consenting patients with a DSM-III-R Axis I diagnosis of Major Depression fulfilling inclusion/exclusion criteria as described in paragraphs 5.2 on page 4 and 5 of study protocol (See enclosure 2) were admitted to the clinical study. Patient's consent was documented by signing a written consent form (See Enclosure 5).

A total of 56 patients with a DSM-III-R Axis I diagnosis of Major Depressive Disorder were admitted to the clinical trial within a period of 12 months. They were recruited by three centers, with each center contributing a different number of patients to the study population. As shown in Table 1, the greatest number, i.e., 44 patients (78.6%), of the total recruited population were contributed by the center in Rio de Janeiro (Brazil), the smallest number, i.e., 4 patients by the center in Monreal (Canada), with the center in Point Claire (Canada) contributing in between, i.e., 8 patients (14.3%) (See Appendix 1).

Table 1
Total Recruited Population
by Center and Country

CENTER	N	PERCENT
Montreal	4	7.1
Point Claire	8	14.3
Canada	12	21.4
Rio de Janeiro	44	78.6
Brazil	44	78.6
Total	56	100.0

In Table 2 and 3 the personal characteristics, i.e. sex, and age, of the total recruited population is presented by center and country. As shown in Table 2, of the total recruited population of 56 patients, 29 (51.8%) patients were male and 27 (48.2%) patients were female, with males outnumbering females, in one of the two countries (Canada: 7 vs 5). As shown in Table 3, patients admitted to the clinical study were 18-years-old or older, ranging in age from 18 to 60 years, with a mean of 41 (+/- 11.1) and a median of 41.5 years. Mean and median age of the Canadian population was higher (45.2 +/- 11.3) and 48.0 years, respectively) than of the Brazilian population (39.9 +/- 10.9 and 40 years).

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All information relevant to the personal characteristics of the total recruited population are presented in Enclosure 6; and all information relevant to the frequency distribution of sex and age (at the time of recruitment to the study) in centers and countries is presented in Appendix 2.

Table 2
Sex Distribution of Total Recruited Population
by Center and Country

CENTER	FEMALE		MALE	
	N	%	N	%
Montreal	2	50.0	2	50.0
Pointe Claire	3	37.5	5	62.5
CANADA	5	41.7	7	58.3
Rio de Janeiro	22	50.0	22	50.0
BRAZIL	22	50.0	22	50.0
TOTAL	27	48.2	29	51.8

Table 3
Age at Time of Recruitment
by Center and Country

CENTER	RANGE	MEAN	MEDIAN
Montreal	50-60	53.3 +/- 4.7	51.5
Pointe Claire	20-54	41.1 +/- 11.6	44.0
CANADA	20-60	45.2 +/- 11.3	48.0
Rio de Janeiro	18-58	39.9 +/- 10.9	40.0
BRAZIL	18-58	39.9 +/- 10.9	40.0
TOTAL	18-60	41.0 +/- 11.1	41.5

In Tables 4 and 5 the physical characteristics, i.e., height (in centimeters) and weight (in kilograms), of the total recruited population is presented by center and country.

All information relevant to the physical characteristics of the total recruited population are presented in Enclosure 7; and all the information relevant to the frequency distribution of height and weight (at the time of recruitment to the study) in centers and countries is presented in Appendix 3.

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Table 4
Height at Time of Recruitment
by Center and Country

CENTER	RANGE	MEAN	MEDIAN
Montreal	152-177	163.5 +/- 12	162.5
Pointe Claire	158-180	168.6 +/- 7.6	167.0
CANADA	152-180	166.9 +/- 9.1	167.0
Rio de Janeiro	150-186	165.7 +/- 8.6	164.5
BRAZIL	150-186	165.7 +/- 8.6	164.5
TOTAL	150-186	166.0 +/- 8.7	165.0

Table 5
Weight at Time of Recruitment
by Center and Country

CENTER	RANGE	MEAN	MEDIAN
Montreal	38-88	58.5 +/- 22.6	54.0
Pointe Claire	49-111	73.8 +/- 20.3	77.0
CANADA	38-111	68.7 +/- 21.4	69.0
Rio de Janeiro	42-82	62.1 +/- 10.6	60.5
BRAZIL	42-82	62.1 +/- 10.6	60.5
TOTAL	38-111	63.5 +/- 13.6	61.5

In Table 6 and 7 the characteristics relevant to the history of depressive illness (i.e., age at the onset of first depressive episode and number of prior episodes) in the total recruited population is presented by center and country. As shown in Table 6, at the time of onset of the first depressive episode age ranged from 7 to 58 years, with a mean of 34.6 (+/- 11.1) and a median of 33.5 years. Mean and median age in the Canadian population (30.6 +/- 13.2 and 31.5 years, respectively) were lower than in the Brazilian population (35.7 +/- 10.4 and 34.0 years). As shown in Table 7, the number of prior depressive episodes (not including the present one), ranged from 0 to 20 with a range in the Canadian population from 1 to 20 and in the Brazilian population from 0 to 10. Mean and median number of prior depressive episodes were higher in the Canadian population (6.2 +/- 5.8 and 5.0, respectively) than in the Brazilian population (2.0 +/- 3.0 and 0).

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All information relevant to the history of depressive illness in the total recruited population is presented in Enclosure 8; and all information relevant to the frequency distribution of the age at the time of the onset of the first depressive episode and the frequency distribution of the number prior depressive episodes is presented in Appendix 4.

Table 6
Age at Time of First Depressive Episode
by Center and Country

CENTER	RANGE	MEAN	MEDIAN
Montreal	31-50	41.5 +/- 7.9	42.5
Pointe Claire	7-44	25.1 +/- 12.0	25.0
CANADA	7-50	30.6 +/- 13.2	31.5
Rio de Janeiro	18-58	35.7 +/- 10.4	34.5
BRAZIL	18-58	35.7 +/- 10.4	34.0
TOTAL	7-58	34.6 +/- 11.1	33.5

Table 7
Number of Prior Depressive Episodes
(not including present episode)
by Center and Country

CENTER	RANGE	MEAN	MEDIAN
Montreal	1-8	2.8 +/- 3.5	1.0
Pointe Claire	1-20	8.0 +/- 6.2	6.0
CANADA	1-20	6.2 +/- 5.8	5.0
Rio de Janeiro	0-10	2.0 +/- 3.0	0.0
BRAZIL	0-10	2.0 +/- 3.0	0.0
TOTAL	0-2	2.8 +/- 4.0	1.0

In Tables 8, 9, 10 and 11 characteristics relevant to the present episode of depressive illness, i.e., precipitating stressors (events), form of onset, subform of illness and duration of episode, is presented in the total recruited population. As shown in Table 8, precipitating events were presented in 15 (26.8%) and absent in 41 (73.2%) patients of the total recruited population. In the Canadian population precipitating events were present relatively more frequently (6 patients; 50%) than in the Brazilian population (9 patients; 20.5%). As shown in Table 9, form of onset was acute or subacute in 45 (80.4%) and insidious in 11 (19.6%) patients in the total recruited population. In the Canadian population form of onset was insidious relatively more frequently (4 patients; 33.3%) than in the Brazilian population (7 patients; 15.9%). As shown in Table 10, subform of illness was single episode in 27 (48.2%), recurrent in 23 (41.1%), recurrent-moderately severe in 1 (1.8%), recurrent-severe without psychotic features in 4 (7.1%) and recurrent-severe with psychotic features in 1 (1.8%) patients in the

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total population. In the Canadian population the prevailing subform of major depression was "recurrent", present in 6 (50%) patients; "recurrent severe (major depression) with psychotic features" was present in 1 (8.3%) patient. In the Brazilian population the prevailing subform was "single episode," present in 27 (61.4%) patients and there was no single patient with psychotic features. As shown in Table 11, the duration of the present episode (in months) ranged from 1 to 12 months, with a mean of 4.6 (+/- 3.0) and a median of 4.0 months in the total recruited population. Mean and median duration of present episode in the Canadian population (3.5 +/- 2.6 and 2.0 months) were shorter than in the Brazilian population (4.8 +/- 3.1 and 4.0 months).

All information relevant to the present episode of depression in the total recruited population is presented in Enclosure 9; and all the information relevant to the frequency distribution of variables relevant to the present episode are presented in Appendix 5.

Table 8
Presence of Precipitating Event in Present Episode
by Center and Country

CENTERS	ABSENT		PROBABLY PRESENT		DEFINITELY PRESENT	
	N	%	N	%	N	%
Montreal	2	50.0	2	50.0	0	0.0
Pointe Claire	4	50.0	4	50.0	0	0.0
CANADA	6	50.0	6	50.0	0	0.0
Rio de Janeiro	35	79.5	5	11.4	4	9.1
BRAZIL	35	79.5	5	11.4	4	9.1
TOTAL	41	73.2	11	19.6	4	7.1

Table 9
Form of Onset of Present Episodes
by Center and Country

CENTERS	ACUTE		SUBACUTE		INSIDIOUS	
	N	%	N	%	N	%
Montreal	0	0.0	0	50.0	2	50.0
Pointe Claire	2	25.0	4	50.0	2	25.0
CANADA	2	16.7	6	50.0	4	33.3
Rio de Janeiro	22	50.0	15	34.1	7	15.9
BRAZIL	22	50.0	15	34.1	7	15.9
TOTAL	24	42.9	21	37.5	11	19.6

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Table 10
Subform of Major Depression
by Center and Country

CENTER	SINGLE EPISODE		RECURR.		RECURR. MOD. SEV.		RECURR. SEVERE WITHOUT PSYCHOTIC FEATURES		RECURR. SEVERE WITH PSYCHOTIC FEATURE	
	N	%	N	%	N	%	N	%	N	%
Montreal	0	0.00	0	0.00	0	0.0	3	75.0	1	25.0
Pointe Claire	0	0.00	6	75.0	1	12.5	1	12.5	0	0.00
Canada	0	0.00	6	50.0	1	8.3	4	33.3	1	8.3
Riode Janeiro	27	61.4	17	38.6	0	0.0	0	0.0	0	0.0
Brazil	27	61.4	17	38.6	0	0.0	0	0.0	0	0.0
TOTAL	27	48.2	23	41.1	1	1.8	4	7.1	1	1.8

Table 11
Duration of Present Episode (in months)
by Center and Country

CENTER	RANGE	MEAN	MEDIAN
Montreal	1-3	2.0+/- .82	2.0
Pointe Claire	2-9	4.3+/-3.0	2.5
CANADA	1-9	3.5+/-2.6	2.0
Rio de Janeiro	1-12	4.8+/-3.1	4.0
BRAZIL	1-12	4.8+/-3.1	4.0
TOTAL	1-12	4.6+/-3.0	4.0

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6.4 Study Medication

The study medication was prepared and supplied by Farmitalia Carlo Erba as specified in paragraph 14 on page 15 in study protocol (See Enclosure 2).

All medication was prepared in capsules, with each capsule containing 2 mg RBX or an inactive PBO, identical in appearance and indistinguishable by sight and taste.

A six-week supply of RBX or PBO, consisting of 215 capsules in one bottle was provided for each patient. Each bottle was labeled with the patient's code number from the randomization lists (See Enclosure 3). The actual medication the patient received was identifiable only by opening the sealed envelope --allowed only in case of emergency -- corresponding with the bottle number.

6.5 Population and Treatment Groups

Patients included in the clinical trial were randomly assigned to one of two treatment groups, i.e., RBX or an inactive PBO, on the basis of prepared randomization schedule (See Enclosure 3). As a result, 28 (50%) of the 56 patients in the total recruited population were assigned to treatment with RBX and 28 (50%) were assigned to treatment with PBO.

In Table 12 personal (sex and age) and physical (height and weight) characteristics, as well as characteristics relevant to the history (age and time of onset of the first depressive episode and number of prior depressive episodes) and to the present episodes (precipitating event, form of onset, subform of major depression and duration) of depressive illness are presented in the two treatment groups. Also as shown in Table 12, the two treatment groups were comparable on all personal and physical characteristics and characteristics relevant to the depressive illness; in none of the variables was there a significant difference between the two groups.

All information relevant to the personal and physical characteristics and characteristics relevant to the depressive illness of each patient in the two treatment groups is presented in Enclosure 10; and all statistics relevant to the comparison of the two treatment groups on these characteristics is presented in Appendix 6.

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Table 12
Personal and Physical Characteristics and Characteristics
Relevant to Depressive Illness in the Two Treatment Groups

	DRUG GROUPS				COMPARISON OF GROUPS:	
	RBX		PBO		RESULTS	TEST
SEX	N	%	N	%		
Females	13	46.4	14	50.0	$\chi^2 = .789$	Chi-square
Males	15	55.6	14	50.0		
Age (yrs) (mean)	41.7		40.0		p = 0.652	ANOVA
PHYSICAL CHARACTERISTICS:						
Height (cm) (mean)	165.4		166.6		p = 0.594	ANOVA
Weight(Kg) (mean)	63.8		63.3		p = 0.900	ANOVA
HISTORY OF ILLNESS:						
Age 1st episode (yrs) (mean)	36.3		32.9		p = 0.268	ANOVA
Prior episodes (N)	2.4		3.2		p = 0.484	ANOVA
PRESENT EPISODES:						
Precipitating events:	%		%		$\chi^2 = .089$	Chi-square
Absent	75.0		71.4			
Probably Present	25.0		14.3			
Definitely Present	0.0		14.3			
Form of Onset:	%		%		$\chi^2 = .253$	Chi-square
Acute	32.1		53.6			
Subacute	42.9		32.1			
Insidious	25.0		14.3			
Subform of Illness:	%		%		$\chi^2 = .658$	Chi-square
296.20	50.0		46.4			
296.30	35.7		46.4			
296.32	3.6		0.0			
296.33	7.1		7.1			
296.34	3.6		0.0			
Duration (mo.) (mean)	4.3		4.8		p = 0.511	ANOVA

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6.6 Treatment Procedure

For all but 1 patient who was treated with a monoamine oxidase inhibitor (MAOI) antidepressant the clinical trial began with a seven-day, single-blind, pretreatment placebo washout period; for the 1 patient treated with a MAOI antidepressant the single-blind, pretreatment placebo washout was 14 days.

At the end of the pretreatment placebo washout all patients were randomly assigned, on the basis of prepared randomization codes, to one of two treatment groups -- as indicated in Sections 6.1 and 6.5 of this report -- and administered RBX or PBO on the basis of a fixed changing dosage regime and divided (twice a day -- b.i.d.) dosage schedule for 42 days in accordance with the study protocol (See Enclosure 2). During the 42 days of treatment, except for birth control pills, no other medication was allowed to be administered as continuous treatment. If necessary, however, laxatives (for constipation), chloral hydrate (for sleep induction) and analgesics (for pain) were allowed on a pro re nata (p.r.n.) basis.

After 42 days of treatment the study medication was discontinued at once and one month following discontinuations a follow-up examination was performed on all patients.

6.7 Assessments

Assessments consisted of clinical interviews, physical examination and laboratory tests. A specially devised assessment battery was completed according to the predetermined assessment (time) schedule shown in Table 13.

The information collected was targeted at inclusion/exclusion criteria (DSM-III-R, HAMD, Vital Signs, Physical Examination, Chest x-Ray, Electrophysiologic tests, Special Laboratory, Hematology, Blood Chemistry and Urinalysis), efficacy (HAMD, ZUNG, CGI) tolerability (NOSS and Vital Signs) safety (Hematology, Blood Chemistry, Urinalysis, Electrophysiologic Tests and Physical Examination) and indirect measures of efficacy at termination (Termination Record) and at follow-up (Follow-up)

A sample of each assessment instrument employed in the clinical trial is presented in Enclosure 11; and the Karch and Lasagna criteria for interpreting the relationship between newly observed signs and symptoms and treatment is presented in Enclosure 12.

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Table 13
Schedule of Assessments

Forms, Scales and Assays	Day Screen	-3 to	-1	0	1	2	3	4	5	6	7	10	14	21	28	35	42	Post 1 Mo.
DSM-III-R-AX.i	*																	
HAM-D (21 item)	*			*				*	*	*	*	*	*	*	*	*	*	*
VITAL SIGNS:																		
Blood Pressure	*			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Pulse Rate	*			*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Temperature	*			*						*		*	*	*	*	*	*	*
Weight	*			*						*		*	*	*	*	*	*	*
PHYSICAL EXAM.	*																	*
CHEST X-RAY	*																	
ELECTROPHYSIOL																		
E.C.G.	*													*				*
E.E.G.	*																	*
SPECIAL LAB:																		
Thyroid T3	*																	
T4	*																	
TSH	*																	
ELISA HIV	*																	
Hbs Ag	*																	
Anti -HBC	*																	
ALT	*																	
AST	*																	
HEMATOLOGY:																		
Hematocrit	*														*			*
Hemoglobin	*														*			*
RBC	*														*			*
WBC	*														*			*
Eosinophils	*														*			*
Neutrophils	*														*			*
Monocytes	*														*			*
Lymphocytes	*														*			*
Basophils	*														*			*
Platelets	*														*			*

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Table 13 (cont.)
Schedule of Assessments

Forms, Scales and Assays	Day Screen	-3 to	-1	0	1	2	3	4	5	6	7	10	14	21	28	35	42	Post 1 Mo.
BLOOD CHEMISTRY:																		
Electrolytes	*													*				*
SGOT	*													*				*
SGPT	*													*				*
γ GT	*													*				*
Alk. Phos.	*													*				*
Glucose	*													*				*
BUN	*													*				*
Creatinine	*													*				*
Uric Acid	*													*				*
Total bilirubin	*													*				*
Total protein	*													*				*
Albumin	*													*				*
Globulins	*													*				*
Cholesterol	*													*				*
Tryglicerides	*													*				*
URINALYSIS:																		
Specific Gravity	*													*				*
Albumin	*													*				*
Sugar	*													*				*
RBC	*													*				*
WBC	*													*				*
ZUNG				*								*		*	*	*	*	*
CGI (SI)				*								*		*	*	*	*	*
(GI)												*		*	*	*	*	*
(EI)												*		*	*	*	*	*
NOSS				*				*			*	*	*	*	*	*	*	*
TERMINATION RECORD																		*
FOLLOW-UP																		*

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6.8 Assessors

The 56 patients were assessed by 4 assessors -- identified by number 1 to 4 -- in the three centers, with the same assessor assessing the same patient throughout the clinical trial. In Enclosure 13 the relationship between assessors and patients are identified.

6.9 Data Analysis

Analysis of data was focused on the efficacy -- including indirect measures of efficacy -- tolerability and safety of treatment with RBX as compared to PBO, as specified on pages 12 to 15 in the study protocol (See paragraphs 12.5 in Enclosure 2).

Efficacy analyses were primarily based on covariance analyses, repeated measures analyses of variance and chi-square comparison; and tolerability and safety analyses were primarily based on descriptive statistics.

In all analyses the SPSS-X/SPSS-PC+ statistical package was employed.

7. EVOLUTION AND DESCRIPTION OF ANALYTIC COHORT

From the total recruited population of 56 patients, 54 qualified for the experimental group and 52 were included in the analytic cohort.

7.1 From Total Recruited Population to Experimental Group.

The reason for not accepting 2 patients, i.e., Patient N°. 17 from the RBX group and Patient N° 48 from the PBO group, from the total recruited population in the experimental group was missing information regarding patient's thyroid functions prior to commencement of treatment, precluding the possibility of proper evaluation of whether these patients fulfilled admission criteria.

None of the patients of the total population were excluded from the experimental group because of the decrease of 20% or greater on the HAMD total scores from screening to Day 0 (See Enclosure 2, paragraph 7.2.1, page 7). As shown in Table 14, there was a slight decrease in mean HAMD total score (from 36.2 to 35.9) in the group to be treated with RBX and a slight increase in HAMD mean total scores (from 34.4 to 34.7) in the group to be treated with PBO. In spite of this, the difference in responsiveness to placebo from screening to Day 0 between the two groups was not statistically significant.

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All information relevant to inclusion/exclusion criteria -- with the normal range of values for the laboratory tests at the three centers -- for each patients in the total population is presented in Enclosure 14; and all information on the statistics relevant to inclusion/exclusion criteria is presented in Appendix 7.

Table 14
HAMD Total Score Means: Screening and Day 0

HAMD TOTAL SCORE	RBX	PBO	Total Pop.	p	Test
Screening	36.2	34.4	35.3	.128	ANOVA
Day 0	35.9	34.7	35.3	.289	ANOVA

7.2 From Experimental Group to Analytic Cohort

In addition to the two patients from the total population who did not qualify for inclusion in the experimental group, another 2 patients -- both from the PBO group -- were excluded from the sample which comprised the final analytic cohort. Of these 2 patients, one (Patient N° 2) was excluded because he refused to continue with treatment after 4th of drug administration; and the other was excluded because of a marked increase in HAMD total scores (from 35 through 39 to 47) within the first seven days of treatment. (One patient from the RBX group was retained in spite of the greater than 20 percent increase of HAMD total scores during the first 14 days).

All information relevant to HAMD total scores for each patient in the total recruited population during the first 14 days of treatment is presented in Enclosure 15.

7.3 Description of Analytic Cohort

In Table 15 personal (sex and age) and physical (height and weight) characteristics, as well as characteristics relevant to the history (age at the time of onset of the first depressive episode and number of prior depressive episodes) and to the present episode (precipitating event, form of onset, subform of major depression and duration) of depressive illness are presented in the two treatment groups of the analytic cohort. Also as shown in Table 15, the two treatment groups of the analytic cohort were comparable on all personal and physical characteristics and characteristics relevant to the depressive illness; in none of the variables was there a significant difference between the two groups. All information relevant to the personal and physical characteristics and characteristics relevant to the depressive illness of each patient in the two treatment groups of the analytic cohort is presented in Enclosure 16; and all statistics relevant to the comparison of the two treatment groups of the analytic cohort on these characteristics is presented in Appendix 8.

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Table 15
Personal and Physical Characteristics and Characteristics Relevant to Depressive Illness in the Two Treatment Groups of the Analytic Cohort

	DRUG GROUPS:				COMPARISON OF GROUPS:	
	RBX		PBO		RESULTS	TEST
PERSONAL CHARACTERISTICS:						
Sex	N	%	N	%		
Females	13	48.1	11	44.0	$\chi^2 = .764$	Chi-square
Males	14	51.9	14	65.0		
Age (yrs)(mean)	41.4		39.9		$p = 0.610$	ANOVA
PHYSICAL CHARACTERISTICS:						
Height (cm) (mean)	165.9		166.9		$p = 0.671$	ANOVA
Weight (kg) (mean)	64.5		64.5		$p = 1.000$	ANOVA
HISTORY OF ILLNESS:						
Age 1st episode (yrs) (mean)	36.4		33.0		$p = 0.266$	ANOVA
Prior Episodes (N)	2.5		2.8		$p = 0.765$	ANOVA
PRESENT EPISODE:						
Precipitating Event:	%		%		$\chi^2 = .076$	Chi-square
Absent	77.8		72.0			
Probably Present	22.2		12.0			
Definitely Present	0.0		16.0			
Form of Onset::	%		%		$\chi^2 = .255$	Chi-square
Acute	33.3		56.0			
Subacute	44.4		28.0			
Insidious	22.2		16.0			
Subform of Illness:	%		%		$\chi^2 = .370$	Chi-square
296.20	51.9		52.0			
296.30	37.0		48.0			
296.32	3.7		0.0			
296.33	7.4		0.0			
Duration (mo) (mean)	4.4		5.2		$p = 0.375$	ANOVA

8. COURSE OF CLINICAL TRIAL

From the 52 patients of the analytic cohort, 32 (61,5%) patients completed the 42-days clinical trial and 20 (38,5%) patients were prematurely terminated.

8.1 Completers

Of the 32 patients completing the clinical trial, 23 (71,9%) were from the RBX group and 9 (28,1%) patients were from the PBO group. The difference between the two treatment groups in terms of number of patients completing the clinical trial was statistically significant ($p < .001$).

8.1.1 Uneventful

In 27 (84,4%) of the 32 completers the course of the clinical trial was uneventful. Of these 27 patients, 18 (66,7%) patients were from the RBX group and 9 (33,3%) patients were from the PBO group.

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8.1.2 Decrease of Dose

In 2 (6.3%) of the 32 completers the dose of medication was decreased in the course of treatment. Both patients were from the RBX group. In 1 of these 2 patients (Patients No. 089) the evening dose was decreased from 3 capsules to 2 capsules from Day 4 to Day 7 because of tremor and from Day 15 to Day 21 for insomnia, and in the other (Patient No. 144) the morning dose was decreased from 2 capsules to 1 capsule from Day 3 to Day 14 and the evening dose was decreased from 3 capsules to 2 capsules from Day 3 to Day 28 because of vomiting.

8.1.3 Counteractive Medication

For 3 (9.4%) of the 32 completers counteractive medication was given to control insomnia, agitation or headache. As shown in Table 16, one of the patients (No. 31) was given chloral hydrate and acetaminophen for agitation-insomnia and headache, respectively; another patient (No. 47) was given chloral hydrate for insomnia; and the third patients (No. 86) was given diazepam for insomnia.

Table 16
Relevant Information on Counteractive Medication
in Three Patients

Pat No.	Ctr. No.	Tx Group	Rater No.	Concomitant Medication	From			To:			Reason
					dy	mo	yr	dy	mo	yr	
31	2	1	2	chloral hydrate	11	08	89	11	21	90	agit/insomnia
31	2	1	2	chloral hydrate	11	21	89	01	02	90	insomnia
31	2	1	2	acetaminophen	11	14	89	11	14	89	headache
47	2	1	3	acetaminophen	11	89	11	11	27	89	headache
86	3	1	4	chloral hydrate							insomnia
				diazepam	10	09	89	10	15	89	insomnia

1 Ctr. 1=Montreal 2=Pointe Claire 3=Rio de Janeiro
 2 Tx Group 1=RBX 2=PBO
 3 Rater 1=Beaucclair 2=Mirmiran 3= Song 4=Nardi

8.2 Dropouts

From the 52 patients of the analytic cohort, 20 patients (38.5%) were prematurely discontinued prior to completion of the 42-day clinical trial. As shown in Table 17, a significantly ($p < .001$) greater number of patients were prematurely discontinued in the PBO-treated group (16 patients; 30.8%) than in the RBX- treated group (4 patients; 7.7%). Reasons for discontinuation were adverse effects in 2 patients -- 1 from the RBX group and 1 from the PBO group -- and lack of therapeutic response or clinical deterioration in 18 patients -- 15 from the PBO group and 3 from the RBX group.

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8.2.1 Adverse Effects

Of the 2 patients discontinued for adverse effects, 1 (No. 32) was a 30-year-old female treated with RBX which was discontinued on Day 30 because of the development of hypomania after taking the morning dose. Other adverse effects reported for the same patients included dry mouth (lasting for 5 days), coldness of extremities (lasting for 1 day), decreased appetite (lasting for 1 day), insomnia (1 night), vomiting (once, lasting for 2 minutes) and sweating (lasting for 2 days). The other patient (No. 34) discontinued for adverse effects was a 46-year-old male treated with PBO which was discontinued before the morning dose on Day 21 because of agitation. Other adverse effects reported for the same patients included drowsiness (lasting for 2 days) diarrhea and vomiting (lasting for 3 days), and dizziness (lasting for 6 days).

Table 17
Reason for Premature Discontinuation
in the Two Treatment Groups

Reason For Discontinuation	RBX		PBO		Level of Significance	Statistical Test
	N	%	N	%		
Adverse Effects	1	3.7	1	4.0	p = .956	Chi-square
Lack of Therapeutic Effect	3	11.1	15	64.0	p < .001	Chi-square
TOTAL	4	20.0	16	80.0	p < .001	Chi-square

8.2.2 Lack of Therapeutic Response

As shown in Table 18, all 18 patients prematurely discontinued for lack of therapeutic response -- on the basis of the Investigator's judgment, irrespective of the changes in HAMD total scores -- were discontinued between Day 14 and Day 30. Two of the 18 patients (Nos 1 and 46) also had -- at one or another time in the course of the clinical trial -- adverse effects recorded on the NOSS.

All information relevant to the course of the clinical trial -- including dispensation of medication -- for each patients in the analytic cohort is presented in Enclosure 17, 18, 19 and 20; and all information relevant to the statistics employed on the course of the clinical trial are presented in Appendices 9 and 10.

8.3 OTHER EVENTS

All 52 patients of the analytic cohort complied with the study protocol and took his/her medication as prescribed; and in none of the patients was a significant life event recorded in the course of the clinical trial. One of the patients from the RBX-treated group was also in milieu therapy throughout the clinical trial.

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Table 18
Relevant Information on Prematurely Discontinued Patients
Due to Lack of Therapeutic Response

Pat No.	Ctr. No.	Tx Group	Rater	HAM-D Total Score (-)			Adverse Effects (Y/N)	Day
				Day 0	Final	% Decrease		
001	1	1	1	35.00	32.00	8.57	Y	30
033	2	2	2	34.00	26.00	23.53	Y	14
035	2	2	2	36.00	34.00	5.56	N	21
046	3	1	3	34.00	30.00	11.76	N	14
082	3	2	4	34.00	43.00	-26.47	N	21
085	3	2	4	33.00	40.00	-21.21	N	21
087	3	2	4	41.00	46.00	-12.20	N	21
094	3	2	4	42.00	45.00	-7.14	N	21
099	3	2	4	38.00	41.00	-7.89	N	21
100	3	2	1	37.00	44.00	-18.92	N	21
129	3	2	4	36.00	37.00	-2.78	N	21
130	3	2	4	33.00	41.00	-24.24	N	21
131	3	1	4	34.00	39.00	-14.71	N	21
133	3	2	4	32.00	36.00	-12.50	N	21
142	3	2	4	35.00	41.00	-17.14	N	21
146	3	2	4	34.00	38.00	-11.76	N	21
147	3	2	4	31.00	37.00	-19.35	N	21
151	3	2	4	35.00	40.00	-14.29	N	21

1 Ctr. 1=Montreal 2=Pointe Claire 3=Rio de Janeiro
 2 Tx Group 1=RBX 2=PBO
 3 Rater 1=Beauclair 2=Mirmiran 3= Song 4=Nardi

(-): increase of scores (worsening)

9. RESULTS

Results of the clinical trial were evaluated in terms of therapeutic efficacy, tolerability, safety, benefit/risk ratio and indirect indications of efficacy at termination and at follow-up.

9.1 Therapeutic Efficacy

Evaluation of therapeutic efficacy, including the onset and profile of therapeutic effects, was based on the analysis of data recorded on HAM-D, ZUNG and Severity of Illness (SI) and Global Improvement (GI) components of the CGI.

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9.1.1 Hamilton Psychiatric Rating Scale for Depression

The primary assessment instrument in the evaluation of therapeutic efficacy was the 21-item HAMD (See Enclosure 11), completed nine times (by the same assessor throughout for the same patient) in the course of the clinical trial, i.e., Day 0 (baseline), and Day 4, 7, 10, 14, 21, 28, 35, and 42 (final assessment) of drug administration. The recorded data of the HAMD on Day 0 and on the final assessment of each patient was used for measuring therapeutic efficacy; and from Day 0 to the final assessment for identifying the onset of therapeutic activity and for delineating the profile of the therapeutic effects.

All information relevant to each patient for measuring therapeutic efficacy and identifying the onset of therapeutic activity by employing the HAMD are presented in Enclosure 21 and for delineating the profile of therapeutic effects in Enclosure 22; and all information regarding the statistics employed in measuring therapeutic efficacy, identifying the onset of therapeutic activity and delineating the profile of therapeutic effects by HAMD are presented in Appendices 11, 12 and 13.

9.1.1.1 THERAPEUTIC EFFICACY

Measurement of therapeutic efficacy was based on a comparison of the changes in the mean total scores of the HAMD -- a continuous measure -- from the baseline (Day 0) assessment to the final assessment (Day 42 or, in case of premature assessment, the last assessment), i.e., pre-post analyses in the RBX and PBO groups of the analytic cohort; and on a comparison of the number and percentages of patients attaining a 50 percent or greater decrease in HAMD total scores from baseline to the final assessment -- a discrete measure -- in the two treatment groups.

9.1.1.1.1 Continuous Measures

Mean total scores of the HAMD in the entire analytic cohort decreased, as shown in Table 19, in a score from 35.4 at the baseline assessment to a score 21.2 at the final assessment, with a decrease from 35.7 to 12.6 in the RBX group and from 35.1 to 30.6 in the PBO group, representing a decrease of 39.1 percent, 64.7 percent and 12.8 percent, respectively. Analysis of variance (pre-post) revealed that the decrease (improvement) in mean total scores from baseline to the final assessment was significantly greater ($p < .001$) in the RBX than in PBO group. There was no interaction between therapeutic efficacy and sex and age (18-37, 38-49 and 50 and above).

9.1.1.1.2 Discrete Measures

The percentage of patients attaining a 50 percent or greater decrease (improvement) from baseline to the final assessment in HAMD total scores in entire population and the two treatment- based subpopulations of the analytic cohort are presented in Figure 1. As shown in Figure 1, 25 (48.1%) patients of the entire analytic cohort attained a 50 % or greater decrease in HAMD total scores from baseline to the final assessment, with 20 (74.1%) patients from the RBX group, and 5

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patients (20%) from the PBO group. Chi-square analyses revealed that a significantly (<.001) greater number of patient attained a 50% or greater decrease (improvement) in HAMD total scores from baseline to the final assessment in the RBX- than in the PBO- treated group. There was a significant difference (p=.029) between countries (Canada and Brazil) regarding the number and percentage of patients attaining a 50 % or greater decrease (improvement) in HAMD total Scores from baseline to the final assessment. This was to the effect that only 1 Canadian patient attained a 50% or greater decrease, whereas 24 Brazilian patients attained a 50% or greater decrease. There was no interaction between the attainment of a 50% decrease in HAMD total scores and sex, country and age (18-37, 38-49 and 50 and above).

Table 19
Changes in Mean HAMD Total Score
from Baseline to Final Assessment

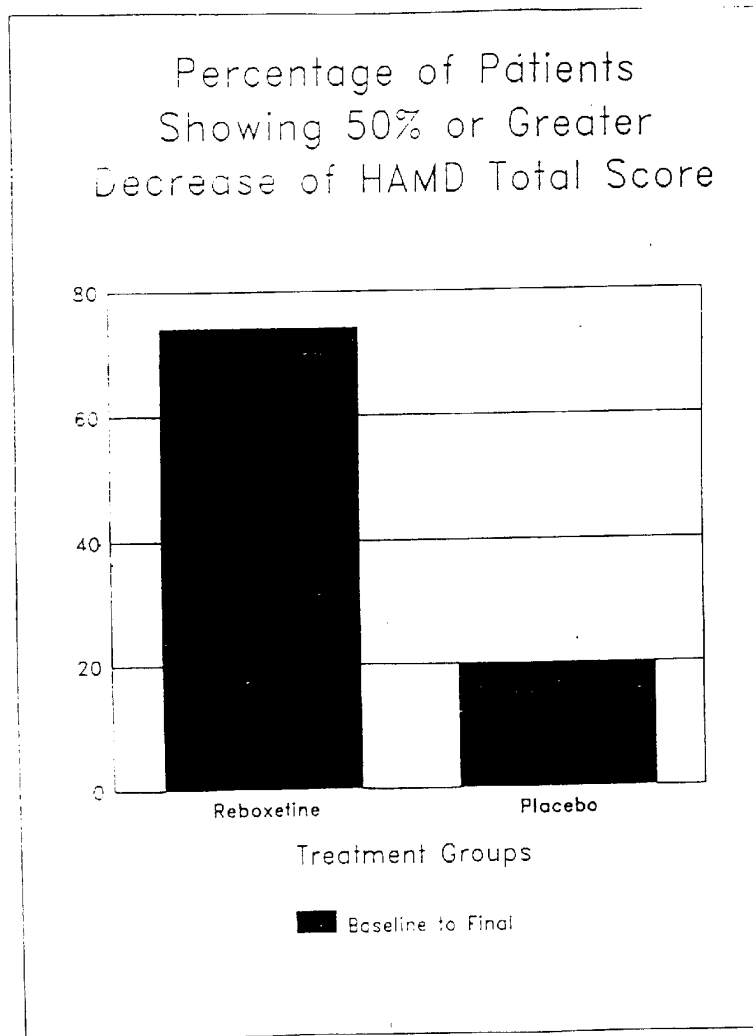
Groups	Baseline Score	Final Assessment Score	Pre-Post Change in Percent
Analytic Cohort	35.4	21.2	39.1
RBX	35.7	12.6	64.7
PBO	35.1	30.6	12.8

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Figure 1



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9.1.1.2 ONSET OF THERAPEUTIC ACTIVITY

Onset of therapeutic activity was examined by comparing the changes in mean HAMD total scores from baseline (Day 0) through all subsequent assessment, i.e., assessment on Days 4, 7, 10, 14, 21, 28 and 35 to the Day 42 or final assessment, in the two treatment groups by employing repeated measures analyses of variance. As a result, as shown in Figure 2, it was found that the decrease (improvement) in mean total scores of the HAMD was sharper during the first 14 days of treatment in the RBX- than in the PBO treated group. The difference in the speed of decrease in mean total scores was to the extent that by the time of the Day 10 assessment mean total scores in the RBX group (26.1+/-6.87) were significantly (p=.006) lower than in the PBO group (31.0+/-5.23). The decrease (improvement) in mean total scores in the PBO group, as shown in Table 20, peaked at the Day 14 assessment, whereas in the RBX group, it continued throughout the 42-day investigational period. There was no interaction between the onset of therapeutic activity and sex and age (18-37 years, 38-49 years and 50 years and above). On the other hand, there was an interaction between country and onset of therapeutic activity. This was to the effect that, as shown in Table 21, during the first 10 days of the clinical trial the Canadian population showed more rapid improvement than the Brazilian population.

Table 20
Mean HAMD Total Scores with Percentage of Change
at 9 Subsequent Assessment in the Two Treatment Groups

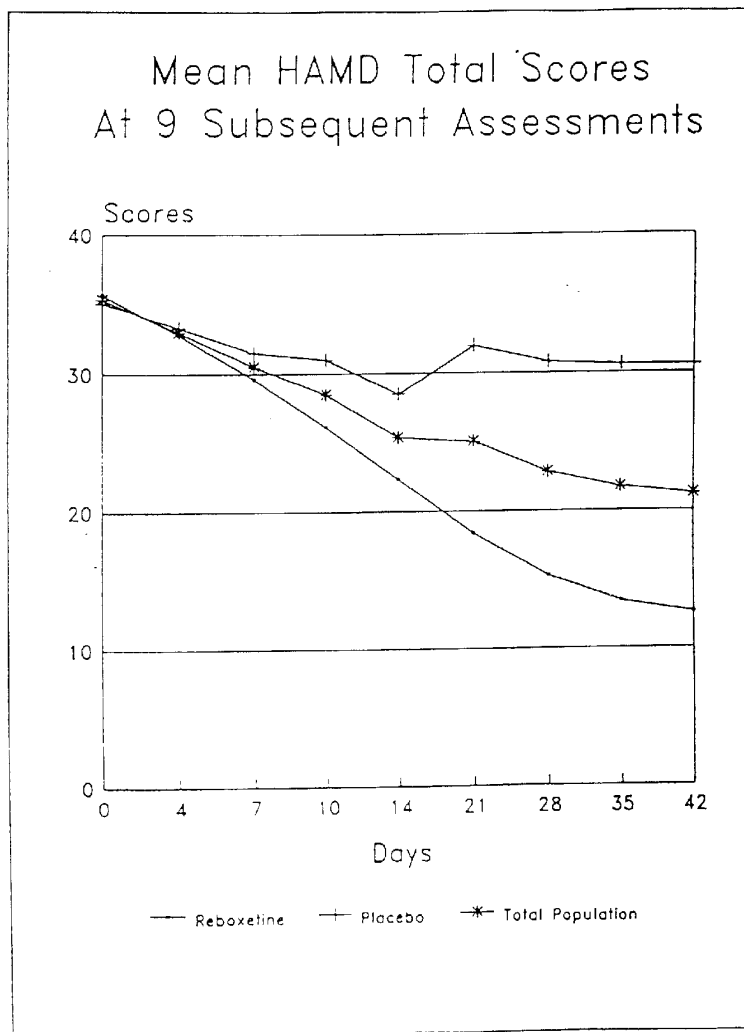
	Baseline	Day 4		Day 7		Day 10		Day 14		Day 21		Day 28		Day 35		Day 42	
	Scores	Score	%	Score	%	Score	%	Score	%	Score	%	Score	%	Score	%	Score	%
Total	35.4	33.0	5.8	30.5	12.8	28.5	18.5	25.3	27.5	25.0	28.4	22.8	34.6	21.7	37.7	21.2	39.1
RBX	35.7	32.8	7.1	29.6	16.1	26.1	25.9	22.3	36.5	18.4	47.5	15.3	56.1	13.4	61.5	12.6	63.7
PBO	35.1	33.3	4.1	31.5	9.3	31.0	10.7	28.5	17.8	32.0	7.8	30.8	11.3	30.6	11.8	30.6	11.8

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Figure 2



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Table 21
Mean HAMD Total Scores with Percentage of Change
at 9 Subsequent Assessment in the Two Treatment Groups

Assessment	Canada		Brazil		Results	Test
	Mean	%	Mean	%		
Day 0	31.9	3.48	36.1	3.34	p = .002	ANOVA
Day 4	25.4	8.48	34.4	4.01	p < .001	ANOVA
Day 7	25.9	11.98	31.4	4.58	p = .0251	ANOVA
Day 10	24.0	10.69	29.3	5.28	p = .034	ANOVA
Day 14	24.1	10.05	25.5	7.21	p = .637	ANOVA
Day 21	23.3	7.42	25.3	11.93	p = .646	ANOVA
Day 28	22.0	10.52	22.9	13.75	p = .864	ANOVA
Day 35	22.0	10.74	21.6	14.67	p = .941	ANOVA
Day 42	21.3	11.12	21.2	15.54	p = .997	ANOVA

9.1.1.3 THERAPEUTIC PROFILE

The profile of therapeutic effects was evaluated by comparing the changes in mean total scores of five variables -- derived with consideration of psychiatric theory -- from baseline (Day 0) through all subsequent assessments on Day 4, 7, 10, 14, 21, 28 and 35 to the Day 42 or final assessment. The five variables derived with consideration of psychiatric theory are depressed mood (the nuclear symptom of depressive illness) and insomnia, activities, anxiety and somatic symptoms, i.e., the accessory symptoms of depressive illness. The scores for these five variables were derived from the 12 of 21 HAMD items, i.e., depressed mood (variable 1), early, middle and late insomnia (variable 2), work and activities and retardation (variable 3), anxiety-psyhic and hypocondriasis (variable 4) and anxiety-somatic, somatic symptoms gastrointestinal, somatic symptoms general and genital symptoms (variable 5). As a result, as shown in Figures from 3 to 7 and in Tables from 22 to 26, there was a significantly greater improvement in the - than in PBO- treated group for variable 1 or depressed mood by Day 10 (p=.044); for variable 2 or insomnia (p = .006) and variable 3 or activities (p=.003) by Day 14; and for variable 4 or anxiety (p<.001) and variable 5 or somatic symptoms (p<.001) by Day 21.

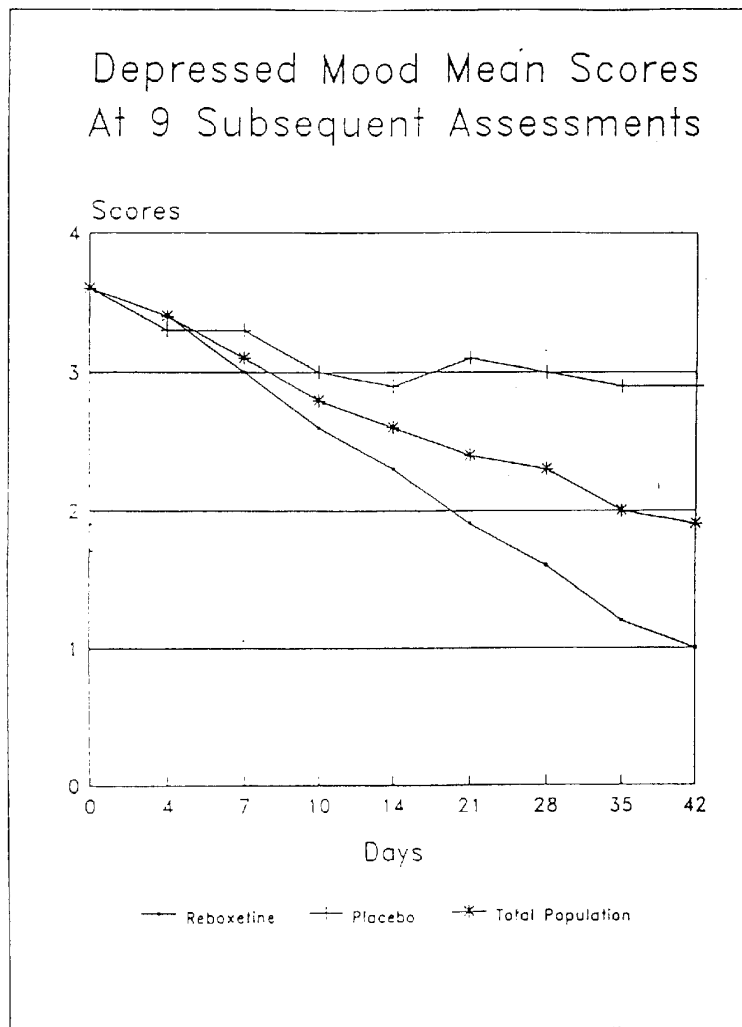
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Figure 3

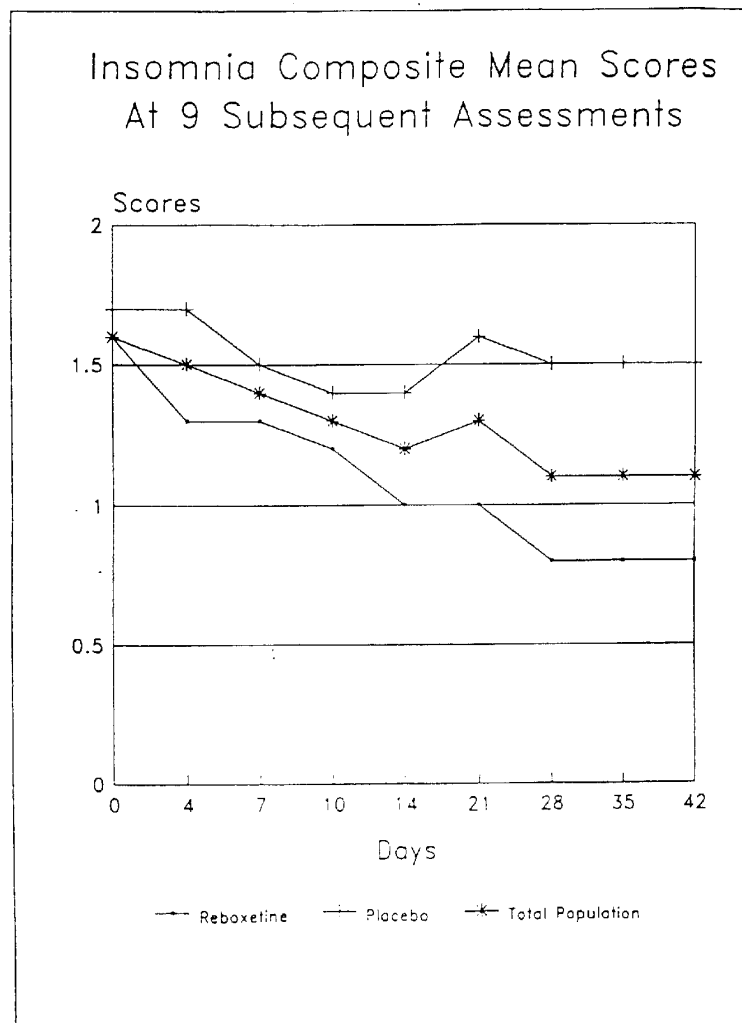


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Figure 4

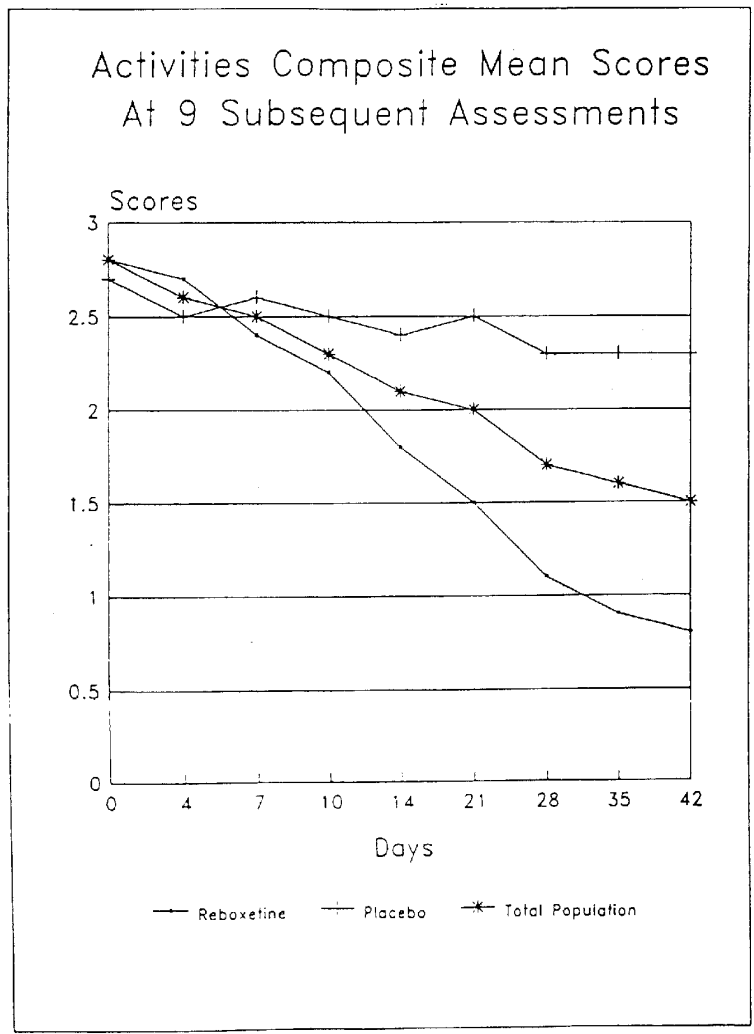


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Figure 5



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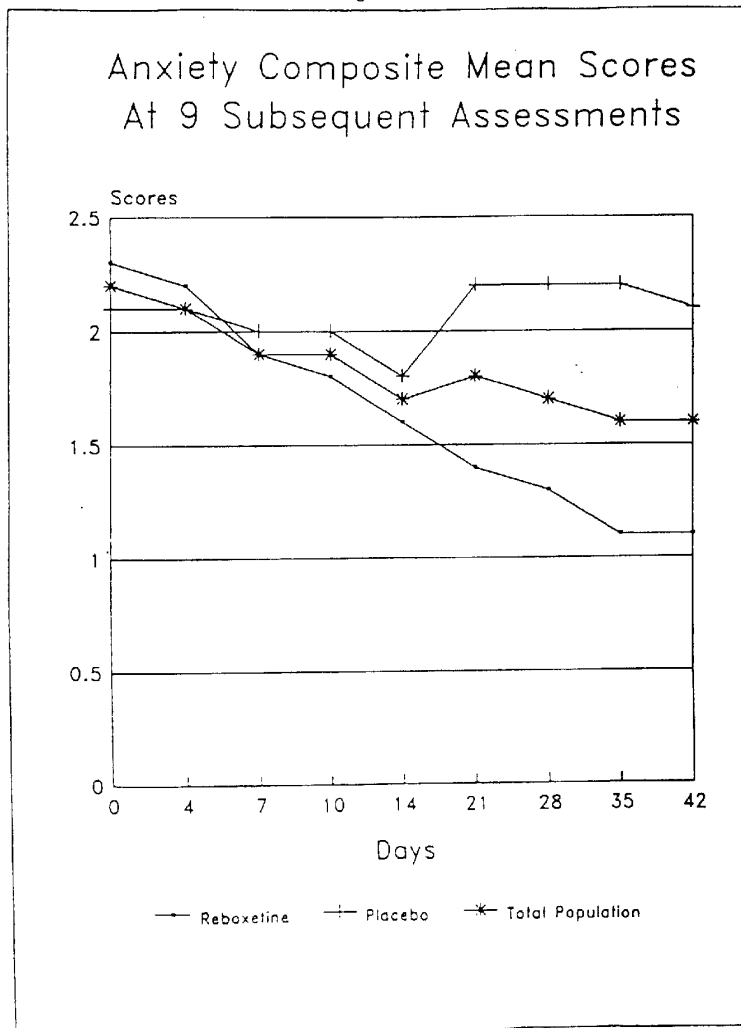
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Figure 6



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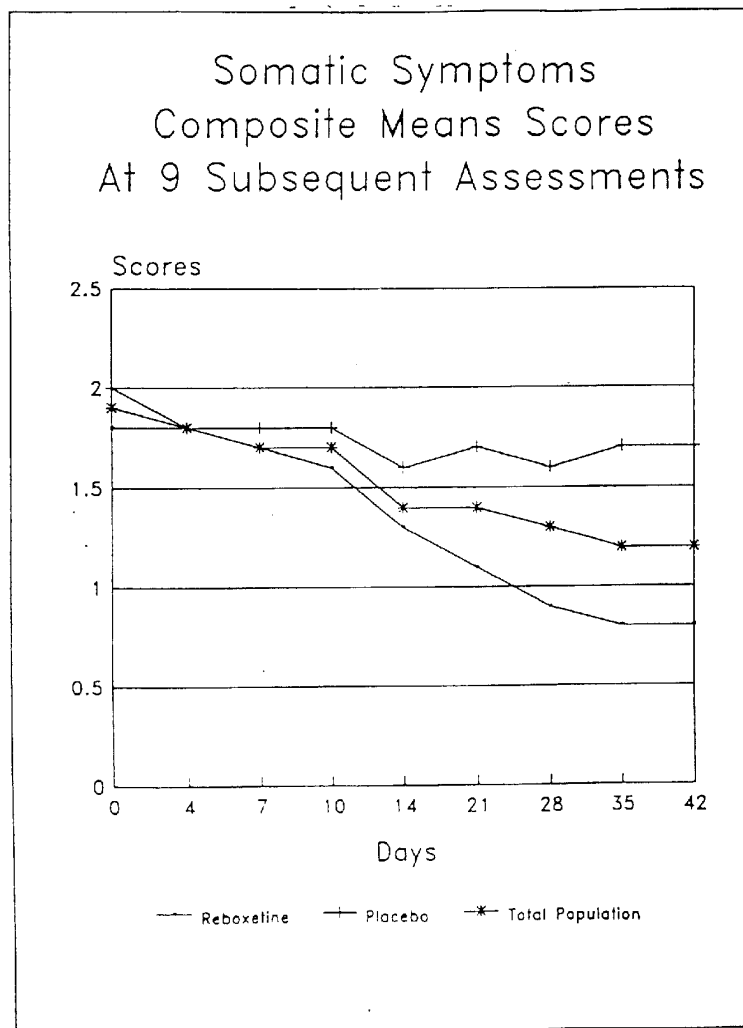
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Figure 7



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Table 22
Changes in the Score of Depressed Mood from Baseline (Day 0) Through Seven Assessments to the Final Assessment

Groups	Baseline Scores	Day 4		Day 7		Day 10		Day 14		Day 21		Day 28		Day 35		Day 42	
		Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓
Tot.	3.6	3.4	4.6	3.1	12.9	2.8	21.2	2.6	26.8	2.4	32.3	2.3	35.1	2.0	43.4	1.9	46.2
RBX	3.6	3.4	4.6	3.0	15.7	2.6	26.8	2.3	35.1	1.9	46.2	1.6	54.6	1.2	65.7	1.0	71.2
PBO	3.6	3.3	7.3	3.3	7.3	3.0	15.7	2.9	18.4	3.1	12.9	3.0	15.7	2.9	18.4	2.9	18.4

Table 23
Changes in the Composite Score of Insomnia from Baseline (Day 0) Through Seven Assessments to the Final Assessment

Groups	Baseline Scores	Day 4		Day 7		Day 10		Day 14		Day 21		Day 28		Day 35		Day 42	
		Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓
Tot.	1.6	1.5	5.3	1.4	11.5	1.3	1.8	1.2	24.0	1.3	17.8	1.1	30.3	1.1	30.3	1.1	30.3
RBX	1.6	1.3	17.8	1.3	17.8	1.2	24.0	1.0	36.5	1.0	36.5	0.8	49.0	0.87	49.0	0.8	49.0
PBO	1.7	1.7	0.0	1.5	10.8	1.4	16.6	1.4	16.6	1.6	4.9	1.5	10.8	1.5	10.8	1.5	10.8

Table 24
Changes in the Composite Score of Activities from Baseline (Day 0) Through Seven Assessments to the Final Assessment

Groups	Baseline Scores	Day 4		Day 7		Day 10		Day 14		Day 21		Day 28		Day 35		Day 42	
		Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓
Tot.	2.8	2.6	6.1	2.5	9.7	2.3	16.9	2.1	24.0	2.0	27.6	1.7	38.3	1.6	42.9	1.5	45.4
RBX	2.8	2.7	2.6	2.4	13.3	2.2	20.4	1.8	34.7	1.5	45.4	1.1	59.7	0.9	66.9	0.8	70.4
PBO	2.7	2.5	6.4	2.6	2.7	2.5	6.4	2.4	10.1	2.5	6.4	2.3	13.8	2.3	13.8	2.3	13.8

Table 25
Changes in the Composite Score of Anxiety from Baseline (Day 0) Through Seven Assessments to the Final Assessment

Groups	Baseline Scores	Day 4		Day 7		Day 10		Day 14		Day 21		Day 28		Day 35		Day 42	
		Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓
Tot.	2.2	2.1	3.5	1.9	12.6	1.9	12.6	1.7	21.7	1.8	17.2	1.7	21.7	1.6	26.3	1.6	26.3
RBX	2.3	2.2	3.3	1.9	16.4	1.8	20.7	1.6	29.4	1.4	38.1	1.3	42.5	1.1	51.2	1.1	51.2
PBO	2.1	2.1	0.0	2.0	3.8	2.0	3.8	1.8	13.3	2.2	-5.8	2.2	-5.8	2.2	-5.8	2.1	0.0

Table 26
Changes in the Composite Somatic Symptoms Score from Baseline (Day 0) Through Seven Assessments to the Final Assessment

Group	Baseline Scores	Day 4		Day 7		Day 10		Day 14		Day 21		Day 28		Day 35		Day 42	
		Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓	Score	% ↓
Total	1.9	1.8	4.3	1.7	9.5	1.7	9.5	1.4	25.3	1.4	25.3	1.3	30.6	1.2	35.8	1.2	35.8
RBX	1.8	1.8	0.0	1.7	4.6	1.6	10.1	1.3	26.8	1.1	37.9	0.9	49.0	0.8	54.6	0.8	54.6
PBO	2.0	1.8	9.0	1.8	9.0	1.8	9.0	1.6	19.0	1.7	14.0	1.6	19.0	1.7	14.0	1.7	14.0

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9.1.2 ZUNG Self-Rating Scale for Depression

Another assessment instrument employed in the evaluation of therapeutic effects was the 20-item ZUNG (See Enclosure 11), completed seven times by the patient in the course of the clinical trial, i.e., Day 0 (Baseline), and at Day 7, 14, 21, 28, 35, and 42 (final assessment) of drug administration. The recorded data of the ZUNG for the first and last assessments for each patient was used for measuring therapeutic activity; and from all assessments for identifying the onset of therapeutic activity.

All information relevant to each patient in the analytic cohort for measuring therapeutic activity and identifying the onset of therapeutic activity by the ZUNG is presented in Enclosure 23; and all the information regarding the statistics used in measuring therapeutic activity and identifying the onset of therapeutic activity by ZUNG is presented in Appendices 14 and 15.

9.1.2.1 THERAPEUTIC EFFICACY

Measurements of therapeutic efficacy was based on a comparison of the changes in the mean total scores of the ZUNG from the baseline assessment (Day 0) to the final (Day 42) assessment in the RBX and PBO groups of the analytic cohort. As a result it was found that mean total scores of the ZUNG in the total analytic cohort decreased (improved), as shown in Table 27, from a score of 65.8 at baseline to 50.4 at the final assessment, with a decrease from a score of 66.3 to a score of 42.8 in the RBX and from a score of 65.2 to a score of 58.6 in the PBO groups, representing a decrease of 22.1%, 33.6% and 9.1% from pre- to post-treatment, respectively. Analyses of variance (pre-post) revealed that the decrease (improvement) in mean total scores from baseline to the final assessment was significantly greater ($p=.001$) in the RBX than in the PBO group. There was no interaction between therapeutic efficacy and sex, country, age (18-37, 38-49, and ≥ 50) and diagnostic subform.

9.1.2.2 ONSET OF THERAPEUTIC ACTIVITY

Onset of therapeutic activity was examined by comparing the changes in the mean total scores of the ZUNG from baseline (Day 0) through all the subsequent assessments, i.e., Day 7, 14, 21, 28 and 35 to the Day 42 or final assessment in the two treatment groups by employing repeated measures analyses of variance. As a result, as shown in Figure 8, it was found that the decrease (improvement) in mean total scores of the ZUNG was sharper during the first 14 days of treatment in the RBX- than in the PBO- treated group. The difference in the speed of the decrease in mean total scores, as shown in Table 28, was to the extent that by the Day 14 assessment mean total scores in the RBX group (54.7 ± 9.63) were significantly ($p=.035$) lower than in the PBO group (60.8 ± 10.61).

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Table 27
Changes in the ZUNG Mean Total and Index Scores
from Baseline to the Final Assessment

Groups	Baseline		Final		Pre-Post %changes	
	Score	Index	Score	Index	Score	Index
Analytic Cohort	65.9	.822	50.4	.630	22.1	22.1
RBX	66.3	.829	42.8	.535	33.6	33.6
PBO	65.2	.815	58.6	.732	9.1	9.1

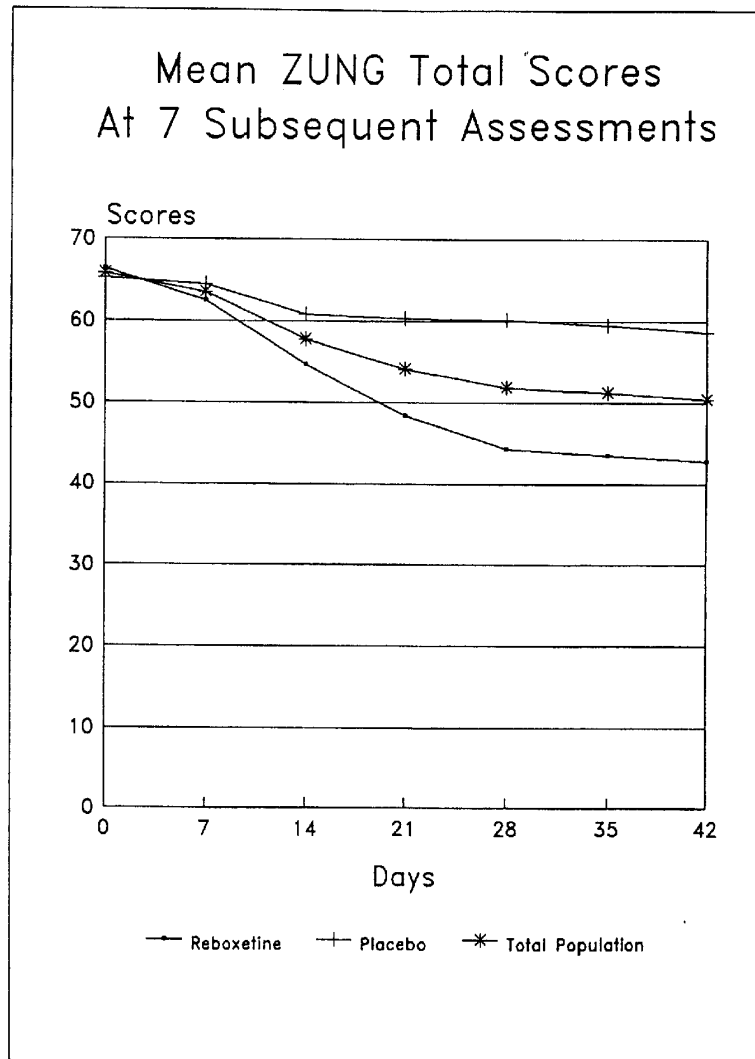
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Figure 8



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Table 28
ZUNG Mean Total and Index Scores at Percentage of Change from Day 0 to Day 42

	RBX Group			PBO Group			Tot Pop.		
	Mean	Index	%Change	Mean	Index	%Change	Mean	Index	%Change
Day 0	66.3	.829	--	65.2	.815	--	65.2	.822	--
Day 7	62.5	.782	5.12	64.5	.807	.22	63.5	.794	2.87
Day 14	54.7	.684	16.25	60.8	.761	5.61	57.7	.721	11.24
Day 21	48.4	.605	25.67	60.3	.734	6.50	54.1	.676	16.65
Day 28	44.3	.553	31.92	60.1	.752	6.72	51.9	.649	20.06
Day 35	43.5	.544	33.12	59.5	.744	7.63	51.2	.640	21.13
Day 42	42.8	.535	33.58	58.6	.732	9.11	50.4	.630	22.06

9.1.3 Severity of Illness

A third assessment instrument employed in the evaluation of therapeutic effects was the SI component of the CGI (see Enclosure 11), completed seven times (by the same assessor throughout for the same patient) in the course of the clinical trial, i.e., Day 0 (baseline), and at Day 7, 14, 21, 28, 35 and 42 (final assessment) of drug administration. The recorded data of the CGI-SI from baseline (Day 0) to the final (Day 42) assessment of each patient was used for measuring therapeutic efficacy and for all seven assessments for identifying the onset of therapeutic activity.

All the information relevant to each patient of the analytic cohort used for measuring therapeutic efficacy and identifying the onset of therapeutic activity by employing the CGI-SI are presented in Enclosure 24; and all the information regarding the statistics used in measuring therapeutic efficacy and onset of therapeutic activity by employing the CGI-SI are presented in Appendices 16 and 17.

9.1.3.1 THERAPEUTIC EFFICACY

Measurement of therapeutic efficacy was based on a comparison of the changes in the mean scores of the CGI-SI from baseline (Day 0) to the final (Day 42) assessment in the RBX and PBO groups of the analytic cohort. As a result, it was found that mean scores of the CGI-SI in the analytic cohort decreased (improved) as shown in Table 29, of a score of 5.58 at baseline to a score of 3.12 at the final assessment with a decrease from a score of 5.74 to a score of 2.07 in the RBX and from a score of 5.40 to a score of 4.24 in the PBO groups, representing a decrease of 42.2%, 62.3% and 20.5%, respectively, from pre- to post-treatment. Analyses of variance (pre-post) revealed that the decrease (improvement) in mean scores from baseline to the final assessment was significantly greater ($p < .001$) in the RBX than in the PBO group. There was non interaction between therapeutic efficacy and sex, country, age (18-37, 38-49 and ≥ 50), diagnostic subform and assessor.

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9.1.3.2 ONSET OF THERAPEUTIC ACTIVITY

Onset of therapeutic activity was examined by comparing the changing in the mean scores of the CGI-SI from baseline (Day 0) through all the subsequent assessments, i.e., Day 7, 14, 21, 28, 35 and 42 or final assessment in the two treatment groups. As a result as shown in Figure 9, it was found that the decrease (improvement) in mean scores of the CGI-SI was sharper during the first 14 days of treatment in the RBX- than in the PBO- treated group.. The difference in the speed of the decrease in mean scores was to the extent that by the time of the Day 14 assessment, mean scores of the RBX group (3.78+/-1.19) were significantly (p=.025) lower than in the PBO group (4.56+/-1.26). The decrease (improvement) of mean scores in the PBO group, as shown in Table 30, peaked at the Day 28 assessment, whereas in the RBX group it continued throughout the remainder of the clinical trial. There was no interaction between therapeutic efficacy and sex, age (18-37, 38-49, and 50 years and above).

Table 29
Changes in the CGI-SI Mean Total Scores
from Baseline to the Final Assessment

Groups	Baseline	+/-	Final	+/-	Pre-Post %changes	+/-
Analytic Cohort	5.58	.537	3.12	2.07	42.2	37.9
RBX	5.74	.447	2.07	1.66	62.3	29.7
PBO	5.40	.577	4.24	1.90	20.5	34.0

Table 30
CGI-SI Mean Total Scores and Percentage of Change
from Baseline to All Subsequent Assessments

	RBX Group		PBO Group		Tot Pop.	
	Mean	%Change	Mean	%Change	Mean	%Change
Day 0	5.74	--	5.40	--	5.58	--
Day 7	4.49	13.6	5.04	5.5	4.96	9.7
Day 14	3.78	32.6	4.56	14.6	4.15	23.9
Day 21	3.00	46.4	4.72	11.5	3.83	29.6
Day 28	2.59	53.4	4.32	19.3	3.42	37.0
Day 35	2.19	60.5	4.28	19.9	3.19	41.0
Day 42	2.07	62.3	4.24	20.5	3.12	42.2

9.1.4 Global Improvement

The fourth and final assessment instrument employed in the evaluation of therapeutic effects was the GI component of the CGI (See Enclosure 11), completed six times (by the same assessor throughout the same patient) in the course of the clinical trial, i.e., at Days 7, 14, 21, 28, 35 and 42 of drug administration

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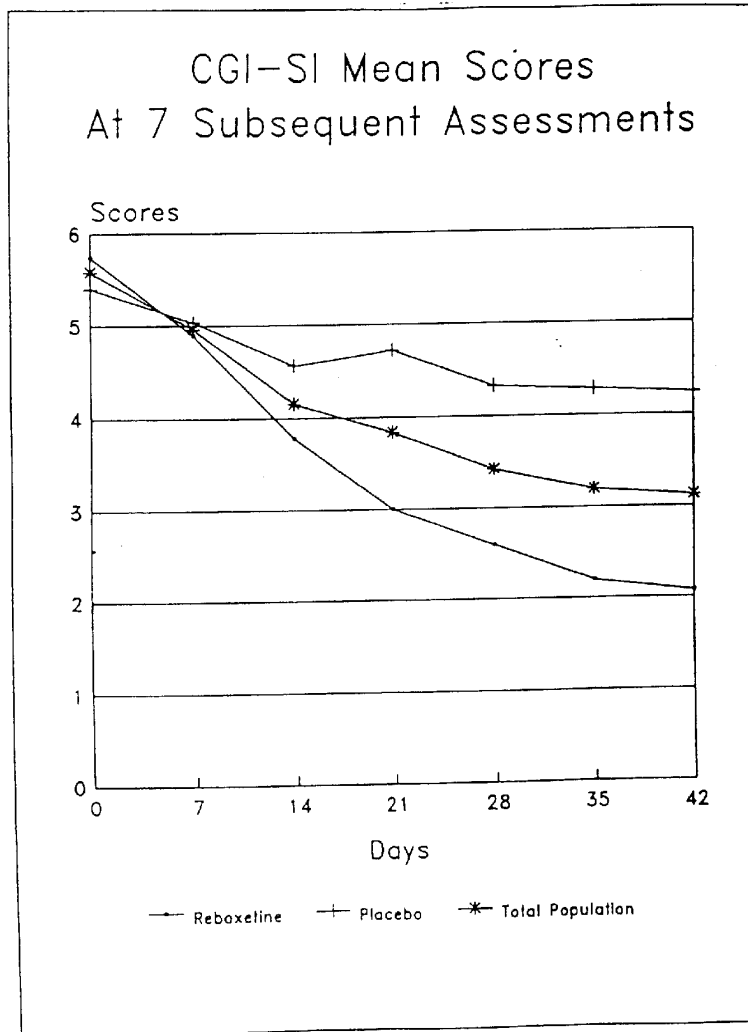
All the information relevant to each patient of the analytic cohort used for measuring therapeutic efficacy and identifying the onset of therapeutic activity by employing the CGI-GI are presented in Enclosure 25; and all the information regarding the statistic used in measuring therapeutic efficacy and onset of therapeutic activity by employing the CGI-GI are presented in Appendices 18 and 19.

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Figure 9



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9.1.4.1 THERAPEUTIC EFFICACY

Measurement of therapeutic efficacy was based on a comparison of mean scores of the CGI-GI and the number of patient showing very much (score = 1) and much (score = 2) improvement at the time of the final (Day 42) assessment in the two treatment groups. As a result it was found that mean CGI-GI scores at the time of the final assessment were significantly ($p < .001$) lower in the RBX- (score: 1.56) than in the PBO- (score: 3.40) treated group, indicating much (score: 2) to very much (score: 1) improvement in RBX- and minimal improvement (score: 3) to no change (score: 4) in PBO- treated group. Corresponding with these results are the findings that by the time of the final assessment, a significantly ($p < .001$) greater number of patients in the RBX- (22 patients; 81.5%) than in the PBO- (7 patients; 28.0%) treated group attained very much (score: 1) and much (score: 2) improvement. There was non interaction between therapeutic efficacy and sex, age (18-37, 38-49 and ≥ 50) diagnostic subform and assessor.

9.1.4.2 ONSET OF THERAPEUTIC ACTIVITY

Onset of therapeutic activity was examined by comparing the mean scores and number of patients attaining very much (score 1) and much (score 2) improvement in the two treatment groups on the six consecutive assessments. As a result, it was found that by the time of the Day 14 assessment, mean scores were significantly ($p < .001$) lower (indicating greater improvement) (RBX 2.41, PBO 3.32), and, as shown in Table 31, the number of patient showing very much (1) or much (2) improvement was significantly ($p = .008$) higher in the RBX than in the PBO group.

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Table 31
Number and Percentage of Patients Showing Different Levels of Change on CGI-GI at the Time of 6 Assessments

Variables	Day 7		Day 14		Day 21		Day 28		Day 35		Day 42	
	N	%	N	%	N	%	N	%	N	%	N	%
1 very much improved												
RBX	1	1.37	3	11.1	10	37.0	15	55.6	20	74.1	20	74.1
PBO	-	-	1	4.0	1	4.0	4	16.0	5	20.0	5	20.0
2 much improved												
RBX	1	1.37	12	44.4	9	33.3	6	22.2	1	3.7	2	7.4
PBO	-	-	4	16.0	4	16.0	3	12.0	3	12.0	2	8.0
3 minimally improved												
RBX	13	48.1	10	37.0	6	22.2	3	11.1	3	11.1	2	7.4
PBO	8	32.0	6	24.0	5	20.0	3	12.0	2	8.0	3	12.0
4 no change												
RBX	12	44.4	2	7.4	2	7.4	3	11.1	3	11.1	3	11.1
PBO	17	68.0	14	56.0	9	36.0	9	36.0	9	36.0	9	36.0
5 minimally worse												
RBX	-	-	-	-	-	-	-	-	-	-	-	-
PBO	-	-	-	-	6	24.0	5	20.0	5	20.0	5	20.0
6 much worse												
RBX	-	-	-	-	-	-	-	-	-	-	-	-
PBO	-	-	-	-	-	-	1	4.0	1	4.0	1	4.0
7 very much worse												
RBX	-	-	-	-	-	-	-	-	-	-	-	-
PBO	-	-	-	-	-	-	-	-	-	-	-	-

9.2 Tolerability

Evaluation of tolerability was based on the analyses of data recorded on the Newly Observed Signs and Symptoms form and four of the five components (blood pressure, heart rate, oral body temperature and body weight) of the Vital Signs form (See Enclosure 11).

9.2.1 Newly Observed Signs and Symptoms

The primary assessment instrument employed in the evaluation of tolerability was the NOSS, a specially designed scale completed 8 times in the course of clinical trial, i.e., Days 0, 4, 7, 10, 14, 21, 28 and 42, as well as at the time when an adverse effect was encountered during the clinical trial. It should be noted that in the variance with efficacy, all analyses relevant to tolerability was conducted on the total population (and were non restricted to the analytic cohort).

9.2.1.1 PLACEBO WASHOUT

To detect adverse effects at the end of pretreatment placebo washout, the NOSS was completed at Day 0, prior to commencement of the 42-day clinical trial; and to detect possible

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differences in the propensity for adverse effects, the different “newly observed signs and symptoms” encountered at Day 0 were compared in the populations to be treated with RBX and PBO. As a result, as shown in Table 32, it was found that of the six different kinds of newly observed signs and symptoms -- providing a total of eight reports -- encountered, two newly observed signs and symptoms --providing for two reports -- were encountered in 1 patient in the RBX group and five newly observed signs and symptoms -- providing for six reports -- were encountered in 3 patients in the PBO group. It was noted that all newly observed signs and symptoms in the RBX group were reported spontaneously, whereas in the PBO group 50% were reported spontaneously and 50% were elicited upon inquiry. It was also noted that the propensity for newly observed signs and symptoms was about three times as high in the PBO than in the RBX group.

All relevant information recorded for each patient on newly observed signs and symptoms encountered at Day 0 in each of the two groups (i.e., in the group to be treated with RBX and in the group to be treated with PBO) is listed in Enclosure 26; and all information regarding the statistics employed on newly observed signs and symptoms encountered at Day 0 is presented in Appendix 20.

Table 32
Newly Observed Signs and Symptoms at Day 0

Adverse Effects	Population to be Treated with RBX			Population to be Treated with PBO			Total Population		
	No. Rpt.	Report: Spont.	Upon Inquiry	No. Rpt.	Report: Spont.	Upon Inquiry	No. Rpt.	Report: Spont.	Upon Inquiry
Dizziness	1	1	0	2	0	2	3	1	2
Headache	1	1	0	0	0	0	1	1	0
Insomnia	0	0	0	1	0	1	1	0	1
Constipation	0	0	0	1	1	0	1	1	0
Agitation	0	0	0	1	1	0	1	1	0
Sexual disturbance	0	0	0	1	0	1	1	0	1

9.2.1.2 CLINICAL TRIAL

To detect adverse effects all newly observed signs and symptoms were recorded at Days 4, 7, 10, 14, 21, 28, 35, 42 in the total recruited population; and to reveal possible differences between RBX- and PBO- induced adverse effects, those which were not encountered at the time of the Day 0 assessment were compared.

9.2.1.2.1 Signs and Symptoms

There were 278 reports dealing with 21 newly observed signs and symptoms encountered in 41 patients from Day 0 to Day 42. Of them, 270 reports dealt with 21 newly observed signs and symptoms encountered in 37 patients from Day 4 to Day 42. In 3 of the 4 patients with newly observed signs and symptoms at Day 0 newly observed signs and symptoms were also reported from Day 4 to Day 42. It was found that of the 21 newly observed signs and symptoms, 18 were

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encountered in 24 (85.7%) patients in the RBX group and 13 were encountered in 13 (46.4%) patients in the PBO group with, as shown in Table 33, 10 (dry mouth, blurred vision, constipation, vomiting, tremor, sexual disturbance, dizziness, headache, agitation and drowsiness) encountered in 35 (94.6%) patients in both treatment groups. It was noted that eight newly observed signs and symptoms (i.e., insomnia, urinary retention, sweating, cold in extremities, hypotension, decreased appetite, pruritus and hypomania) were encountered exclusively in 12 patients treated with RBX, whereas three (urinary incontinence, diarrhea and lassitude) were encountered exclusively in 4 patients treated with PBO.

All relevant information reported for each patient on newly observed signs and symptoms which occurred during the 42-day clinical trial in each of the two treatment groups is listed in Enclosure 27; and all the information regarding the statistics employed on newly observed signs and symptoms which occurred during the 42-days clinical trial is presented in Appendix 21.

Table 33
Newly Observed Signs and Symptoms (not present at pre-treatment)

Symptoms:	RBX		PBO	
	No	%	No	%
Dry mouth	16	57.1	6	21.4
Insomnia	7	25.0	0	0.0
Blurred Vision	5	17.9	1	3.6
Sweating	5	17.9	0	0.0
Constipation	4	14.3	2	7.1
Vomiting	4	14.3	1	3.6
Tremor	4	14.3	3	10.7
Hypotension	3	10.7	0	0.0
Decreased appetite	3	10.7	0	0.0
Sexual Disturbance	3	7.1	1	3.6
Dizziness	2	7.1	1	3.6
Headache	2	7.1	5	17.9
Agitation	1	3.6	1	3.6
Drowsiness	1	3.6	1	3.6
Urinary Retention	1	3.6	0	0.0
Pruritus	1	3.6	0	0.0
Cold Extremities	1	3.6	0	0.0
Hypomania	1	3.6	0	0.0
Diarrhea	0	0.0	2	7.1
Urinary Incontinence	0	0.0	1	3.6
Lassitude	0	0.0	1	3.6

9.2.1.2.2 Reporting Method

There were 270 reports dealing with 21 newly observed signs and symptoms encountered in 37 patients and from these 270 reports the method of reporting was recorded for 266. As shown in Table 34, there were 212 reports encountered in 24 patients of RBX- and 54 encountered in 13 patients of the PBO-treated group. In both treatment groups, the number of spontaneously reported

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newly observed signs and symptoms was higher (RBX: 143 reports; PBO: 40 reports) than the number of reports elicited upon inquiry (RBX: 69 reports; PBO: 15 reports).

Table 34
Method of Reporting

Group	Total No. of Reports	Spontaneously	Upon Inquiry
RBX	212	143	69
PBO	54	39	15
Tot. Pop.	266	182	84

9.2.1.2.3 Present at Day 0

As shown in Table 35, of the 21 newly observed signs and symptoms encountered in 41 patients from Day 0 to Day 42, six (dizziness, headache, insomnia, constipation, agitation, and sexual disturbance) were already present in 4 patients at Day 0. Of the 18 newly observed signs and symptoms encountered in 24 patients from Day 0 to Day 42 in the RBX group, two (headache and dizziness) were present already in 1 patient at Day 0; and of the 13 newly observed signs and symptoms encountered in 13 patients in the PBO group, five (dizziness, insomnia, constipation, sexual disturbance and agitation) were present already in 3 patients at Day 0.

Table 35
Number and Percentage of Patients with Newly Observed Signs and Symptoms Present at Day 0 in the Two Treatment Groups of the Total Population

Symptoms:	RBX Group		PBO Group		Tot. Pop.	
	No	%	No	%	No	%
Dizziness	1	3.6	2	7.1	3	5.4
Headache	1	3.6	0	0.0	1	1.8
Insomnia	0	0.0	1	3.6	1	1.8
Constipation	0	0.0	1	3.6	1	1.8
Agitation	0	0.0	1	3.6	1	1.8
Sexual Disturbance	0	0.0	1	3.6	1	1.8

9.2.1.2.4 Day of Onset

The onset for each of the 21 newly observed signs and symptoms, in terms of number of patients at the time of the different assessment, i.e., Days 4, 7, 10, 14, 21, 28, 35 and 42, is presented in Table 36. As shown in this Table, the onset of all but two (pruritus and hypomania) of the 18 newly observed signs and symptoms encountered in the RBX group was within the first 10 days of

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treatment in the majority of patients, although the onset of sexual disturbance in 1 patient was as late as the 35th day and the onset of blurred vision in 1 patient was as late as the 28th day. Also as shown in Table 36, with the exception of blurred vision in 1 patient, which was reported on Day 14, all newly observed signs and symptoms in the PBO group were encountered within the first seven days of treatment.

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Table 36
Day of Onset of Newly Observed Signs and Symptoms
in Number of Patients in the Two Treatment Groups

Symptoms:	RBX Group								PBO Group							
	Day								Day							
	4	7	10	14	21	28	35	42	4	7	10	14	21	28	35	42
Dry mouth	11	2	1	0	2	0	0	0	3	3	0	0	0	0	0	0
Insomnia	1	2	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Blurred Vision	0	3	1	0	0	1	0	0	0	0	0	1	0	0	0	0
Sweating	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Constipation	1	1	2	0	0	0	0	0	1	1	0	0	0	0	0	0
Vomiting	1	2	0	1	0	0	0	0	0	1	0	0	0	0	0	0
Tremor	2	1	1	0	0	0	0	0	2	1	0	0	0	0	0	0
Hypotension	0	2	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Decreased appetite	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
Sexual Disturbance	0	1	1	0	0	0	1	0	1	1	0	0	0	0	0	0
Dizziness	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Headache	0	1	0	0	0	0	0	0	4	1	0	0	0	0	0	0
Agitation	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Drowsiness	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Urinary Retention	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pruritus	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Cold Extremities	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hyponomania	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Diarrhea	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
Urinary Incontinence	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Lassitude	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0

9.2.1.2.5 Duration

As shown in Table 37, the mean number of days newly observed signs and symptoms -- regardless of their nature -- were present in the 24 RBX- treated patients with newly observed signs and symptoms was significantly ($p < .001$) longer (mean 10.22+/-7.66 days) than the mean number of days newly observed signs and symptoms were present in the 13 PBO-treated patients with newly observed signs and symptoms (mean 2.72+/-2.86 days).

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Table 37
Range and Mean Number of Days of Symptom Duration
in the Two Treatment Groups

	Range	Mean	S.D.	Results	Test
RBX	1-39	10.22	7.66	p < .001	ANOVA
PBO	1-11	2.72	2.86		
Tot. Pop.	1-39	9.21	8.30		

As shown in Table 38, the duration of the 18 newly observed signs and symptoms encountered ranged from 1 to 39 days in individual patients in the 24 RBX group; and the duration of the 13 newly observed signs and symptoms ranged from 1 to 11 days in the individual patients in the PBO group. And as also shown in Table 38, the mean number of days of the 18 different newly observed signs and symptoms displayed in the RBX-treated group ranged from 1 (cold extremities) to 17.2 (sexual disturbance) days; and the mean number of days of the 13 different newly observed signs and symptoms displayed in the PBO-treated group ranged from 1 (blurred vision) to 6.13 (dry mouth) days.

9.2.1.2.6 Severity

In the Table 39 the severity profile in terms of mild, moderate, severe and very severe of the 270 reports on the 21 newly observed signs and symptoms encountered in 37 patients is presented in the two treatment groups. As shown in Table 39, newly observed signs and symptoms with mild intensity were encountered with comparable frequency (RBX: 79.6% and PBO: 70.4%) in the two treatment groups, whereas newly observed signs and symptoms with severe intensity were encountered significantly (p=.038) more often in the RBX- (13 reports; 6.0%) than in the PBO- (1 reports; 1.85%) treated group.

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Table 38

Range of Duration (in Mean Number of Days) of each Newly Observed Sign and Symptoms in Individual Patients and the Mean Duration of each Newly Observed Sign and Symptom in the Two Treatment Groups.

Symptom	RBX		PBO	
	Range	Mean	Range	Mean
Hypotension	1-3	2.00	n/a	n/a
Dry Mouth	1-26	9.06	2-10	6.13
Drowsiness	4-5	4.50	n/a	3.00
Insomnia	1-22	6.50	n/a	n/a
Sweating	2-38	13.72	n/a	n/a
Headache	1-5	3.33	1-4	2.60
Constipation	1-30	11.41	1-9	5.67
Dizziness	2-4	2.67	3-6	4.50
Diarrhea	n/a	n/a	2-4	3.00
Vomiting	2-7	3.17	n/a	3.00
Blurred Vision	1-28	11.32	n/a	1.00
Lassitude	n/a	n/a	n/a	6.00
Pruritus	n/a	7.00	n/a	n/a
Agitation	n/a	3.00	n/a	4.00
Tremor	1-30	11.85	2-11	5.56
Decreased Appetite	2-35	14.55	n/a	n/a
Urinary Retention	4-29	13.67	n/a	n/a
Sexual Disturbance	1-39	17.20	3-4	3.50
Urinary Incontinence	n/a	n/a	3-5	4.00
Hyponomania	n/a	n/a	3.50	n/a
Cold Extremities	n/a	1.00	n/a	n/a

Table 39

Severity Profile of 270 Reports of Newly Observed Signs and Symptoms in the Two Treatment Groups.

Intensity	RBX		PBO	
	N	%	N	%
Mild	172	79.6	38	70.4
Moderate	31	14.4	15	27.8
Severe	13	6.0	1	1.8

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9.2.1.2.7 Counteractive Measures: Frequency

Counteractive measures -- regardless of their nature -- were recorded in a similar proportion of reports on newly observed signs and symptoms in the RBX- (103 reports; 47.7%) treated group and in the reports of newly observed signs and symptoms in the PBO- (26 reports; 47.3%) treated group.

9.2.1.2.8 Counteractive Measures: Nature

Counteractive measures for newly observed signs and symptoms consisted of transient decrease in the dosage of medication in 2 RBX-treated patients (See 8.1.2); the administration of counteractive medication in 4 RBX-treated patients -- of which 3 patients were completers (See 8.1.3 and Table 16) and 1 patient who was to become a dropout -- and in 1 PBO-treated patient who was to become a dropout; and discontinuation of medication in 1 RBX- and in 1 PBO-treated patient (See 8.2.1). The counteractive medications given to the RBX-treated patient (No. 1) who was to become a dropout were urecholine for urinary retention and surfak for constipation; and the counteractive medication given to the PBO-treated patient (No. 33) who was to become a dropout was acetaminophen.

9.2.1.2.9 Persistence

In 1 RBX-treated patient (No. 121), newly observed signs and symptoms, i.e., sweating, decreased appetite and sexual disturbance, persisted after discontinuation of treatment for three, five and three days, respectively.

9.2.1.2.10 Outcome

In all patients of the RBX-treated group the outcome of each newly observed signs and symptom at the time when recorded for the last time in the course of the clinical trial was marked "fully recovered" (even for the outcome of "sweating", "decreased appetite" and "sexual disturbance" which persisted after discontinuation of treatment); and in all but 1 patient from the PBO-treated group (No. 33) the outcome of each newly observed sign and symptom at the time when recorded for the last time in the course of the clinical trial was marked "fully recovered". In this 1 patient the outcome of "headache" was marked as "recovered with sequelae".

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9.2.1.2.11 Relationship to Treatment

In Table 40 the relationship between newly observed signs and symptoms and treatment in terms of unknown, possible/doubtful, probable and certain for the two treatment groups. As shown in Table 40, the proportion of newly observed signs and symptoms which were attributed definitely (certain) to treatment was higher in the RBX-(145 reports; 67.1%) than the PBO- (20 reports; 37.7%) treated group. The difference between the number of reports attributed definitely to treatment was statistically significant ($p < .001$).

Table 40
Newly Observed Signs and Symptoms:
Relationship to Treatment

Relationship	RBX		PBO	
	N	%	N	%
Unknown	5	2.3	1	1.9
Possible/Doubtful	17	7.9	17	32.1
Probable	49	22.7	15	28.3
Certain	145	67.1	20	37.7

9.2.1.2.12 Course

In Table 41 the course of newly observed signs and symptoms in the two treatment groups is identified in terms of: **a)** cleared, trial drug continued, **b)** persisted, trial drug continued, **c)** cleared, after dose lowered, **d)** persisted, after dose lowered, **e)** trial drug temporarily stopped and **f)** trial drug permanently stopped. There was no significant difference in the course of newly observed signs and symptoms between the two treatment groups.

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Table 41
Newly Observed Signs and Symptoms:
Course

Course	RBX		PBO	
	N	%	N	%
cleared, trial drug continued	32	28.6	12	22.6
persisted, trial drug continued	163	77.3	39	73.6
cleared, after dose lowered	0	0.0	0	0.0
persisted, after dose lowered	9	4.3	0	0.0
trial drug temporarily stopped	0	0.0	0	0.0
trial drug permanently stopped	7	3.3	2	3.8

9.2.2 Vital Signs

Tolerability was also assessed by the monitoring of vital signs, including blood pressure, heart rate, body temperature and weight. These measurements were recorded at Day 0, 1, 2, 3, 4, 5, 6, 7, 10, 14, 21, 28, 35, and 42.

All information relevant to vital signs for each patient in both treatment groups is presented in Enclosure 28; and all information regarding the statistics on vital signs are presented in Appendix 22.

9.2.2.1 FIRST FOUR DAYS

For the detection of early changes in blood pressure and heart rate, vital signs were monitored twice daily during the first four days of drug administration.

9.2.2.1.1 Systolic Blood Pressure

In Table 42 and 43 the number of patients with a systolic blood pressure outside the normal range (i.e. below 100 Hgmm or above 140 Hgmm) before the morning and the evening dose, respectively, are presented during the first four days of treatment in the two treatment groups; and in Table 44 the number of patients with possible postural changes, i.e., a drop of systolic blood pressure from lying to standing, is presented for the same time period. As shown in Table 42 and 43, the number of patients with a systolic blood pressure outside the normal range were comparable in the two treatment groups during the first four days of treatment. Although as shown in Table 44, a consistently greater number of patients showed a drop in systolic pressure after

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changing from a supine to an upright position from the RBX-treated group than from the PBO-treated group, in none of the patients in either of the two treatment groups was the drop in systolic blood pressure of clinical significance.

Table 42
Systolic Blood Pressure - Lying and Standing
Outside the Normal Range in Two Treatment Groups
During the First Four Days Before the Morning Dose

	Day 1		Day 2		Day 3		Day 4	
	Lying	Standing	Lying	Standing	Lying	Standing	Lying	Standing
RBX	2	1	2	1	3	2	3	0
PBO	2	1	2	2	2	2	2	1
Tot. Pop.	4	2	4	3	5	4	5	2

Table 43
Systolic Blood Pressure - Lying and Standing
Outside the Normal Range in Two Treatment Groups
During the First Four Days Before the Evening Dose

	Day 1		Day 2		Day 3		Day 4	
	Lying	Standing	Lying	Standing	Lying	Standing	Lying	Standing
RBX	2	1	1	1	3	2	2	1
PBO	1	1	1	1	1	2	0	1
Tot. Pop.	3	2	2	2	4	4	2	2

Table 44
Number of Patients with Postural Changes (Drop)
in Systolic Blood Pressure from Lying to Standing
During the First Four Days of Treatment

	Morning:				Evening:			
	Day 1	Day 2	Day 3	Day 4	Day 1	Day 2	Day 3	Day 4
RBX	19	20	26	22	20	20	16	20
PBO	14	17	14	14	8	8	11	17
Total	33	37	40	36	28	28	27	37

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9.2.2.1.2 Diastolic Blood Pressure

Table 45 and 46 show the number of patients with a diastolic blood pressure outside the range (i.e., below 60 Hgmm or above 90 Hgmm and above) prior to the morning and prior to the evening doses from Day 1 to Day 4 in both treatment groups. As shown in Tables 45 and 46, the number of patients with a diastolic blood pressure outside the normal range was comparable in the two treatment groups during the first four days of treatment.

Table 45
Diastolic Blood Pressure - Lying and Standing
Outside the Normal Range in Two Treatment Groups
During the First Four Days Prior to the Morning Dose

	Day 1		Day 2		Day 3		Day 4	
	Lying	Standing	Lying	Standing	Lying	Standing	Lying	Standing
RBX	2	1	2	1	1	2	2	2
PBO	0	2	1	3	0	1	1	0
Tot. Pop.	2	3	3	4	1	3	3	2

Table 46
Diastolic Blood Pressure - Lying and Standing
Outside the Normal Range in Two Treatment Groups
During the First Four Days Prior to the Evening Dose

	Day 1		Day 2		Day 3		Day 4	
	Lying	Standing	Lying	Standing	Lying	Standing	Lying	Standing
RBX	3	3	2	1	4	1	2	2
PBO	0	1	1	3	1	2	0	0
Tot. Pop.	3	4	3	4	5	3	2	2

9.2.2.1.3 Heart Rate

Tables 47 and 48 show the number of patients with an acceleration of heart rate from lying to standing by at least 10% prior to the morning and evening doses, respectively from Day 1 to Day 4 for both treatment groups. As shown in Tables 47 and 48, the number of patients with an acceleration of heart rate was comparable in the two treatment groups during the first four days of treatment.

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Table 47
Number of Patients with a 10% Acceleration in Heart Rate
During the First Four Days Prior to the Morning Dose

	Day 1 to Day 2		Day 1 to Day 3		Day 1 to Day 4	
	Lying	Standing	Lying	Standing	Lying	Standing
RBX	4	5	5	5	6	5
PBO	3	3	4	3	8	4
Tot. Pop.	7	8	9	8	14	9

Table 48
Number of Patients with a 10% Acceleration in Heart Rate
During the First Four Days Prior to the Evening Dose

	Day 1 to Day 2		Day 1 to Day 3		Day 1 to Day 4	
	Lying	Standing	Lying	Standing	Lying	Standing
RBX	1	2	4	3	4	6
PBO	4	6	5	8	5	7
Tot. Pop.	5	8	9	11	9	13

9.2.2.2 CLINICAL TRIAL

For the detection of changes in vital signs during the clinical trial, blood pressure, heart rate, body temperature and weight were recorded at regular intervals. I.e., blood pressure and heart rate at Days 0, 1, 2, 3, 4, 5, 6, 7, 10, 14, 21, 28, 35, and 42, and body temperature and weight at Days 0, 7, 14, 21, 28, 35 and 42.

9.2.2.2.1 Systolic-Supine Blood Pressure

Repeated measures analyses of variance across all treatment periods on lying systolic blood pressure indicated no significant difference between the two treatment groups. Pre-post ANCOVA (using Day 0 as the covariate) on lying systolic blood pressure, however indicated a trend (p=.064) toward significance. This was to the effect that, as shown in Table 49, mean lying systolic blood pressure readings in the RBX group decreased from 123.6 to 122.1 Hgmm from Day 0 to Day 42, whereas in the PBO group it increased from 120.7 to 121.8 Hgmm during the same period.

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Table 49
Supine Systolic Blood Pressure

Recording Day	Treatment RBX	Group PBO	Total Pop.
0	123.6	120.7	122.2
1	125.1	122.3	123.7
2	124.8	123.1	124.0
3	125.2	124.3	124.7
4	123.9	121.3	122.6
5	122.4	119.3	120.9
6	123.6	119.3	121.5
7	112.9	119.7	121.3
10	120.4	120.6	120.5
14	122.8	120.1	121.5
21	123.0	120.2	121.7
28	122.4	120.7	121.9
35	122.5	119.5	121.6
42	122.1	121.8	122.0

9.2.2.2.2 Systolic-Standing Blood Pressure

Repeated measures analyses of variance across all treatment periods on standing systolic blood pressure indicated no significant difference between the two treatment groups. Pre-post ANCOVA (using Day 0 as the covariate) on standing systolic blood pressure, however indicated a significant ($p=0.036$) difference between the two treatment groups. As shown in Table 50, mean standing systolic blood pressure in the RBX group decreased to a greater extent (from 121.3 to 116.8 Hgmm) from Day 0 to Day 42 than in the PBO group (from 118.7 to 118.0 Hgmm) during the same period.

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Table 50
Standing Systolic Blood Pressure

Recording Day	Treatment RBX	Group PBO	Total Pop.
0	121.3	118.7	120.0
1	121.4	119.2	120.3
2	118.4	120.6	119.5
3	116.3	121.3	118.8
4	116.3	118.9	117.5
5	115.2	116.4	115.8
6	115.2	118.9	117.0
7	114.9	118.0	116.4
10	114.4	117.0	115.7
14	116.4	119.0	117.7
21	115.6	118.5	117.0
28	115.8	117.3	116.3
35	115.2	115.5	115.3
42	116.8	118.0	117.2

9.2.2.2.3 Diastolic-Supine Blood Pressure

Repeated measures analyses of variance across all treatment periods on lying diastolic blood pressure indicated no significant difference between the two treatment groups. The same applies to pre-post ANCOVAs (using Day 0 as the covariate).

9.2.2.2.4 Diastolic-Standing Blood Pressure

Repeated measures analyses of variance across all treatment periods on standing diastolic blood pressure indicated no significant difference between the two treatment groups. The same applies to pre-post ANCOVAs (using Day 0 as the covariate).

9.2.2.2.5 Heart Rate-Supine

Repeated measures analyses of variance across all treatment periods on lying heart rate readings indicated no significant difference between the two treatment groups. The same applies to pre-post ANCOVAs (using Day 0 as the covariate).

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9.2.2.2.6 Heart Rate-Standing

Repeated measures analyses of variance across all treatment periods on standing heart rate readings indicated no significant difference between the two treatment groups. The same applies to pre-post ANCOVAs (using Day 0 as the covariate).

9.2.2.2.7 Weight

Repeated measures analyses of variance across all treatment periods on body weight indicated no significant difference between the two treatment groups. The same applies to pre-post ANCOVAs (using Day 0 as the covariate).

9.2.2.2.8 Body Temperature

Repeated measures analyses of variance across all treatment periods on body temperature indicated no significant difference between the two treatment groups. On the other hand, as shown in Table 51, pre-post ANCOVAs (using Day 0 as the covariate) on mean body temperature indicated a trend (p=.052) for a difference between the two treatment groups; this however was not of clinical significance.

Table 51
Pre-Post ANCOVA of Body Temperature

	Pre	Post	Results	Test
RBX	36.6536	36.5364	p=.052	ANCOVA
PBO	36.6929	36.6400		
Tot. Pop.	36.6732	36.5688		

9.3 Safety

Evaluation of safety was based on the analyses of the clinical laboratory (hematology, blood chemistry and urinalysis) and electrophysiologic laboratory (ECG and EEG) data, as well as on the findings of physical examinations.

9.3.1 Clinical Laboratory Tests

Laboratory tests relevant to the safety evaluation included three batteries of assays, one dealing with hematology (hemoglobin, hematocrit, RBC, WBC, neutrophils, lymphocytes, eosinophils,

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monocytes, basophils and platelets), a second with blood chemistry (electrolytes, SGOT, SGPT, gamma GT, alkaline phosphatase, glucose, BUN, creatinine, uric acid, total bilirubin, total protein, albumin, globulins, cholesterol and triglycerides) and a third with urinalysis (specific gravity, albumin, sugar, RBC and WBC). Analyses of data for each test in each of the assays was based on a comparison of the number of patients with out-of-range values from the pretreatment (within 72 hours of Day 0) to the Day 21 and Day 42 assessments; and a comparison of the number of out-of-range values in the two treatment groups on the Day 21 and Day 42 assessments.

All the information relevant to the laboratory tests for each patient in each treatment group is presented in Enclosure 29; and all information relevant to the statistics on laboratory tests are presented in Appendix 23.

9.3.1.1 HEMATOLOGY

In Table 52 number and percentage of patients with out-of-range values at pretreatment and at Day 21 and 42 of treatment at the particular assessment period for each test in the battery of assays dealing with hematology is presented for the two treatment groups. As shown in Table 52, the percentage of patients with out-of-range values in the RBX group increased from pretreatment to the final assessment (Day 42) on five tests (Hemoglobin, Hematocrit, RBC, Eosinophils, Platelets) whereas the percentage of patients with out-of-range values in the PBO group increased on four tests (Hemoglobin, Hematocrit, RBC, Monocytes) from pre-treatment to Day 42 treatment. In neither of the two treatment groups, however, was any of the out-of-range values of clinical significance.

Table 52
Hematology:
Number and Percentage of Patients with Out-of-Range Values

	RBX						PBO:					
	Pretreat..		Day 21		Day 42		Pretreat..		Day 21		Day 42	
	N	%	N	%	N	%	N	%	N	%	N	%
Hemoglobin	5	18.5	5	20.0	7	29.2	4	16.0	9	37.5	2	22.2
Hematocrit	1	3.7	2	8.0	4	16.7	2	8.0	2	8.3	1	11.1
RBC	12	44.4	8	32.0	13	54.2	9	36.0	11	45.8	5	55.6
WBC	12	42.9	9	34.6	9	37.5	13	48.1	12	46.2	4	44.4
Neutrophils	7	25.0	3	11.5	5	20.8	7	25.9	10	38.5	1	11.1
Lymphocytes	14	50.0	11	42.3	12	50.0	16	59.3	17	65.4	4	44.4
Eosinophils	10	37.0	13	50.0	12	50.0	12	44.4	12	46.2	3	33.3
Monocytes	15	57.7	13	50.0	13	52.0	15	55.6	18	69.2	6	66.7
Basophils	0	0.0	0	0.0	0	0.0	0	0.0	1	3.8	0	0.0
Platelets	0	0.0	3	11.5	1	4.2	2	7.4	2	7.7	0	0.0

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9.3.1.2 BLOOD CHEMISTRY

In Table 53 the number and percentage of patients with out-of-range values at pretreatment and at Day 21 and 42 of treatment at the particular assessment period for each test in the battery of assays dealing with blood chemistry is presented for the two treatment groups. As shown in Table 53, the percentage of patients with out-of-range values from pretreatment to the final (Day 42) assessment in the RBX group increased in 6 cases (Ca⁺⁺, blood sugar, alkaline phosphatase, creatinine, cholesterol, tryglicerides) and in the PBO group in 4 cases (blood sugar, creatinine, total bilirubin and triglycerides) In neither of the two treatment groups, however, was any of the out-of-range values of clinical significance.

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Table 53
Blood Chemistry:
Number and Percentage of Patients with Out-of-Range Values

	RBX						PBO:					
	Pretreat.:		Day 21		Day 42		Pretreat.:		Day 21		Day 42	
	N	%	N	%	N	%	N	%	N	%	N	%
Na ⁺	7	25.0	6	23.1	6	25.0	6	22.2	4	15.4	1	11.1
K ⁺	3	10.7	2	7.7	1	4.2	1	3.7	0	0.0	0	0.0
Cl ⁻	2	7.1	3	11.5	1	4.2	3	11.1	0	0.0	1	11.1
Ca ⁺⁺	0	0.0	4	15.4	2	8.7	3	11.1	2	7.7	0	0.0
PO ₄	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
SGOT	5	17.9	2	7.7	4	17.4	7	25.9	8	30.8	2	22.2
SGPT	7	25.0	1	3.8	5	21.7	10	37.0	7	26.9	2	22.2
γ GT	10	37.0	8	32.0	8	36.4	7	30.4	12	50.0	2	22.2
Blood Sugar	1	3.6	3	11.5	3	12.5	4	14.8	6	23.1	2	22.2
Alkaline Phosphatase	2	7.4	3	11.5	3	12.5	5	19.2	1	3.8	2	22.2
BUN	2	7.1	3	7.7	1	4.2	2	8.3	0	0.0	1	11.1
Creatinine	7	25.9	7	28.0	12	50.0	8	32.0	14	58.3	5	55.6
Uric Acid	2	7.4	3	12.0	2	8.4	2	8.0	2	8.3	1	11.1
Tot. Bilirubin	2	7.1	1	3.7	1	4.2	1	3.7	1	3.8	1	11.1
Tot. Protein	7	25.0	5	18.5	3	12.5	4	14.8	2	7.7	0	0.0
Blood Albumin	0	0.0	0	0.0	0	0.0	2	7.4	1	3.8	0	0.0
Cholesterol	9	33.3	8	32.0	10	41.7	6	24.0	7	29.2	2	22.2
Triglycerides	4	14.3	5	19.2	5	20.8	6	22.2	6	23.1	3	33.3
Globulins α-1	1	3.7	0	0.0	0	0.0	1	3.8	1	3.8	0	0.0
α-2	1	3.7	1	3.8	2	8.7	2	7.7	3	11.5	0	0.0
β	0	0.0	2	7.7	1	4.3	3	11.5	2	7.7	2	22.2
γ	0	0.0	0	0.0	0	0.0	1	3.8	1	3.8	0	0.0

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9.3.1.3 URINALYSIS

In Table 54 the number and percentage of patients with out-of-range values at pretreatment and at Day 21 and 42 of treatment at the particular assessment period for each test in the battery of assays dealing with urinalysis is presented for the two treatment groups. As shown in Table 54, in the RBX group the number of patients with out-of-range values increased on two tests, decreased on one test and remained the same on one test from pretreatment to Day 42 of treatment, whereas in the PBO group the number of patients with out-of-range values decreased on one tests and remained the same on all tests from pretreatment to Day 42 of treatment. In neither of the two treatment groups, however, was any of the out-of-range values of clinical significance.

9.3.2 Electrophysiologic Tests

Electrophysiologic laboratory tests relevant to safety evaluation included the ECG and EEG. Analyses of data was based on a comparison of the number of patients with abnormal tracing from pretreatment (within 72 hours prior to Day 0) to Day 21 and Day 42 assessments in case of the ECGs, and from pretreatment to the Day 42 assessment in case of the EEGs; and a comparison of the number of abnormal tracings in the two treatment groups at the time of the final (Day 42) assessment.

All information relevant to electrophysiologic tests for each patient in each treatment group is presented in Enclosure 30.

Table 54
 Urinalysis:
 Number and Percentage of Patients with Out-of-Range Values

	RBX						PBO:					
	Pretreat.:		Day 21		Day 42		Pretreat.:		Day 21		Day 42	
	N	%	N	%	N	%	N	%	N	%	N	%
Albumin	1	3.6	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0
Sugar	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0
RBC	3	10.7	4	14.3	5	17.9	4	14.3	6	21.4	2	7.1
WBC	2	7.1	4	14.3	6	21.4	3	10.7	4	14.3	0	0.0

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9.3.2.1 ELECTROCARDIOGRAM

Few patients had abnormal ECG tracing both at pre-treatment and during treatment. In Table 55 the number of patients with abnormal ECG tracing at pretreatment and at Day 21 and 42 assessments are presented for each treatment group. As shown in Table 55, the number of abnormal tracing -- and as shown in Table 56, the nature of abnormal tracing -- did not change during the 42-day clinical trial. (The decrease in the number of patients with abnormal tracing in the both RBX and PBO groups was due to missing data).

Table 55
Number of Patients with Abnormal ECGs
at Day 0, 21 and 42 in the Two Treatment Groups

	RBX	PBO	Total Pop.
Day 0	5	5	10
Day 21	4	3	7
Day 42	5	2	7

Table 56
Nature of ECG Abnormalities

RBX:	Pt. No.	17:	few ventricular extra systoles; limited ECG:
	Pt. No.	81	left ventricular hypertrophy
	Pt. No.	86	left anterior divisional block
	Pt. No.	89	left atrial enlargement
	Pt. No.	92	left ventricular hypertrophy
PBO:	Pt. No.	2	minimal tachycardia; auricular hypertrophy
	Pt. No.	16	minimal tachycardia; auricular hypertrophy
	Pt. No.	93	left axis deviation; 1st degree A-V block
	Pt. No.	94	sinus bradycardia; left atrial enlargement
	Pt. No.	146	1st grade heart block

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9.3.2.2 ELECTROENCEPHALOGRAM

There was no abnormal EEG tracing encountered at any time from pretreatment to the end of the clinical trial (Day 42). Nevertheless, a favorable change in EEG tracing for 1 patient in the RBX group was reported at Day 42. This was to the effect that in patient No. 125 "more alpha rhythm was present with greater topographic distribution" at Day 42 than at pretreatment.

9.3.3 Physical Examination

With the exception of 1 patient (No. 34) who at the time of the pretreatment (screening) physical examination had a black eye and broken tooth (as a result of a fall in the emergency room); no abnormalities was recorded on the physical examination in any other patients at any time during the clinical trial.

All information relevant to physical examination for each patient in the two treatment groups is presented in Enclosure 31.

9.4 Benefit/Risk Ratio

Benefit/risk ratio was evaluated by completing the Efficacy Index (EI), the third component of CGI, at Days 7, 15, 21, 28, 35 and 42. As shown in Table 57, mean index scores-- calculated by employing the algorithm presented in the ECDEU Manual -- increased (improved) in both treatment groups during the investigational period. The increase (improvement) in the RBX-treated group from Day 7 to Day 42 was somewhat greater than in the PBO-treated group, but not sufficiently greater to yield statistical significance.

All information relevant to EI for each patient in both treatment groups is presented in Enclosure 32; and all information regarding the statistics on EI are presented in Appendix 24.

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Table 57
CGI-EI Mean Scores in the Two Treatment Groups

	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
RBX	.967	1.60	1.99	2.55	2.94	3.30
PBO	1.066	1.49	1.66	3.00	3.30	3.20
Tot. Pop.	1.016	1.54	1.83	2.68	3.04	3.27

9.5 Indirect Indicators of Efficacy at Termination

Evaluation of treatment was extended beyond the direct measures of efficacy, tolerability, safety and benefit/risk ratio to indirect indicators of efficacy, such as number of days in treatment, disposition at the time of termination of treatment and (Investigator's) readiness to continue with treatment. Evaluation of indirect indicators of efficacy was based on analyses of data recorded in three components of Treatment Termination Record, i.e., experimental treatment (dealing with treatment duration), final conclusion (dealing with readiness - willingness -- to continue treatment) and disposition at termination of treatment (See Enclosure 11).

All information relevant to indirect indicators of efficacy for each patient in each treatment group is presented in Enclosure 32; and all information regarding the statistics on indirect indicators of efficacy are presented in Appendix 25.

9.5.1 NUMBER OF DAYS IN TREATMENT

The average number of days patients received medication during the 42-days clinical trial were compared in the two treatment groups. As a result, it was found that the mean number of days patients received medication was significantly ($p < .001$) different in the two treatment groups. The difference was to the effect that the mean number of days in treatment, i.e., the duration of treatment, was 11.1 days longer in the RBX-treated (mean 38.1 +/- 9.27) than in PBO-treated (mean 27.0 +/- 12.11) group.

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9.5.2 DISPOSITION AT TERMINATION

In Table 58 the disposition at the time of termination of treatment in terms of number of patients remaining hospitalized -- with or without the prescription of new medication -- or discharged -- with or without the prescription of new medication -- is presented. Analyses of the data was directed towards revealing possible difference in terms of hospitalized vs discharged and new medication prescribed vs non medication prescribed in the treatment groups. As a result, as shown in Table 58, it was found that by the time of termination of treatment a significantly ($p=.023$) greater number and higher proportion of patients were discharged from the RBX-(13 patients; 48.1%) than from the PBO-treated (4 patients; 14.8%) group. There was also a significant ($p=.002$) difference in the number of patients (regardless whether hospitalized or discharged) who were prescribed a new medication. This was to the effect that as many as 19 (70.4%) PBO patients were prescribed new psychotropic medication upon termination of treatment, whereas as few as 7 (26.9%) RBX patient were prescribed new medication. The different drug chosen after discontinuation of treatment for patients in whom pharmacologic treatment was continued is presented in Table 59 for the two treatment groups.

Table 58
Disposition at Termination
in the Two Treatment Groups

	Remain	Hospitalized		Discharged		
	Total	With Meds	Without Meds	Total	With Meds	Without Meds
RBX	14	6	8	13	1	12
PBO	22	18	4	4	1	3
Tot.Pop.	36	24	12	17	2	15

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Table 59
Psychotropic medication prescribed after Discontinuation of Treatment for Hospitalized Patients

	Medication	No. of Pats.
RBX	Brazepam	1
	Desipramine	1
	Fluoxetine	1
	Imipramine	3
PBO	Brazepam	1
	Imipramine	15
	Chlordiazepoxide	1
	Fluoxetine	1

9.5.3 CHOICE TO CONTINUE TREATMENT

In Table 60, Investigator's choice to continue with the treatment the patient was receiving during the 42 days of drug administration at termination of the clinical trial is presented in terms of number of patients for whom the choice regarding the continuation was "definitely no" "inclined to say no", "undecided", "inclined to say yes" and "definitely yes"; and analyses of the data was directed towards revealing possible differences on any of these variables between the two treatment groups. As a result, as shown in Table 60, it was found that the choice for continuation was "definitely yes" in a significantly ($p=0.01$) greater number and higher proportion of patients from the RBX group (19; 76%) than from the PBO group (4; 16.7%).

Table 60
Choice to Continue Patients on Experimental Treatment in the Two Treatment Groups

	Definitely No	Inclined to No	Undecided	Inclined to Yes	Definitely Yes
RBX	3	1	1	1	19
PBO	14	3	1	2	4
Tot. Pop:	17	4	2	3	23

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9.6 Indirect Indicators of Efficacy at Follow-up

Evaluation at follow-up was based on analyses of data recorded on a specially devised "follow-up" form completed (from 5 to 77 days) after discontinuation of treatment. The information collected at follow-up dealt with "signs or symptoms newly observed upon treatment discontinuation" (i.e., detection of withdrawal effects and/or recurrence of depressive manifestations) "antidepressant medication" (i.e., delineation whether the patient is or is not on antidepressant medication) and patient status (i.e., delineation whether patient is an in-or out- patient and, in case of the latter whether patient was discharged between termination of the clinical trial and the follow-up assessment).

All information relevant to follow-up for each patient in each treatment group is presented in Enclosure 33; and all information regarding the statistics on follow-up are presented in Appendix 26.

9.6.1 NEWLY OBSERVED SIGNS OR SYMPTOMS AFTER DISCONTINUATION

There was only 2 patients with newly observed signs or symptoms at the time of the follow-up assessment. From the RBX group, 1 patient (No. 1) who was prematurely terminated because of lack of therapeutic response at Day 30 and from PBO group, 1 patient (No. 93), who completed the clinical trial, displayed depressed mood, loss of interest in activities, motor retardation and suicidal intention.

9.6.2 ANTIDEPRESSANT MEDICATION

In Table 61 the number of patients on antidepressant medication at the time of the follow-up assessment are presented for the two treatment groups; and in Table 62 the different drugs used in each patient with identification of dose and specification of efficacy and tolerability are presented. There was a statistically significant difference ($p < .001$) between the two treatment groups in terms of number of patients on antidepressant medication at the time of the follow-up assessment. This was to the effect that more PBO-treated patients (19; 73.1%) than RBX-treated patients (6; 23.1%) were on antidepressant medication at the time of the follow-up.

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9.6.3 PATIENT STATUS

In Table 63 the number of in- and out-patients, with indicating number of patients discharged between termination of the clinical trial and the follow-up assessment, are identified for each treatment group. Although there was no significant difference in term of patient status at the time of the follow-up between the two treatment groups, it was noted that twice as many patients from the PBO group (4 patients) than from the RBX group (2 patients) were hospitalized at the time of the follow-up assessment.

Table 61
Number of Patients on Antidepressant Medication
at the Time of the Follow-up Assessment

	Yes	No	Results	Test
RBX	6	20	p < .001	Chi-square
PBO	19	7		
Tot. Pop.	25	27		

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Table 62
Medication Used at Follow-up with
Dosage, Efficacy and Tolerability

	Medication	Dosage	Efficacy	Tolerability
RBX	Desipramine	50mg	good	good
	Imipramine	60mg	good	good
	Imipramine	300mg	good	fair
	Imipramine	300mg	good	good
	Imipramine	200mg	good	good
	Imipramine	300mg	good	good
PBO	Amitriptyline	100mg	good	fair
	Imipramine	300mg	good	good
	Imipramine	-	good	poor
	Imipramine	200mg	good	good
	Imipramine	250mg	good	good
	Imipramine	300mg	good	good
	Imipramine	300mg	good	poor
	Imipramine	250mg	good	good
	Imipramine	200mg	poor	poor
	Imipramine	275mg	good	good
	Imipramine	250mg	good	good
	Imipramine	300mg	good	good
	Imipramine	250mg	good	good
	Imipramine	250mg	good	good
	Imipramine	150mg	good	poor
	Imipramine	300mg	good	good
	Imipramine	250mg	good	good
	Imipramine	250mg	good	good
	Imipramine	300mg	good	good

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Table 63
Patient Status at Follow-up

	Inpatient	Outpatient	Discharged
RBX	2	21	3
PBO	4	21	1

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ENCLOSURE 1

Certificates of Analyses

(Extra 4 Pages)

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ANALYSIS CERTIFICATE

PLACEBO for FCE 20124 capsules .
Batch SF : B97 .

MANUFACTURING DATE : MAY, 1987 .

APPEARANCE : opaque-white, hard gelatin capsule, self locking, size No.4, containing an off white powder .

IDENTIFICATION : absence of FCE 20124 (HPLC method) .

AVERAGE WEIGHT : mg 88.35 .

WEIGHT VARIATION : according to Europ. Pharm. Section V.5.2 .

DISINTEGRATION TIME : 2 minutes and 40 seconds .

ANALYZED BY : Silvio Gambini .

Silvio Gambini

APPROVED BY : Virginio Busnelli .

Busnelli Virginio

DATE : JUNE 22, 1987 .

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ANALYSIS CERTIFICATE

FCE 20124 hard-gelatin capsules .
Capsules mg : 2 Batch : 898 .

MANUFACTURING DATE : JUNE, 1987 .
EXPIRATION DATE : JUNE, 1989 (stored at room temperature) .
APPEARANCE : opaque-white, hard gelatin capsule, self
locking, size No.4, containing a white
granular powder .
IDENTIFICATION : positive (HPLC method) .
AVERAGE WEIGHT : mg 91,22 .
UNIFORMITY OF WEIGHT : within the limits, according to European
Pharm. 1980, Section V.5.2 .
CONTENT UNIFORMITY : complies, according to USP XXI page 1277 .
ASSAY : mg 2.018 of FCE 20124/capsule .
DISINTEGRATION TIME : 3 minutes .

ANALYZED BY : Silvio Gambini . *Silvio Gambini*
APPROVED BY : Virginio Busnelli : *Busnelli Virginio*
DATE : JUNE 22, 1987 .

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ANALYSIS CERTIFICATE

FCE 20124 hard-gelatin capsules .
Capsules mg : 2.0 Batch : SF 967

MANUFACTURING DATE : September, 1988

EXPIRATION DATE : September, 1990

APPEARANCE : opaque-white, hard-gelatin capsule, self-locking, size No. 4, containing a white granular powder

IDENTIFICATION : positive (HPLC method)

AVERAGE WEIGHT : mg 90.92

UNIFORMITY OF WEIGHT : within the limits, according to USP XXI

CONTENT UNIFORMITY : within the limits, according to USP XXI

ASSAY : mg 2.026 of FCE 20124/capsule

DISINTEGRATION TIME : 1 minute and 30 seconds

ANALYZED BY : E. Affanni *Affanni*

APPROVED BY : V. Busnelli *Busnelli*

DATE : September 27, 1988

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ANALYSIS CERTIFICATE

PLACEBO for FCE 20124 capsules .
Batch SF : 1039

MANUFACTURING DATE : July, 1989

APPEARANCE : opaque white, hard gelatin capsule,
self-locking, size No. 4, containing
a white powder

IDENTIFICATION : negative (HPLC)

AVERAGE WEIGHT : mg 87.27

WEIGHT VARIATION : complies, according to Eur. Ph., 2nd Ed.,
Section V.5.2

DISINTEGRATION TIME : 3 minutes

ANALYZED BY : E. Affanni *Affanni E.*

APPROVED BY : V. Busnelli *Busnelli V.*

DATE : July 6, 1989

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ENCLOSURE 2

Study Protocol

(Extra 28 Pages)

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CLINICAL PROTOCOL

TITLE: PHASE II PLACEBO-CONTROLLED CLINICAL STUDY
WITH REBOXETINE IN MAJOR DEPRESSIONS

CLINICAL
STUDY NO: 091002-999

STUDY
CHAIRMAN: Dr. Guy Chouinard

DATE OF PROTOCOL: May 25, 1988

REVISION #1: September 12, 1988

REVISION #2: February 8, 1989

REVISION #3: March 30, 1989

SIGNATURES:

Principal Investigator Date

Manager, Biostatistics Date
Adria Laboratories, Columbus, Ohio

Associate Director, Clinical Research Date
Adria Laboratories, Canada

Vice-President and Director Date
Medical Research Centre
Adria Laboratories, Columbus, Ohio

Adria Laboratories of Canada Ltd
5476 Gorvan Drive
Mississauga ON L4W 3E8 (416) 625-4552

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REVISION #3 - MARCH 30, 1989

General Revision:

1. To revise Participants' List.
2. To revise table of contents as required.

Section 4.2, paragraph 1, previous text:

150 evaluable patients will be studied; of them, 75 will be treated with reboxetine and 75 with placebo. Of the 150 evaluable patients to be studied, approximately 90 will be contributed from Canadian sites.

Revised Text:

150 evaluable patients will be studied; of them, 75 will be treated with reboxetine and 75 with placebo. Of the 150 evaluable patients to be studied, approximately 90 will be contributed from Canadian sites. **It is intended that each site contribute a minimum of 20 patients.**

Section 5.1

The study population will consist of adult hospitalized patients with a DSM-III-R diagnosis of major depressive disorder.

Revised Text:

The study population will consist of adult hospitalized patients with a DSM-III-R diagnosis of major depressive disorder. **Patients may be managed on an outpatient basis after 3-4 weeks of hospitalization, providing that the HAM-D score has decreased by 50% or more.**

Section 5.2.4

HAM-D Score of 20 or above (21 item scale).

Revised Text:

HAM-D Score of 20 or above (21 item scale), on Day 0 of the drug treatment period.

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Section 7.2.3, previous text:

At the end of the double-blind treatment period, responders will be provided with medication. Adria Laboratories of Canada Ltd. will supply medication for up to six months past the treatment period.

Revised Text:

If the systolic blood pressure falls under 100 mg Hg, the treatment dose will be lowered as above (Section 7.2.2). If improvement is not seen in 1-2 days, treatment will be discontinued.

Section 9.3, previous text:

9.3 Blood Pressure and Pulse On Days 0, 1(2x), 2(2x), 3(2x), 4(2x), 5, 6, 7, 10, 14, 21, 28, 35 and 42.

Both will be measured supine and standing before the morning dose and, on days when done twice, also before the evening dose. Supine recording will be done after the patient has been recumbent for 5 minutes; and standing recording 1 minute after the patient has been erect.

Revised Text:

9.3 Blood Pressure and Pulse On Days 0, 5, 6, 7, 10, 14, 21, 28, 35 and 42. Blood pressure and pulse will be taken twice.

On Days 1, 2, 3 and 4. Blood pressure and pulse will be taken 3 times.

Both will be measured supine and standing before the morning dose and 3 hours afterward. On days that the recording is done three times (Days 1, 2, 3 and 4) it will also be taken before the evening dose. Supine recording will be done after the patient has been recumbent for 5 minutes; and standing recording 1 minute after the patient has been erect.

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Section 12.2 , paragraph 4, previous text:

Treatment response will be dichotomized into clinically significant treatment response versus no treatment response. The criteria for a clinically significant treatment response will be a 50% reduction in the HAM-D Total Score over the course of the clinical trial. In the event that a subject is discontinued or withdraws from the study and hence has incomplete data, the last known data point will be utilized as an estimate of post-treatment response. Supplemental analysis will also be performed examining reductions in score on the CGI and ZUNG. For the analysis of treatment response, appropriate non-parametric analyses will be utilized with respect to the dichotomous nature of the dependent variable.

Revised Text:

Treatment response will be dichotomized into clinically significant treatment response versus no treatment response. The criteria for a clinically significant treatment response will be a 50% reduction in the HAM-D Total Score over the course of the clinical trial. In the event that a subject is discontinued or withdraws from the study and hence has incomplete data, the last known data point will be utilized as an estimate of post-treatment response, **providing that the patient has completed at least 14 days of treatment.** Supplemental analysis will also be performed examining reductions in score on the CGI and ZUNG. For the analysis of treatment response, appropriate non-parametric analyses will be utilized with respect to the dichotomous nature of the dependent variable.

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REVISION #2 - FEBRUARY 8, 1989

General Revision:

1. To revise "Reboxetine" to "reboxetine" throughout the protocol.
2. To revise the Participants' List.

Section 4.2, paragraph 1, previous text:

150 evaluable patients will be studied; of them, 75 will be treated with reboxetine and 75 with placebo. Of the 150 evaluable patients to be studied, 90 will be contributed from Canadian sites.

Revised Text:

150 evaluable patients will be studied; of them, 75 will be treated with reboxetine and 75 with placebo. Of the 150 evaluable patients to be studied, **approximately** 90 will be contributed from Canadian sites.

Section 5.3.2, previous text:

Presence and/or history of Schizophrenia, Schizophreniform Disorder, Delusional Disorder, or Psychotic Disorder NOS, according to DSM-III-R.

Revised Text:

Presence and/or history of Schizophrenia, Schizophreniform Disorder, Delusional Disorder, or Psychotic Disorder NOS (**not otherwise specified**), according to DSM-III-R.

Section 6.1, previous text:

After washout with placebo, all eligible patients will be registered within 24 hours with Adria Laboratories of Canada, by telephoning Mr. David Mee or the Clinical Trials Secretary (416) 625-4552, between 8:30 am and 4:30 pm, Eastern Standard Time, Monday through Friday...

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Revised Text:

After washout with placebo, all eligible patients will be registered within 24 hours with Adria Laboratories of Canada, by telephoning Ms Patricia Shannon, Medical Research Associate, between 8:30 am and 4:30 pm, Eastern Standard Time, Monday through Friday...

Section 6.3, previous text:

All data will be collected on specially designed forms (original and two copies) that will be supplied by the sponsor. At the end of each week of therapy the investigator will send to the sponsor a copy of the case report forms...

Revised Text:

All data will be collected on specially designed forms (original and two copies) that will be supplied by the Sponsor. At the end of each week of therapy the investigator will send to the Sponsor a photocopy of the case report forms...

Section 7.2.2, Paragraph 1, previous text:

... After the last dose on day 42 the double-blind study will end.

Revised Text:

... After the last dose on Day 42 the double-blind study will end.

Section 10.2, Paragraph 1, previous text:

Serious and/or unexpected events must be reported immediately by telephone to the study monitors Mr. David Mee (416) 625-4552 or Dr. David Cook (416) 625-4552. The verbal report should be followed by a written report within 5 working days.

Revised Text:

Serious and/or unexpected events must be reported immediately by telephone to the study monitors, Patricia Shannon or Dr. Sunil Gupta, (416) 625-4552. The verbal report should be followed by a written report within 5 working days.

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section 10.3, previous text:

Adria Telephone Contact:

Mr. David Mee	or if absent	Dr. David Cook
Off: 1-416-625-4552		Off: 1-416-625-4552
Res: 1-416-762-0588		Res: 1-416-873-2377

Revised Text:

Adria Telephone Contact:

Ms Patricia Shannon	or if absent	Dr. Sunil Gupta
Off: 1-416-625-4552		Off: 1-416-625-4552
Res: 1-416-542-2956		Res: 1-416-828-9332

Section 14.0, Paragraph 4, previous text:

All unused medication should be returned to the sponsor at the following address:

Mr. David Mee
Medical Research Associate
Adria Laboratories of Canada Ltd.
5476 Gorvan Drive
Mississauga ON L4W 3E8

Revised Text:

All unused medication should be returned to the Sponsor at the following address:

Ms Patricia Shannon
Medical Research Associate
Adria Laboratories of Canada Ltd.
5476 Gorvan Drive
Mississauga ON L4W 3E8

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REVISION #1 - SEPTEMBER 12, 1988

4.2 Number of Patients

Add sentence: "Of the 150 evaluable patients to be studied, 90 will be contributed from Canadian sites."

8.0 DIAGNOSIS AND EFFICACY ASSESSMENTS

Add subsection:

8.6 FOLLOW-UP One month following discontinuation from the study.

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PHASE II PLACEBO-CONTROLLED CLINICAL STUDY WITH
REBOXETINE IN MAJOR DEPRESSION

1.0 INTRODUCTION

Reboxetine or RS, RS 2-[α -(2-ethoxy-phenoxy)benzyl] morpholine methanesulphonate is a new chemical entity which shares pharmacological properties with the standard antidepressants, eg: reserpine antagonism and norepinephrine (NE) reuptake inhibition. Interestingly, in animal studies a single oral dose of reboxetine has been shown to inhibit clonidine induced hypothermia. In contrast, multiple doses of the standard antidepressants were needed to inhibit clonidine effects. Because of this observation it is postulated that reboxetine may have a faster onset of therapeutic action than standard antidepressants.

Early pharmacokinetic studies in healthy volunteers revealed that after the administration of a single dose of 2 mg of ^{14}C -reboxetine almost three quarters (73% in terms of AUC) of the radioactivity in the circulating plasma, was accounted for by the unchanged substance. In the same studies plasma half-life was estimated to be 13.2 hours.

On the basis of plasma samples obtained from patients exposed to the chronic administration of different doses it was suggested that the drug has linear pharmacokinetics and that steady state levels can be expected to be attained within 3 days.

In Phase I studies, carried out in healthy volunteers, reboxetine was well tolerated in single oral doses below 5 mg. Administration of 5 mg resulted in orthostatic hypotension associated with tachycardia and other symptoms consistent with a disturbance of circulatory regulation.

In a dose ranging study in patients suffering from major depressive disorders, reboxetine was found to be well tolerated in doses ranging up to 10 mg a day over a period of 28 days. Clinical improvement was observed and appeared to be dose related. The findings from this dose determination study suggested that the appropriate therapeutic daily dose is from 6 mg to 10 mg a day. Patients given 12 mg a day did not tolerate the drug well.

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2.0 RATIONALE

A faster onset of action is postulated since single oral doses of reboxetine have been shown to prevent clonidine induced effects. This has not been observed with other currently used antidepressants.

3.0 AIMS OF STUDY

The purpose of this study is to evaluate treatment with reboxetine in patients with major depressive disorders and more specifically:

- 3.1 To test the hypothesis that reboxetine in the daily dosage of 6 to 10 mg is superior in therapeutic effects to an inactive placebo within a period of 42 days;
- 3.2 To identify the time of onset of therapeutic effects;
- 3.3 To identify therapeutically responsive subform(s) within major depressive disorders;
- 3.4 To provide further evidence of the tolerability of reboxetine in the daily doses from 6 to 10 mg over a period of 42 days.

4.0 DESIGN

4.1 Description

This will be a multi-centre, double-blind, placebo-controlled clinical trial. The patients will be stratified according to sex and randomly assigned to treatment groups. It will be carried out with the participation of several collaborating centres within a period of two years.

4.2 Number of Patients

150 evaluable patients will be studied; of them, 75 will be treated with reboxetine and 75 with placebo. Of the 150 evaluable patients to be studied, approximately 90 will be contributed from Canadian sites. It is intended that each site contribute a minimum of 20 patients.

This sample size has been calculated using the following assumptions:

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- a) A response ($\geq 50\%$ decrease in the total score of the HAM-D) will be observed in approximately 40% of the patients receiving placebo
- b) Response will be observed in at least 60% of the patients receiving reboxetine
- c) The probability of a type I error is $\alpha = .05$
- d) The probability of a type II error is $\beta = .20$ (the power of the test is $1 - \beta = .80$)
- e) The response rates of the two treatment groups will be compared using a test for equality of binomial proportions.

In order to minimize the number of patients exposed to an active drug which may have unacceptable toxicities, an interim analysis of safety will be done after 60 patients (30 per group) have been entered to the study.

After 60 patients, the efficacy of the two treatment groups will also be compared. The significance levels will be adjusted according to the method of O'Brien and Fleming¹. In order to maintain an overall significance level of $\alpha = .05$ and an approximate power of 80%, at the interim analysis the null hypothesis of equal efficacy will be tested using $\alpha_1 = .005$. If the null hypothesis is not rejected, the remaining 90 patients (45 per group) will be entered into the study for a total of 75 patients per group. At this time the null hypothesis of equal efficacy will be tested using $\alpha_2 = 0.048$.

5.0

STUDY POPULATION

5.1 Source of Patients

The study population will consist of adult hospitalized patients with a DSM-III-R diagnosis of major depressive disorder. Patients may be managed on an outpatient basis after 3-4 weeks of hospitalization, providing that the HAM-D score has decreased by 50% or more.

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5.2 Inclusion Criteria

- 5.2.1 Male or female. Women who are at risk of pregnancy may be included in the study providing they are using oral contraception.
- 5.2.2 From 18 to 65 years of age.
- 5.2.3 DSM-III-R diagnosis of major depression (Axis I diagnosis).
- 5.2.4 HAM-D Score of 20 or above (21 item scale), on Day 0 of the drug treatment period.
- 5.2.5 Signed written informed consent.

5.3 Exclusion Criteria

- 5.3.1 Women at risk of pregnancy who are not using an oral contraceptive.
- 5.3.2 Presence and/or history of Schizophrenia, Schizophreniform Disorder, Delusional Disorder, or Psychotic Disorder NOS (not otherwise specified), according to DSM-III-R.
- 5.3.3 Presence and/or history of substance abuse disorder (DSM-III-R) within last year.
- 5.3.4 Presence of non-psychiatric medical disorder(s) which require pharmacological treatment(s) and/or is known to interfere with the absorption, distribution, metabolism and excretion of drugs. Chronic use of medications is not permitted except for birth control pills. The occasional use of the following medications are permitted on a p.r.n. basis:
 - 1) laxatives
 - 2) Chloral Hydrate (should not be given for more than 3 consecutive days)
 - 3) analgesics (ie: tylenol, aspirin).
- 5.3.5 Presence of neurological disorder and/or the history of brain trauma with loss of consciousness and/or cerebral seizures.

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- 5.3.6 History or presence of glaucoma, or prostate enlargement. Presence of thyroid disease.
- 5.3.7 Pregnancy or breast feeding.
- 5.3.8 History of hypersensitivity to psychotropic drugs.
- 5.3.9 Participation in a clinical trial with a psychotropic drug within four weeks prior to Day 0.
- 5.3.10 Clinically meaningful abnormal findings on physical examination and/or laboratory tests, including ECG, EEG, and chest x-ray.
- 5.3.11 Patients who in the investigator's judgement are at suicidal risk.
- 5.3.12 Patients with 20% or greater decrease in the baseline HAM-D score during washout.
- 5.3.13 Patients treated with electroconvulsive therapy (ECT) within the last 3 months of entry into the placebo washout period.
- 5.3.14 History or presence of hepatitis B, non-A, non-B hepatitis, or AIDS.

6.0 REGISTRATION/RANDOMIZATION PROCEDURES/DATA MANAGEMENT

6.1 Registration

After washout with placebo, all eligible patients will be registered within 24 hours with Adria Laboratories of Canada, by telephoning Ms Patricia Shannon, Medical Research Associate, between 8:30 am and 4:30 pm, Eastern Standard Time, Monday through Friday. At this time, it will be ascertained that the patient fulfills the eligibility criteria. At the time of registration, a prestudy form will be filled by the investigator who will forward a copy to Adria Laboratories of Canada Ltd., 5476 Gorvan Drive, Mississauga, Ontario, L4W 3E8.

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6.2 Randomization

Those patients who at the end of the washout period show a decrease of less than 20% from baseline in the HAM-D score will be eligible for randomization. Patients in whom the HAM-D score improves 20% or more while on placebo washout will be taken off study.

6.3 Data Management

All data will be collected on specially designed forms (original and two copies) that will be supplied by the Sponsor. At the end of each week of therapy the investigator will send to the Sponsor a photocopy of the case report forms. The data will be reviewed by the Medical Research Associate (MRA) at Adria Laboratories and, if necessary, the investigator will be contacted for clarifications. Once the data corresponding to a full course of therapy has been thus reviewed and completed, the investigator will mail to the Sponsor the top two copies of the case report forms and photocopies of laboratory studies, and other reports. Pre-paid, addressed envelopes will be supplied to investigators for the dispatch of case report forms to Adria.

To comply with good monitoring standards the Adria MRA will make monthly site visits or as frequently as required to ensure compliance with the protocol. In addition, Dr. Thomas Ban, the Scientific Coordinator, will make 2 visits to each investigator during the study so that he can audit the performance of the investigators in their performance of the evaluation scales.

7.0 TREATMENT PLAN

7.1 Washout Period

7.1.1 For all patients, except those treated with a MAOI antidepressant, the study will begin with a 7 day, single blind placebo washout period.

7.1.2 For those patients treated with a MAOI antidepressant the pre-treatment placebo washout period will be 14 days.

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7.2 Treatment Period

7.2.1 The HAM-D scale will be scored on Day 0 and all those patients with a total score 20% below the score at baseline will be excluded from the clinical trial even if they fulfill other admission criteria.

7.2.2 Patients will be randomly assigned to one of two medication regimens (reboxetine or placebo) and treated in a double-blind manner with one of the two medications for 42 days on the basis of a fixed changing dosage regime. After the last dose on Day 42 the double-blind study will end.

For each patient the drug regimen will be as follows:

Day 1: Total daily dose of 6 mg of reboxetine or placebo:

1 capsule in the morning and
2 capsules in the evening

Day 2: Total daily dose of 8 mg of reboxetine or placebo:

2 capsules in the morning and
2 capsules in the evening

Day 3-42: Total daily dose of 10 mg of reboxetine or placebo:

2 capsules in the morning and
3 capsules in the evening

Medication will be administered in the morning (10:00 am) and in the evening (8:00 pm). If the medication is not well tolerated in the judgement of the investigator, the dosage may be decreased by 1 capsule per day until well tolerated or, in case of serious adverse reaction (see Section 10.0), discontinued.

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- 7.2.3 If the systolic blood pressure falls under 100 mg Hg, the treatment dose will be lowered as above (Section 7.2.2). If improvement is not seen in 1-2 days, treatment will be discontinued.

8.0 DIAGNOSIS AND EFFICACY ASSESSMENTS

- 8.1 DSM-III-R At the time of screening.
- 8.2 CODE-DD (Composite Diagnostic Evaluation - Depressive Disorders)
Completed by Day 1.
- 8.3 HAM-D At the time of screening and on Days 0, 4 (\pm 48 h), 7, 10 (\pm 48 h), 14, 21, 28, 35 and 42.
- 8.4 CGI On Days 0, 7, 14, 21, 28, 35 and 42.
- 8.5 ZUNG-SRDS On Days 0, 7, 14, 21, 28, 35 and 42.
- 8.6 FOLLOW-UP One month following discontinuation from the study.

9.0 CLINICAL ASSESSMENTS

- 9.1 Physical Examination Screening, and on Day 42.
- 9.2 Chest X-ray Within past 6 months of screening.
- 9.3 Blood Pressure and Pulse On Days 0, 5, 6, 7, 10, 14, 21, 28, 35 and 42. Blood pressure and pulse will be taken twice.
- On Days 1, 2, 3 and 4. Blood pressure and pulse will be taken 3 times.

Both will be measured supine and standing before the morning dose and 3 hours afterward. On days that the recording is done three times (Days 1, 2, 3 and 4) it will also be taken before the evening dose. Supine recording will be done after the patient has been recumbent for 5 minutes; and standing recording 1 minute after the patient has been erect.

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- 9.4 Temperature On Days 0, 7, 14, 21, 28, 35 and 42.
- 9.5 Weight On Days 0, 7, 14, 21, 28, 35 and 42.
- 9.6 NOSS (Newly Observed Signs/Symptoms)
On Days 0, 4, 7, 10, 14, 21, 28, 35 and 42.

NOSS will also be completed at times when adverse reactions occur. Any serious or damaging adverse reaction, whether or not related to study medication, will be reported immediately (within 24 hours) to the MRA.

- 9.7 ECG Within 72 h prior to Day 0, Days 21 and 42.
- 9.8 EEG Within 72 h prior to Day 0, Day 42.
- 9.9 T₃ and T₄ and TSH Within 72 h prior to Day 0.
- 9.10 Hematology (Hemoglobin, Hematocrit, RBC, WBC, Neutrophils, Lymphocytes, Eosinophils, Monocytes, Basophils, Platelets)
Within 72 h prior to Day 0, Days 21 and 42.
- 9.11 Blood Chemistry (Electrolytes, SGOT, SGPT, GAMMA GT, Alkaline Phosphatase, Glucose, BUN, Creatinine, Uric Acid, Total Bilirubin, Total Protein, Albumin, Globulins, Cholesterol, Triglycerides)
Within 72 h prior to Day 0, Days 21 and 42.
- 9.12 Urinalysis (Specific Gravity, Albumin, Sugar, RBC, WBC)
Within 72 h prior to Day 0, Days 21 and 42.

Samples for laboratory tests will be taken before the morning dose, after an overnight fast. Significantly abnormal laboratory findings, (ie: > 15% above or below the respective limits of normal) will be repeated and persistent abnormal values will be followed up until cause is determined and/or return to baseline.

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9.13 Reboxetine
Plasma Levels Screening, Days 7, 21 and 42.

9.14 HBs Ag, anti-HBc for hepatitis B, ELISA HIV for
AIDS, and ALT, AST for non-A, non-B hepatitis
Within 72 h prior to Day 0.

10.0 ADVERSE EVENTS

10.1 All adverse experiences (AE's) must be recorded on
the case report form.

10.2 Serious and/or Unexpected Events

Serious and/or unexpected events must be reported
immediately by telephone to the study monitors,
Patricia Shannon or Dr. Sunil Gupta, (416) 625-
4552. The verbal report should be followed by a
written report within 5 working days.

"SERIOUS" is defined as any one of the following:

- Life-threatening
- Permanently disabling
- In-Patient hospitalization for treatment
of toxicity
- Death (See Section 10.3)

"UNEXPECTED" is defined as any one of the
following:

- Not previously reported in association
with the given investigational drug (as
referenced in Investigators' Brochure
and clinical protocol).
- Symptomatically and pathophysiologically
related to a known toxicity but differs
because of greater severity or
specificity.

The investigator is required to complete an
Adverse Reaction form (provided by Adria) and send
this to the Study Monitor within 14 working days.

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10.3 Death on Study

All deaths on study must be reported immediately:

- 1) by telephone to the Study Monitor and
- 2) by a written report which should be sent to Adria Laboratories of Canada Ltd.

Adria Telephone Contact:

Ms Patricia Shannon	or if absent	Dr. Sunil Gupta
Off: 1-416-625-4552		Off: 1-416-625-4552
Res: 1-416-542-2956		Res: 1-416-828-9332

11.0 DISCONTINUATION OF PATIENTS FROM STUDY

If a patient is discontinued from the study, all assessments scheduled for Day 42 will be completed. Patients may be discontinued for the following reasons:

11.1 Nonresponse or Clinical Deterioration

If the patient does not respond to treatment (assessed using HAM-D), or shows clinical deterioration (increase of 20% in the HAM-D total score) after 2 weeks of treatment, he or she will be withdrawn from the study. Such patients will not be replaced.

11.2 Adverse Reaction or Clinical Deterioration

Prematurely terminated patients for adverse reactions will not be replaced.

11.3 Premature Discontinuation

All prematurely terminated patients for:

- a) withdrawal of consent,
- b) administrative reasons and/or
- c) intercurrent medical illness, prior to the 14th day assessment, will be replaced.

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12.0 DATA PROCESSING AND ANALYSIS

12.1 General

Data documentation will be carried out at Vanderbilt University. The analyses will be conducted utilizing the SPSS-X/SPSS-PC+ statistical analysis system.

12.2 Components

The project will involve three major data analysis components:

To examine the efficacy of reboxetine as compared to placebo treatment;

To examine the pattern of therapeutic latency for reboxetine as compared to placebo treatment; and

To explore possible differential efficacy of reboxetine in different depressive subtypes.

For each of these components, the primary definition of efficacy will involve reductions in the Hamilton Depression Scale (HAM-D) Total Score; the HAM-D is the most widely used rating scale for the assessment of depression.

As supplements to the HAM-D, two other instruments will also be utilized as measures of treatment response: the Zung Self-Rating Depression Scale (ZUNG); and the Clinical Global Impressions Scale (CGI).

Treatment response will be dichotomized into clinically significant treatment response versus no treatment response. The criteria for a clinically significant treatment response will be a 50% reduction in the HAM-D Total Score over the course of the clinical trial. In the event that a subject is discontinued or withdraws from the study and hence has incomplete data, the last known data point will be utilized as an estimate of post-treatment response, providing that the patient has completed at least 14 days of treatment. Supplemental analysis will also be performed examining reductions in score on the CGI and ZUNG. For the analysis of treatment response, appropriate non-parametric analyses will be utilized with respect to the dichotomous nature of the dependent variable.

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The three components of the analysis will be structured as follows:

12.3 Efficacy Evaluation

To examine the relative efficacy of reboxetine as measured against placebo treatment, a comparison of response rates between subjects in the placebo and active treatment will be conducted. Initially, a log-linear analysis will be conducted examining the effects of Treatment Group, Sex, and Centre as between-subjects factors, although no hypotheses are advanced with respect to the latter two factors (no differences across sex or treatment centre are hypothesized but this possibility will be investigated; should no differences emerge, this factor will be ignored in subsequent analyses). The dependent variables for these analyses will involve the dichotomized treatment response described in section 12.2. Supplemental analyses will also examine response rates on the ZUNG and the CGI.

12.4 Therapeutic Latency Evaluation

The identification of effect onset will utilize a one way (between subjects: treatment) repeated measures analysis of variance, with the repeated dependent variable involving a dichotomized dummy variable representing treatment response data from seven study observation periods (Days 7, 10, 14, 21, 28, 35 and 42). Planned comparisons will focus upon the interaction between trial period and experimental group, utilizing results from the within-subject (ie: period) contrasts. Follow-up non-parametric analyses will be utilized to determine where treatment response differences are first evident. It is hypothesized that a treatment by period interaction will be obtained, with contrasts indicating differences in efficacy between treatments emerging as soon as Day 7.

12.5 Subtype Interaction Evaluation

The exploratory analyses for the identification of therapeutically responsive depressive subforms will require the use of a two-way (between subjects), 2 (experimental group) x N (depressive subtype) repeated measures analysis of variance. The dependent variable will involve HAM-D scores collected at eight different points in treatment (Days 0, 7, 10, 14, 21, 28, 35 and 42).

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Identification of clinically significant depressive subforms will involve an examination of type by treatment interactions followed by planned contrasts between depressive subgroups.

In addition to the analyses described above, descriptive analyses will also be conducted to identify and isolate treatment emergent abnormalities in laboratory tests (hematology, blood chemistry, and urinalysis). As a first step, the laboratory findings for patients receiving reboxetine will be compared pre- and post-treatment, with the proportion of abnormal results before and after treatment being compared using the McNemar test². These analyses will involve a separate pre- and post-treatment comparison of laboratory test values, with a separation of these values into those within normal limits, those above normal limits, and those below normal limits. If significantly more deviations (abnormal test findings) are noted post-treatment, similar analyses will be conducted with the placebo group to determine if the laboratory test changes are different from what would be expected under placebo treatment.

As a complement to the results of the data analyses described above, a complete reporting of scores on the primary instruments for each subject will be provided. These reports will include the following for each patient:

Days 0, 4, 7, 10, 14, 21, 28, 35, 42:

HAM-D total score
Newly Observed Signs/Symptoms (NOSS)
ZUNG (not administered Days, 4, 10)

Days 0, 7, 14, 21, 28, 35, 42:

CGI

Days 0, 21, 42:

ECG
Laboratory Tests

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13.0 CRITERIA FOR RESPONSE

Analyses will be conducted dichotomizing treatment effects into clinically significant treatment response versus no treatment response. The criteria for a clinically significant treatment response will be a 50% reduction in the relevant instrument, the Hamilton Depression Scale, over the course of the clinical trial. Supplemental analyses will also be performed examining 50% reductions in score on the Zung Depression Scale. The former, continuous data analyses will allow greater statistical power in terms of identifying significant treatment response patterns, while the latter, dichotomous analyses will present treatment response results in a manner which may be more clinically meaningful. For the analyses of treatment response, appropriate non-parametric analyses will be utilized with respect to the ordinal nature of the dependent variable.

14.0 STUDY MEDICATIONS

Study drug will be prepared in capsules containing 2 mg of reboxetine or capsules of identical appearance containing placebo and will be supplied to the investigator by the Sponsor.

A 6-week supply of reboxetine or placebo, consisting of 215 capsules in one bottle, will be provided for each patient. Each bottle will be labelled with the patient's code number. An additional supply of placebo capsules will be provided for the washout period.

The actual medication the patient receives will be identifiable by opening the sealed envelope corresponding with the bottle number. PLEASE NOTE THAT THIS MAY ONLY BE OPENED IF IT WILL AID IN THE MANAGEMENT OF THE PATIENT. ADRIA LABORATORIES OF CANADA LTD. MUST BE NOTIFIED IF THIS BECOMES NECESSARY.

All unused medication should be returned to the Sponsor at the following address:

Ms Patricia Shannon
Medical Research Associate
Adria Laboratories of Canada Ltd.
5476 Gorvan Drive
Mississauga ON L4W 3E8

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15.0 ETHICAL AND LEGAL CONSIDERATIONS

The clinical study will be carried out in accordance with the Tokyo revision of the Helsinki declaration. Implementation of the study will depend on approval of protocol by the Canadian HPB and of Institutional Review Board (IRB's) participating centres. Local IRB's will also review "patient consent form."

Participation in this study will be voluntary. Prior to signing consent, the investigator and/or their associates will ensure that the patient is fully aware of the potential risk and benefits involved and the right to withdraw from the study at any time and without delay on request.

It is understood that no protocol change will be made once the study is implemented without the approval of Sponsor, Scientific Coordinator, local IRB and the HPB. Modifications of protocol for patient's safety, however, will be expected.

16.0 INVESTIGATORS' MEETINGS

There will be at least two investigators' meetings: one prior to commencement of the clinical trial and one after completion of data analysis.

17.0 PUBLICATIONS

Results of collaborative study will be published in single publication. In the list of authors, the principal investigators will be listed sequentially according to the number of patients that each institution contributed to the trial, starting by the name of the investigator who enrolled the largest number of patients. Whenever associate investigators have participated, their names will appear following the list of principal investigators, and according to the same sequence. The members of the team responsible for the scientific coordination and any appropriate Adria personnel will also be included as coauthors. Other publications and/or presentations of data will need to be cleared with the Sponsor and the Scientific Coordinator.

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18.0 BIBLIOGRAPHY

1. Pocock, S.J., Geller, N.L. (1986). Interim Analysis in Randomized Clinical Trials, Drug Information Journal, 20:263-269.
2. Sigel, S. (1956). Non-parametric statistics for the behavioural sciences. Toronto: McGraw-Hill, pg. 63.

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ENCLOSURE 3

Randomization Codes

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REBOXETINE

CLINICAL STUDY NO. 091002-999

RANDOMIZATION CODE

CENTER 1 : Montreal

PRINCIPAL INVESTIGATOR : Dr. Guy Chouinard

<u>Patient No.</u>	<u>Treatment</u>	<u>Patient No.</u>	<u>Treatment</u>
1	R	11	P
2	P	12	R
3	R	13	R
4	P	14	P
5	R	15	R
6	P	16	P
7	R	17	R
8	P	18	R
9	P	19	P
10	R	20	P

R = REBOXETINE 2 mg
P = PLACEBO

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REBOXETINE

CLINICAL STUDY NO. 091002-999

RANDOMIZATION CODE

CENTER 2 : Pointe Claire

PRINCIPAL INVESTIGATOR : Dr. M. Amin

<u>Patient No.</u>	<u>Treatment</u>	<u>Patient No.</u>	<u>Treatment</u>
21	P	36	R
22	P	37	R
23	R	38	P
24	R	39	R
25	R	40	P
26	P	41	R
27	R	42	R
28	P	43	P
29	P	44	P
30	R	45	P
31	R	46	R
32	R	47	R
33	P	48	P
34	P	49	R
35	P	50	P

R = REBOXETINE 2 mg
P = PLACEBO

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REBOXETINE

CLINICAL STUDY NO. 091002-999

RANDOMIZATION CODE

CENTER 3 : Rio de Janeiro

PRINCIPAL INVESTIGATOR : Dr. M. Versiani

<u>Patient No.</u>	<u>Treatment</u>	<u>Patient No.</u>	<u>Treatment</u>
81	R	121	R
82	P	122	R
83	P	123	P
84	R	124	P
85	P	125	R
86	R	126	P
87	P	127	R
88	P	128	R
89	R	129	P
90	R	130	P
91	R	131	R
92	R	132	R
93	P	133	P
94	P	134	P
95	R	135	R
96	P	136	P
97	R	137	P
98	R	138	P
99	P	139	P
100	P	140	R

R = REBOXETINE 2 mg
P = PLACEBO

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R E B O X E T I N E

CLINICAL STUDY NO. 091002-999

RANDOMIZATION CODE

CENTER 3 : Rio de Janeiro

PRINCIPAL INVESTIGATOR : Dr. M. Versiani

<u>Patient No.</u>	<u>Treatment</u>
141	P
142	P
143	R
144	R
145	R
146	P
147	P
148	R
149	R
150	P
151	P
152	P
153	R

R = REBOXETINE 2 mg
P = PLACEBO

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ENCLOSURE 4

Centers and Investigators

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STATEMENT OF INVESTIGATOR

NAME OF INVESTIGATOR: Dr. Guy Chouinard

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STATEMENT OF EDUCATION AND EXPERIENCE

COLLEGES, UNIVERSITIES AND MEDICAL OR OTHER PROFESSIONAL SCHOOLS ATTENDED,
WITH DATES OF ATTENDANCE, DEGREES, AND DATES DEGREES WERE AWARDED.

POSTGRADUATE MEDICAL OR OTHER PROFESSIONAL TRAINING (INDICATE DATES, NAMES OF
INSTITUTIONS, AND NATURE OF TRAINING)

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STATEMENT OF INVESTIGATOR

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STATEMENT OF INVESTIGATOR

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STATEMENT OF INVESTIGATOR

NAME OF CO-INVESTIGATOR: Dr. J. Mirmiran

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STATEMENT OF INVESTIGATOR

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STATEMENT OF INVESTIGATOR

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STATEMENT OF INVESTIGATOR

NAME OF CO-INVESTIGATOR: Dr. A.E. Nardi

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ENCLOSURE 5

Consent Forms

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Consent Form in English (for Canadian patients whose mother tongue is English).

A sample of the Consent Form is archived in the Study Master File.

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Consent Form in French (for Canadian patients whose mother tongue is French).

A sample of the Consent Form is archived in the Study Master File.

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Consent Form in Portuguese (for all Brazilian patients).

A sample of the Consent Form is archived in the Study Master File.

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ENCLOSURE 6

**Total Population:
Personal Characteristics**

165

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Pat No.	Ctr. ¹ No.	Patient Initials	Sex ²	Age (yrs)
1	1	PR	1	50
2	1	GB	1	60
16	1	PJ	0	53
17	1	LB	0	50
31	2	HB	1	46
32	2	CG	1	30
33	2	SS	1	53
34	2	MD	1	46
35	2	YL	1	54
46	2	LB	0	42
47	2	DP	0	38
48	2	CG	0	20
81	3	MC	1	34
82	3	CS	1	33
83	3	CC	1	20
84	3	AM	1	33
85	3	SP	1	47
86	3	EP	1	38
87	3	MC	1	27
88	3	AL	1	37
89	3	NM	1	49
90	3	DC	1	24
91	3	MA	0	37
92	3	LZ	0	43
93	3	JM	0	51
94	3	SF	0	29
95	3	MA	0	48
96	3	AC	0	55
97	3	CO	0	30
98	3	RL	0	26
99	3	LM	0	18
100	3	AR	0	34
121	3	SF	1	38
122	3	PC	1	34
123	3	AC	1	41
124	3	IG	1	41
125	3	CS	1	39
126	3	OF	1	32
127	3	AJ	1	47
128	3	JA	1	42
129	3	RA	1	26
130	3	CV	1	40

¹ CTR: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² SEX: 0 = Female 1 = Male

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Pat No.	Ctr. ¹ No.	Patient Initials	Sex ²	Age (yrs)
131	3	MP	1	25
133	3	CM	1	47
141	3	EB	0	43
142	3	OC	0	25
143	3	RR	0	58
144	3	MM	0	50
145	3	ML	0	52
146	3	IP	0	58
147	3	JN	0	40
148	3	VG	0	50
149	3	ES	0	58
150	3	CF	0	52
151	3	BS	0	48
153	3	AC	0	57

¹ CTR: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² SEX: 0 = Female 1 = Male

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ENCLOSURE 7

**Total Population:
Physical Characteristics**

168

47

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Pat No.	Ctr. ¹ No.	Height (cm)	Weight (kg)
1	1	177	88
2	1	170	64
16	1	155	38
17	1	152	44
31	2	178	111
32	2	172	80
33	2	180	85
34	2	165	80
35	2	166	74
46	2	158	49
47	2	162	53
48	2	168	58
81	3	156	50
82	3	176	78
83	3	156	58
84	3	150	42
85	3	159	59
86	3	169	74
87	3	160	51
88	3	160	59
89	3	160	75
90	3	162	52
91	3	165	62
92	3	160	55
93	3	170	72
94	3	174	60
95	3	164	63
96	3	163	48
97	3	163	58
98	3	169	51
99	3	160	47
100	3	166	62
121	3	173	75
122	3	180	82
123	3	164	61
124	3	172	72
125	3	186	70
126	3	174	66
127	3	180	63
128	3	169	77
129	3	178	77
130	3	180	80
131	3	166	55
133	3	178	72

¹ CTR: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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Pat No.	Ctr. ¹ No.	Height (cm)	Weight (kg)
141	3	173	70
142	3	167	56
143	3	160	52
144	3	165	68
145	3	157	71
146	3	150	44
147	3	150	55
148	3	158	60
149	3	161	60
150	3	168	68
151	3	163	58

¹ CTR: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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ENCLOSURE 8

**Total Population:
History of Depressive Illness**

171

50

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Pat No.	Ctr. ¹ No.	Age at Onset	No. of Prior Episodes
1	1	50	1
2	1	42	8
16	1	43	1
17	1	31	1
31	2	44	4
32	2	23	1
33	2	25	5
34	2	32	10
35	2	25	6
46	2	34	.
47	2	7	20
48	2	11	10
81	3	34	0
82	3	33	0
83	3	20	0
84	3	27	2
85	3	40	3
86	3	38	0
87	3	27	0
88	3	32	2
89	3	49	0
90	3	24	0
91	3	37	0
92	3	30	5
93	3	40	4
94	3	29	0
95	3	48	0
96	3	42	7
97	3	30	0
98	3	26	0
99	3	18	0
100	3	34	2
121	3	36	1
122	3	34	0
123	3	30	5
124	3	28	8
125	3	30	1
126	3	32	0
127	3	47	0
128	3	35	6
129	3	26	0
130	3	25	6
131	3	19	5
133	3	46	0

¹ CTR: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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Pat No.	Ctr. ¹ No.	Age at Onset	No. of Prior Episodes
141	3	32	2
142	3	24	0
143	3	58	0
144	3	35	10
145	3	52	0
146	3	58	0
147	3	40	0
148	3	50	0
149	3	30	8
150	3	40	10
151	3	48	0
153	3	57	0

¹ CTR: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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ENCLOSURE 9

**Total Population:
Present Episode of Depressive Illness**

174

53

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Pat. No.	CTR. ¹ No.	Precip. Stressor ²	Form of Onset ³	Subform of Illness ⁴	Duration (in months)
1	1	2	3	29633	3
2	1	1	2	29633	2
16	1	1	2	29633	2
17	1	2	3	29634	1
31	2	2	2	29633	3
32	2	1	3	29632	8
33	2	1	2	29630	6
34	2	1	1	29630	2
35	2	2	3	29630	9
46	2	1	2	29630	2
47	2	2	2	29630	2
48	2	2	1	29630	2
81	3	1	2	29620	4
82	3	1	1	29620	5
83	3	1	1	29620	2
84	3	1	2	29630	3
85	3	1	2	29630	4
86	3	2	2	29620	6
87	3	2	1	29620	10
88	3	1	1	29620	8
89	3	1	2	29620	8
90	3	2	1	29620	3
91	3	1	2	29620	4
92	3	1	3	29630	4
93	3	1	2	29630	4
94	3	3	1	29620	8
95	3	1	3	29620	1
96	3	1	2	29630	2
97	3	1	1	29620	1
98	3	1	2	29620	10
99	3	3	1	29620	4
100	3	1	3	29630	12
121	3	1	1	29630	4
122	3	1	1	29620	3
123	3	1	1	29630	3
124	3	1	1	29630	1
125	3	1	2	29630	6

¹ CTR: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Precip. Stressor: 1 = Absent 2 = Prob. Present 3 = Def. Present

³ Form of Onset: 1 = Acute 2 = Subacute 3 = Insidious

⁴ Subform of Illness:

29620 - Major Depression, Single Episode

29630 - Major Depression, Recurrent

29632 - Major Depression, Recurrent, Moderately Severe

29633 - Major Depression, Recurrent, Severe without Psychotic Features

29634 - Major Depression, Recurrent, Severe with Psychotic Features

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Pat. No.	Ctr. ¹ No.	Precip. Stressor ²	Form of Onset ³	Subform of Illness ⁴	Duration (in months)
126	3	1	1	29620	3
127	3	1	2	29620	9
128	3	1	1	29630	2
129	3	1	1	29620	3
130	3	1	3	29630	5
131	3	1	1	29630	2
133	3	1	2	29620	4
141	3	2	2	29630	2
142	3	3	1	29620	10
143	3	2	1	29620	2
144	3	1	1	29630	5
145	3	1	1	29620	4
146	3	1	2	29620	9
147	3	1	1	29620	3
148	3	1	3	29620	12
149	3	1	3	29630	4
150	3	1	3	29630	9
151	3	3	1	29620	1
153	3	1	2	29620	4

¹ CTR: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Precip. Stressor: 1 = Absent 2 = Prob. Present 3 = Def. Present

³ Form of Onset: 1 = Acute 2 = Subacute 3 = Insidious

⁴ Subform of Illness:

29620 - Major Depression, Single Episode

29630 - Major Depression, Recurrent

29632 - Major Depression, Recurrent, Moderately Severe

29633 - Major Depression, Recurrent, Severe without Psychotic Features

29634 - Major Depression, Recurrent, Severe with Psychotic Features

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ENCLOSURE 10

**Total Population:
Characteristics of the Two Treatment Groups**

177

56

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Reboxetine Treatment Group

Pat. No.	Ctr. No.	Sex ²	At Admission to Study:			History:		Present Episode:			Illness Dur. (months)
			Age	Height (cm)	Weight (kg)	Onset Age	No. of Prior Episodes	Precip. Stress ³	Form of Onset ⁴	Subform of Illness ⁵	
1	1	1	50	177	88	50	1	2	3	29633	3
17	1	0	50	152	44	31	1	2	3	29634	1
31	2	1	46	178	111	44	4	2	2	29633	3
32	2	1	30	172	80	23	1	1	3	29632	8
46	2	0	42	158	49	34	.	1	2	29630	2
47	2	0	38	162	53	7	20	2	2	29630	2
81	3	1	34	156	50	34	0	1	2	29620	4
84	3	1	33	150	42	27	2	1	2	29630	3
86	3	1	38	169	74	38	0	2	2	29620	6
89	3	1	49	160	75	49	0	1	2	29620	8
90	3	1	24	162	52	24	0	2	1	29620	3
91	3	0	37	165	62	37	0	1	2	29620	4
92	3	0	43	160	55	30	5	1	3	29630	4
95	3	0	48	164	63	48	0	1	3	29620	1
97	3	0	30	163	58	30	0	1	1	29620	1
98	3	0	26	169	51	26	0	1	2	29620	10
121	3	1	38	173	75	36	1	1	1	29630	4
122	3	1	34	180	82	34	0	1	1	29620	3
125	3	1	39	186	70	30	1	1	2	29630	6
127	3	1	47	180	63	47	0	1	2	29620	9
128	3	1	42	169	77	35	6	1	1	29630	2
131	3	1	25	166	55	19	5	1	1	29630	2
143	3	0	58	160	52	58	0	2	1	29620	2
144	3	0	50	165	68	35	10	1	1	29630	5
145	3	0	52	157	71	52	0	1	1	29620	4
148	3	0	50	158	60	50	0	1	3	29620	12
149	3	0	58	161	60	30	8	1	3	29630	4
153	3	0	57	158	45	57	0	1	2	29620	4

¹ Ctr.: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Sex: 0 = Female 1 = Male
³ Precip. Stress: 1 = Absent 2 = Prob. Present 3 = Def. Present
⁴ Form of Onset: 1 = Acute 2 = Subacute 3 = Insidious
⁵ Subform of Illness:
 296.20 - Major Depression, Single Episode
 296.30 - Major Depression, Recurrent
 296.32 - Major Depression, Recurrent, Moderately Severe
 296.33 - Major Depression, Recurrent, Severe, without psychotic features
 296.34 - Major Depression, Recurrent, Severe, with psychotic features

Placebo Treatment Group

Pat. No.	Ctr. ¹ No.	Sex ²	At Admission to Study:		History:		Present Episode:			Illness Dur. (months)	
			Age	Height (cm)	Weight (kg)	Onset Age	No. of Prior Episodes	Precip. Stress ³	Form of Onset ⁴		Subform of Illness ⁵
2	1	1	60	170	64	42	8	1	2	29633	2
16	1	0	53	155	38	43	1	1	2	29633	2
33	2	1	53	180	85	25	5	1	2	29630	6
34	2	1	46	165	80	32	10	1	1	29630	2
35	2	1	54	166	74	25	6	2	3	29630	9
48	2	0	20	168	58	11	10	2	1	29630	2
82	3	1	33	176	78	33	0	1	1	29620	5
83	3	1	20	156	58	20	0	1	1	29620	2
85	3	1	47	159	59	40	3	1	2	29630	4
87	3	1	27	160	51	27	0	2	1	29620	10
88	3	1	37	160	59	32	2	1	1	29620	8
93	3	0	51	170	72	40	4	1	2	29630	4
94	3	0	29	174	60	29	0	3	1	29620	8
96	3	0	55	163	48	42	7	1	2	29630	2
99	3	0	18	160	47	18	0	3	1	29620	4
100	3	0	34	166	62	34	2	1	3	29630	12
123	3	1	41	164	61	30	5	1	1	29630	3
124	3	1	41	172	72	28	8	1	1	29630	1
126	3	1	32	174	66	32	0	1	1	29620	3
129	3	1	26	178	77	26	0	1	1	29620	3
130	3	1	40	180	80	25	6	1	3	29630	5
133	3	1	47	178	72	46	0	1	2	29620	4
141	3	0	43	173	70	32	2	2	2	29630	2
142	3	0	25	167	56	24	0	3	1	29620	10
146	3	0	58	150	44	58	0	1	2	29620	9
147	3	0	40	150	55	40	0	1	1	29620	3
150	3	0	52	168	68	40	10	1	3	29630	9
151	3	0	48	163	58	48	0	3	1	29620	1

¹ Ctr.: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Sex: 0 = Female 1 = Male

³ Precip. Stress: 1 = Absent 2 = Prob. Present 3 = Def. Present

⁴ Form of Onset: 1 = Acute 2 = Subacute 3 = Insidious

⁵ Subform of Illness:

296.20 - Major Depression, Single Episode

296.30 - Major Depression, Recurrent

296.32 - Major Depression, Recurrent, Moderately Severe

296.33 - Major Depression, Recurrent, Severe, without psychotic features

296.34 - Major Depression, Recurrent, Severe, with psychotic features

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ENCLOSURE 11

Assessment Instruments Employed

180

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A sample of blank Patient Identification is archived in the Study Master File.

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181

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A sample of blank DSM III-R Diagnosis / Present Episode / History of Illness is archived in the Study Master File .

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182

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A sample of blank Hamilton Depression Rating Scale (HAM-D) is archived in the Study Master File .

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A sample of blank Physical Examination Form is archived in the Study Master File .

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A sample of blank Newly Observed Signs and Symptoms Checklist is archived in the Study Master File.

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A sample of blank Vital Signs Form is archived in the Study Master File.

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A sample of blank Clinical Global Impression (CGI) Form is archived in the Study Master File.

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A sample of blank ZUNG - SDS Form is archived in the Study Master File.

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188

67

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A sample of blank Laboratory Tests Form is archived in the Study Master File.

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189

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A sample of blank Clinical Global Impression - Global Improvement (CGI-GI) Form is archived in the Study Master File.

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A sample of blank Treatment Termination Record Form is archived in the Study Master File.

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A sample of the Follow-up Form is archived in the Study Master File.

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ENCLOSURE 12

Karch and Lasagna's Criteria

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RELATIONSHIP OF NEWLY OBSERVED SIGNS AND SYMPTOMS
TO EXPERIMENTAL TREATMENT

Adapted from Karch and Lasagna (1975) Journal of the American Medical Association 234: 1236-41.

1. **Definite.** A reaction that follows a reasonable temporal sequence from administration of the drug or in which the drug level has been established in body fluids or tissues; that follows a known or expected response pattern to the suspected drug; and that is confirmed by improvement on stopping or reducing the dosage of the drug, and reappearance of the reaction on repeated exposure (rechallenge).
2. **Probable.** A reaction that follows a reasonable temporal sequence from administration of the drug; that follows a known or expected response pattern to the suspected drug; that is confirmed by stopping or reducing the dosage of the drug; and that could not be reasonably explained by the known characteristics of the patient's clinical state.
3. **Possible.** A reaction that follows a reasonable temporal sequence from administration of the drug; that follows a known or expected response pattern to the suspected drug; but that could readily have been produced by a number of other factors.
4. **Unknown.** Relationship for which no evaluation can be made.
5. **Not related.** A reaction for which sufficient information exists to indicate that the etiology is unrelated to the study drug.

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ENCLOSURE 13

**Total Population:
Patients and Assessors**

195

74

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Pat. No.	Ctr. ¹ No.	Assessor ² No.
1	1	1
2	1	1
16	1	1
17	1	1
31	2	2
32	2	2
33	2	2
34	2	3
35	2	3
46	2	3
47	2	3
48	2	3
81	3	4
82	3	4
83	3	4
84	3	4
85	3	4
86	3	4
87	3	4
88	3	4
89	3	4
90	3	4
91	3	4
92	3	4
93	3	4
94	3	4
95	3	4
96	3	4
97	3	4
98	3	4
99	3	4
100	3	4
121	3	4
122	3	4
123	3	4
124	3	4
125	3	4
126	3	4
127	3	4
128	3	4
129	3	4
130	3	4

¹ Ctr: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Assessor: 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi

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Pat. No.	Ctr. ¹ No.	Assessor ² No.
131	3	4
133	3	4
141	3	4
142	3	4
143	3	4
144	3	4
145	3	4
146	3	4
147	3	4
148	3	4
149	3	4
150	3	4
151	3	4
153	3	4

¹ Ctr: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Assessor: 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi

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ENCLOSURE 14

**Total Population:
Inclusion/Exclusion Criteria
(Normal Laboratory Values)**

198

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Abbreviations:

HGB	Hemoglobin
HCT	Hematocrit
RBC	Red Blood Cells
WBC	White Blood Cells
Na +	Sodium
K +	Potassium
Cl-	Chlorine
Ca + +	Calcium
PO4	Phosphates
SGOT	Aspartate Aminotransferase
SGPT	Alanine Aminotransferase
γ GT	Gamma Glutamyl Transpeptidase
Alk. Phos.	Alkaline Phosphatase
BUN	Blood Urea Nitrogen
Tot.	Total
Dir.	Direct
T3	Thyroxine
T4	Thyroxine
TSH	Thyrotropin (Thyroid-stimulating Hormone)
HBs Ag, Anti-HBC for Hepatitis B	
ALT, AST	Alanine Aminotransferase/Aspartate Aminotransferase

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CENTER 1 - Montreal
 RANGE OF NORMAL LABORATORY VALUES

<u>TEST</u>		<u>UNITS</u>
HGB	140 - 160 males 120 - 150 females	GMS/100
HCT42 - .50 males .37 - .45 females	GMS/100
RBC	4.5 - 5.0 males 4.0 - 4.5 females	$\times 10^6/\text{mm}^3$
WBC	4.5 - 10.0	mm^3
Neutrophils	65 - 72	%
Lymphocytes	20 - 35	%
Eosinophils	1 - 3	%
Monocytes	3 - 7	%
Basophils	0 - 1	%
Platelets	150 - 400	$\times 10^3/\text{mm}^3$
NA+	135 - 145	mEq/l
K+	3.5 - 5.0	mEq/l
Cl-	98 - 108	mEq/l
Ca++	2.12 - 2.62	mEq/l
PO4	0.80 - 1.45	mEq/l
SGOT	0 - 26	U/L
SGPT	0 - 26	U/L
γ GT	8 - 38 males 5 - 25 females	U/L
Blood Sugar	3.9 - 5.8	mEq/l
Alk. Phos.	20 - 70	U/L
BUN	2.5 - 8.0	mEq/l

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CENTER 1 - Montreal

RANGE OF NORMAL LABORATORY VALUES (cont.)

<u>TEST</u>	<u>UNITS</u>
Creatinine 60 - 120 males 50 - 110 females	µmol/l
Uric Acid 200 - 460 males 150 - 360 females	µmol/l
Tot. Bilirubin .. 1.8 - 18.0	µmol/l
Dir. Bilirubin .. 0.0 - 8.0	µmol/l
Tot. Protein 60 - 80	G/L
Blood Albumin 35 - 52	G/L
Cholesterol 3.35 - 7.25 males 3.35 - 8.0 females	mmol/L
Triglycerides ... 0.4 - 1.92	mmol/L
Globulins α-1 ... 0.03 - 0.06	G/L
Globulins α-2 ... 0.07 - 0.12	G/L
Globulins β 0.09 - 0.15	G/L
Globulins γ 0.12 - 0.20	G/L
T3 0.25 - 0.35	%
T4 64 - 167	mol/L
TSH 0.5 - 4.0	µU/ml
HBs Ag, Anti-HBC for Hepatitis B . neg	
ELISA HIV neg	
ALT, AST neg	

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CENTER 1 - Montreal

RANGE OF NORMAL LABORATORY VALUES (cont.)

<u>TEST</u>	<u>UNITS</u>
URINALYSIS:	
Specific Gravity	1.014 - 1.028
Albumin	neg
Sugar	neg
RBC	0 - 3
WBC	0 - 5

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CENTER 2 - Pointe Claire
RANGE OF NORMAL LABORATORY VALUES

<u>TEST</u>		<u>UNITS</u>
HGB	134 - 176 males 117 - 153 females	G/L
HCT	.41 - .50 males .35 - .46 females	L/L
RBC	4.3 - 5.5 males 3.8 - 5.1 females	$\times 10^{12}/L$
WBC	4.0 - 11.0	$\times 10^9/L$
Neutrophils	.42 - .75	$\times 10^9/L$
Lymphocytes	.20 - .51	$\times 10^9/L$
Eosinophils	0 - .45	$\times 10^9/L$
Monocytes	.14 - .86	$\times 10^9/L$
Basophils	0 - .124	$\times 10^9/L$
Platelets	140 - 440	$\times 10^9/L$
NA+	136 - 146	mmo1/L
K+	3.5 - 5.0	mmo1/L
Cl-	100 - 110	mmo1/L
Ca++	2.10 - 2.59	mmo1/L
PO4	0.80 - 1.55	mmo1/L
SGOT	7 - 24	U/L
SGPT	4 - 31	U/L
γ GT	0 - 14	U/L
Blood Sugar	< 6.7	mmo1/L
Alk. Phos.	40 - 170	U/L
BUN	2.8 - 9.3	mmo1/L

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CENTER 2 - Pointe Claire

RANGE OF NORMAL LABORATORY VALUES (cont.)

<u>TEST</u>		<u>UNITS</u>
Creatinine	35 - 133	µmol/l
Uric Acid	130 - 470	µmol/l
Tot. Bilirubin ..	5 - 25	µmol/l
Tot. Protein	65 - 80	G/L
Blood Albumin	39 - 50	G/L
Cholesterol	3.36 - 6.20	mmol/L
Triglycerides ...	0.34 - 1.92	mmol/L
Globulins α-1 ...	1 - 4	G/L
Globulins α-2 ...	4 - 10	G/L
Globulins β	5 - 12	G/L
Globulins γ	6 - 16	G/L
T3	0.30 - 0.40	l
T4	57 - 140	nmol/L
TSH	0.4 - 4.0	µU/ml
HBs Ag, Anti-HBC for Hepatitis B .	neg	
ELISA HIV	neg	
Specific Gravity	1.003 - 1.030	
Albumin	neg	
Sugar	neg	
RBC	0 - 5	
WBC	0 - 5	

204

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CENTER 3 - Rio de Janeiro
RANGE OF NORMAL LABORATORY VALUES

<u>TEST</u>			<u>UNITS</u>
HGB	14.0 - 16.5 12.5 - 15.5	males females	g/dl
HCT	40 - 50 37 - 47	males females	%
RBC	5x10 ⁶ - 5.8x10 ⁶ 4.4x10 ⁶ - 5.2x10 ⁶	males females	/mm ³
WBC	5000 - 7000		/mm ³
Neutrophils	54 - 73		%
Lymphocytes	20 - 30		%
Eosinophils	2 - 4		%
Monocytes	4 - 8		%
Basophils	0 - 1		%
Platelets	2x10 ⁵ - 4x10 ⁵		/mm ³
Na+	138 - 148		mEq/L
K+	3.8 - 5.5		mEq/L
Cl-	95 - 110		mEq/L
Ca++	8.8 - 10.2		mg/dl
SGOT	0 - 18 0 - 15	males females	U/L
SGPT	0 - 22 0 - 17	males females	U/L
γ GT	6 - 28 4 - 18	males females	U/L
Blood Sugar	70 - 110		mg/dl
Alk. Phos.	13 - 43		U.l.
Creatinine	0.8 - 1.6		mg/dl

205

84

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CENTER 3 - Rio de Janeiro

RANGE OF NORMAL LABORATORY VALUES (cont.)

<u>TEST</u>	<u>UNITS</u>
Uric Acid	3.0 - 7.0 mg/dl
Tot. Bilirubin ..	0.0 - 1.2 mg/dl
Tot. Protein	5.5 - 8.0 g/dl
Blood Albumin ...	3.5 - 5.2 g/dl
Cholesterol	150 - 250 mg/dl
Triglycerides	50 - 135 mg/dl
Globulins α -1	50 - 60 %
Globulins α -2 ...	4.0 - 7.0 %
Globulins γ ...	15.0 - 22.0 %
Globulins β ...	11.0 - 14.0 %
T3	0.6 - 2.1 ng/dl
T4	4.5 - 12.5 μ g/dl
TSH	0.0 - 4.0 mIU/ml
HBs Ag	neg
Anti-HBC	neg
ELISA HIV	neg
URINALYSIS:	
Specific Gravity	
Albumin	trace
Sugar	absent
RBC	0 - 2
WBC	0 - 4

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Pat. No.	Ctr. ¹ No.	Tx ² Group	Sex ³	Age	DSM ⁴ Subform	HAMD Total Screening	Score: Day 0
1	1	1	1	50	29633	35.00	35.00
2	1	2	1	60	29633	35.00	37.00
16	1	2	0	53	29633	33.00	35.00
17	1	1	0	50	29634	38.00	39.00
31	2	1	1	46	29633	26.00	27.00
32	2	1	1	30	29632	26.00	27.00
33	2	2	1	53	29630	36.00	34.00
34	2	2	1	46	29630	27.00	31.00
35	2	2	1	54	29630	37.00	36.00
46	2	1	0	42	29630	33.00	34.00
47	2	1	0	38	29630	28.00	31.00
48	2	2	0	20	29630	22.00	22.00
81	3	1	1	34	29620	34.00	34.00
82	3	2	1	33	29620	37.00	34.00
83	3	2	1	20	29620	37.00	38.00
84	3	1	1	33	29630	36.00	37.00
85	3	2	1	47	29630	36.00	33.00
86	3	1	1	38	29620	38.00	37.00
87	3	2	1	27	29620	38.00	41.00
88	3	2	1	37	29620	38.00	40.00
89	3	1	1	49	29620	44.00	41.00
90	3	1	1	24	29620	39.00	39.00
91	3	1	0	37	29620	40.00	43.00
92	3	1	0	43	29630	43.00	41.00
93	3	2	0	51	29630	38.00	36.00
94	3	2	0	29	29620	39.00	42.00
95	3	1	0	48	29620	37.00	37.00
96	3	2	0	55	29630	40.00	41.00
97	3	1	0	30	29620	32.00	34.00
98	3	1	0	26	29620	38.00	41.00
99	3	2	0	18	29620	40.00	38.00
100	3	2	0	34	29630	35.00	37.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Tx Group 1 = RBX 2 = PBO

³ Sex 0 = Female 1 = Male

⁴ DSM Subform:

29620 Single Episode

29630 Recurrent

29632 Recurrent, Moderately Severe

29633 Recurrent, Severe, without Psychotic Features

29634 Recurrent, Severe, with Psychotic Features

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	Sex ³	Age	DSM ⁴ Subform	HAMD Total Score: Screening	Day 0
121	3	1	1	38	29630	35.00	35.00
122	3	1	1	34	29620	35.00	36.00
123	3	2	1	41	29630	26.00	30.00
124	3	2	1	41	29630	31.00	34.00
125	3	1	1	39	29630	34.00	35.00
126	3	2	1	32	29620	34.00	34.00
127	3	1	1	47	29620	40.00	38.00
128	3	1	1	42	29630	41.00	37.00
129	3	2	1	26	29620	39.00	36.00
130	3	2	1	40	29630	35.00	33.00
131	3	1	1	25	29630	38.00	34.00
133	3	2	1	47	29620	32.00	32.00
141	3	2	0	43	29630	27.00	30.00
142	3	2	0	25	29620	35.00	35.00
143	3	1	0	58	29620	37.00	39.00
144	3	1	0	50	29630	44.00	38.00
145	3	1	0	52	29620	37.00	37.00
146	3	2	0	58	29620	34.00	34.00
147	3	2	0	40	29620	33.00	31.00
148	3	1	0	50	29620	34.00	32.00
149	3	1	0	58	29630	36.00	31.00
150	3	2	0	52	29630	34.00	33.00
151	3	2	0	48	29620	34.00	35.00
153	3	1	0	57	29620	36.00	35.00

- ¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO
³ Sex 0 = Female 1 = Male
⁴ DSM Subform:
 29620 Single Episode
 29630 Recurrent
 29632 Recurrent, Moderately Severe
 29633 Recurrent, Severe, without Psychotic Features
 29634 Recurrent, Severe, with Psychotic Features

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	Lying B.P. (sys)	B.P. (dia)	Heart Rate	Standing B.P. (sys)	B.P. (dia)	Heart Rate	Temp.	Weight
1	1	1	165	85	102	150	88	98	37.00	87.80
2	1	2	165	88	112	166	90	106	36.40	64.30
16	1	2	118	70	105	105	70	103	36.60	37.50
17	1	1	138	78	70	122	68	72	37.20	44.00
31	2	1	144	92	70	142	94	84	36.70	110.80
32	2	1	112	52	60	110	78	78	36.80	80.20
33	2	2	116	66	72	114	80	88	36.60	85.00
34	2	2	116	88	84	122	94	90	37.00	80.40
35	2	2	156	88	90	150	100	100	37.00	73.00
46	2	1	130	80	76	120	70	79	37.00	48.60
47	2	1	120	80	100	122	86	115	37.20	53.10
48	2	2	120	60	70	94	58	90	37.20	57.50
81	3	1	130	80	76	125	80	78	36.40	50.00
82	3	2	120	75	80	175	70	78	36.50	78.00
83	3	2	110	70	64	110	60	66	36.40	58.00
84	3	1	135	80	66	125	75	68	36.60	42.00
85	3	2	110	75	62	110	70	64	36.60	59.00
86	3	1	120	80	74	120	70	72	36.60	74.00
87	3	2	110	70	72	105	65	69	36.40	51.00
88	3	2	115	75	76	110	70	74	36.40	59.00
89	3	1	110	70	64	105	65	66	36.40	75.00
90	3	1	115	75	64	115	70	66	36.40	52.00
91	3	1	130	80	72	135	80	74	36.50	62.00
92	3	1	120	80	76	115	85	74	36.60	55.00
93	3	2	125	75	80	130	80	78	36.40	72.00
94	3	2	110	70	64	110	65	66	36.50	60.00
95	3	1	120	75	66	115	70	66	36.50	63.00
96	3	2	110	70	68	100	60	66	36.50	48.00
97	3	1	115	75	64	110	70	66	36.50	58.00
98	3	1	105	65	64	110	65	66	36.50	51.00
99	3	2	120	70	68	120	60	66	36.50	47.00
100	3	2	120	75	72	110	65	68	36.50	62.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
 B.P. Blood Pressure
 sys Systolic
 dia Diastolic
 Temp. Temperature

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	Lying B.P. (sys) (dia)	Heart Rate	Standing B.P. (sys) (dia)	Heart Rate	Temp.	Weight		
121	3	1	120	85	76	125	90	82	36.60	75.00
122	3	1	130	90	82	135	85	85	36.70	82.00
123	3	2	130	80	74	125	80	75	36.50	61.00
124	3	2	120	85	74	115	80	78	36.70	72.00
125	3	1	110	80	68	115	75	72	36.50	70.00
126	3	2	115	75	84	120	85	86	36.40	66.00
127	3	1	135	90	86	135	85	90	36.80	63.00
128	3	1	140	95	86	135	90	87	36.60	77.00
129	3	2	120	80	72	120	70	74	36.70	77.00
130	3	2	125	85	68	120	75	72	36.70	80.00
131	3	1	130	80	74	135	75	76	36.80	55.00
133	3	2	130	75	78	130	80	80	36.80	72.00
141	3	2	110	70	68	115	75	71	36.60	70.00
142	3	2	125	75	76	120	75	78	36.60	56.00
143	3	1	140	95	70	135	90	74	36.50	52.00
144	3	1	120	70	70	115	65	72	36.70	68.00
145	3	1	110	60	64	105	60	66	36.70	71.00
146	3	2	115	75	90	110	75	86	36.70	44.00
147	3	2	100	65	64	100	60	66	36.50	55.00
148	3	1	110	70	66	110	75	67	36.60	60.00
149	3	1	110	75	64	105	70	66	36.50	60.00
150	3	2	115	75	60	115	70	64	36.60	68.00
151	3	2	125	80	72	120	75	70	36.60	58.00
153	3	1	125	75	78	120	70	81	36.60	45.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
 B.P. Blood Pressure
 sys Systolic
 dia Diastolic
 Temp. Temperature

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Pat. No.	Ctr. ¹ No.	Tx ² Group	ECG ³	EEG ³	Chest x-ray	Abnormality
1	1	1	0	0	0	
2	1	2	1	0	0	ECG-Min.Tachycard./Auric.Hypertrophy
16	1	2	1	0	0	ECG-Min.Tachycard./Auric.Hypertrophy
17	1	1	1	0	0	ECG-Few Extrasyst.Ventric./Limited
31	2	1	0	0	0	
32	2	1	0	0	0	
33	2	2	0	0	0	
34	2	2	0	0	0	
35	2	2	0	0	0	
46	2	1	0	0	0	
47	2	1	0	0	0	
48	2	2	0	0	0	
81	3	1	1	0	0	ECG-Lft.Ventric.Hypertrophy
82	3	2	0	0	0	
83	3	2	0	0	0	
84	3	1	0	0	0	
85	3	2	0	0	0	
86	3	1	1	0	0	ECG-Anterior Divisional Block
87	3	2	0	0	0	
88	3	2	0	0	0	
89	3	1	1	0	0	ECG-Lft.Atrial Enlargement
90	3	1	0	0	0	
91	3	1	0	0	0	
92	3	1	1	0	0	ECG-Unspec.Repolar.Alter./QT Prolong.
93	3	2	1	0	0	ECG-Lft.Axis Deviat./1st Deg. A-V Block
94	3	2	1	0	0	ECG-Sinus Bradycard./Lft.Atrial.Enlarg.
95	3	1	0	0	0	
96	3	2	0	0	0	
97	3	1	0	0	0	
98	3	1	0	0	0	
99	3	2	0	0	0	
100	3	2	0	0	0	

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Tx Group 1 = RBX 2 = PBO

³ E.C.G. & E.E.G. 0 = Normal 1 = Abnormal

Abbreviations:

ECG = Electrocardiogram

EEG = Electroencephalogram

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	ECG ³	EEG ³	Chest x-ray	Abnormality
121	3	1	0	0	0	
122	3	1	0	0	0	
123	3	2	0	0	0	
124	3	2	0	0	0	
125	3	1	0	0	0	
126	3	2	0	0	0	
127	3	1	0	0	0	
128	3	1	0	0	0	
129	3	2	0	0	0	
130	3	2	0	0	0	
131	3	1	0	0	0	
133	3	2	0	0	0	
141	3	2	0	.	0	
142	3	2	0	0	0	
143	3	1	0	0	0	
144	3	1	0	0	0	
145	3	1	0	0	0	
146	3	2	1	0	0	ECG-Heart Block 1st Grade
147	3	2	0	0	0	
148	3	1	0	0	0	
149	3	1	0	0	0	
150	3	2	0	0	0	
151	3	2	0	0	0	
153	3	1	0	0	0	

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Tx Group 1 = RBX 2 = PBO

³ E.C.G. & E.E.G. 0 = Normal 1 = Abnormal

Abbreviations:

ECG = Electrocardiogram

EEG = Electroencephalogram

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	HGB	HCT	RBC	WBC	NEUT.	LYMP.	EOS.	MONO.
1	1	1	15.70	47.50	4.93	12.90	72.00	20.00	.00	7.00
2	1	2	16.20	47.20	5.15	7.20	83.00	14.00	.00	3.00
16	1	2	14.80	44.70	5.08	9.70	88.00	11.00	.00	1.00
17	1	1	12.10	33.50	3.28	6.30	62.00	24.00	1.00	3.00
31	2	1	16.00	47.40	5.10	8.90	75.00	19.00	1.00	1.00
32	2	1	15.30	45.30	4.75	4.90	65.00	31.00	1.00	1.00
33	2	2	15.60	47.50	5.07	6.40	67.00	27.00	.00	2.00
34	2	2	16.50	48.90	5.30	14.00	74.50	20.80	.00	4.70
35	2	2	14.00	41.40	4.77	12.10	65.00	30.20	4.80	1.00
46	2	1	14.10	41.80	4.69	7.70	69.00	23.00	3.00	1.00
47	2	1	13.70	41.90	4.45	8.30	63.00	32.00	.	.50
48	2	2	13.20	37.30	3.94	6.80	60.00	36.00	1.00	1.00
81	3	1	13.10	40.00	4.56	5.00	58.00	36.00	1.00	5.00
82	3	2	14.50	44.00	4.32	5.50	64.00	28.00	1.00	7.00
83	3	2	14.70	45.00	5.06	6.50	67.00	26.00	3.00	4.00
84	3	1	14.00	42.00	4.70	10.40	53.00	43.00	2.00	2.00
85	3	2	14.00	43.00	4.80	7.60	56.00	38.00	2.00	4.00
86	3	1	14.10	42.00	4.70	3.50	45.00	42.00	2.00	7.00
87	3	2	14.10	43.00	4.89	7.50	70.00	24.00	4.00	2.00
88	3	2	13.10	39.00	4.41	10.00	66.00	27.00	2.00	5.00
89	3	1	14.10	43.00	4.81	8.10	72.00	20.00	4.00	4.00
90	3	1	13.60	40.00	4.35	7.00	72.00	22.00	1.00	5.00
91	3	1	12.50	38.00	4.30	5.80	55.00	33.00	3.00	8.00
92	3	1	11.20	36.00	4.16	5.20	66.00	26.00	2.00	5.00
93	3	2	15.30	46.00	5.16	6.20	53.00	35.00	7.00	4.00
94	3	2	15.60	47.00	5.28	3.30	66.00	27.00	2.00	5.00
95	3	1	13.00	38.00	4.32	5.40	63.00	29.00	2.00	6.00
96	3	2	13.40	42.00	4.73	4.50	62.00	31.00	4.00	3.00
97	3	1	11.80	38.00	4.01	19.50	80.00	8.00	.00	2.00
98	3	1	13.40	42.00	4.75	7.20	65.00	25.00	3.00	3.00
99	3	2	13.60	40.00	4.55	6.40	36.00	50.00	12.00	2.00
100	3	2	13.50	42.00	4.73	6.50	65.00	29.00	2.00	4.00
121	3	1	16.00	49.00	5.40	4.70	56.00	29.00	8.00	6.00
122	3	1	13.90	43.00	4.80	6.40	67.00	26.00	4.00	3.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:

HGB Hemoglobin WBC White Blood Cells EOS. Eosinophils
HCT Hematocrit NEUT. Neutrophils MONO. Monocytes
RBC Red Blood Cells LYMP. Lymphocytes

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	HGB	HCT	RBC	WBC	NEUT.	LYMP.	EOS.	MONO.
123	3	2	14.50	44.00	4.90	4.70	63.00	31.00	4.00	2.00
124	3	2	14.30	43.00	4.80	5.20	62.00	33.00	4.00	1.00
125	3	1	14.00	43.00	4.80	4.30	51.00	42.00	3.00	3.00
126	3	2	16.00	49.00	5.40	9.70	71.00	27.00	1.00	1.00
127	3	1	15.20	45.00	5.10	6.40	40.00	53.00	4.00	2.00
128	3	1	15.00	45.00	5.20	8.70	65.00	31.00	1.00	3.00
129	3	2	14.90	44.00	5.20	6.00	52.00	44.00	1.00	3.00
130	3	2	14.40	43.00	5.00	7.60	62.00	34.00	2.00	2.00
131	3	1	14.40	43.00	4.90	5.20	59.00	36.00	2.00	3.00
133	3	2	13.80	42.00	4.90	7.90	61.00	33.00	2.00	4.00
141	3	2	14.30	42.00	4.80	6.50	60.00	37.00	2.00	1.00
142	3	2	14.50	44.00	4.90	5.20	81.00	17.00	1.00	1.00
143	3	1	13.60	40.00	4.50	4.60	62.00	34.00	2.00	2.00
144	3	1	14.50	43.00	5.10	6.00	63.00	33.00	1.00	2.00
145	3	1	15.50	45.00	5.20	5.90	53.00	41.00	4.00	1.00
146	3	2	12.00	36.00	4.10	7.10	76.00	18.00	2.00	4.00
147	3	2	14.40	45.00	4.70	5.90	55.00	41.00	1.00	3.00
148	3	1	12.50	38.00	4.60	4.20	69.00	29.00	1.00	1.00
149	3	1	13.00	38.00	4.60	7.30	65.00	32.00	1.00	2.00
150	3	2	13.70	40.00	4.70	5.80	57.00	41.00	1.00	1.00
151	3	2	14.00	41.00	4.60	7.10	70.00	28.00	1.00	1.00
153	3	1	14.00	42.00	4.90	6.90	66.00	30.00	1.00	3.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
HGB Hemoglobin WBC White Blood Cells EOS. Eosinophils
HCT Hematocrit NEUT. Neutrophils MONO. Monocytes
RBC Red Blood Cells LYMP. Lymphocytes

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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Pat. No.	Ctr. ¹ No.	Tx ² Group	BASO	PLATE.	NA+	K+	CL-	CA++	PO4	SGOT
1	1	1	1.00	387.00	141.00	4.30	103.00	2.61	1.01	42.00
2	1	2	.00	405.00	137.00	4.20	99.00	2.42	1.02	16.00
16	1	2	.00	391.00	140.00	4.60	102.00	2.39	1.23	23.00
17	1	1	.00	323.00	141.00	4.20	106.00	2.27	1.04	14.00
31	2	1	1.00	263.00	141.00	4.20	104.00	2.21	.84	17.00
32	2	1	.00	203.00	144.00	4.10	109.00	2.31	1.07	12.00
33	2	2	.00	194.00	143.00	4.00	105.00	2.26	.90	11.00
34	2	2	.20	245.00	144.00	4.40	105.00	2.38	1.11	19.00
35	2	2	.20	251.00	143.00	3.50	105.00	2.24	.79	14.00
46	2	1	.00	303.00	143.00	4.30	105.00	2.45	1.00	14.00
47	2	1	.00	360.00	139.00	4.60	104.00	2.22	1.18	15.00
48	2	2	.00	319.00	142.00	4.20	105.00	2.22	1.35	12.00
81	3	1	.00	295.00	136.00	4.10	98.00	9.00	4.00	10.00
82	3	2	.00	241.00	140.00	3.80	102.00	8.80	3.00	14.00
83	3	2	.00	262.00	143.00	4.50	95.00	9.00	2.50	25.00
84	3	1	.00	240.00	140.00	4.50	102.00	8.80	2.80	7.00
85	3	2	.00	230.00	140.00	4.30	100.00	8.80	2.50	19.00
86	3	1	.00	205.00	140.00	4.60	105.00	9.40	2.90	25.00
87	3	2	.00	305.00	136.00	3.80	102.00	9.00	3.00	11.00
88	3	2	.00	445.00	136.00	4.70	94.00	9.10	3.70	15.00
89	3	1	.00	239.00	139.00	3.60	100.00	8.80	3.00	15.00
90	3	1	.00	215.00	135.00	3.80	100.00	8.80	2.50	13.00
91	3	1	1.00	225.00	135.00	3.70	99.00	8.80	2.50	15.00
92	3	1	1.00	210.00	138.00	4.00	100.00	9.00	2.70	10.00
93	3	2	1.00	225.00	140.00	4.10	98.00	8.00	2.60	8.00
94	3	2	.00	255.00	136.00	4.10	103.00	12.10	3.70	12.00
95	3	1	.00	208.00	140.00	4.10	102.00	8.90	2.70	5.00
96	3	2	.00	240.00	141.00	4.20	103.00	8.50	3.20	12.00
97	3	1	.00	285.00	135.00	5.10	102.00	8.80	2.50	40.00
98	3	1	.00	230.00	138.00	3.80	100.00	8.80	2.50	10.00
99	3	2	.00	245.00	135.00	4.10	105.00	9.00	2.70	11.00
100	3	2	.00	235.00	138.00	4.20	96.00	8.90	2.50	18.00
121	3	1	1.00	248.00	137.00	3.50	94.00	9.10	3.50	12.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
 BASO Basophils K+ Phosphorous PO4
 PLATE Platelet Count CL- Chlorine SGOT Aspartate Amino
 NA+ Sodium CA++ Calcium Transferase

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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Pat. No.	Ctr. ¹ No.	Tx ² Group	BASO	PLATE.	NA+	K+	CL-	CA++	PO4	SGOT
122	3	1	.00	229.00	135.00	3.90	93.00	8.90	4.00	14.00
123	3	2	.00	225.00	140.00	3.80	97.00	8.90	2.70	18.00
124	3	2	.00	240.00	141.00	4.10	100.00	8.80	2.80	10.00
125	3	1	1.00	246.00	142.00	4.40	102.00	8.90	2.90	20.00
126	3	2	.00	225.00	134.00	3.90	90.00	10.10	3.90	25.00
127	3	1	1.00	226.00	142.00	4.60	100.00	8.80	2.70	13.00
128	3	1	.00	260.00	139.00	4.70	97.00	8.80	2.70	15.00
129	3	2	.00	250.00	142.00	3.90	100.00	9.50	4.10	12.00
130	3	2	.00	228.00	139.00	4.40	100.00	9.10	4.10	17.00
131	3	1	.00	236.00	140.00	4.40	100.00	9.50	3.70	12.00
133	3	2	.00	236.00	141.00	4.20	92.00	8.80	2.90	14.00
141	3	2	.00	238.00	138.00	4.00	95.00	9.10	3.30	9.00
142	3	2	.00	240.00	136.00	3.60	96.00	9.60	4.20	18.00
143	3	1	.00	237.00	143.00	4.20	105.00	8.90	4.50	27.00
144	3	1	1.00	230.00	138.00	4.40	102.00	9.20	3.20	12.00
145	3	1	1.00	256.00	139.00	4.30	98.00	10.20	5.00	12.00
146	3	2	.00	240.00	140.00	3.90	100.00	9.90	3.90	15.00
147	3	2	.00	242.00	139.00	4.50	97.00	8.90	4.10	17.00
148	3	1	.00	238.00	140.00	3.80	98.00	9.00	3.00	11.00
149	3	1	.00	320.00	141.00	4.50	102.00	8.80	2.50	8.00
150	3	2	.00	340.00	142.00	4.50	103.00	9.30	3.30	10.00
151	3	2	.00	290.00	142.00	4.60	102.00	10.20	5.00	19.00
153	3	1	.00	236.00	137.00	4.60	100.00	8.80	2.60	12.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
 BASO Basophils K+ Phosphorous PO4
 PLATE Platelet Count CL- Chlorine SGOT Aspartate Amino
 NA+ Sodium CA++ Calcium Transferase

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Pat. No.	Ctr. ¹ No.	Tx ² Group	SGPT	γ GT	BLOOD SUGAR	ALK. PHOS.	BUN	CREAT.	URIC ACID	TOT. BILI.
1	1	1	57.00	62.00	5.30	87.00	7.00	81.00	457.00	11.00
2	1	2	14.00	32.00	8.80	90.00	4.10	72.00	299.00	9.90
16	1	2	26.00	16.00	4.70	71.00	7.40	61.00	274.00	10.90
17	1	1	11.00	41.00	4.70	51.00	4.80	74.00	274.00	7.90
31	2	1	17.00	24.00	5.10	125.00	3.70	83.00	361.00	6.00
32	2	1	7.00	4.00	4.30	76.00	4.50	102.00	256.00	5.00
33	2	2	8.00	.	4.60	85.00	4.50	93.00	396.00	14.00
34	2	2	29.00	.	5.80	.	6.60	127.00	495.00	5.00
35	2	2	7.00	10.00	5.00	15.00	6.40	131.00	437.00	9.00
46	2	1	7.00	6.00	5.40	.	6.80	75.00	187.00	10.00
47	2	1	8.00	16.00	5.60	61.00	3.30	95.00	236.00	4.90
48	2	2	5.00	.	10.50	86.00	4.90	101.00	196.00	6.00
81	3	1	9.00	5.00	100.00	22.00	22.00	.90	3.60	.70
82	3	2	25.00	26.00	75.00	50.00	5.00	.80	5.60	.70
83	3	2	27.00	24.00	93.00	39.00	31.00	.50	7.30	.70
84	3	1	5.00	8.00	87.00	24.00	8.00	.70	3.50	.50
85	3	2	18.00	8.00	86.00	34.00	18.00	.60	3.30	.90
86	3	1	38.00	25.00	56.00	34.00	5.00	.90	4.10	.50
87	3	2	38.00	4.00	76.00	20.00	23.00	.70	4.60	.60
88	3	2	35.00	20.00	55.00	27.00	8.00	.50	4.80	.70
89	3	1	19.00	20.00	84.00	26.00	23.00	.50	2.60	.70
90	3	1	23.00	18.00	87.00	24.00	4.00	.70	5.60	.70
91	3	1	17.00	11.00	81.00	28.00	22.00	.80	5.40	.60
92	3	1	12.00	18.00	91.00	36.00	4.00	.80	3.20	.60
93	3	2	32.00	47.00	178.00	37.00	38.00	.50	6.20	2.00
94	3	2	10.00	17.00	89.00	27.00	2.00	1.10	4.00	1.20
95	3	1	10.00	9.00	95.00	22.00	30.00	.90	3.50	.70
96	3	2	15.00	26.00	50.00	47.00	5.00	.80	3.70	.20
97	3	1	16.00	44.00	103.00	37.00	21.00	.70	3.20	.80
98	3	1	13.00	11.00	95.00	25.00	0.00	.80	3.40	.60
99	3	2	12.00	35.00	85.00	33.00	15.00	.80	4.40	.40
100	3	2	26.00	38.00	85.00	38.00	1.00	1.00	4.80	.20
121	3	1	35.00	38.00	88.00	28.00	34.00	.90	5.00	1.00
122	3	1	22.00	39.00	82.00	34.00	7.00	.90	6.40	.50
123	3	2	22.00	28.00	84.00	28.00	25.00	.80	6.00	1.00
124	3	2	13.00	12.00	73.00	34.00	0.00	1.20	4.80	1.20

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
 SGPT Alanine Aminotransferase
 γ GT
 ALK. Alkaline Phosphatase
 PHOS.
 BUN Urea Nitrogen
 CREAT. Creatinine
 TOT. Total
 BILI. Bilirubin

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Pat. No.	Ctr. ¹ No.	Tx ² Group	SGPT	γ GT	BLOOD SUGAR	ALK. PHOS.	BUN	CREAT.	URIC ACID	TOT. BILI.
125	3	1	28.00	11.00	82.00	25.00	32.00	.90	3.80	.90
126	3	2	33.00	4.00	83.00	33.00	6.00	.90	3.00	.60
127	3	1	14.00	13.00	96.00	28.00	28.00	.80	3.30	.50
122	3	1	22.00	39.00	82.00	34.00	7.00	.90	6.40	.50
123	3	2	22.00	28.00	84.00	28.00	25.00	.80	6.00	1.00
124	3	2	13.00	12.00	73.00	34.00	0.00	1.20	4.80	1.20
125	3	1	28.00	11.00	82.00	25.00	32.00	.90	3.80	.90
126	3	2	33.00	4.00	83.00	33.00	6.00	.90	3.00	.60
127	3	1	14.00	13.00	96.00	28.00	28.00	.80	3.30	.50
128	3	1	33.00	43.00	89.00	25.00	8.00	1.00	6.20	.60
129	3	2	13.00	8.00	89.00	30.00	40.00	.90	4.40	.60
130	3	2	13.00	12.00	78.00	20.00	7.00	.90	3.80	1.10
131	3	1	13.00	10.00	93.00	25.00	39.00	.90	4.40	.90
133	3	2	31.00	21.00	79.00	19.00	0.00	.80	5.80	.60
141	3	2	13.00	10.00	95.00	23.00	13.00	.50	3.00	1.20
142	3	2	9.00	6.00	82.00	32.00	6.00	.60	3.20	.80
143	3	1	27.00	5.00	83.00	46.00	19.00	.50	2.50	.70
144	3	1	15.00	8.00	101.00	20.00	6.00	1.00	3.90	.60
145	3	1	12.00	10.00	84.00	33.00	38.00	.80	3.70	.80
146	3	2	16.00	8.00	87.00	32.00	1.00	.90	3.00	.60
147	3	2	26.00	40.00	79.00	24.00	24.00	.60	4.10	1.10
148	3	1	13.00	22.00	89.00	28.00	6.00	.90	3.10	.70
149	3	1	9.00	8.00	91.00	38.00	17.00	.50	3.30	1.10
150	3	2	13.00	7.00	78.00	28.00	4.00	.90	3.20	.90
151	3	2	19.00	13.00	77.00	34.00	37.00	1.10	4.90	1.00
153	3	1	15.00	20.00	96.00	25.00	8.00	.60	3.50	1.40

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
 SGPT Alanine Aminotransferase ALK. Alkaline Phosphatase PHOS. Phosphatase BUN Urea Nitrogen CREAT. Creatinine TOT. Total BILI. Bilirubin

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Pat. No.	Ctr. ¹ No.	Tx ² Group	DIR. BILI.	TOT. PROT.	BLOOD ALBU.	CHOL.	TRIG.	GLOBULINS:		β
								α-1	α-2	
1	1	1	.00	71.00	41.00	5.64	.95	3.00	16.00	13.00
2	1	2	1.20	70.00	38.00	6.54	3.09	3.00	13.00	12.00
16	1	2	.50	72.00	39.00	5.53	1.13	.	.	.
17	1	1	.00	59.90	38.00	6.39	1.68	.	.	.
31	2	1	.00	70.00	42.00	6.00	.05	3.00	7.00	8.00
32	2	1	.	59.00	42.00	5.01	.78	3.00	4.00	7.00
33	2	2	.	66.00	43.00	5.33	1.04	3.00	4.00	7.00
34	2	2	.	75.00	45.00	5.33	3.31	4.00	7.00	9.00
35	2	2	.	74.00	48.00	6.02	1.25	3.00	4.00	8.00
46	2	1	.	71.00	45.00	5.30	1.26	4.00	4.00	6.00
47	2	1	.	67.00	46.00	7.49	1.74	3.00	8.00	10.00
48	2	2	.	61.00	35.00	4.84	1.00	3.00	5.00	8.00
81	3	1	.20	7.20	4.20	100.00	38.00	4.00	7.00	12.00
82	3	2	.20	6.40	3.50	166.00	82.00	5.00	7.00	12.00
83	3	2	.20	6.90	3.70	272.00	181.00	3.00	10.00	14.00
84	3	1	.10	8.10	4.40	150.00	66.00	9.00	7.00	12.00
85	3	2	.20	6.60	3.60	208.00	73.00	4.00	7.00	12.00
86	3	1	.30	7.20	4.60	159.00	90.00	4.00	7.00	12.00
87	3	2	.20	7.50	4.20	135.00	38.00	6.00	8.00	13.00
88	3	2	.20	7.40	4.00	177.00	39.00	6.00	9.00	13.00
89	3	1	.20	7.80	4.20	282.00	89.00	4.00	7.00	13.00
90	3	1	.30	7.10	4.10	201.00	105.00	5.00	7.00	12.00
91	3	1	.10	6.80	3.50	138.00	58.00	4.00	7.00	12.00
92	3	1	.10	6.90	4.30	183.00	91.00	4.00	7.00	12.00
93	3	2	.80	8.00	4.00	180.00	141.00	4.00	7.00	14.00
94	3	2	.40	8.10	5.00	130.00	39.00	4.00	7.00	12.00
95	3	1	.20	7.10	4.30	174.00	44.00	4.00	7.00	12.00
96	3	2	.50	7.30	4.50	168.00	60.00	5.00	7.00	12.00
97	3	1	.20	7.20	4.80	161.00	76.00	5.00	7.00	13.00
98	3	1	.20	6.80	4.20	167.00	60.00	5.00	7.00	12.00
99	3	2	1.80	7.60	4.80	158.00	106.00	7.00	11.00	15.00
100	3	2	.60	7.50	4.30	191.00	70.00	5.00	7.00	15.00
121	3	1	.40	6.60	4.40	191.00	60.00	4.00	8.00	12.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:

DIR. Direct
 BILI. Bilirubin
 CHOL. Cholesterol
 TOT. Total
 PROT. Protein
 TRIG. Triglycerides
 BLOOD ALBU. Blood Albumin

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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Pat. No.	Ctr. ¹ No.	Tx ² Group	DIR. BILI.	TOT. PROT.	BLOOD			GLOBULINS:		
					ALBU.	CHOL.	TRIG.	α-1	α-2	β
122	3	1	.10	8.30	4.60	231.00	296.00	6.00	9.00	14.00
123	3	2	.30	7.10	3.70	293.00	120.00	5.00	7.00	13.00
124	3	2	.40	7.10	4.40	186.00	97.00	4.00	7.00	13.00
125	3	1	.20	7.10	3.60	184.00	89.00	7.00	11.00	14.00
126	3	2	.10	7.50	4.20	215.00	145.00	6.00	8.00	14.00
127	3	1	1.00	6.80	3.50	195.00	148.00	4.00	7.00	12.00
128	3	1	.10	6.60	3.80	262.00	133.00	4.00	7.00	13.00
129	3	2	.20	7.60	4.10	140.00	36.00	4.00	8.00	13.00
130	3	2	.40	7.00	3.60	173.00	74.00	6.00	9.00	14.00
131	3	1	.20	6.50	4.10	200.00	44.00	5.00	8.00	13.00
133	3	2	.10	6.80	4.50	254.00	195.00	4.00	7.00	12.00
141	3	2	.30	7.00	3.80	213.00	80.00	6.00	8.00	12.00
142	3	2	.20	7.10	4.00	166.00	79.00	4.00	7.00	13.00
143	3	1	.10	6.50	3.80	219.00	67.00	4.00	7.00	12.00
144	3	1	.20	7.00	3.80	332.00	115.00	7.00	10.00	13.00
145	3	1	.20	7.00	3.80	276.00	142.00	4.00	7.00	12.00
146	3	2	.10	6.10	3.40	206.00	116.00	7.00	11.00	13.00
147	3	2	.40	7.60	3.80	229.00	71.00	4.00	8.00	13.00
148	3	1	.20	7.50	4.20	184.00	84.00	4.00	7.00	12.00
149	3	1	.30	6.70	3.60	253.00	97.00	4.00	7.00	12.00
150	3	2	.30	7.40	3.90	196.00	99.00	5.00	7.00	13.00
151	3	2	.30	6.30	3.20	227.00	106.00	7.00	12.00	15.00
153	3	1	.30	7.50	4.30	296.10	106.00	6.00	11.00	14.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:

DIR. Direct TOT. Total
 BILI. Bilirubin PROT. Protein BLOOD Blood
 CHOL. Cholesterol TRIG. Triglycerides ALBU. Albumin

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Pat. No.	Ctr. ¹ No.	Tx ² Group	Globulins: τ	T3	T4	TSH	HBS Ag ³	AIDS ³	ALT/AST Non-HEP. ³
1	1	1	13.00	.26	75.00	1.50	1	1	.
2	1	2	14.00	.28	112.00	.50	1	1	1
16	1	2	.	.26	135.00	.30	1	.	.
17	1	1
31	2	1	11.00	.96	77.00	.56	1	1	.
32	2	1	7.00	.79	96.00	2.17	.	.	.
33	2	2	5.00	.81	85.00	.84	1	.	.
34	2	2	13.00	1.10	136.00	1.89	0	1	1
35	2	2	11.00	.90	105.00	2.30	0	1	1
46	2	1	7.00	.87	107.00	.77	1	1	1
47	2	1	6.00	.28	118.00	1.30	1	1	1
48	2	2	10.00	.	.	.	1	1	1
81	3	1	15.00	1.30	7.00	1.10	1	1	1
82	3	2	15.00	1.05	6.00	.50	1	1	1
83	3	2	16.00	1.30	10.20	.48	1	1	1
84	3	1	15.00	1.20	6.20	3.20	1	1	1
85	3	2	15.00	1.55	7.00	2.50	1	1	1
86	3	1	15.00	1.45	7.00	3.20	1	1	1
87	3	2	15.00	1.10	9.00	2.80	1	1	1
88	3	2	17.00	1.30	8.50	.22	1	1	1
89	3	1	15.00	1.20	8.00	2.90	1	1	1
90	3	1	15.00	1.15	5.80	2.60	1	1	1
91	3	1	15.00	1.10	6.40	.22	1	1	1
92	3	1	16.00	1.30	7.00	1.10	1	1	1
93	3	2	15.00	1.60	8.00	1.70	1	1	1
94	3	2	15.00	1.40	6.40	1.80	1	1	1
95	3	1	15.00	1.40	9.00	.22	1	1	1
96	3	2	16.00	1.20	10.00	.48	1	1	1
97	3	1	16.00	1.30	11.00	.50	1	1	1
98	3	1	17.00	2.00	9.00	5.20	1	1	1
99	3	2	21.00	1.15	8.00	4.50	1	1	1
100	3	2	16.00	1.30	12.50	2.00	1	1	1

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO
³ HBS ag/AIDS/Non-HEP 1 = Negative 0 = Positive

Abbreviations:

T3 HBS AG ALT/AST
T4 Thyroxine AIDS NON-HEP.
TSH Thyrotropin (Thyroid-stimulating Hormone)

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Pat. No.	Ctr. ¹ No.	Tx ² Group	Globulins: τ	TSH			HBS AG	AIDS	ALT/AST Non-HEP.
				T3	T4	TSH			
121	3	1	17.00	1.15	6.40	1.80	1	1	1
122	3	1	17.00	1.80	7.70	5.30	1	1	1
123	3	2	21.00	1.30	9.50	5.20	1	1	1
124	3	2	16.00	1.50	8.50	2.70	1	1	1
125	3	1	22.00	1.20	8.50	5.00	1	1	1
126	3	2	20.00	1.70	7.20	5.20	1	1	1
127	3	1	15.00	1.35	8.50	2.40	1	1	1
128	3	1	15.00	1.00	7.70	13.00	1	1	1
129	3	2	15.00	.	.	.	1	1	1
130	3	2	17.00	1.30	7.80	.30	1	1	1
131	3	1	19.00	1.30	9.00	2.00	1	1	1
133	3	2	16.00	1.00	5.60	3.40	1	1	1
141	3	2	16.00	1.50	7.50	1.00	1	1	1
142	3	2	15.00	1.45	7.20	5.00	1	1	1
143	3	1	16.00	1.20	8.80	5.50	1	1	1
144	3	1	20.00	1.20	7.70	2.00	1	1	1
145	3	1	15.00	1.10	8.50	1.20	1	1	1
146	3	2	19.00	.85	6.20	.60	1	1	1
147	3	2	15.00	1.70	12.00	1.20	1	1	1
148	3	1	15.00	1.30	8.00	2.70	1	1	1
149	3	1	16.00	1.90	11.50	.30	1	1	1
150	3	2	16.00	.88	5.40	1.50	1	1	1
151	3	2	22.00	.75	6.50	2.00	1	1	1
153	3	1	21.00	1.55	10.00	.10	1	1	1

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Tx Group 1 = RBX 2 = PBO

³ HBS ag/AIDS/Non-HEP 1 = Negative 0 = Positive

Abbreviations:

T3 HBS AG ALT/AST
 T4 Thyroxine AIDS NON-HEP.
 TSH Thyrotropin (Thyroid-stimulating Hormone)

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	Specific Gravity	Albumin	Sugar	RBC	WBC
1	1	1	1.014	-	-	-	0-3
2	1	2	1.020	-	-	3-5	0-3
16	1	2	1.015	-	-	-	0-3
17	1	1	1.030	-	-	-	0-3
31	2	1	1.020	-	-	-	-
32	2	1	1.025	-	-	-	0-1
33	2	2	1.020	0	0	0-1	0-1
34	2	2	1.010	-	-	-	-
35	2	2	1.020	-	-	-	-
46	2	1
47	2	1	1.015	0001+	neg	trace	55-60
48	2	2	1.015	00000	00000	20-30	00-03
81	3	1	1.010	++	-	2a4	35a40
82	3	2	1.028	+	-	1a2	1a2
83	3	2	1.022	+	-	1a2	1a3
84	3	1	1.020	+	-	2a4	2a4
85	3	2	1.017	+	-	-	2a4
86	3	1	1.020	+	-	=0	=0
87	3	2	1.020	+	-	1a2	2a4
88	3	2	1.025	+	-	1a2	3a5
89	3	1	1.022	+	-	=0	1a2
90	3	1	1.016	+	-	-	1a2
91	3	1	1.022	+	-	=0	1a2
92	3	1	1.025	+	-	=0	=0
93	3	2	1.020	+	-	=0	2a4
94	3	2	1.025	++	-	1a3	15a20
95	3	1	1.012	+	-	=0	1a2
96	3	2	1.016	+	-	4a6	1a2
97	3	1	1.011	+	-	=0	=0
98	3	1	1.014	+	-	=0	2a4
99	3	2	1.010	+	-	1a2	2a4
100	3	2	1.013	+	-	1a2	=0
121	3	1	1.028	+	-	-	-
122	3	1	1.015	+	-	-	-
123	3	2	1.021	+	-	1a2	-
124	3	2	1.017	+	-	-	-

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
RBC Red Blood Cells WBC White Blood Cells

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	Specific Gravity	Albumin	Sugar	RBC	WBC
125	3	1	1.010	+	-	-	-
126	3	2	1.019	+	-	-	-
127	3	1	1.015	+	-	-	-
128	3	1	1.018	+	-	-	-
129	3	2	1.023	+	-	1a2	-
130	3	2	1.013	+	-	1a2	-
131	3	1	1.019	+	-	1a2	-
133	3	2	1.015	+	-	-	-
141	3	2	1.006	+	-	1a2	-
142	3	2	1.021	+	-	-	-
143	3	1	1.020	+	-	-	-
144	3	1	1.012	+	-	-	-
145	3	1	1.013	+	-	1a2	-
146	3	2	1.012	+	-	-	-
147	3	2	1.010	+	-	1a3	8a10
148	3	1	1.022	+	-	2a4	-
149	3	1	1.010	+	-	-	-
150	3	2	1.007	+	-	-	-
151	3	2	1.024	+	-	-	-
153	3	1	1.021	+	-	-	-

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
RBC Red Blood Cells WBC White Blood Cells

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	Important Prior Disease
1	1	1	High Blood Pressure/Arthritis/Gout
2	1	2	Hemicolectomy-'87
16	1	2	Appendectomy/Hysterectomy
17	1	1	Appendectomy/Hysterectomy/General Surgery
31	2	1	
32	2	1	
33	2	2	
34	2	2	Malaria-age 10
35	2	2	High Blood Pressure
46	2	1	
47	2	1	'77 C-Section/'85 Tubal Ligation
48	2	2	
81	3	1	
82	3	2	
83	3	2	
84	3	1	
85	3	2	
86	3	1	
87	3	2	
88	3	2	
89	3	1	
90	3	1	
91	3	1	
92	3	1	
93	3	2	
94	3	2	
95	3	1	
96	3	2	
97	3	1	
98	3	1	
99	3	2	
100	3	2	Hemicolectomy-'87

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx ² Group	Important Prior Disease
121	3	1	
122	3	1	
123	3	2	
124	3	2	
125	3	1	
126	3	2	
127	3	1	
128	3	1	
129	3	2	
130	3	2	
131	3	1	
133	3	2	
141	3	2	
142	3	2	
143	3	1	
144	3	1	
145	3	1	
146	3	2	
147	3	2	
148	3	1	
149	3	1	
150	3	2	
151	3	2	
153	3	1	

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

FCE 20124/706 i

ENCLOSURE 15

**Total Population:
HAMD Total Scores (From Day 0 to Day 14)**

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

FCE 20124/706 i

Pat. No.	Ctr. No.	Tx Group ²	HAM-D Total Score:									
			Day 0	Day 4	% Change ³	Day 7	% Change	Day 10	% Change	Day 14	% Change	
1	1	1	35.00	32.00	8.57	33.00	5.71	26.00	25.71	34.00	2.86	
2	1	2	37.00	27.00	27.03	
16	1	2	35.00	39.00	-11.43	47.00	-34.29	
17	1	1	39.00	27.00	30.77	19.00	51.28	
31	2	1	27.00	34.00	-25.93	34.00	-25.93	32.00	-18.52	35.00	-29.63	
32	2	1	27.00	12.00	55.56	13.00	51.85	11.00	59.26	21.00	22.22	
33	2	2	34.00	32.00	5.88	33.00	2.94	33.00	2.94	26.00	23.53	
34	2	2	31.00	27.00	12.90	17.00	45.16	22.00	29.03	18.00	41.94	
35	2	2	36.00	28.00	22.22	33.00	8.33	.	.	25.00	30.56	
46	2	1	34.00	25.00	26.47	38.00	-11.76	30.00	11.76	.	.	
47	2	1	31.00	13.00	58.06	6.00	80.65	5.00	83.87	4.00	87.10	
48	2	2	22.00	18.00	18.18	8.00	63.64	20.00	9.09	22.00	.00	
81	3	1	34.00	36.00	-5.88	33.00	2.94	27.00	20.59	23.00	32.35	
82	3	2	34.00	36.00	-5.88	34.00	.00	34.00	.00	34.00	.00	
83	3	2	38.00	31.00	18.42	34.00	10.53	31.00	18.42	29.00	23.68	
84	3	1	37.00	38.00	-2.70	32.00	13.51	31.00	16.22	24.00	35.14	
85	3	2	33.00	32.00	3.03	33.00	.00	33.00	.00	32.00	3.03	
86	3	1	37.00	38.00	-2.70	34.00	8.11	28.00	24.32	23.00	37.84	
87	3	2	41.00	39.00	4.88	38.00	7.32	38.00	7.32	39.00	4.88	
88	3	2	40.00	39.00	2.50	38.00	5.00	35.00	12.50	32.00	20.00	
89	3	1	41.00	37.00	9.76	32.00	21.95	28.00	31.71	29.00	29.27	
90	3	1	39.00	34.00	12.82	27.00	30.77	29.00	25.64	22.00	43.59	
91	3	1	43.00	40.00	6.98	34.00	20.93	27.00	37.21	16.00	62.79	
92	3	1	41.00	38.00	7.32	30.00	26.83	25.00	39.02	19.00	53.66	
93	3	2	36.00	35.00	2.78	33.00	8.33	28.00	22.22	17.00	52.78	
94	3	2	42.00	44.00	-4.76	43.00	-2.38	42.00	.00	40.00	4.76	
95	3	1	37.00	31.00	16.22	28.00	24.32	24.00	35.14	18.00	51.35	
96	3	2	41.00	39.00	4.88	35.00	14.63	33.00	19.51	30.00	26.83	
97	3	1	34.00	32.00	5.88	24.00	29.41	19.00	44.12	15.00	55.88	
98	3	1	41.00	39.00	4.88	33.00	19.51	32.00	21.95	26.00	36.59	
99	3	2	38.00	37.00	2.63	38.00	.00	35.00	7.89	36.00	5.26	
100	3	2	37.00	41.00	-10.81	40.00	-8.11	40.00	-8.11	40.00	-8.11	
121	3	1	35.00	31.00	11.43	33.00	5.71	31.00	11.43	29.00	17.14	
122	3	1	36.00	31.00	13.89	29.00	19.44	23.00	36.11	15.00	58.33	
123	3	2	30.00	31.00	-3.33	26.00	13.33	23.00	23.33	21.00	30.00	
124	3	2	34.00	31.00	8.82	26.00	23.53	25.00	26.47	25.00	26.47	
125	3	1	35.00	37.00	-5.71	31.00	11.43	26.00	25.71	19.00	45.71	

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO
³ Change is calculated from Day 0

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Tx Group ²	HAM-D Total Score:								
			Day 0	Day 4	% Change	Day 7	% Change	Day 10	% Change	Day 14	% Change
126	3	2	34.00	29.00	14.71	24.00	29.41	25.00	26.47	16.00	52.94
127	3	1	38.00	37.00	2.63	31.00	18.42	28.00	26.32	23.00	39.47
128	3	1	37.00	35.00	5.41	27.00	27.03	22.00	40.54	14.00	62.16
129	3	2	36.00	33.00	8.33	36.00	.00	32.00	11.11	30.00	16.67
130	3	2	33.00	28.00	15.15	24.00	27.27	28.00	15.15	29.00	12.12
131	3	1	34.00	33.00	2.94	31.00	8.82	33.00	2.94	32.00	5.88
133	3	2	32.00	29.00	9.38	25.00	21.88	30.00	6.25	28.00	12.50
141	3	2	30.00	26.00	13.33	23.00	23.33	21.00	30.00	19.00	36.67
142	3	2	35.00	35.00	.00	31.00	11.43	31.00	11.43	31.00	11.43
143	3	1	39.00	38.00	2.56	36.00	7.69	31.00	20.51	21.00	46.15
144	3	1	38.00	35.00	7.89	26.00	31.58	18.00	52.63	12.00	68.42
145	3	1	37.00	36.00	2.70	32.00	13.51	28.00	24.32	24.00	35.14
146	3	2	34.00	31.00	8.82	31.00	8.82	32.00	5.88	30.00	11.76
147	3	2	31.00	32.00	-3.23	30.00	3.23	32.00	-3.23	32.00	-3.23
148	3	1	32.00	28.00	12.50	26.00	18.75	22.00	31.25	19.00	40.63
149	3	1	31.00	29.00	6.45	31.00	.00	36.00	-16.13	30.00	3.23
150	3	2	33.00	34.00	-3.03	32.00	3.03	28.00	15.15	24.00	27.27
151	3	2	35.00	33.00	5.71	31.00	11.43	31.00	11.43	30.00	14.29
153	3	1	35.00	37.00	-5.71	35.00	.00	34.00	2.86	26.00	25.71

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO
³ Change is calculated from Day 0

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FCE 20124/706 i

ENCLOSURE 16

**Analytic Cohort:
Characteristics of the Two Treatment Groups**

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FCE 20124/706 i

Reboxetine Treatment Group

Pat. No.	Ctr. No.	Sex ²	At Admission to Study:			History:		Present Episode:			Illness Dur. (months)
			Age	Height (cm)	Weight (kg)	Onset Age	No. of Prior Episodes	Precip. Stress ²	Form of Onset ⁴	Subform of Illness ⁵	
1	1	1	50	177	88	50	1	2	3	29633	3
31	2	1	46	178	111	44	4	2	2	29633	3
32	2	1	30	172	80	23	1	1	3	29632	8
46	2	0	42	158	49	34	.	1	2	29630	2
47	2	0	38	162	53	7	20	2	2	29630	2
81	3	1	34	156	50	34	0	1	2	29620	4
84	3	1	33	150	42	27	2	1	2	29630	3
86	3	1	38	169	74	38	0	2	2	29620	6
89	3	1	49	160	75	49	0	1	2	29620	8
90	3	1	24	162	52	24	0	2	1	29620	3
91	3	0	37	165	62	37	0	1	2	29620	4
92	3	0	43	160	55	30	5	1	3	29630	4
95	3	0	48	164	63	48	0	1	3	29620	1
97	3	0	30	163	58	30	0	1	1	29620	1
98	3	0	26	169	51	26	0	1	2	29620	10
121	3	1	38	173	75	36	1	1	1	29630	4
122	3	1	34	180	82	34	0	1	1	29620	3
125	3	1	39	186	70	30	1	1	2	29630	6
127	3	1	47	180	63	47	0	1	2	29620	9
128	3	1	42	169	77	35	6	1	1	29630	2
131	3	1	25	166	55	19	5	1	1	29630	2
143	3	0	58	160	52	58	0	2	1	29620	2
144	3	0	50	165	68	35	10	1	1	29630	5
145	3	0	52	157	71	52	0	1	1	29620	4
148	3	0	50	158	60	50	0	1	3	29620	12
149	3	0	58	161	60	30	8	1	3	29630	4
153	3	0	57	158	45	57	0	1	2	29620	4

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

Abbreviations:

No. = Number

Precip. = Precipitating

Dur. = Duration

23 i

FCB 20124/706 i

Placebo Treatment Group

Pat. No.	Ctr. No.	Sex ¹	At Admission to Study:			History:		Present Episode:			Illness Dur. (months)
			Age	Height (cm)	Weight (kg)	Onset Age	No. of Prior Episodes	Precip. Stress ¹	Form of Onset ¹	Subform of Illness ¹	
33	2	1	53	180	85	25	5	1	2	29630	6
34	2	1	46	165	80	32	10	1	1	29630	2
35	2	1	54	166	74	25	6	2	3	29630	9
82	3	1	33	176	78	33	0	1	1	29620	5
83	3	1	20	156	58	20	0	1	1	29620	2
85	3	1	47	159	59	40	3	1	2	29630	4
87	3	1	27	160	51	27	0	2	1	29620	10
88	3	1	37	160	59	32	2	1	1	29620	8
93	3	0	51	170	72	40	4	1	2	29630	4
94	3	0	29	174	60	29	0	3	1	29620	8
96	3	0	55	163	48	42	7	1	2	29630	2
99	3	0	18	160	47	18	0	3	1	29620	4
100	3	0	34	166	62	34	2	1	3	29630	12
123	3	1	41	164	61	30	5	1	1	29630	3
124	3	1	41	172	72	28	8	1	1	29630	1
126	3	1	32	174	66	32	0	1	1	29620	3
129	3	1	26	178	77	26	0	1	1	29620	3
130	3	1	40	180	80	25	6	1	3	29630	5
133	3	1	47	178	72	46	0	1	2	29620	4
141	3	0	43	173	70	32	2	2	2	29630	2
142	3	0	25	167	56	24	0	3	1	29620	10
146	3	0	58	150	44	58	0	1	2	29620	9
147	3	0	40	150	55	40	0	1	1	29620	3
150	3	0	52	168	68	40	10	1	3	29630	9
151	3	0	48	163	58	48	0	3	1	29620	1

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

Abbreviations:

No. = Number

Precip. = Precipitating

Dur. = Duration

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FCE 20124/706 i

ENCLOSURE 17

**Analytic Cohort:
Course I (Duration and Premature Discontinuation)**

233

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FCE 20124/706 i

Reboxetine Group								
Pat. No.	Ctr. ¹ No.	Trial Duration	Premat. ² Discon.	Non. ³ Resp.	% Change Day 0 To Final HAMD Score	Adver. ⁴ React.	Int. ⁵ Ill.	W/Drew ⁶ Con.
1	1	30	1	1	8.57	0	0	0
31	1	42	0	.	48.15	0	0	0
32	4	30	1	.	48.15	1	0	0
46	4	14	1	1	11.76	0	0	0
47	4	42	0	0	93.55	0	0	0
81	7	42	0	0	73.53	0	0	0
84	7	42	0	0	78.38	0	0	0
86	7	42	0	0	72.97	0	0	0
89	7	42	0	0	73.17	0	0	0
90	7	42	0	0	82.05	0	0	0
91	7	42	0	0	86.05	0	0	0
92	7	42	0	0	78.05	0	0	0
95	7	42	0	0	89.19	0	0	0
97	7	42	0	0	85.29	0	0	0
98	7	42	0	0	85.37	0	0	0
121	7	42	0	0	22.86	0	0	0
122	7	42	0	0	83.33	0	0	0
125	7	42	0	0	85.71	0	0	0
127	7	42	0	0	84.21	0	0	0
128	7	42	0	0	89.19	0	0	0
131	7	21	1	1	-14.71	0	0	0
143	7	42	0	0	76.92	0	0	0
144	7	42	0	0	86.84	0	0	0
145	7	42	0	0	70.27	0	0	0
148	7	42	0	0	81.25	0	0	0
149	7	42	0	0	-25.81	0	0	0
153	7	42	0	0	54.29	0	0	0

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Premat.Discon. 0 = No 1 = Yes (Premature Discontinuation)
³ Non.Resp. 0 = No 1 = Yes (Non-Response/Clinical Deterioration)
⁴ Adver.React. 0 = No 1 = Yes (Adverse Reaction)
⁵ Int. Ill. 0 = No 1 = Yes (Intercurrent Illness)
⁶ W/Drew Con. 0 = No 1 = Yes (Withdrew Consent)

(-) indicates worsening (deterioration)

FCE 20124/706 i

Placebo Group								
Pat. No.	Ctr. ¹ No.	Trial Duration	Premat. ² Discon.	Non. ³ Resp.	% Change Day 0 To Final HAMD Score	Adver. ⁴ React.	Int. ⁵ Ill.	W/Drew ⁶ Con.
33	4	15	1	1	23.53	0	0	0
34	4	17	1	0	41.94	1	0	0
35	4	21	1	1	5.56	0	0	0
82	7	21	1	1	-26.47	0	0	0
83	7	42	0	0	34.21	0	0	0
85	7	21	1	1	-21.21	0	0	0
87	7	21	1	1	-12.20	0	0	0
88	7	42	0	0	37.50	0	0	0
93	7	42	0	0	66.67	0	0	0
94	7	21	1	1	-7.14	0	0	0
96	7	42	0	0	73.17	0	0	0
99	7	21	1	1	-7.89	0	0	0
100	7	21	1	1	-18.92	0	0	0
123	7	42	0	0	56.67	0	0	0
124	7	42	0	0	-8.82	0	0	0
126	7	42	0	0	79.41	0	0	0
129	7	21	1	1	-2.78	0	0	0
130	7	21	1	1	-24.24	0	0	0
133	7	21	1	1	-12.50	0	0	0
141	7	42	0	0	33.33	0	0	0
142	7	21	1	1	-17.14	0	0	0
146	7	21	1	1	-11.76	0	0	0
147	7	21	1	1	-19.35	0	0	0
150	7	42	0	0	78.79	0	0	0
151	7	21	1	1	-14.29	0	0	0

- ¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Premat.Discon. 0 = No 1 = Yes (Premature Discontinuation)
³ Non.Resp. 0 = No 1 = Yes (Non-Response/Clinical Deterioration)
⁴ Adver.React. 0 = No 1 = Yes (Adverse Reaction)
⁵ Int. Ill. 0 = No 1 = Yes (Intercurrent illness)
⁶ W/Drew Con. 0 = No 1 = Yes (Withdrew Consent)

(-) indicates worsening (deterioration) 235

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ENCLOSURE 18

Analytic Cohort:

Course II (Compliance, Other Therapy & Life Events)

236

115

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Took Prescribed Medication, Non-Pharmacological Treatment and Life Events for Total Population

Pat. No.	Ctr. ¹ No.	Tx ² Group	Took Meds. As Prescribed Yes/No ³	Non-Pharmacol. Treatment Yes/No	Significant Life Events Yes/No
1	1	1	1	0	0
2	1	2	0	0	0
16	1	2	0	0	0
17	1	1	1	0	0
31	2	1	1	1	0
32	2	1	1	0	0
33	2	2	1	0	0
34	2	2	1	0	0
35	2	2	1	0	0
46	2	1	1	0	0
47	2	1	1	0	0
48	2	2	1	0	0
81	3	1	1	0	0
82	3	2	1	0	0
83	3	2	1	0	0
84	3	1	1	0	0
85	3	2	1	0	0
86	3	1	1	0	0
87	3	2	1	0	0
88	3	2	1	0	0
89	3	1	1	0	0
90	3	1	1	0	0
91	3	1	1	0	0
92	3	1	1	0	0
93	3	2	1	0	0
94	3	2	1	0	0
95	3	1	1	0	0
96	3	2	1	0	0
97	3	1	1	0	0
98	3	1	1	0	0
99	3	2	1	0	0
100	3	2	1	0	0
121	3	1	1	0	0
122	3	1	1	0	0
123	3	2	1	0	0
124	3	2	1	0	0

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = Reboxetine 2 = Placebo
³ Yes/No 1 = Yes 0 = No

FCE 20124/706 i

Took Prescribed Medication, Non-Pharmacological Treatment and Life Events for Total Population

Pat. No.	Ctr. ¹ No.	Tx ² Group	Took Meds. As Prescribed Yes/No ³	Non-Pharmacol. Treatment Yes/No	Significant Life Events Yes/No
125	3	1	1	0	0
126	3	2	1	0	0
127	3	1	1	0	0
128	3	1	1	0	0
129	3	2	1	0	0
130	3	2	1	0	0
131	3	1	1	0	0
133	3	2	1	0	0
141	3	2	1	0	0
142	3	2	1	0	0
143	3	1	1	0	0
144	3	1	1	0	0
145	3	1	1	0	0
146	3	2	1	0	0
147	3	2	1	0	0
148	3	1	1	0	0
149	3	1	1	0	0
150	3	2	1	0	0
151	3	2	1	0	0
153	3	1	1	0	0

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = Reboxetine 2 = Placebo
³ Yes/No 1 = Yes 0 = No

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ENCLOSURE 19

**Analytic Cohort:
Treatment Record I (Drugs)**

239

118

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Evening Dose: Scheduled - Days 1-2 2 Caps., Days 3-42, 3 Caps.
Given -

Pat. No.	DAY:	111111111122222222223333333333444	Dur. (dys)	Reason for Discontinuation
1	2	2	30	Lack of therap. response
31	2	2	42	Completed
32	2	2	29	Adverse reaction
46	2	2	14	Lack of therap. response
47	2	2	42	Completed
81	2	2	42	Completed
84	2	2	42	Completed
86	2	2	42	Completed
89	2	2	42	Completed
90	2	2	42	Completed
91	2	2	42	Completed
92	2	2	42	Completed
95	2	2	42	Completed
97	2	2	42	Completed
98	2	2	42	Completed
121	2	2	42	Completed
122	2	2	42	Completed
125	2	2	42	Completed
127	2	2	42	Completed
128	2	2	42	Completed
131	2	2	21	Lack of therap. response
143	2	2	42	Completed
144	2	2	42	Completed
145	2	2	42	Completed
148	2	2	42	Completed
149	2	2	42	Completed
153	2	2	42	Completed

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FCE 20124/706 i

Treatment Medication Record

Placebo Treatment Group

Morning Dose: Scheduled - Day 1, 1 Cap., Days 2-42, 2 Caps.
Given -

Pat. DAY: 111111111122222222223333333333444
No. 1 23456789012345678901234567890123456789012

33 1 222222222222.....
34 1 2222222222222222.....
35 1 2222222222222222.....
82 1 2222222222222222.....
83 1 2222222222222222222222222222222222
85 1 2222222222222222.....
87 1 2222222222222222.....
88 1 2222222222222222222222222222222222
93 1 2222222222222222222222222222222222
94 1 2222222222222222.....
96 1 2222222222222222222222222222222222
99 1 2222222222222222.....
100 1 2222222222222222.....
123 1 2222222222222222222222222222222222
124 1 2222222222222222222222222222222222
126 1 2222222222222222222222222222222222
129 1 2222222222222222.....
130 1 2222222222222222.....
133 1 2222222222222222.....
141 1 2222222222222222222222222222222222
142 1 2222222222222222.....
146 1 2222222222222222.....
147 1 2222222222222222.....
150 1 2222222222222222222222222222222222
151 1 2222222222222222.....

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ENCLOSURE 20

**Analytic Cohort:
Treatment Record II (Schedule & Duration)**

244

123

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FCE 20124/706 i

Reboxetine Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation
			From:			To:				
			mo	dy	yr	mo	dy	yr		
001	1	2	12	5	89	12	5	89	1	
	2	2	12	6	89	12	6	89	1	
	2	3	12	7	89	12	14	89	8	
	2	2	12	15	89	1	3	90	20	Non-response (Dose reduction: from Day 11 [12/15/89] for urinary retention)
									<u>Total Days in Trial: 30</u>	
031	1	2	11	22	89	11	22	89	1	
	2	2	11	23	89	11	23	89	1	
	2	3	11	24	89	1	2	90	40	Completed
									<u>Total Days in Trial: 42</u>	
032	1	2	1	19	90	1	19	90	1	
	2	2	1	20	90	1	20	90	1	
	2	3	1	21	90	2	16	90	27	
	2	-	2	17	90	2	17	90	1	Hypomania
									<u>Total Days in Trial: 30</u>	
046	1	2	7	18	90	7	18	90	1	
	2	2	7	19	90	7	19	90	1	
	2	3	7	20	90	7	22	90	3	
	2	-	7	23	90	7	23	90	1	
	2	3	7	24	90	7	31	90	8	Non-response (Omission of p.m. dose on: Day 6)
									<u>Total Days in Trial: 14</u>	
047	1	2	10	18	90	10	18	90	1	
	2	2	10	19	90	10	19	90	1	
	2	3	10	20	90	11	28	90	40	Completed
									<u>Total Days in Trial: 42</u>	
081	1	2	10	7	89	10	7	89	1	
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	11	17	89	40	Completed
									<u>Total Days in Trial: 42</u>	

FCE 20124/706 i

Reboxetine Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation
			From:			To:				
			mo	dy	yr	mo	dy	yr		
084	1	2	10	7	89	10	7	89	1	Completed
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	11	17	89	40	
									<u>Total Days in Trial: 42</u>	
086	1	2	10	7	89	10	7	89	1	Completed
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	11	17	89	40	
									<u>Total Days in Trial: 42</u>	
089	1	2	10	7	89	10	7	89	1	Completed
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	10	9	89	1	
	2	2	10	10	89	10	13	89	4	
	2	3	10	14	89	10	20	89	7	
	2	2	10	21	89	10	27	89	7	
	2	3	10	28	89	11	17	89	21	
									(Dose reduction from Day 4 [10/10/89] for four days for tremors) (Dose reduction from Day 15 [10/21/89] for seven days for insomnia)	
									<u>Total Days in Trial: 42</u>	
090	1	2	10	7	89	10	7	89	1	Completed
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	11	17	89	40	
									<u>Total Days in Trial: 42</u>	
091	1	2	11	15	89	11	15	89	1	Completed
	2	2	11	16	89	11	16	89	1	
	2	3	11	17	89	12	26	89	40	
									<u>Total Days in Trial: 42</u>	
092	1	2	11	15	89	11	15	89	1	Completed
	2	2	11	16	89	11	16	89	1	
	2	3	11	17	89	12	26	89	40	
									<u>Total Days in Trial: 42</u>	

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Reboxetine Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation	
			From:			To:					
			mo	dy	yr	mo	dy	yr			
095	1	2	11	15	89	11	15	89	1	Completed	
	2	2	11	16	89	11	16	89	1		
	2	3	11	17	89	12	26	89	40		
									<u>Total Days in Trial:</u>	42	
097	1	2	11	15	89	11	15	89	1	Completed	
	2	2	11	16	89	11	16	89	1		
	2	3	11	17	89	12	26	89	40		
									<u>Total Days in Trial:</u>	42	
098	1	2	11	15	89	11	15	89	1	Completed	
	2	2	11	16	89	11	16	89	1		
	2	3	11	17	89	12	26	89	40		
									<u>Total Days in Trial:</u>	42	
121	1	2	4	14	89	4	14	89	1	Completed	
	2	2	4	15	89	4	15	89	1		
	2	3	4	16	89	5	25	89	40		
									<u>Total Days in Trial:</u>	42	
122	1	2	4	15	89	4	15	89	1	Completed	
	2	2	4	16	89	4	16	89	1		
	2	3	4	17	89	5	26	89	40		
									<u>Total Days in Trial:</u>	42	
125	1	2	4	15	89	4	15	89	1	Completed	
	2	2	4	16	89	4	16	89	1		
	2	3	4	17	89	5	26	89	40		
									<u>Total Days in Trial:</u>	42	
127	1	2	4	15	89	4	15	89	1	Completed	
	2	2	4	16	89	4	16	89	1		
	2	3	4	17	89	5	26	89	40		
									<u>Total Days in Trial:</u>	42	

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Reboxetine Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation	
			From:			To:					
			mo	dy	yr	mo	dy	yr			
128	1	2	5	18	89	5	18	89	1	Completed	
	2	2	5	19	89	5	19	89	1		
	2	3	5	20	89	6	28	89	40		
									<u>Total Days in Trial:</u>	42	
131	1	2	6	1	89	6	1	89	1	Non-response	
	2	2	6	2	89	6	2	89	1		
	2	3	6	3	89	6	21	89	19		
									<u>Total Days in Trial:</u>	21	
143	1	2	4	15	89	4	15	89	1	Completed	
	2	2	4	16	89	4	16	89	1		
	2	3	4	17	89	5	26	89	40		
									<u>Total Days in Trial:</u>	42	
144	1	2	5	18	89	5	18	89	1	Completed	
	2	2	5	19	89	5	20	89	2		
	1	2	5	21	89	6	1	89	12		
	2	2	6	2	89	6	14	89	13		
	2	3	6	15	89	6	28	89	14		
(Dose reduction from Day 3 [5/20/89] for 1 day for vomiting)											
									<u>Total Days in Trial:</u>	42	
145	1	2	5	18	89	5	18	89	1	Completed	
	2	2	5	19	89	5	19	89	1		
	2	3	5	20	89	6	28	89	40		
									<u>Total Days in Trial:</u>	42	
148	1	2	5	18	89	5	18	89	1	Completed	
	2	2	5	19	89	5	19	89	1		
	2	3	5	20	89	6	28	89	40		
									<u>Total Days in Trial:</u>	42	
149	1	2	5	18	89	5	18	89	1	Completed	
	2	2	5	19	89	5	19	89	1		
	2	3	5	20	89	6	28	89	40		
									<u>Total Days in Trial:</u>	42	

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Reboxetine Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation
			From:			To:				
			mo	dy	yr	mo	dy	yr		
153	1	2	6	1	89	6	1	89	1	Completed
	2	2	6	2	89	6	2	89	1	
	2	3	6	3	89	7	12	89	40	
<u>Total Days in Trial:</u>									42	

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Placebo Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation
			From:			To:				
			mo	dy	yr	mo	dy	yr		
033	1	2	3	9	90	3	9	90	1	Non-response
	2	2	3	10	90	3	10	90	1	
	2	3	3	11	90	3	22	90	12	
	<u>Total Days in Trial:</u>								14	
034	1	2	7	11	90	7	11	90	1	Agitation
	2	2	7	12	90	7	12	90	1	
	2	3	7	13	90	7	30	90	18	
	<u>Total Days in Trial:</u>								20	
035	1	2	8	29	90	8	29	90	1	Non-response
	2	2	8	30	90	8	30	90	1	
	2	3	8	31	90	9	18	90	19	
	<u>Total Days in Trial:</u>								21	
082	1	2	10	7	89	10	7	89	1	Non-response
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	10	27	89	19	
	<u>Total Days in Trial:</u>								21	
083	1	2	10	7	89	10	7	89	1	Completed
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	11	17	89	40	
	<u>Total Days in Trial:</u>								42	
085	1	2	10	7	89	10	7	89	1	Non-response
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	10	27	89	19	
	<u>Total Days in Trial:</u>								21	
087	1	2	10	7	89	10	7	89	1	Non-response
	2	2	10	8	89	10	8	89	1	
	2	3	10	9	89	10	27	89	19	
	<u>Total Days in Trial:</u>								21	

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Placebo Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation	
			From:			To:					
			mo	dy	yr	mo	dy	yr			
088	1	2	10	7	89	10	7	89	1	Completed	
	2	2	10	8	89	10	8	89	1		
	2	3	10	9	89	11	17	89	40		
									<u>Total Days in Trial:</u>	42	
093	1	2	11	15	89	11	15	89	1	Completed	
	2	2	11	16	89	11	16	89	1		
	2	3	11	17	89	12	26	89	40		
									<u>Total Days in Trial:</u>	42	
094	1	2	11	15	89	11	15	89	1	Non-response	
	2	2	11	16	89	11	16	89	1		
	2	3	11	17	89	12	5	89	19		
									<u>Total Days in Trial:</u>	21	
096	1	2	11	15	89	11	15	89	1	Completed	
	2	2	11	16	89	11	16	89	1		
	2	3	11	17	89	12	26	89	40		
									<u>Total Days in Trial:</u>	42	
099	1	2	11	15	89	11	15	89	1	Non-response	
	2	2	11	16	89	11	16	89	1		
	2	3	11	17	89	12	5	89	19		
									<u>Total Days in Trial:</u>	21	
100	1	2	11	15	89	11	15	89	1	Non-response	
	2	2	11	16	89	11	16	89	1		
	2	3	11	17	89	12	5	89	19		
									<u>Total Days in Trial:</u>	21	
123	1	2	4	15	89	4	15	89	1	Completed	
	2	2	4	16	89	4	16	89	1		
	2	3	4	17	89	5	26	89	40		
									<u>Total Days in Trial:</u>	42	

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Placebo Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation
			From:			To:				
			mo	dy	yr	mo	dy	yr		
124	1	2	4	15	89	4	15	89	1	Completed
	2	2	4	16	89	4	16	89	1	
	2	3	4	17	89	5	26	89	40	
	<u>Total Days in Trial:</u> 42									
126	1	2	4	15	89	4	15	89	1	Completed
	2	2	4	16	89	4	16	89	1	
	2	3	4	17	89	5	26	89	40	
	<u>Total Days in Trial:</u> 42									
129	1	2	5	18	89	5	18	89	1	Non-response
	2	2	5	19	89	5	19	89	1	
	2	3	5	20	89	6	7	89	19	
	<u>Total Days in Trial:</u> 21									
130	1	2	5	18	89	5	18	89	1	Non-response
	2	2	5	19	89	5	19	89	1	
	2	3	5	20	89	6	7	89	19	
	<u>Total Days in Trial:</u> 21									
133	1	2	6	1	89	6	1	89	1	Non-response
	2	2	6	2	89	6	2	89	1	
	2	3	6	3	89	6	21	89	19	
	<u>Total Days in Trial:</u> 21									
141	1	2	4	15	89	4	15	89	1	Completed
	2	2	4	16	89	4	16	89	1	
	2	3	4	17	89	5	26	89	40	
	<u>Total Days in Trial:</u> 42									
142	1	2	4	15	89	4	15	89	1	Non-response
	2	2	4	16	89	4	16	89	1	
	2	3	4	17	89	5	5	89	19	
	<u>Total Days in Trial:</u> 21									

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Placebo Treatment Group

Pat. No.	A.M. Dose (cps)	P.M. Dose (cps)	Treatment Dates:						Duration (days)	Reason for Discontinuation
			From:			To:				
			mo	dy	yr	mo	dy	yr		
146	1	2	5	18	89	5	18	89	1	Non-response
	2	2	5	19	89	5	19	89	1	
	2	3	5	20	89	6	7	89	19	
	<u>Total Days in Trial:</u>								21	
147	1	2	6	22	89	6	22	89	1	Non-response
	2	2	6	23	89	6	23	89	1	
	2	3	6	24	89	7	12	89	19	
	<u>Total Days in Trial:</u>								21	
150	1	2	6	1	89	6	1	89	1	Completed
	2	2	6	2	89	6	2	89	1	
	2	3	6	3	89	7	12	89	40	
	<u>Total Days in Trial:</u>								42	
151	1	2	6	1	89	6	1	89	1	Non-response
	2	2	6	2	89	6	2	89	1	
	2	3	6	3	89	6	21	89	19	
	<u>Total Days in Trial:</u>								21	

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ENCLOSURE 21

**Analytic Cohort:
HAM-D in the Two Treatment Groups
(Item and Total Scores)**

254

133

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Reboxetine Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
1	00	4	2	2	2	2	2	3	0	2	2	3	0	2	2	2	2	0	2	1	0	0	0	35.00
17	00	4	4	4	2	2	2	3	1	1	3	1	2	1	2	1	2	0	1	1	0	0	2	39.00
31	00	3	1	2	2	1	2	4	0	1	2	1	1	1	2	0	1	0	1	2	0	0	0	27.00
32	00	4	2	2	2	1	0	4	1	0	3	1	0	1	2	0	1	1	1	1	0	0	0	27.00
46	00	4	1	1	2	2	2	4	0	1	4	2	1	1	2	2	0	1	1	1	1	0	1	34.00
47	00	4	2	3	2	2	2	4	0	3	4	2	0	1	2	0	0	0	0	0	0	0	0	31.00
81	00	3	2	1	2	1	2	3	2	0	3	3	2	2	0	2	0	0	1	2	2	0	1	34.00
84	00	3	1	0	2	2	2	4	3	0	3	3	2	2	2	2	0	0	1	2	2	0	1	37.00
86	00	4	2	1	1	2	2	4	3	0	3	2	2	2	2	3	1	1	0	0	2	0	0	37.00
89	00	4	2	2	1	1	2	4	2	0	3	2	2	2	2	2	1	1	1	2	3	1	1	41.00
90	00	4	2	1	2	1	2	3	3	0	3	3	2	2	2	3	0	0	1	2	2	0	1	39.00
91	00	3	0	2	2	2	2	4	0	3	4	3	2	2	2	2	1	1	1	2	3	1	1	43.00
92	00	4	2	3	2	1	2	4	3	0	3	3	2	2	2	2	0	1	1	1	3	0	0	41.00
95	00	4	0	2	2	2	2	3	0	3	3	3	2	2	2	2	0	2	0	0	3	0	0	37.00
97	00	4	0	0	0	1	0	4	3	0	4	4	2	2	2	1	2	2	0	0	3	0	0	34.00
98	00	4	2	2	2	2	4	3	0	3	3	2	2	2	1	1	2	1	2	1	2	1	0	41.00
121	00	4	2	0	2	2	1	4	3	0	3	3	0	2	1	1	1	1	1	2	2	0	0	35.00
122	00	3	0	2	2	1	2	4	3	0	3	2	0	2	2	1	2	2	1	2	2	0	0	36.00
125	00	3	0	2	1	2	2	4	2	0	3	2	2	2	1	3	0	2	1	2	1	0	0	35.00
127	00	4	2	0	2	2	2	4	2	0	3	2	2	2	1	2	0	2	1	2	2	1	0	38.00
128	00	3	2	0	2	1	2	4	2	0	3	3	2	2	2	3	0	1	1	2	0	0	2	37.00
131	00	3	2	2	1	2	2	3	2	0	3	2	2	2	2	2	0	1	0	0	3	0	0	34.00
143	00	4	2	3	1	2	2	4	2	0	3	3	2	2	1	2	0	2	1	2	1	0	0	39.00
144	00	4	2	2	2	1	1	4	3	0	2	2	2	2	2	2	0	0	2	1	2	0	2	38.00
145	00	3	2	0	2	1	2	4	3	0	2	2	1	2	2	3	1	2	0	0	3	2	0	37.00
148	00	4	2	2	0	1	2	4	3	0	2	2	1	2	1	1	0	1	0	0	2	0	2	32.00
149	00	3	2	0	1	2	1	4	2	0	3	2	0	2	2	2	0	2	0	0	2	1	0	31.00
153	00	3	2	3	1	1	2	4	0	3	2	2	2	2	1	0	0	2	1	2	2	0	0	35.00

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Reboxetine Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21	
1	04	3	2	1	2	1	1	1	3	1	2	2	2	0	2	2	2	2	0	2	1	0	0	1	32.00
17	04	3	2	2	2	2	1	3	0	1	0	2	1	2	2	0	0	0	2	1	0	0	1	27.00	
31	04	4	2	2	1	1	1	4	0	3	4	2	1	1	2	1	0	1	1	1	1	1	0	34.00	
32	04	2	1	0	0	0	0	4	0	1	1	1	0	1	1	0	0	0	0	0	0	0	0	12.00	
46	04	3	1	3	2	1	2	4	0	1	2	2	0	1	1	1	0	0	0	0	0	0	1	25.00	
47	04	2	0	1	1	0	0	3	0	1	3	1	0	0	1	0	0	0	0	0	0	0	0	13.00	
81	04	3	2	2	2	1	2	3	2	0	3	3	2	2	1	2	0	0	1	1	3	0	1	36.00	
84	04	3	1	0	2	1	2	4	3	0	3	3	2	2	2	3	0	0	1	2	3	0	1	38.00	
86	04	4	2	1	2	2	2	4	3	0	3	3	2	2	2	2	0	1	0	0	3	0	0	38.00	
89	04	4	2	2	1	1	1	4	2	0	3	2	2	2	2	2	0	1	1	1	2	1	1	37.00	
90	04	4	2	1	2	1	1	3	2	0	2	3	2	2	2	3	0	0	1	1	1	0	1	34.00	
91	04	3	0	1	2	2	1	3	0	3	3	3	2	2	2	3	1	1	1	2	3	1	1	40.00	
92	04	4	2	2	2	1	2	4	3	0	3	3	2	2	2	1	0	1	1	1	2	0	0	38.00	
95	04	4	0	2	2	1	2	3	0	2	3	2	2	2	1	1	0	2	0	0	2	0	0	31.00	
97	04	4	0	0	0	1	0	4	3	0	3	3	2	2	2	1	2	0	0	3	0	0	0	32.00	
98	04	4	2	2	2	2	2	4	3	0	4	3	2	2	2	1	0	2	1	1	0	0	0	39.00	
121	04	4	2	0	2	2	1	4	3	0	3	2	0	2	1	1	0	1	1	1	1	0	0	31.00	
122	04	3	0	1	1	1	2	4	3	0	2	2	0	2	2	0	1	2	1	2	2	0	0	31.00	
125	04	3	0	2	2	2	2	4	2	0	3	2	2	2	2	2	1	2	1	2	1	0	0	37.00	
127	04	4	1	0	2	2	2	4	2	0	2	2	2	2	1	2	1	2	1	2	2	1	0	37.00	
128	04	3	2	0	1	1	2	4	2	0	3	2	2	2	2	3	0	1	1	2	1	0	1	35.00	
131	04	3	2	2	1	1	2	3	2	0	2	2	2	2	2	3	1	1	0	0	2	0	0	33.00	
143	04	4	2	2	1	2	2	4	2	0	3	2	2	2	1	2	0	2	1	2	2	0	0	38.00	
144	04	4	2	1	1	1	1	4	3	0	2	2	2	2	1	2	0	0	2	1	2	0	2	35.00	
145	04	3	1	0	2	1	2	4	2	0	3	2	2	2	2	3	1	2	0	0	2	2	0	36.00	
148	04	4	2	1	0	1	1	3	3	0	2	2	1	2	1	1	0	1	0	0	2	0	1	28.00	
149	04	3	2	0	1	1	1	4	2	0	2	2	0	2	2	2	0	2	0	0	2	1	0	29.00	
153	04	3	2	2	1	1	2	4	0	3	2	2	2	2	2	1	1	2	1	2	2	0	0	37.00	

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Reboxetine Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
1	07	4	2	2	2	2	2	3	0	2	2	2	0	2	2	2	0	0	2	1	0	0	1	33.00
17	07	2	2	1	1	0	0	3	0	0	2	2	1	1	0	0	0	0	2	1	0	0	1	19.00
31	07	4	1	1	2	2	2	4	0	1	4	2	1	1	2	1	2	0	1	1	1	0	1	34.00
32	07	0	0	0	0	0	2	3	0	0	1	1	1	0	1	0	2	0	1	1	0	0	0	13.00
46	07	4	2	2	0	2	2	4	0	4	4	3	0	2	2	3	2	1	0	0	1	0	0	38.00
47	07	0	0	0	0	1	1	1	0	1	0	1	0	0	1	0	0	0	0	0	0	0	0	6.00
81	07	3	1	1	2	2	2	3	2	0	3	2	2	2	1	2	0	0	1	1	2	0	1	33.00
84	07	3	1	0	2	1	1	3	3	0	3	2	2	2	1	3	0	0	1	1	2	0	1	32.00
86	07	4	2	1	1	1	1	3	3	0	3	3	2	2	2	2	1	1	0	0	2	0	0	34.00
89	07	3	2	2	1	1	1	2	2	0	2	2	2	2	2	1	0	1	1	1	2	1	1	32.00
90	07	3	1	1	1	1	1	2	2	0	2	2	2	2	1	2	0	0	1	1	1	0	1	27.00
91	07	3	0	1	2	2	1	3	0	2	2	2	2	2	1	2	1	1	1	2	2	1	1	34.00
92	07	3	1	1	2	1	2	3	2	0	3	2	2	2	1	1	0	1	1	1	1	0	0	30.00
95	07	4	0	2	1	1	2	3	0	2	2	2	2	2	1	1	0	1	0	0	2	0	0	28.00
97	07	3	0	0	0	1	0	3	3	0	3	3	1	2	1	1	0	1	0	0	2	0	0	24.00
98	07	3	2	1	2	1	2	4	2	0	3	3	2	2	2	1	0	1	1	1	0	0	0	33.00
121	07	4	1	0	2	2	1	4	3	0	2	2	2	2	1	1	0	2	1	2	1	0	0	33.00
122	07	3	0	1	1	1	2	3	2	0	2	2	2	2	1	1	1	1	1	2	1	0	0	29.00
125	07	3	0	1	2	2	2	4	2	0	2	2	1	2	1	2	1	2	1	1	0	0	0	31.00
127	07	3	1	0	1	1	2	3	2	0	2	2	2	2	1	1	1	2	1	1	2	1	0	31.00
128	07	2	2	0	1	1	1	3	2	0	2	2	2	2	1	2	0	1	1	1	0	0	1	27.00
131	07	3	2	1	1	2	2	3	2	0	2	2	2	2	1	2	1	1	0	0	2	0	0	31.00
143	07	3	2	2	1	2	2	4	2	0	3	2	2	2	1	1	1	2	1	2	1	0	0	36.00
144	07	3	1	1	1	0	1	3	2	0	2	2	2	0	1	2	0	0	2	1	1	0	1	26.00
145	07	3	1	0	2	1	2	3	2	0	2	2	2	2	2	2	1	2	0	0	2	1	0	32.00
148	07	3	2	1	0	1	1	3	3	0	2	2	1	2	1	1	0	0	0	0	2	0	1	26.00
149	07	3	2	1	1	2	1	4	2	0	3	2	0	2	1	2	0	2	0	0	2	1	0	31.00
153	07	3	2	2	1	1	1	4	0	2	2	3	2	2	1	1	1	1	1	2	3	0	0	35.00

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Reboxetine Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
1	10	3	0	1	2	1	1	3	0	1	2	2	0	2	2	2	0	0	2	1	0	0	1	26.00
17	10
31	10	4	1	1	2	2	2	4	0	1	4	2	1	1	2	1	0	0	1	1	1	0	1	32.00
32	10	0	0	0	0	0	2	3	0	0	1	1	1	0	1	0	0	0	1	1	0	0	0	11.00
46	10	4	2	2	2	2	4	0	1	4	2	1	1	2	1	0	0	0	0	0	0	0	0	30.00
47	10	0	0	0	1	0	1	1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	5.00
81	10	2	1	1	1	1	2	3	2	0	2	2	2	2	1	2	0	0	0	0	2	0	1	27.00
84	10	2	1	0	2	1	1	3	3	0	3	2	2	2	2	2	0	0	1	1	2	0	1	31.00
86	10	4	2	1	1	0	1	3	2	0	2	2	2	2	1	2	1	1	0	0	1	0	0	28.00
89	10	3	2	2	1	0	1	2	2	0	2	2	2	2	1	2	0	1	0	0	1	1	1	28.00
90	10	3	1	1	1	1	2	2	1	0	2	2	2	2	1	3	0	0	1	1	2	0	1	29.00
91	10	2	0	1	1	1	1	2	0	2	2	2	1	2	1	2	0	0	1	2	2	1	1	27.00
92	10	2	1	1	2	1	1	2	2	0	2	2	2	2	1	1	0	0	1	1	1	0	0	25.00
95	10	3	0	1	1	2	1	2	0	1	2	2	2	2	1	1	0	1	0	0	2	0	0	24.00
97	10	3	0	0	0	1	0	2	2	0	2	2	1	2	1	1	0	1	0	0	1	0	0	19.00
98	10	3	2	1	2	1	2	3	2	0	3	3	2	2	2	1	0	1	1	1	0	0	0	32.00
121	10	3	2	0	2	1	2	4	3	0	2	2	2	2	1	1	0	1	1	1	1	0	0	31.00
122	10	2	0	1	1	1	1	3	2	0	2	1	2	2	1	1	0	0	1	1	1	0	0	23.00
125	10	2	0	1	2	1	2	3	2	0	2	2	1	2	1	1	0	2	1	1	0	0	0	26.00
127	10	3	0	0	1	1	2	3	2	0	1	2	2	2	1	1	1	2	1	1	1	1	0	28.00
128	10	2	1	0	1	0	1	2	1	0	2	2	2	2	1	2	0	0	1	1	0	0	1	22.00
131	10	3	2	1	1	2	4	3	0	2	2	2	2	2	1	2	1	1	0	0	2	0	0	33.00
143	10	2	1	2	1	1	2	4	2	0	3	2	2	2	1	1	0	2	1	1	1	0	0	31.00
144	10	2	1	0	1	0	1	3	2	0	1	1	1	0	1	2	0	0	0	0	1	0	1	18.00
145	10	2	1	0	1	1	1	3	2	0	2	1	2	2	2	2	1	2	0	0	2	1	0	28.00
148	10	3	1	1	0	1	1	3	2	0	2	2	1	0	1	1	0	0	0	0	2	0	1	22.00
149	10	4	2	1	2	2	2	4	2	0	2	2	2	2	1	2	1	2	0	0	2	1	0	36.00
153	10	3	2	2	1	1	2	3	0	2	3	2	2	2	2	1	1	1	1	1	2	0	0	34.00

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Reboxetine Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
1	14	3	2	2	2	2	2	3	0	2	2	2	0	2	2	2	1	0	2	1	1	0	1	34.00
17	14
31	14	4	1	1	2	1	2	4	0	3	4	1	1	1	2	1	2	0	1	2	1	1	0	35.00
32	14	4	1	2	0	1	0	3	1	1	3	2	1	1	1	0	0	0	0	0	0	0	0	21.00
46	14
47	14	0	0	0	1	0	1	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	4.00
81	14	2	1	1	1	1	2	2	1	0	2	2	2	2	0	1	0	0	0	0	2	0	1	23.00
84	14	2	1	0	1	1	1	2	2	0	2	2	1	2	1	2	0	0	1	1	1	0	1	24.00
86	14	3	1	1	1	0	1	2	2	0	2	2	2	2	1	2	0	0	0	0	1	0	0	23.00
89	14	2	1	2	2	2	2	1	0	2	2	2	2	1	2	0	0	0	0	2	1	1	1	29.00
90	14	2	1	0	1	1	2	2	2	0	2	2	1	2	1	1	0	0	0	0	1	0	1	22.00
91	14	1	0	0	1	0	1	1	0	1	2	1	1	2	1	1	0	0	0	0	1	1	1	16.00
92	14	2	0	0	1	1	1	2	1	0	2	1	1	2	2	1	1	0	0	0	1	0	0	19.00
95	14	2	0	1	1	1	1	1	0	1	2	1	1	2	1	1	0	1	0	0	1	0	0	18.00
97	14	2	0	0	0	0	0	2	2	0	2	2	1	1	1	1	0	0	0	0	1	0	0	15.00
98	14	2	1	1	1	1	2	2	2	0	2	2	2	2	2	1	0	1	1	1	0	0	0	26.00
121	14	3	2	0	2	1	1	4	2	0	2	2	2	2	1	0	1	1	1	1	1	0	0	29.00
122	14	1	0	0	1	1	1	2	1	0	1	1	2	0	1	1	0	0	1	1	0	0	0	15.00
125	14	2	0	1	1	1	0	3	1	0	1	1	2	2	1	1	0	0	1	1	0	0	0	19.00
127	14	2	0	0	1	1	1	3	1	0	2	1	2	2	1	1	1	0	1	1	1	1	0	23.00
128	14	1	1	0	0	0	1	2	1	0	2	2	0	0	1	2	0	0	0	0	0	0	1	14.00
131	14	3	1	2	1	1	2	4	3	0	2	2	2	2	1	2	1	1	0	0	2	0	0	32.00
143	14	2	1	1	1	1	1	3	1	0	2	1	0	0	0	1	0	2	1	1	1	1	0	21.00
144	14	2	1	0	0	0	1	2	1	0	1	1	0	0	0	1	0	0	0	0	1	0	1	12.00
145	14	2	1	0	1	1	1	3	1	0	2	1	1	2	2	2	0	1	0	0	2	1	0	24.00
148	14	2	1	1	0	1	1	3	2	0	1	2	1	0	1	1	0	0	0	0	1	0	1	19.00
149	14	3	1	1	1	2	1	3	2	0	2	2	2	2	1	2	1	2	0	0	1	1	0	30.00
153	14	3	2	1	1	1	1	3	0	2	2	2	1	2	1	0	0	1	1	1	1	0	0	26.00

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Reboxetine Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
1	21	2	2	1	2	2	1	1	0	0	2	2	0	1	2	2	0	0	2	1	1	0	1	25.00
17	21
31	21	3	0	0	2	2	2	4	0	2	2	1	0	1	2	0	0	0	1	1	0	0	0	23.00
32	21	3	1	0	0	1	1	4	0	2	2	1	0	1	2	0	0	0	1	1	0	0	0	20.00
46	21
47	21	0	0	0	2	2	2	1	0	0	0	1	0	1	0	1	0	0	0	0	0	0	0	10.00
81	21	1	0	0	1	1	1	2	1	0	2	1	2	2	0	1	0	0	0	0	1	0	1	17.00
84	21	2	0	0	1	1	1	2	1	0	2	2	1	2	1	2	0	0	1	1	1	0	1	22.00
86	21	2	1	0	1	0	1	2	1	0	2	1	1	2	1	2	0	0	0	0	1	0	0	18.00
89	21	2	1	1	1	1	1	2	1	0	2	2	2	2	0	1	0	0	0	0	1	1	1	22.00
90	21	1	0	0	1	1	1	1	1	0	2	1	1	2	1	2	0	0	0	0	0	0	1	16.00
91	21	1	0	0	1	1	0	1	0	1	2	1	1	2	1	1	0	0	0	0	0	1	1	15.00
92	21	1	0	0	1	1	1	1	1	0	2	1	0	2	1	1	1	0	0	0	0	0	0	14.00
95	21	1	0	0	1	1	1	1	0	1	2	1	1	2	1	1	0	0	0	0	1	0	0	15.00
97	21	1	0	0	0	0	0	1	1	0	1	1	1	0	0	1	0	0	0	0	0	0	0	7.00
98	21	2	1	1	1	0	1	2	1	0	2	1	2	2	1	1	0	0	1	1	0	0	0	20.00
121	21	3	1	0	2	1	1	3	2	0	1	2	2	2	1	0	1	1	1	2	1	0	0	27.00
122	21	1	0	0	1	0	1	2	1	0	1	1	0	0	1	1	0	0	0	0	0	0	0	10.00
125	21	2	0	0	1	0	1	2	1	0	1	1	0	0	1	1	0	1	1	1	0	0	0	14.00
127	21	3	0	0	1	1	0	3	1	0	2	1	0	2	1	1	0	0	0	0	1	1	0	18.00
128	21	0	0	0	0	0	1	1	1	0	1	1	0	0	0	1	0	0	0	0	0	0	1	7.00
131	21	4	2	2	2	2	2	4	3	0	3	3	2	2	2	2	0	1	0	0	3	0	0	39.00
143	21	2	0	0	1	0	1	2	1	0	2	1	0	2	0	1	0	0	0	0	0	0	0	13.00
144	21	1	0	0	0	0	1	1	1	0	1	1	0	0	1	1	0	0	0	0	0	0	1	9.00
145	21	2	1	0	1	1	1	2	1	0	2	1	1	2	1	2	0	1	0	0	1	1	0	21.00
148	21	1	0	0	0	1	0	2	1	0	1	1	1	0	0	1	0	0	0	0	0	0	1	10.00
149	21	3	1	2	1	2	2	4	2	0	2	1	2	2	1	1	1	1	0	0	2	1	0	31.00
153	21	2	2	1	1	1	1	3	0	2	1	2	1	2	1	0	0	1	1	1	1	0	0	24.00

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

31	28	3	1	1	1	0	1	3	0	2	3	1	0	0	1	0	0	0	0	1	1	0	0	0	0	1		
32	28	1	0	0	1	0	2	1	0	1	1	3	0	1	0	0	2	0	0	0	0	0	1	0	1	0	1	
46	28	
47	28	1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	
81	28	0	0	0	1	1	0	1	0	0	1	1	0	2	0	1	0	0	0	0	0	1	0	1	1	1	1	
84	28	1	0	0	1	1	1	1	1	0	1	2	0	2	1	2	0	0	1	1	1	0	0	1	1	1	1	
86	28	2	1	0	1	0	0	1	1	0	2	1	1	2	0	2	0	0	0	0	0	1	0	0	1	1	1	
89	28	1	1	1	1	0	1	1	1	0	1	1	1	2	0	1	0	0	0	0	0	0	1	1	1	1	1	
90	28	1	0	0	1	0	1	1	0	0	1	1	1	2	0	1	0	0	0	0	0	0	0	1	1	1	1	
91	28	0	0	0	1	0	0	0	0	1	2	1	0	1	0	1	0	0	0	0	0	0	0	0	1	1	1	
92	28	0	0	0	1	1	1	0	0	0	1	2	0	2	2	1	0	0	0	0	0	0	0	0	0	1	1	
95	28	1	0	0	1	0	1	1	0	1	1	1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	
97	28	1	0	0	0	0	0	0	0	0	1	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	
98	28	0	0	0	1	0	1	1	0	0	2	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	
21	28	3	2	0	1	1	1	4	2	0	2	2	2	2	1	1	1	1	1	1	1	1	1	0	0	0	2	
22	28	1	0	0	1	0	1	1	1	0	1	1	0	0	1	1	0	0	0	0	0	1	0	0	0	1	1	
25	28	1	0	0	1	0	0	2	1	0	1	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	1	
27	28	2	0	0	1	1	0	2	1	0	1	1	0	0	1	1	0	0	0	0	0	1	1	0	1	1	1	
28	28	0	0	0	0	1	0	1	1	0	1	0	0	0	0	1	0	0	0	0	0	0	0	1	1	1	1	
31	28
43	28	2	0	0	1	0	0	2	1	0	2	2	0	0	0	1	0	0	0	0	0	0	0	0	0	1	1	
44	28	1	0	0	0	0	1	1	1	0	1	0	0	0	1	1	0	0	0	0	0	0	0	1	1	1	1	
45	28	2	0	0	1	1	1	2	1	0	2	1	1	2	1	2	0	0	0	0	0	1	1	0	1	1	1	
48	28	0	0	0	0	1	0	0	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0	0	1	1	1	
49	28	4	1	2	1	2	1	3	2	0	2	2	2	2	1	2	0	1	0	0	0	2	1	0	3	3	3	
53	28	2	0	1	1	1	1	3	0	2	2	2	1	0	1	0	0	1	1	1	1	2	0	0	0	2	2	

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Reboxetine Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
1	35
17	35
31	35	3	1	0	2	1	2	1	0	1	3	1	0	1	1	0	0	0	1	1	1	0	0	20.00
32	35
46	35
47	35	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	2.00
81	35	0	0	0	1	1	1	0	0	0	2	1	1	2	0	1	0	0	0	0	0	0	0	11.00
84	35	1	0	0	1	1	0	1	0	0	1	1	0	2	0	1	0	0	0	0	0	0	0	10.00
86	35	1	0	0	1	0	0	1	0	0	2	1	0	2	0	1	0	0	0	0	2	0	0	11.00
89	35	1	0	0	1	0	1	1	0	0	1	2	1	2	0	1	0	0	0	0	0	1	1	13.00
90	35	0	0	0	1	0	1	1	0	0	1	1	0	2	0	1	0	0	0	0	0	0	0	9.00
91	35	0	0	0	1	0	1	0	0	1	2	1	0	2	0	1	0	0	0	0	0	0	0	10.00
92	35	0	0	0	1	1	1	0	0	0	1	1	1	2	2	0	0	0	0	0	0	0	0	10.00
95	35	0	0	0	1	0	1	0	0	1	1	0	0	1	0	0	0	0	0	0	0	0	0	5.00
97	35	0	0	0	0	1	0	0	0	0	1	1	1	0	1	1	0	0	0	0	0	0	0	6.00
98	35	0	0	0	1	0	1	0	0	0	1	1	0	2	0	0	0	0	0	0	0	0	0	6.00
121	35	3	2	0	1	2	1	3	2	0	2	2	2	2	1	1	1	1	1	1	1	0	0	28.00
122	35	0	0	0	1	0	1	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	5.00
125	35	1	0	0	1	0	0	2	0	0	1	1	0	0	1	1	0	0	0	0	0	0	0	8.00
127	35	1	1	0	0	1	0	0	2	0	0	1	1	0	0	0	1	0	0	0	0	0	0	9.00
128	35	0	0	0	0	0	1	0	1	0	1	0	0	0	0	1	0	0	0	0	0	0	0	5.00
131	35
143	35	1	0	0	1	0	0	2	1	0	2	1	0	0	0	1	0	0	0	0	0	0	0	9.00
144	35	1	0	0	0	0	0	0	1	0	1	0	0	0	1	1	0	0	0	0	0	0	0	6.00
145	35	1	0	0	1	0	1	2	1	0	2	1	0	0	1	1	0	0	0	0	1	1	0	13.00
148	35	0	0	0	0	1	0	1	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0	7.00
149	35	3	1	2	1	1	1	3	2	0	2	2	2	2	1	1	0	1	0	0	2	1	0	28.00
153	35	2	0	1	1	0	0	2	0	1	2	1	0	0	1	0	0	1	1	1	1	0	0	15.00

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Reboxetine Treatment Group

Pat. No.	Per. (dy)	Items																					Total Score	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19	20		21
1	42
17	42
31	42	2	1	0	2	1	1	1	0	1	1	0	1	1	1	0	0	0	0	0	0	0	0	14.00
32	42
46	42
47	42
81	42	0	0	0	1	1	0	0	0	0	1	1	1	2	0	1	0	0	0	0	0	0	1	9.00
84	42	0	0	0	1	1	0	0	0	0	1	1	0	2	0	1	0	0	0	0	0	0	1	8.00
86	42	1	0	0	1	0	0	1	0	0	2	1	0	2	0	1	0	0	0	0	1	0	0	10.00
89	42	1	0	0	1	0	0	0	0	0	2	1	1	2	0	1	0	0	0	0	0	1	1	11.00
90	42	0	0	0	1	1	1	0	0	0	1	1	0	0	0	1	0	0	0	0	0	0	1	7.00
91	42	0	0	0	1	0	0	0	0	1	1	1	0	1	0	0	0	0	0	0	0	0	1	6.00
92	42	0	0	0	1	1	1	0	0	0	1	1	1	2	1	0	0	0	0	0	0	0	0	9.00
95	42	0	0	0	0	0	1	1	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	4.00
97	42	0	0	0	0	0	0	0	0	0	1	1	1	0	1	1	0	0	0	0	0	0	0	5.00
98	42	0	0	0	1	0	1	0	0	0	1	1	0	2	0	0	0	0	0	0	0	0	0	6.00
121	42	3	1	0	1	1	1	3	2	0	2	2	2	2	1	1	1	1	1	1	1	0	0	27.00
122	42	0	0	0	1	1	0	1	0	0	1	1	0	0	0	1	0	0	0	0	0	0	0	6.00
125	42	0	0	0	1	0	0	1	0	0	1	1	0	0	0	1	0	0	0	0	0	0	0	5.00
127	42	0	0	0	1	0	0	1	0	0	1	1	0	0	0	1	0	0	0	0	0	1	0	6.00
128	42	0	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	4.00
131	42
143	42	1	0	0	1	0	0	2	1	0	2	1	0	0	0	1	0	0	0	0	0	0	0	9.00
144	42	0	0	0	0	0	1	1	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	5.00
145	42	1	0	0	1	1	0	1	1	0	1	1	0	0	1	1	0	0	0	0	1	1	0	11.00
148	42	0	0	0	0	1	0	0	1	0	1	1	0	0	0	1	0	0	0	0	0	0	1	6.00
149	42	4	2	2	2	2	4	3	0	3	2	2	2	2	2	2	0	1	0	0	2	2	0	39.00
153	42	1	0	1	1	1	0	2	0	2	1	2	0	0	1	0	0	1	1	1	1	0	0	16.00

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Placebo Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
2	00	4	3	2	2	2	1	3	1	1	3	1	1	2	2	0	2	1	2	2	1	0	1	37.00
16	00	4	0	0	2	2	2	4	3	1	4	3	2	2	2	0	0	1	1	2	0	0	0	35.00
33	00	4	1	0	2	2	2	4	0	3	4	2	1	1	1	0	2	0	2	2	0	1	0	34.00
34	00	4	2	2	0	2	2	4	0	2	3	2	1	2	2	2	0	0	0	0	0	1	0	31.00
35	00	4	2	1	1	2	2	3	0	3	4	3	1	1	2	2	1	0	1	1	1	0	1	36.00
48	00	4	0	3	2	1	1	3	0	1	2	1	0	1	1	0	0	0	1	1	0	0	0	22.00
82	00	3	2	1	1	2	2	3	0	2	3	2	2	2	1	1	1	1	1	2	2	0	0	34.00
83	00	4	1	2	1	1	2	4	3	0	3	3	2	2	2	3	1	0	1	1	2	0	0	38.00
85	00	4	0	2	1	1	2	3	3	0	3	2	2	2	0	2	0	1	0	0	3	1	1	33.00
87	00	4	2	2	1	2	2	4	0	3	4	3	2	2	2	2	0	1	0	0	3	1	1	41.00
88	00	4	2	2	1	2	2	4	3	0	3	2	2	2	2	3	0	1	1	2	2	0	0	40.00
93	00	4	0	1	2	2	2	3	3	0	3	3	2	2	2	2	0	1	1	2	1	0	0	36.00
94	00	4	2	1	2	1	2	4	3	0	3	3	2	2	2	1	2	1	2	1	2	0	2	42.00
96	00	4	2	2	2	1	2	3	3	0	4	3	2	2	2	3	0	2	1	2	1	0	0	41.00
99	00	3	2	2	2	2	1	3	3	0	3	3	2	2	2	3	0	2	0	0	3	0	0	38.00
100	00	4	2	1	2	1	2	3	2	0	3	3	2	2	2	1	0	2	1	2	0	0	2	37.00
123	00	3	0	1	2	1	2	4	3	0	3	2	2	2	2	0	1	2	0	0	0	0	0	30.00
124	00	4	0	1	2	1	2	4	3	0	2	3	2	2	2	0	2	0	1	2	1	0	0	34.00
126	00	3	2	0	2	1	2	4	3	0	2	1	2	2	1	3	2	2	0	0	2	0	0	34.00
129	00	3	0	2	2	2	2	4	0	3	3	2	2	2	1	2	0	2	1	2	1	0	0	36.00
130	00	4	2	0	2	1	2	4	2	0	2	2	2	2	1	0	1	2	1	1	2	0	0	33.00
133	00	4	0	2	2	1	2	4	0	3	3	3	2	2	1	0	0	0	0	0	2	0	1	32.00
141	00	3	2	1	2	1	1	4	2	0	2	2	0	2	2	2	0	0	1	1	2	0	0	30.00
142	00	3	1	1	2	2	2	4	0	3	2	3	2	2	2	2	0	1	1	1	1	0	0	35.00
146	00	3	0	0	2	2	2	4	3	0	2	3	2	2	2	0	0	1	1	2	2	1	0	34.00
147	00	3	1	1	1	2	2	3	3	0	2	2	2	2	1	0	1	1	1	1	2	0	0	31.00
150	00	3	2	1	2	1	2	3	1	0	2	2	2	2	1	2	0	1	1	2	2	0	1	33.00
151	00	3	0	2	1	1	2	4	3	0	3	3	2	2	2	0	0	0	2	2	2	0	1	35.00

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Placebo Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
2	04	3	3	2	1	1	1	3	0	2	2	0	1	2	2	0	0	0	2	1	0	1	0	27.00
16	04	3	2	2	2	1	0	4	3	2	3	2	2	1	2	2	2	2	1	2	0	1	0	39.00
33	04	4	1	0	2	2	2	4	0	3	4	2	1	1	1	0	0	0	2	2	0	1	0	32.00
34	04	2	2	0	2	2	2	3	0	3	2	1	0	2	2	1	1	0	0	1	1	0	0	27.00
35	04	4	1	1	1	2	2	4	0	2	2	2	0	1	2	1	0	0	0	0	1	1	1	28.00
48	04	4	1	2	0	0	0	3	0	0	3	1	0	2	1	1	0	0	0	0	0	0	0	18.00
82	04	3	1	1	1	2	2	4	0	2	3	3	2	2	2	2	0	1	1	1	3	0	0	36.00
83	04	3	1	2	2	2	2	2	0	2	2	2	2	2	1	2	0	0	1	1	2	0	0	31.00
85	04	3	0	1	2	1	2	3	3	0	3	2	2	2	1	2	0	1	0	0	2	1	1	32.00
87	04	4	2	2	1	2	2	3	0	3	3	3	2	2	1	2	1	1	0	0	3	1	1	39.00
88	04	4	1	2	1	2	2	4	3	0	3	3	2	2	2	3	0	1	1	2	1	0	0	39.00
33	07	4	1	0	2	2	2	4	2	4	4	2	1	1	1	0	0	0	1	1	0	0	1	33.00
34	07	4	0	0	0	0	0	4	2	0	2	1	0	2	0	1	0	1	0	0	0	0	0	17.00
35	07	4	3	0	0	1	2	4	0	2	4	3	1	1	2	1	1	0	1	2	0	0	1	33.00
48	07	1	0	1	0	0	0	2	0	1	1	0	0	1	1	0	0	0	0	0	0	0	0	8.00
82	07	3	1	2	1	2	2	4	0	2	2	2	2	2	1	2	1	0	1	2	2	0	0	34.00
83	07	4	2	1	2	1	2	3	3	0	3	2	2	2	2	2	0	0	1	1	1	0	0	34.00
85	07	3	0	2	1	2	2	3	3	0	3	2	2	2	1	2	0	1	0	0	2	1	1	33.00
87	07	3	2	2	2	1	2	3	0	3	4	3	2	2	1	2	1	1	0	0	2	1	1	38.00
88	07	4	2	1	1	2	2	4	3	0	3	3	2	2	1	2	1	1	1	1	2	0	0	38.00
93	07	4	0	2	2	1	2	3	2	0	3	3	2	2	2	1	0	1	1	1	1	0	0	33.00
94	07	3	2	2	2	1	2	4	3	0	4	3	2	2	2	2	1	0	2	2	2	0	2	43.00
96	07	4	2	2	2	1	2	2	2	0	2	2	2	2	2	3	1	1	1	1	1	0	0	35.00
99	07	4	2	1	2	2	1	4	3	0	3	3	2	2	2	3	1	1	0	0	2	0	0	38.00
100	07	4	2	2	2	1	2	3	2	0	3	3	2	2	2	2	1	1	1	2	1	0	2	40.00
123	07	3	1	0	2	1	2	4	2	0	2	1	1	2	2	0	1	2	0	0	0	0	0	26.00
124	07	4	0	2	2	1	2	4	2	0	2	2	2	0	1	0	0	0	1	1	0	0	0	26.00
126	07	2	2	0	2	1	2	3	2	0	2	1	2	2	1	2	0	0	0	0	0	0	0	24.00
129	07	3	1	1	2	2	2	4	0	2	3	3	2	2	1	3	1	1	1	1	1	0	0	36.00
130	07	3	1	0	1	1	1	3	2	0	2	1	2	1	1	0	1	1	1	1	1	0	0	24.00
133	07	3	0	2	2	1	1	3	0	2	2	2	2	2	1	0	0	0	0	0	1	0	1	25.00
141	07	2	1	0	1	1	1	4	2	0	2	1	1	2	1	1	0	0	1	1	1	0	0	23.00
142	07	3	2	1	2	1	2	4	0	2	2	2	2	2	1	1	1	0	1	1	1	0	0	31.00
146	07	3	0	0	1	1	2	4	3	0	3	2	2	2	1	0	1	1	1	2	1	1	0	31.00
147	07	3	1	2	1	1	2	3	3	0	2	2	2	2	1	0	0	1	1	1	2	0	0	30.00
150	07	2	2	1	1	1	2	3	1	0	3	2	2	2	2	2	0	1	1	2	1	0	1	32.00
151	07	3	0	2	2	1	2	3	2	0	2	2	2	2	1	0	0	0	2	2	2	0	0	30.00

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Placebo Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21	
2	10	
16	10	
33	10	4	1	0	2	2	2	4	2	4	4	2	1	1	1	0	0	0	1	1	0	0	1	33.00	
34	10	4	0	1	0	0	0	4	2	1	2	1	0	2	1	0	0	0	0	0	0	2	0	2	22.00
35	10
48	10	3	1	2	1	1	1	3	0	1	1	2	1	1	2	0	0	0	0	0	0	0	0	0	20.00
82	10	3	1	2	1	1	2	4	0	2	3	2	2	2	2	1	1	0	1	2	2	0	0	0	34.00
83	10	3	1	1	1	2	2	3	2	0	2	2	2	2	2	2	0	0	1	1	2	0	0	0	31.00
85	10	3	0	2	1	2	1	3	3	0	2	3	2	2	1	2	0	1	0	0	3	1	1	1	33.00
87	10	3	2	1	2	1	2	3	0	3	3	3	2	2	2	3	1	1	0	0	2	1	1	1	38.00
88	10	3	2	2	1	2	1	4	3	0	3	3	2	2	1	2	0	0	1	1	2	0	0	0	35.00
93	10	3	0	2	2	1	1	2	2	0	3	2	2	2	2	1	0	1	1	1	0	0	0	0	28.00
94	10	3	2	2	2	1	2	4	3	0	4	3	2	2	2	2	1	0	2	1	2	0	2	2	42.00
96	10	3	2	2	2	1	1	2	2	0	3	3	2	2	2	2	0	1	1	1	1	0	0	0	33.00
99	10	3	2	1	2	2	1	3	3	0	3	2	2	2	2	3	1	1	0	0	2	0	0	0	35.00
100	10	4	2	2	2	1	2	3	2	0	4	3	2	2	2	2	1	1	1	1	1	0	2	2	40.00
123	10	2	1	0	1	1	2	3	2	0	2	1	1	1	2	1	0	1	0	0	2	0	0	0	23.00
124	10	4	0	1	2	1	2	4	2	0	2	1	2	0	1	0	0	0	1	1	1	0	0	0	25.00
126	10	2	2	0	2	2	2	3	2	0	2	1	2	2	0	2	0	0	0	0	1	0	0	0	25.00
129	10	3	0	1	2	1	2	4	0	2	2	2	2	2	1	2	1	1	1	1	2	0	0	0	32.00
130	10	3	2	0	1	1	2	3	2	0	2	2	2	1	1	1	1	0	1	1	2	0	0	0	28.00
133	10	3	0	2	2	1	2	3	0	3	3	2	2	2	1	1	0	0	0	0	2	0	1	1	30.00
141	10	2	1	0	1	1	1	3	2	0	1	1	1	2	1	1	0	0	1	1	1	0	0	0	21.00
142	10	3	1	1	2	2	1	4	0	3	2	3	2	2	1	1	1	0	0	0	2	0	0	0	31.00
146	10	3	0	0	1	2	2	3	3	0	3	3	2	2	1	1	1	1	1	1	1	1	0	0	32.00
147	10	3	1	2	1	2	1	3	2	0	2	3	2	2	2	1	0	1	1	1	2	0	0	0	32.00
150	10	2	1	1	1	1	2	3	1	0	2	2	2	2	1	2	0	1	1	1	1	0	1	1	28.00
151	10	3	0	2	1	1	2	3	3	0	3	2	2	2	1	0	0	0	2	2	2	0	0	0	31.00

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Placebo Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
2	14
16	14
33	14	4	1	1	0	1	2	4	0	1	3	2	0	0	0	0	2	0	1	2	0	1	1	26.00
34	14	4	2	0	0	0	0	4	2	0	1	0	0	1	1	0	0	0	2	1	0	0	0	18.00
35	14	4	2	1	0	2	2	3	0	1	2	2	1	0	2	1	0	0	1	1	0	0	0	25.00
48	14	4	1	2	1	1	1	3	0	2	1	2	1	1	2	0	0	0	0	0	0	0	0	22.00
82	14	3	1	1	1	1	2	4	0	3	2	3	2	2	1	2	1	0	1	2	2	0	0	34.00
83	14	3	1	1	2	2	2	2	2	0	2	2	2	2	1	2	0	0	1	1	1	0	0	29.00
85	14	3	0	1	2	1	1	3	3	0	3	3	2	2	2	2	0	0	0	0	2	1	1	32.00
87	14	3	2	2	1	1	2	4	0	2	4	3	2	2	2	3	1	1	0	0	2	1	1	39.00
88	14	3	2	1	1	1	2	3	2	0	3	3	2	2	1	2	0	0	1	1	2	0	0	32.00
93	14	1	0	0	1	1	1	2	1	0	2	2	0	2	1	1	0	0	1	1	0	0	0	17.00
94	14	3	2	2	2	1	2	4	3	0	3	3	2	2	2	2	1	0	2	1	1	0	2	40.00
96	14	2	1	1	2	1	2	2	2	0	3	2	2	2	2	2	0	1	1	1	1	0	0	30.00
99	14	3	2	1	2	2	1	4	3	0	3	3	2	2	2	2	1	1	0	0	2	0	0	36.00
100	14	4	2	2	2	2	1	3	2	0	3	3	2	2	2	2	1	1	1	2	1	0	2	40.00
123	14	2	1	0	1	2	2	3	2	0	2	1	1	0	2	0	0	1	0	0	1	0	0	21.00
124	14	4	0	1	2	2	2	4	2	0	2	1	1	0	1	0	0	0	1	1	1	0	0	25.00
126	14	2	1	0	1	1	1	2	2	0	2	1	0	2	0	1	0	0	0	0	0	0	0	16.00
129	14	3	0	1	2	1	2	3	0	2	2	2	2	2	1	2	1	1	1	1	1	0	0	30.00
130	14	3	1	0	1	2	2	3	2	0	3	2	2	1	1	0	1	1	1	1	2	0	0	29.00
133	14	3	0	1	2	2	2	4	0	2	2	2	2	2	1	1	0	0	0	0	1	0	1	28.00
141	14	2	1	0	1	0	1	3	1	0	1	1	1	1	1	1	0	0	1	1	2	0	0	19.00
142	14	3	1	1	2	2	2	4	0	2	3	2	2	2	1	2	1	0	0	0	1	0	0	31.00
146	14	3	0	1	1	2	2	3	3	0	2	2	2	2	1	1	0	1	1	1	1	1	0	30.00
147	14	3	1	2	0	2	2	4	3	0	2	2	1	2	2	0	0	1	1	1	3	0	0	32.00
150	14	2	1	0	1	1	2	2	1	0	2	2	0	2	1	2	0	1	1	1	1	0	1	24.00
151	14	3	1	2	1	1	2	3	3	0	2	2	2	2	1	0	0	0	2	1	2	0	0	30.00

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Placebo Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
2	21
16	21
33	21	4	1	1	0	1	2	4	0	1	3	2	0	0	0	0	2	0	1	2	0	1	1	26.00
34	21
35	21	4	2	2	1	1	2	4	0	3	4	3	1	1	2	2	0	0	1	1	0	0	0	34.00
48	21	2	0	1	0	0	0	3	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	9.00
82	21	4	2	2	2	2	4	0	4	3	3	2	2	2	2	1	0	1	2	3	0	0	0	43.00
83	21	2	1	1	2	1	2	2	2	0	2	2	1	2	1	2	0	0	1	1	1	0	0	26.00
85	21	4	1	2	2	2	4	3	0	3	3	2	2	2	3	0	0	0	0	3	1	1	1	40.00
87	21	4	2	2	2	2	4	0	3	4	3	2	2	2	3	1	1	1	1	3	1	1	1	46.00
88	21	2	1	1	1	1	2	2	0	3	2	2	2	1	2	0	0	1	1	1	0	0	0	27.00
93	21	1	0	0	1	1	1	1	0	2	2	0	2	1	1	0	0	0	0	0	0	0	0	14.00
94	21	4	2	2	2	2	4	3	0	4	3	2	2	2	2	0	0	2	2	3	0	2	2	45.00
96	21	2	1	1	2	1	2	2	0	2	2	2	2	1	2	0	0	1	1	1	0	0	0	27.00
99	21	4	2	2	2	2	4	3	0	4	3	2	2	2	3	0	1	0	0	3	0	0	0	41.00
100	21	4	2	2	2	2	3	3	0	4	3	2	2	2	2	1	1	1	2	2	0	2	2	44.00
123	21	2	0	0	1	1	1	2	0	2	1	1	2	2	0	0	1	0	0	1	0	0	0	19.00
124	21	4	0	2	2	2	1	4	2	0	2	1	1	0	2	0	0	0	1	2	0	0	0	26.00
126	21	2	1	0	1	0	1	2	0	2	1	0	2	0	1	0	0	0	0	0	0	0	0	15.00
129	21	3	0	2	2	2	2	4	0	2	3	2	2	2	2	1	1	1	2	2	0	0	0	37.00
130	21	4	2	1	2	2	2	4	3	0	3	3	2	2	2	2	0	1	1	2	3	0	0	41.00
133	21	4	0	2	2	2	2	4	0	3	3	3	2	2	2	0	0	0	0	2	0	1	1	36.00
141	21	1	1	0	1	1	1	3	1	0	2	1	1	2	0	1	0	0	1	1	1	0	0	19.00
142	21	3	2	2	2	2	4	0	3	3	3	2	2	2	3	1	1	1	1	2	0	0	0	41.00
146	21	3	0	2	2	2	2	4	3	0	3	3	2	2	1	2	0	1	1	2	2	1	0	38.00
147	21	3	2	2	1	2	2	4	3	0	3	2	2	2	2	1	0	1	1	2	2	0	0	37.00
150	21	2	1	0	1	0	2	2	1	0	2	2	0	2	1	1	0	0	1	1	1	0	1	21.00
151	21	3	1	2	2	2	2	4	3	0	3	3	2	2	1	1	1	0	2	2	3	0	1	40.00

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Placebo Treatment Group

Pat. No.	Per. (dy)	Items																					Total Score	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19	20		21
2	28
16	28
33	28
34	28
35	28	4	2	2	1	1	2	4	0	3	4	3	1	1	2	2	0	0	1	1	0	0	0	34.00
48	28	1	0	0	1	0	0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	6.00
82	28
83	28	2	1	1	2	2	1	2	1	0	2	2	1	2	1	1	0	0	1	1	2	0	0	25.00
85	28
87	28
88	28	2	1	1	1	1	2	2	1	0	3	2	2	2	1	2	0	0	1	1	2	0	0	27.00
93	28	0	0	0	1	1	1	0	0	0	2	1	0	2	1	1	0	0	0	0	0	0	0	10.00
94	28
96	28	2	0	0	1	1	1	1	2	0	1	1	1	1	1	2	0	1	1	1	1	0	0	19.00
99	28
100	28
123	28	2	0	0	1	0	1	2	2	0	2	1	1	2	1	0	0	0	0	0	0	0	0	15.00
124	28	4	0	2	2	1	2	4	2	0	3	2	1	0	2	1	0	0	1	2	0	0	0	29.00
126	28	1	0	0	1	0	1	2	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0	9.00
129	28
130	28
133	28
141	28	1	0	0	1	1	1	2	1	0	2	1	0	2	1	1	0	0	0	0	2	0	0	16.00
142	28
146	28
147	28
150	28	2	0	0	1	0	1	2	0	0	2	1	0	2	1	1	0	0	0	0	0	0	1	14.00
151	28

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Placebo Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
2	35
16	35
33	35
34	35
35	35
48	35	1	0	0	0	0	0	1	0	0	2	0	0	0	0	0	1	0	0	0	0	0	0	5.00
82	35
83	35	2	1	1	2	1	2	2	1	0	2	2	1	2	2	2	0	0	1	1	1	0	0	26.00
85	35
87	35
88	35	2	1	0	1	1	2	2	1	0	3	2	2	2	1	2	0	0	1	1	1	0	0	25.00
93	35	0	0	0	1	1	1	0	1	0	2	2	0	2	0	1	0	0	0	0	0	0	0	11.00
94	35
96	35	1	0	0	1	1	1	1	1	0	1	1	1	1	1	1	0	0	0	0	1	0	0	13.00
99	35
100	35
123	35	2	0	0	1	1	1	2	2	0	2	2	2	0	1	0	0	0	0	0	0	0	0	16.00
124	35	4	0	1	2	2	2	4	2	0	3	2	2	2	2	1	0	0	1	1	1	0	0	32.00
126	35	0	0	0	1	0	1	1	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0	7.00
129	35
130	35
133	35
141	35	1	0	0	1	1	2	2	1	0	2	1	1	2	1	2	0	0	1	1	1	0	0	20.00
142	35
146	35
147	35
150	35	1	0	0	1	0	0	1	0	0	1	1	0	0	1	1	0	0	0	0	0	0	1	8.00
151	35

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Placebo Treatment Group

Pat. No.	Per. (dy)	Items																				Total Score		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18a	18b	19		20	21
2	42
16	42
33	42
34	42
35	42
48	42	1	0	0	0	0	0	1	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	6.00
82	42
83	42	2	1	1	1	1	2	2	1	0	2	2	1	2	1	2	0	0	1	1	2	0	0	25.00
85	42
87	42
88	42	2	1	0	1	1	2	2	2	0	2	2	2	2	1	2	0	0	1	1	1	0	0	25.00
93	42	0	0	0	1	1	1	0	0	0	2	2	1	2	1	1	0	0	0	0	0	0	0	12.00
94	42
96	42	1	0	0	1	0	1	1	0	0	1	1	1	1	1	0	0	0	0	0	1	0	0	11.00
99	42
100	42
123	42	2	0	0	1	0	1	2	1	0	1	1	2	0	1	1	0	0	0	0	0	0	0	13.00
124	42	4	0	2	2	2	2	4	3	0	3	3	2	2	2	1	0	1	1	2	1	0	0	37.00
126	42	0	0	0	1	0	1	1	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0	7.00
129	42
130	42
133	42
141	42	2	1	0	1	1	2	3	1	0	1	1	2	2	1	1	0	0	0	0	1	0	0	20.00
142	42
146	42
147	42
150	42	0	0	0	1	0	0	1	0	0	1	1	0	0	1	1	0	0	0	0	0	0	1	7.00
151	42

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ENCLOSURE 22

**Analytic Cohort: Therapeutic Profile
(Depressed Mood, Insomnia, Activities, Anxiety
& Somatic Symptoms)**

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Variable 1 - Depressed Mood

Reboxetine Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	4.00	3.00	4.00	3.00	3.00	2.00	4.00	.	.
17	1	4.00	3.00	2.00
31	2	3.00	4.00	4.00	4.00	4.00	3.00	3.00	3.00	2.00
32	2	4.00	2.00	.00	.00	4.00	3.00	1.00	.	.
46	2	4.00	3.00	4.00	4.00
47	2	4.00	2.00	.00	.00	.00	.00	1.00	.00	.
81	3	3.00	3.00	3.00	2.00	2.00	1.00	.00	.00	.00
84	3	3.00	3.00	3.00	2.00	2.00	2.00	1.00	1.00	.00
86	3	4.00	4.00	4.00	4.00	3.00	2.00	2.00	1.00	1.00
89	3	4.00	4.00	3.00	3.00	2.00	2.00	1.00	1.00	1.00
90	3	4.00	4.00	3.00	3.00	2.00	1.00	1.00	.00	.00
91	3	3.00	3.00	3.00	2.00	1.00	1.00	.00	.00	.00
92	3	4.00	4.00	3.00	2.00	2.00	1.00	.00	.00	.00
95	3	4.00	4.00	4.00	3.00	2.00	1.00	1.00	.00	.00
97	3	4.00	4.00	3.00	3.00	2.00	1.00	1.00	.00	.00
98	3	4.00	4.00	3.00	3.00	2.00	2.00	.00	.00	.00
121	3	4.00	4.00	4.00	3.00	3.00	3.00	3.00	3.00	3.00
122	3	3.00	3.00	3.00	2.00	1.00	1.00	1.00	.00	.00
125	3	3.00	3.00	3.00	2.00	2.00	2.00	1.00	1.00	.00
127	3	4.00	4.00	3.00	3.00	2.00	3.00	2.00	1.00	.00
128	3	3.00	3.00	2.00	2.00	1.00	.00	.00	.00	.00
131	3	3.00	3.00	3.00	3.00	3.00	4.00	.	.	.
143	3	4.00	4.00	3.00	2.00	2.00	2.00	2.00	1.00	1.00
144	3	4.00	4.00	3.00	2.00	2.00	1.00	1.00	1.00	.00
145	3	3.00	3.00	3.00	2.00	2.00	2.00	2.00	1.00	1.00
148	3	4.00	4.00	3.00	3.00	2.00	1.00	.00	.00	.00
149	3	3.00	3.00	3.00	4.00	3.00	3.00	4.00	3.00	4.00
153	3	3.00	3.00	3.00	3.00	3.00	2.00	2.00	2.00	1.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Variable 1 - Depressed Mood

Placebo Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
2	1	4.00	3.00
16	1	4.00	3.00	4.00
33	2	4.00	4.00	4.00	4.00	4.00	4.00	.	.	.
34	2	4.00	2.00	4.00	4.00	4.00
35	2	4.00	4.00	4.00	.	4.00	4.00	4.00	.	.
48	2	4.00	4.00	1.00	3.00	4.00	2.00	1.00	1.00	1.00
82	3	3.00	3.00	3.00	3.00	3.00	4.00	.	.	.
83	3	4.00	3.00	4.00	3.00	3.00	2.00	2.00	2.00	2.00
85	3	4.00	3.00	3.00	3.00	3.00	4.00	.	.	.
87	3	4.00	4.00	3.00	3.00	3.00	4.00	.	.	.
88	3	4.00	4.00	4.00	3.00	3.00	2.00	2.00	2.00	2.00
93	3	4.00	4.00	4.00	3.00	1.00	1.00	.00	.00	.00
94	3	4.00	4.00	3.00	3.00	3.00	4.00	.	.	.
96	3	4.00	4.00	4.00	3.00	2.00	2.00	2.00	1.00	1.00
99	3	3.00	3.00	4.00	3.00	3.00	4.00	.	.	.
100	3	4.00	4.00	4.00	4.00	4.00	4.00	.	.	.
123	3	3.00	3.00	3.00	2.00	2.00	2.00	2.00	2.00	2.00
124	3	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
126	3	3.00	3.00	2.00	2.00	2.00	2.00	1.00	.00	.00
129	3	3.00	3.00	3.00	3.00	3.00	3.00	.	.	.
130	3	4.00	3.00	3.00	3.00	3.00	4.00	.	.	.
133	3	4.00	4.00	3.00	3.00	3.00	4.00	.	.	.
141	3	3.00	2.00	2.00	2.00	2.00	1.00	1.00	1.00	2.00
142	3	3.00	3.00	3.00	3.00	3.00	3.00	.	.	.
146	3	3.00	3.00	3.00	3.00	3.00	3.00	.	.	.
147	3	3.00	3.00	3.00	3.00	3.00	3.00	.	.	.
150	3	3.00	3.00	2.00	2.00	2.00	2.00	2.00	1.00	.00
151	3	3.00	3.00	3.00	3.00	3.00	3.00	.	.	.

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Variable 2 - Insomnia

Reboxetine Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	2.00	1.33	2.00	1.33	2.00	1.67	2.00	.	.
17	1	2.00	1.67	.33
31	2	1.67	1.00	2.00	2.00	1.67	2.00	.67	1.67	1.33
32	2	1.00	.00	.67	.67	.33	.67	1.00	.	.
46	2	2.00	1.67	1.33	2.00
47	2	2.00	.33	.67	.67	.67	2.00	.00	.00	.
81	3	1.67	1.67	2.00	1.33	1.33	1.00	.67	1.00	.67
84	3	2.00	1.67	1.33	1.33	1.00	1.00	1.00	.67	.67
86	3	1.67	2.00	1.00	.67	.67	.67	.33	.33	.33
89	3	1.33	1.00	1.00	.67	2.00	1.00	.67	.67	.33
90	3	1.67	1.33	1.00	1.33	1.33	1.00	.67	.67	1.00
91	3	2.00	1.67	1.67	1.00	.67	.67	.33	.67	.33
92	3	1.67	1.67	1.67	1.33	1.00	1.00	1.00	1.00	1.00
95	3	2.00	1.67	1.33	1.33	1.00	1.00	.67	.67	.33
97	3	.33	.33	.33	.33	.00	.00	.00	.33	.00
98	3	2.00	2.00	1.67	1.67	1.33	.67	.67	.67	.67
121	3	1.67	1.67	1.67	1.67	1.33	1.33	1.00	1.33	1.00
122	3	1.67	1.33	1.33	1.00	1.00	.67	.67	.67	.67
125	3	1.67	2.00	2.00	1.67	.67	.67	.33	.33	.33
127	3	2.00	2.00	1.33	1.33	1.00	.67	.67	.33	.33
128	3	1.67	1.33	1.00	.67	.33	.33	.33	.33	.33
131	3	1.67	1.33	1.67	1.67	1.33	2.00	.	.	.
143	3	1.67	1.67	1.67	1.33	1.00	.67	.33	.33	.33
144	3	1.33	1.00	.67	.67	.33	.33	.33	.00	.33
145	3	1.67	1.67	1.67	1.00	1.00	1.00	1.00	.67	.67
148	3	1.00	.67	.67	.67	.67	.33	.33	.33	.33
149	3	1.33	1.00	1.33	2.00	1.33	1.67	1.33	1.00	2.00
153	3	1.33	1.33	1.00	1.33	1.00	1.00	1.00	.33	.67

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Variable 2 - Insomnia

Placebo Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
2	1	1.67	1.00
16	1	2.00	1.00	2.00
33	2	2.00	2.00	2.00	2.00	1.00	1.00	.	.	.
34	2	1.33	2.00	.00	.00	.00
35	2	1.67	1.67	1.00	.	1.33	1.33	1.33	.	.
48	2	1.33	.00	.00	1.00	1.00	.00	.33	.00	.00
82	3	1.67	1.67	1.67	1.33	1.33	2.00	.	.	.
83	3	1.33	2.00	1.67	1.67	2.00	1.67	1.67	1.67	1.33
85	3	1.33	1.67	1.67	1.33	1.33	2.00	.	.	.
87	3	1.67	1.67	1.67	1.67	1.33	2.00	.	.	.
88	3	1.67	1.67	1.67	1.33	1.33	1.33	1.33	1.33	1.33
93	3	2.00	1.67	1.67	1.33	1.00	1.00	1.00	1.00	1.00
94	3	1.67	2.00	1.67	1.67	1.67	2.00	.	.	.
96	3	1.67	1.67	1.67	1.33	1.67	1.67	1.00	1.00	.67
99	3	1.67	1.67	1.67	1.67	1.67	2.00	.	.	.
100	3	1.67	1.67	1.67	1.67	1.67	2.00	.	.	.
123	3	1.67	2.00	1.67	1.33	1.67	1.00	.67	1.00	.67
124	3	1.67	2.00	1.67	1.67	2.00	1.67	1.67	2.00	2.00
126	3	1.67	1.67	1.67	2.00	1.00	.67	.67	.67	.67
129	3	2.00	1.67	2.00	1.67	1.67	2.00	.	.	.
130	3	1.67	1.33	1.00	1.33	1.67	2.00	.	.	.
133	3	1.67	1.33	1.33	1.67	2.00	2.00	.	.	.
141	3	1.33	1.33	1.00	1.00	.67	1.00	1.00	1.33	1.33
142	3	2.00	2.00	1.67	1.67	2.00	2.00	.	.	.
146	3	2.00	1.67	1.33	1.67	1.67	2.00	.	.	.
147	3	1.67	1.67	1.33	1.33	1.33	1.67	.	.	.
150	3	1.67	1.33	1.33	1.33	1.33	1.00	.67	.33	.33
151	3	1.33	1.67	1.67	1.33	1.33	2.00	.	.	.

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Variable 3 - Activities

Reboxetine Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	1.50	2.00	1.50	1.50	1.50	.50	1.50	.	.
17	1	2.00	1.50	1.50
31	2	2.00	2.00	2.00	2.00	2.00	2.00	1.50	.50	.50
32	2	2.50	2.00	1.50	1.50	2.00	2.00	.50	.	.
46	2	2.00	2.00	2.00	2.00
47	2	2.00	1.50	.50	.50	.00	.50	.00	.50	.
81	3	2.50	2.50	2.50	2.50	1.50	1.50	.50	.00	.00
84	3	3.50	3.50	3.00	3.00	2.00	1.50	1.00	.50	.00
86	3	3.50	3.50	3.00	2.50	2.00	1.50	1.00	.50	.50
89	3	3.00	3.00	2.00	2.00	1.50	1.50	1.00	.50	.00
90	3	3.00	2.50	2.00	1.50	2.00	1.00	.50	.50	.00
91	3	2.00	1.50	1.50	1.00	.50	.50	.00	.00	.00
92	3	3.50	3.50	2.50	2.00	1.50	1.00	.00	.00	.00
95	3	1.50	1.50	1.50	1.00	.50	.50	.50	.00	.50
97	3	3.50	3.50	3.00	2.00	2.00	1.00	.00	.00	.00
98	3	3.50	3.50	3.00	2.50	2.00	1.50	.50	.00	.00
121	3	3.50	3.50	3.50	3.50	3.00	2.50	3.00	2.50	2.50
122	3	3.50	3.50	2.50	2.50	1.50	1.50	1.00	.50	.50
125	3	3.00	3.00	3.00	2.50	2.00	1.50	1.50	1.00	.50
127	3	3.00	3.00	2.50	2.50	2.00	2.00	1.50	1.00	.50
128	3	3.00	3.00	2.50	1.50	1.50	1.00	1.00	.50	.00
131	3	2.50	2.50	2.50	3.50	3.50	3.50	.	.	.
143	3	3.00	3.00	3.00	3.00	2.00	1.50	1.50	1.50	1.50
144	3	3.50	3.50	2.50	2.50	1.50	1.00	1.00	.50	.50
145	3	3.50	3.00	2.50	2.50	2.00	1.50	1.50	1.50	1.00
148	3	3.50	3.00	3.00	2.50	2.50	1.50	.50	1.00	.50
149	3	3.00	3.00	3.00	3.00	2.50	3.00	2.50	2.50	3.50
153	3	2.00	2.00	2.00	1.50	1.50	1.50	1.50	1.00	1.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Variable 3 - Activities

Placebo Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
2	1	2.00	1.50
16	1	3.50	3.50	4.00
33	2	2.00	2.00	3.00	3.00	2.00	2.00	.	.	.
34	2	2.00	1.50	3.00	3.00	3.00
35	2	1.50	2.00	2.00	.	1.50	2.00	2.00	.	.
48	2	1.50	1.50	1.00	1.50	1.50	2.00	1.00	.50	.50
82	3	1.50	2.00	2.00	2.00	2.00	2.00	.	.	.
83	3	3.50	2.00	3.00	2.50	2.00	2.00	1.50	1.50	1.50
85	3	3.00	3.00	3.00	3.00	3.00	3.50	.	.	.
87	3	2.00	1.50	1.50	1.50	2.00	2.00	.	.	.
88	3	3.50	3.50	3.50	3.50	2.50	2.00	1.50	1.50	2.00
93	3	3.00	2.50	2.50	2.00	1.50	1.00	.00	.50	.00
94	3	3.50	3.00	3.50	3.50	3.50	3.50	.	.	.
96	3	3.00	2.50	2.00	2.00	2.00	2.00	1.50	1.00	.50
99	3	3.00	3.50	3.50	3.00	3.50	3.50	.	.	.
100	3	2.50	2.50	2.50	2.50	2.50	3.00	.	.	.
123	3	3.50	3.50	3.00	2.50	2.50	2.00	2.00	2.00	1.50
124	3	3.50	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.50
126	3	3.50	3.00	2.50	2.50	2.00	2.00	1.50	1.00	1.00
129	3	2.00	1.50	2.00	2.00	1.50	2.00	.	.	.
130	3	3.00	3.00	2.50	2.50	2.50	3.50	.	.	.
133	3	2.00	2.00	1.50	1.50	2.00	2.00	.	.	.
141	3	3.00	3.00	3.00	2.50	2.00	2.00	1.50	1.50	2.00
142	3	2.00	2.00	2.00	2.00	2.00	2.00	.	.	.
146	3	3.50	3.50	3.50	3.00	3.00	3.50	.	.	.
147	3	3.00	2.50	3.00	2.50	3.50	3.50	.	.	.
150	3	2.00	2.00	2.00	2.00	1.50	1.50	1.00	.50	.50
151	3	3.50	3.00	2.50	3.00	3.00	3.50	.	.	.

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Variable 4 - Anxiety

Reboxetine Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	2.00	2.00	2.00	2.00	2.00	2.00	2.00	.	.
17	1	2.00	.00	1.00
31	2	1.00	2.50	2.50	2.50	2.50	1.00	1.50	1.50	1.00
32	2	1.50	.50	.50	.50	1.50	1.00	.50	.	.
46	2	3.00	1.50	3.50	2.50
47	2	2.00	1.50	.00	.00	.00	.50	.00	.50	.
81	3	2.50	2.50	2.50	2.00	1.50	1.50	1.00	1.50	1.00
84	3	2.50	3.00	3.00	2.50	2.00	2.00	1.50	1.00	1.00
86	3	3.00	2.50	2.50	2.00	2.00	2.00	2.00	1.50	1.50
89	3	2.50	2.50	1.50	2.00	2.00	1.50	1.00	1.00	1.50
90	3	3.00	2.50	2.00	2.50	1.50	2.00	1.00	1.00	1.00
91	3	3.00	3.00	2.00	2.00	1.50	1.50	1.50	1.50	.50
92	3	2.50	2.00	2.00	1.50	1.50	1.50	1.00	.50	.50
95	3	2.50	2.00	1.50	1.50	1.50	1.50	1.00	.50	.50
97	3	2.50	2.50	2.00	1.50	1.50	1.00	1.00	1.00	1.00
98	3	2.00	2.50	2.00	2.00	1.50	1.50	1.00	.50	.50
121	3	2.00	2.00	1.50	1.50	1.00	.50	1.50	1.50	1.50
122	3	2.00	1.00	1.50	1.50	1.00	1.00	1.00	.50	1.00
125	3	3.00	2.50	2.00	1.50	1.00	1.00	1.00	1.00	1.00
127	3	2.50	2.00	1.50	1.00	1.50	1.50	1.00	.00	1.00
128	3	3.00	3.00	2.00	2.00	2.00	1.00	1.00	1.00	1.00
131	3	2.50	2.50	2.00	2.00	2.00	2.50	.	.	.
143	3	2.50	2.50	2.00	2.00	1.50	1.50	1.50	1.50	1.50
144	3	2.00	2.00	2.00	1.50	1.00	1.00	1.00	1.00	1.00
145	3	2.50	3.00	2.00	2.00	2.00	2.00	2.00	1.50	1.00
148	3	1.50	1.50	1.50	1.50	1.00	1.00	1.00	1.00	1.00
149	3	2.50	2.00	2.50	2.00	2.00	1.50	2.00	1.50	2.50
153	3	1.00	1.50	1.50	2.00	1.00	.50	1.00	1.00	.50

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Variable 4 - Anxiety

Placebo Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
2	1	1.50	1.00
16	1	2.00	2.50	2.50
33	2	2.00	2.00	2.00	2.00	1.50	1.50	.	.	.
34	2	2.50	1.50	1.50	1.00	.50
35	2	3.00	1.50	2.50	.	1.50	3.00	3.00	.	.
48	2	1.00	2.00	.50	.50	.50	.50	1.00	1.00	1.00
82	3	2.00	2.50	2.00	2.00	2.00	2.50	.	.	.
83	3	3.00	2.00	2.50	2.00	2.00	2.00	1.50	2.00	2.00
85	3	2.50	2.50	2.50	2.00	2.50	3.00	.	.	.
87	3	3.00	2.50	3.00	3.00	3.50	3.50	.	.	.
88	3	3.00	3.00	2.50	2.50	2.50	2.50	2.50	2.50	2.00
93	3	2.50	3.00	2.00	2.00	1.50	1.50	1.50	1.50	1.50
94	3	2.00	3.00	3.00	3.00	2.50	3.00	.	.	.
96	3	3.50	3.00	2.50	2.50	2.50	2.00	1.50	1.00	1.00
99	3	3.00	3.00	3.00	3.00	2.50	3.50	.	.	.
100	3	2.00	2.50	2.50	3.00	2.50	3.00	.	.	.
123	3	1.50	1.50	1.00	1.50	1.00	1.00	1.00	1.00	1.00
124	3	1.00	1.00	1.00	1.00	1.00	1.00	2.00	2.00	2.00
126	3	2.50	2.00	2.00	2.00	1.50	1.50	1.00	1.00	1.00
129	3	2.50	2.50	3.00	2.00	2.00	2.50	.	.	.
130	3	1.00	1.00	1.00	1.50	1.50	2.50	.	.	.
133	3	1.50	1.50	1.00	2.00	1.50	2.50	.	.	.
141	3	2.00	1.50	1.50	1.00	1.00	1.50	1.50	2.00	1.00
142	3	2.00	2.00	1.50	1.50	2.50	3.00	.	.	.
146	3	1.00	1.50	1.50	2.00	1.50	2.50	.	.	.
147	3	1.00	1.00	1.00	1.50	1.00	2.00	.	.	.
150	3	2.00	2.50	2.50	2.00	2.00	1.50	1.50	1.00	1.00
151	3	1.50	1.50	1.00	1.50	1.00	2.00	.	.	.

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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Variable 5 - Somatic Symptoms

Reboxetine Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	1.75	1.50	1.50	1.50	1.50	1.25	1.75	.	.
17	1	1.50	1.75	1.00
31	2	1.25	1.50	1.50	1.50	1.25	1.00	.50	.75	.75
32	2	1.00	.75	.75	.75	1.25	1.00	1.00	.	.
46	2	1.50	1.00	1.75	1.50
47	2	1.25	.50	.50	.25	.25	.50	.25	.00	.
81	3	1.75	2.00	1.75	1.75	1.50	1.25	.75	1.00	1.00
84	3	2.25	2.25	1.75	2.00	1.50	1.50	1.25	.75	.75
86	3	2.00	2.25	2.25	1.75	1.75	1.25	1.00	.75	.75
89	3	2.00	2.00	2.00	1.75	1.75	1.50	1.00	1.25	1.00
90	3	2.25	2.25	1.75	1.75	1.50	1.25	1.00	.75	.25
91	3	2.25	2.25	1.75	1.50	1.25	1.25	.50	.75	.50
92	3	2.25	2.25	1.75	1.75	1.50	1.00	1.50	1.50	1.25
95	3	2.25	1.75	1.75	1.75	1.25	1.25	.50	.25	.25
97	3	2.50	2.25	1.75	1.50	1.25	.50	.75	.75	.75
98	3	2.25	2.25	2.25	2.25	2.00	1.50	1.00	.75	.75
121	3	1.50	1.25	1.75	1.75	1.75	1.75	1.75	1.75	1.75
122	3	1.50	1.50	1.75	1.50	1.00	.50	.50	.25	.25
125	3	1.75	2.00	1.50	1.50	1.50	.50	.50	.50	.25
127	3	1.75	1.75	1.75	1.75	1.50	1.00	.50	.50	.25
128	3	2.25	2.00	1.75	1.75	.75	.25	.00	.00	.00
131	3	2.00	2.00	1.75	1.75	1.75	2.25	.	.	.
143	3	2.00	1.75	1.75	1.75	.25	.75	.50	.25	.25
144	3	2.00	1.75	1.25	.75	.25	.50	.25	.25	.00
145	3	1.75	2.00	2.00	1.75	1.50	1.25	1.25	.50	.50
148	3	1.50	1.50	1.50	1.00	1.00	.50	.25	.25	.25
149	3	1.50	1.50	1.25	1.75	1.75	1.50	1.75	1.75	2.00
153	3	1.75	2.00	2.00	2.00	1.50	1.50	1.00	.50	.75

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Variable 5 - Somatic Symptoms

Placebo Group

Pat. No.	Ctr. ¹ No.	Day 0	Day 4	Day 7	Day 10	Day 14	Day 21	Day 28	Day 35	Day 42
2	1	1.50	1.25
16	1	2.25	1.75	1.50
33	2	1.25	1.25	1.25	1.25	.50	.50	.	.	.
34	2	1.75	1.25	.75	1.00	.50
35	2	1.75	1.25	1.75	.	1.25	1.75	1.75	.	.
48	2	.75	1.00	.50	1.50	1.50	.25	.00	.00	.00
82	3	1.75	2.25	1.75	2.00	2.00	2.25	.	.	.
83	3	2.25	1.75	2.00	2.00	1.75	1.50	1.50	1.75	1.50
85	3	1.50	1.75	1.75	2.00	2.25	2.25	.	.	.
87	3	2.25	2.00	2.00	2.25	2.25	2.25	.	.	.
88	3	2.00	2.25	2.00	2.00	2.00	1.75	1.75	1.75	1.75
93	3	2.25	2.25	2.25	2.00	1.25	1.25	1.00	1.00	1.50
94	3	2.25	2.25	2.25	2.25	2.25	2.25	.	.	.
96	3	2.25	2.25	2.00	2.25	2.00	1.75	1.00	1.00	1.00
99	3	2.25	2.25	2.25	2.00	2.25	2.25	.	.	.
100	3	2.25	2.50	2.25	2.25	2.25	2.25	.	.	.
123	3	2.00	1.75	1.50	1.25	1.00	1.50	1.25	1.25	1.00
124	3	2.25	1.75	1.25	1.00	.75	1.00	1.25	2.00	2.25
126	3	1.50	1.75	1.50	1.25	.75	.75	.25	.25	.25
129	3	1.75	2.00	2.00	1.75	1.75	2.00	.	.	.
130	3	1.75	1.50	1.25	1.50	1.50	2.25	.	.	.
133	3	2.00	1.75	1.75	1.75	1.75	2.25	.	.	.
141	3	1.50	1.25	1.25	1.25	1.00	1.00	1.00	1.25	1.50
142	3	2.25	1.75	1.75	2.00	1.75	2.25	.	.	.
146	3	2.25	1.75	1.75	2.00	1.75	2.00	.	.	.
147	3	1.75	1.75	1.75	2.25	1.75	2.00	.	.	.
150	3	1.75	1.75	2.00	1.75	1.25	1.25	1.00	.50	.50
151	3	2.25	1.75	1.75	1.75	1.75	2.00	.	.	.

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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ENCLOSURE 23

**Analytic Cohort:
ZUNG in the Two Treatment Groups
(Item, Total & Index Scores)**

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FCE 20124/706 i

Reboxetine Treatment Group
Day 0

Pat. No.	Ctr. No.	Items:																	Total Score	Index Score			
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7			8	9	0
1	1	4	1	3	4	3	1	3	1	4	4	1	1	4	1	4	1	1	1	2	1	71.00	.89
31	2	3	1	3	3	4	2	1	1	3	2	2	1	3	2	4	1	1	1	2	1	59.00	.74
32	2	3	1	2	4	4	1	2	2	1	3	2	1	2	2	2	1	2	1	3	2	57.00	.71
46	2	3	1	4	4	2	2	3	2	3	3	4	2	4	2	3	2	2	2	1	1	60.00	.75
47	2	4	2	2	2	3	3	1	1	3	2	2	1	2	1	3	2	1	2	1	2	52.00	.65
81	3	3	1	4	3	1	2	2	3	4	3	1	2	2	2	3	2	2	1	4	2	65.00	.81
84	3	4	1	4	4	1	1	3	2	3	4	1	2	3	1	3	2	1	2	4	1	71.00	.89
86	3	4	3	2	3	1	1	2	3	2	4	1	2	3	2	4	1	1	2	2	1	64.00	.80
89	3	4	4	3	4	1	1	2	3	4	3	1	2	3	4	3	2	1	2	3	1	66.00	.83
90	3	4	1	4	3	1	1	2	3	4	4	1	1	2	1	3	1	1	1	3	2	71.00	.89
91	3	4	1	4	3	1	1	3	4	3	3	4	2	3	2	3	1	1	1	3	2	67.00	.84
92	3	4	1	4	3	4	3	4	3	4	4	1	1	4	1	3	1	1	1	4	1	72.00	.90
95	3	4	2	4	3	1	1	3	4	3	2	3	1	4	1	4	3	2	2	3	1	67.00	.84
97	3	4	3	4	2	3	1	4	4	4	3	1	1	3	1	4	1	1	1	1	1	69.00	.86
98	3	4	1	3	4	2	1	4	3	3	4	1	2	3	1	4	2	1	1	4	1	73.00	.91
121	3	4	1	4	3	3	1	2	2	3	4	1	1	1	1	4	2	1	1	2	1	66.00	.83
122	3	4	1	4	4	1	2	3	1	3	4	1	2	2	1	3	1	1	2	3	1	68.00	.85
125	3	4	2	3	4	1	1	3	1	2	4	1	1	2	1	4	1	2	1	2	1	67.00	.84
127	3	4	1	4	4	1	1	2	2	3	3	1	1	2	1	4	2	1	3	1	2	65.00	.81
128	3	4	1	4	4	1	1	1	3	3	3	2	1	3	2	3	2	1	2	1	1	65.00	.81
131	3	4	2	3	4	1	1	2	3	3	4	1	2	3	2	1	1	1	1	3	1	67.00	.84
143	3	4	1	4	4	1	1	2	2	3	4	1	2	2	1	3	2	1	1	3	1	69.00	.86
144	3	4	3	4	4	1	1	2	2	3	3	1	1	2	1	4	1	1	1	3	1	69.00	.86
145	3	4	3	4	4	2	1	2	2	2	3	2	1	2	1	3	2	1	1	2	1	63.00	.79
148	3	4	2	3	4	1	1	2	3	3	4	1	2	2	1	4	1	2	1	3	1	69.00	.86
149	3	4	2	3	3	2	1	2	2	4	3	1	1	2	1	4	1	1	1	1	2	65.00	.81
153	3	4	1	4	4	1	1	2	3	3	4	1	1	4	2	3	2	1	1	4	1	73.00	.91

1 Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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Pat. No.	Ctr. No.	Placebo Treatment Group																		Total Score	Index Score		
		Day 0																					
		Items:																					
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	Total Score	Index Score
33	2	3	1	2	3	2	2	3	1	3	3	2	2	3	2	3	1	2	.	1	1	.	.
34	2	4	1	1	3	3	3	1	1	1	3	1	2	2	2	1	2	2	2	1	2	48.00	.60
35	2	2	2	1	2	2	3	1	1	1	2	2	2	2	3	2	2	2	1	1	2	44.00	.55
82	3	4	1	2	3	1	2	3	2	4	2	2	1	3	1	3	1	1	1	3	2	66.00	.83
83	3	3	1	4	4	1	1	3	3	4	2	2	1	2	1	3	2	1	2	3	1	68.00	.85
85	3	3	3	2	3	2	1	2	3	4	3	1	2	2	1	2	2	1	1	4	2	62.00	.78
87	3	4	2	3	4	1	1	2	2	3	3	1	1	4	1	4	1	2	1	3	1	70.00	.88
88	3	4	1	3	4	2	1	2	4	3	4	2	2	3	1	3	1	1	2	4	1	70.00	.88
93	3	3	1	2	3	2	1	4	3	2	3	1	1	4	1	3	1	1	1	2	2	67.00	.84
94	3	4	2	3	4	1	1	4	3	2	3	1	1	3	1	4	1	2	2	4	1	71.00	.89
96	3	4	1	4	3	1	1	2	3	3	4	1	2	2	1	4	3	3	1	3	1	67.00	.84
99	3	4	2	4	3	1	1	3	3	3	4	1	2	4	2	4	1	1	2	2	1	70.00	.88
100	3	4	1	3	4	1	1	3	3	3	4	1	1	2	1	4	1	1	2	3	2	71.00	.89
123	3	3	3	4	4	1	1	4	1	3	3	1	1	2	2	3	1	1	2	2	1	65.00	.81
124	3	4	1	4	4	1	1	3	1	2	4	1	1	2	1	4	1	1	2	2	2	68.00	.85
126	3	3	2	4	4	1	1	2	2	3	4	1	1	2	1	3	2	1	1	3	1	68.00	.85
129	3	4	1	2	4	2	1	2	2	3	4	1	2	3	2	4	1	2	1	3	1	67.00	.84
130	3	3	1	2	3	1	2	2	3	2	2	2	1	1	2	2	1	1	3	1	2	55.00	.69
139	3	3	3	2	4	1	2	2	3	3	2	2	1	4	2	4	1	2	2	3	3	61.00	.76
141	3	4	1	2	4	2	1	3	2	2	4	1	1	2	1	4	2	1	2	2	1	66.00	.83
142	3	4	2	3	4	1	1	2	3	2	4	1	2	4	4	3	1	1	1	2	2	65.00	.81
146	3	4	1	4	4	1	1	2	2	3	4	1	2	3	1	3	1	2	2	1	1	67.00	.84
147	3	4	1	4	4	1	1	3	3	2	4	4	1	2	1	3	2	1	1	2	2	66.00	.83
150	3	3	1	3	4	1	1	2	3	4	3	1	1	3	1	4	1	1	1	3	2	71.00	.89
151	3	4	3	3	4	1	1	3	3	4	4	1	1	2	1	4	1	1	1	3	1	72.00	.90

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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Reboxetine Treatment Group
Day 7

Pat. No.	Ctr. No.	Items:																	Total Score	Index Score			
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7			8	9	0
1	1	4	1	4	4	4	1	4	3	4	4	1	1	4	1	4	1	1	1	3	1	75.00	.94
31	2	3	2	3	3	3	1	1	1	2	2	2	1	3	1	1	2	2	1	2	1	55.00	.69
32	2	1	4	2	3	3	4	3	2	1	1	1	1	3	4	2	4	4	4	1	4	39.00	.49
46	2	3	1	3	4	2	3	4	2	3	3	3	2	4	2	4	2	3	2	2	2	60.00	.75
47	2	1	3	1	2	3	4	1	1	1	2	4	4	1	4	1	3	3	3	1	4	27.00	.34
81	3	3	1	4	3	2	2	1	3	2	3	1	2	2	1	3	1	1	1	4	2	64.00	.80
84	3	3	2	3	3	1	2	1	2	3	3	3	2	1	2	4	3	1	2	2	2	55.00	.69
86	3	4	3	2	4	1	1	3	2	3	4	1	3	2	1	4	2	1	1	3	1	66.00	.83
89	3	4	1	3	2	2	2	1	3	3	4	2	2	3	1	4	2	1	1	2	2	63.00	.79
90	3	4	1	2	3	2	2	1	4	3	3	2	1	3	1	4	2	1	1	3	1	66.00	.83
91	3	3	1	3	4	1	1	3	2	4	3	2	1	3	1	3	1	1	1	3	2	69.00	.86
92	3	4	1	2	4	2	3	2	2	4	3	1	2	4	2	3	2	1	2	4	2	64.00	.80
95	3	4	3	3	2	3	2	1	4	3	3	1	3	2	1	4	2	2	1	3	1	60.00	.75
97	3	4	3	3	2	2	2	2	3	4	3	1	1	2	1	4	1	1	1	2	2	64.00	.80
98	3	4	1	3	4	1	1	2	3	3	4	1	1	3	1	3	2	2	1	3	1	70.00	.88
121	3	4	1	4	4	2	1	1	2	3	3	2	1	2	1	4	1	1	1	2	1	67.00	.84
122	3	4	1	4	3	1	2	2	1	3	4	1	2	3	1	4	1	1	2	2	1	67.00	.84
125	3	4	1	2	4	1	1	3	4	2	3	1	1	2	1	4	1	1	1	2	1	70.00	.88
127	3	4	2	3	3	1	1	3	2	2	1	1	2	1	1	4	1	1	1	2	1	63.00	.79
128	3	3	2	3	3	2	1	2	3	3	3	2	2	2	1	3	2	2	1	1	2	59.00	.74
131	3	4	2	3	4	1	1	3	3	3	4	1	2	2	1	4	2	1	1	3	2	69.00	.86
143	3	4	1	3	3	1	1	3	2	3	3	1	1	2	1	4	1	1	1	3	2	69.00	.86
144	3	4	3	3	2	1	1	2	3	3	2	2	1	2	3	4	2	1	1	2	2	60.00	.75
145	3	3	3	3	4	1	1	2	2	3	2	3	2	3	1	4	1	1	1	2	1	63.00	.79
148	3	4	2	3	3	1	1	2	3	3	3	1	2	3	1	3	2	1	1	2	2	65.00	.81
149	3	4	2	4	4	1	1	2	3	3	4	2	2	1	1	3	1	1	1	2	1	67.00	.84
153	3	4	1	4	4	1	1	3	2	3	4	2	1	4	1	3	2	1	1	3	1	72.00	.90

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Placebo Treatment Group
Day 7

Pat. No.	Ctr. No.	Items:																	Total Score	Index Score		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7			8	9
33	2	3	1	2	3	2	3	2	1	2	4	2	2	3	1	2	2	1	1	2	55.00	.69
34	2	4	2	2	1	2	3	1	2	2	3	2	2	3	1	2	1	2	1	2	55.00	.69
35	2	2	1	2	3	.	4	2	1	2	3	2	2	2	3	2	2	3	1	1	.	.
82	3	4	1	4	3	1	1	3	3	4	3	1	1	4	2	3	1	1	1	2	72.00	.90
83	3	3	1	3	3	1	1	1	4	2	3	2	2	2	1	3	2	2	1	4	63.00	.79
85	3	4	2	2	3	2	2	2	4	4	4	2	1	2	1	1	2	1	1	4	64.00	.80
87	3	4	2	2	4	1	2	2	3	4	3	1	1	3	1	2	2	1	1	3	67.00	.84
88	3	4	1	3	3	4	3	4	3	2	2	3	2	2	1	4	3	1	1	2	59.00	.74
93	3	3	1	3	4	2	1	2	3	4	4	1	1	3	1	4	2	1	1	3	71.00	.89
94	3	4	3	4	4	1	1	4	3	2	3	2	1	4	1	4	2	1	1	3	71.00	.89
96	3	4	2	3	4	1	1	3	3	3	4	1	1	2	1	4	2	1	1	3	71.00	.89
99	3	4	2	3	4	1	1	4	3	3	4	1	2	4	3	4	1	1	1	3	72.00	.90
100	3	4	1	3	3	1	1	3	2	3	4	2	1	2	1	4	1	1	2	3	68.00	.85
123	3	3	3	4	4	1	2	2	2	3	3	2	1	1	1	2	1	1	2	1	59.00	.74
124	3	4	1	4	3	1	2	3	1	2	3	1	2	2	1	3	2	1	2	2	63.00	.79
126	3	3	3	2	3	2	2	1	2	3	3	2	1	2	3	2	3	2	2	1	50.00	.63
129	3	4	2	2	3	1	1	3	2	4	4	2	1	4	1	4	1	1	1	4	72.00	.90
130	3	3	1	2	2	1	2	3	4	3	3	1	2	3	2	3	2	2	1	2	63.00	.79
133	3	4	3	3	4	1	1	2	3	4	3	1	1	3	1	4	3	1	2	2	67.00	.84
141	3	3	1	2	3	2	2	2	1	2	3	1	2	1	2	3	2	1	2	1	54.00	.68
142	3	4	1	4	4	1	1	3	3	2	4	1	1	3	1	2	2	1	1	2	70.00	.88
146	3	4	1	4	3	1	1	3	2	3	3	1	1	3	1	3	2	1	1	1	67.00	.84
147	3	4	1	2	4	1	1	2	3	3	4	2	1	3	1	4	2	1	1	3	69.00	.86
150	3	3	1	4	3	1	1	2	1	3	4	2	2	1	2	3	2	1	1	2	60.00	.75
151	3	4	3	3	4	1	1	2	3	4	4	2	1	2	2	4	1	1	1	3	68.00	.85

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

090177e1803f22f8\Approved\Approved On: 11-Nov-2002 20:34

FCE 20124/706 i

Reboxetine Treatment Group
Day 14

Pat. No.	Ctr. No.	Items:																		Total Score	Index Score		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8			9	0
1	1	3	3	3	4	4	1	3	3	3	3	1	2	3	1	3	1	1	1	4	3	64.00	.80
31	2	3	1	3	3	3	1	2	1	2	2	2	1	3	1	4	2	1	1	3	1	62.00	.78
32	2	4	1	3	1	3	1	1	1	1	4	1	1	1	1	3	1	1	1	3	1	60.00	.75
46	2	3	1	4	4	2	2	2	2	3	3	2	1	3	3	4	2	2	1	2	1	63.00	.79
47	2	1	3	1	2	4	4	1	1	1	2	4	4	1	4	1	3	3	3	1	4	26.00	.33
81	3	2	4	2	2	3	2	1	3	3	2	3	3	1	3	2	3	1	2	2	2	47.00	.59
84	3	3	1	2	2	3	2	1	2	3	2	3	2	3	2	4	3	2	3	1	2	50.00	.63
86	3	3	4	3	2	2	2	1	3	3	4	3	1	2	2	4	3	1	2	2	1	59.00	.74
89	3	3	2	3	4	3	2	1	3	2	4	2	2	3	2	4	1	2	3	2	2	58.00	.73
90	3	3	1	3	3	3	2	1	3	2	3	4	2	3	2	1	2	2	1	2	2	53.00	.66
91	3	2	3	1	2	3	2	1	4	2	2	3	2	3	4	2	3	3	2	1	3	42.00	.53
92	3	2	3	3	3	1	1	2	2	4	2	3	4	2	3	3	3	4	3	2	2	48.00	.60
95	3	2	4	3	3	4	3	2	3	4	3	2	3	3	1	4	2	1	3	2	3	56.00	.70
97	3	3	3	2	2	3	2	1	3	2	3	3	2	3	2	3	2	2	1	1	3	50.00	.63
98	3	3	2	3	4	2	2	1	2	3	3	2	1	4	2	4	3	2	3	2	2	58.00	.73
121	3	4	1	3	3	1	1	4	2	3	4	1	1	2	1	4	1	1	1	1	1	69.00	.86
122	3	3	2	2	3	2	1	2	3	2	2	3	1	2	3	1	2	1	2	1	3	51.00	.64
125	3	2	2	3	2	3	2	1	2	3	2	1	1	1	3	3	1	2	2	1	3	50.00	.63
127	3	3	2	3	2	1	1	3	3	2	3	2	1	1	1	3	2	3	2	1	1	58.00	.73
128	3	2	3	1	2	3	2	1	2	3	3	2	2	2	3	3	2	3	1	3	1	44.00	.55
131	3	3	2	3	4	1	1	3	3	3	4	1	1	2	1	3	1	1	1	3	1	70.00	.88
143	3	2	1	2	2	1	3	1	2	3	2	3	1	1	1	3	3	1	1	2	2	53.00	.66
144	3	2	3	2	2	1	3	3	2	2	3	2	2	3	2	3	1	2	1	3	1	48.00	.60
145	3	3	2	3	3	2	1	3	3	4	3	2	1	2	2	3	3	1	2	2	3	60.00	.75
148	3	3	3	2	3	1	2	1	3	2	2	3	2	1	3	3	3	2	1	2	4	48.00	.60
149	3	4	2	3	3	1	1	3	2	3	4	1	3	1	4	3	2	1	1	2	1	61.00	.76
153	3	3	1	4	4	1	1	2	3	3	4	1	3	2	1	4	2	1	1	4	1	70.00	.88

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Pat. No.	Ctr. No.	Placebo Treatment Group															Total Score	Index Score					
		Day 14																					
		Items:																					
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0		
33	2	3	1	2	3	1	3	3	1	3	3	1	1	3	1	3	1	2	1	1	2	51.00	.76
34	2	1	1	1	1	4	4	1	1	1	4	4	1	4	4	1	4	4	1	4	4	32.00	.40
35	2	2	1	2	3	3	3	1	1	2	2	2	2	2	3	2	2	3	1	1	2	46.00	.57
82	3	4	1	3	3	1	1	4	4	4	2	1	1	3	1	2	1	1	1	3	1	72.00	.90
83	3	4	1	2	3	2	2	1	4	3	2	2	2	3	3	4	3	2	1	3	2	59.00	.74
85	3	4	2	3	4	2	1	1	3	3	4	1	1	2	1	3	2	1	1	3	1	67.00	.84
87	3	4	1	2	3	1	1	3	3	2	4	1	1	3	1	3	1	1	1	3	1	70.00	.88
88	3	4	2	3	3	2	2	2	3	4	4	2	2	3	1	4	3	1	2	2	1	64.00	.80
93	3	3	2	2	2	3	2	1	3	4	3	3	1	3	2	4	2	3	3	1	2	53.00	.66
94	3	4	2	3	3	1	1	3	4	3	4	2	1	4	1	2	1	1	2	4	1	71.00	.89
96	3	3	2	2	3	2	1	1	3	4	3	1	2	3	1	4	3	2	1	2	2	61.00	.76
99	3	3	3	4	4	2	1	4	3	3	4	2	1	3	1	4	1	1	1	4	1	72.00	.90
100	3	4	1	4	4	1	2	3	2	3	3	1	1	4	1	3	1	2	1	4	1	72.00	.90
123	3	2	3	2	4	2	2	1	3	2	2	3	2	1	3	1	2	3	3	1	2	44.00	.55
124	3	4	2	4	3	2	2	1	2	3	3	2	1	3	1	3	1	1	2	1	2	61.00	.76
126	3	2	4	2	2	3	3	1	3	3	2	3	2	1	3	2	2	2	3	1	4	43.00	.54
129	3	3	2	3	3	1	1	3	3	4	4	2	1	3	1	3	1	1	2	3	1	69.00	.86
130	3	4	2	3	4	1	2	2	3	3	3	2	1	2	1	3	2	1	1	2	1	65.00	.81
133	3	3	3	3	4	2	1	2	3	3	4	1	1	4	1	4	3	1	2	1	1	65.00	.81
141	3	2	2	1	3	3	2	1	1	3	2	1	2	2	1	3	2	2	3	1	1	50.00	.63
142	3	4	1	2	4	1	1	3	2	1	4	1	1	4	1	3	2	1	2	2	1	67.00	.84
146	3	4	1	3	2	1	1	2	2	3	2	1	1	2	1	4	1	1	1	2	1	66.00	.83
147	3	3	1	3	3	2	1	2	3	2	4	1	2	2	1	4	1	1	1	2	1	66.00	.83
150	3	3	2	3	3	2	1	3	1	4	3	3	2	3	2	3	2	1	2	1	3	57.00	.71
151	3	4	3	4	4	1	1	3	2	3	2	1	1	2	1	4	1	1	1	2	1	68.00	.85

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Reboxetine Treatment Group
Day 21

Pat. No.	Ctr. No.	Items:																	Total Score	Index Score			
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7			8	9	0
1	1	3	1	2	4	4	1	1	2	3	4	1	3	4	1	4	2	1	3	4	3	61.00	.76
31	2	2	2	2	3	3	2	3	1	2	2	3	2	2	2	2	2	2	2	2	2	49.00	.61
32	2	4	1	4	2	4	1	1	1	2	3	1	1	2	1	4	1	1	1	4	1	64.00	.80
46	2	3	1	4	4	2	2	2	2	3	3	2	1	3	3	4	2	2	1	2	1	63.00	.79
47	2	1	2	1	4	4	4	1	1	1	2	4	3	1	4	1	3	3	3	1	3	31.00	.39
81	3	2	1	3	2	1	3	2	3	3	2	2	3	2	4	2	3	2	3	1	2	48.00	.60
84	3	2	1	3	2	4	2	1	3	2	2	3	2	1	3	2	3	2	2	1	3	44.00	.55
86	3	2	3	1	2	4	2	1	2	3	4	2	3	2	3	4	3	2	2	1	2	46.00	.57
89	3	3	3	2	3	2	3	1	2	2	3	2	3	2	3	2	3	1	3	2	2	47.00	.59
90	3	2	3	1	2	3	2	1	1	2	1	3	2	3	2	1	3	2	2	1	3	40.00	.50
91	3	2	1	2	3	4	3	1	4	2	1	3	2	2	3	2	4	3	3	1	4	40.00	.50
92	3	2	3	2	2	1	1	3	2	3	4	3	2	2	3	4	3	3	2	1	3	51.00	.64
95	3	2	4	1	2	3	4	1	3	3	2	4	2	2	3	3	3	2	3	1	4	41.00	.51
97	3	1	4	3	1	2	3	1	3	1	3	4	3	2	3	1	4	3	2	1	3	39.00	.49
98	3	2	2	3	4	3	2	1	3	2	3	4	3	2	2	3	4	1	3	2	3	48.00	.60
121	3	4	1	4	3	1	1	4	2	3	4	1	1	3	1	4	1	1	1	2	1	73.00	.91
122	3	2	3	2	2	3	2	1	2	3	2	4	3	1	4	3	2	2	1	1	4	41.00	.51
125	3	2	3	2	2	3	4	1	2	2	1	3	3	1	4	2	3	2	3	1	4	34.00	.43
127	3	2	3	3	2	3	2	1	1	3	2	3	2	2	3	4	2	3	2	1	3	45.00	.56
128	3	1	3	1	2	4	3	1	2	2	2	3	4	2	3	2	3	2	3	1	4	34.00	.43
131	3	4	1	3	4	1	1	3	2	3	4	1	1	3	1	3	1	1	1	3	1	72.00	.90
143	3	2	3	1	2	3	4	1	2	3	2	3	2	2	3	2	3	3	2	1	3	39.00	.49
144	3	2	4	2	2	3	2	1	2	1	2	4	4	1	3	2	3	3	2	1	4	37.00	.46
145	3	2	3	2	2	3	2	1	3	4	3	3	3	2	3	2	3	2	1	1	3	46.00	.57
148	3	2	4	2	2	3	2	1	2	3	2	3	3	2	4	4	3	3	2	1	4	43.00	.54
149	3	3	1	3	3	1	2	3	2	2	4	1	1	1	4	4	2	1	1	3	1	63.00	.79
153	3	3	1	3	4	1	1	2	2	3	3	2	1	3	1	3	1	1	1	2	1	67.00	.84

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Placebo Treatment Group
Day 21

Pat. No.	Ctr. No.	Items:																		Total Score	Index Score		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8			9	0
33	2	3	1	2	3	1	2	3	1	3	3	1	1	3	1	3	1	1	1	1	2	63.00	.79
34	2	1	1	1	1	4	4	1	1	1	4	4	1	4	4	1	4	4	1	4	32.00	.40	
35	2	2	1	2	2	4	4	1	1	2	2	2	2	2	3	2	2	3	1	1	2	43.00	.54
82	3	4	1	4	4	1	1	3	2	4	4	1	1	4	1	4	2	1	1	3	1	75.00	.94
83	3	2	1	3	4	2	2	1	1	3	3	3	2	1	2	3	3	2	2	3	3	52.00	.65
85	3	4	2	4	4	1	1	1	3	4	4	1	2	1	1	4	2	1	1	4	1	70.00	.88
87	3	4	1	4	4	1	1	3	2	4	3	1	1	4	1	4	2	1	1	3	1	74.00	.93
88	3	4	1	2	3	3	2	1	3	2	4	2	1	2	2	3	3	1	1	2	2	58.00	.73
93	3	1	3	2	2	3	3	1	4	3	2	3	4	3	3	4	3	3	2	1	3	43.00	.54
94	3	4	3	4	4	1	1	1	4	4	4	1	1	4	1	3	2	1	1	4	1	73.00	.91
96	3	3	2	3	3	3	2	1	2	3	1	2	2	3	1	3	2	3	2	2	2	53.00	.66
99	3	4	2	4	4	1	1	4	3	3	4	1	2	4	1	4	1	2	1	4	1	75.00	.94
100	3	1	4	3	3	1	1	4	3	3	4	1	2	3	1	4	1	1	1	4	1	71.00	.89
123	3	2	3	3	2	3	2	1	2	1	2	3	3	1	3	2	2	2	2	1	3	41.00	.51
124	3	4	1	4	3	1	2	3	1	2	4	1	2	2	1	4	1	1	1	2	1	67.00	.84
126	3	2	3	3	2	3	3	1	3	2	3	4	3	2	3	3	2	2	3	1	3	43.00	.54
129	3	4	2	3	4	1	1	3	1	4	2	3	2	2	1	3	1	1	1	3	1	65.00	.81
130	3	4	1	3	4	1	1	4	3	3	4	1	1	2	1	3	1	1	1	3	1	73.00	.91
133	3	4	2	2	4	1	1	2	3	3	3	2	1	4	1	4	1	1	1	3	1	70.00	.88
141	3	2	3	1	3	2	2	1	1	2	2	3	2	1	2	1	1	2	3	1	1	44.00	.55
142	3	4	1	4	4	1	1	3	2	2	4	1	2	3	1	4	1	1	1	3	1	72.00	.90
146	3	4	1	4	4	1	1	2	3	4	4	1	1	3	1	4	2	1	1	2	1	73.00	.91
147	3	4	1	3	4	1	1	2	2	3	3	2	1	2	1	3	1	1	1	3	2	67.00	.84
150	3	2	2	1	2	3	1	1	2	3	2	4	3	1	3	2	4	3	2	1	4	38.00	.48
151	3	4	3	4	4	1	1	4	3	4	3	1	1	2	1	4	1	1	2	3	1	72.00	.90

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Reboxetine Treatment Group
Day 28

Pat. No.	Ctr. No.	Items:																		Total Score	Index Score		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8			9	0
1	1	3	1	2	4	4	1	1	4	3	3	2	2	4	1	4	2	1	2	4	2	64.00	.80
31	2	2	2	2	3	2	2	1	2	2	2	2	2	2	2	2	2	2	1	2	2	49.00	.61
32	2	1	4	2	4	4	4	1	4	2	3	4	4	4	3	3	4	4	1	4	4	41.00	.51
46	2	3	1	4	4	2	2	2	2	3	3	2	1	3	3	4	2	2	1	2	1	63.00	.79
47	2	2	2	1	2	4	4	1	1	1	2	3	3	1	3	1	3	3	3	1	4	31.00	.39
81	3	1	3	1	3	3	4	2	2	3	2	3	2	1	3	2	4	3	3	1	3	37.00	.46
84	3	2	2	1	2	4	3	1	2	1	3	3	4	2	3	2	4	3	2	1	3	36.00	.45
86	3	2	4	2	2	4	3	1	2	3	3	3	4	1	3	3	4	2	3	1	3	40.00	.50
89	3	2	3	2	2	4	3	1	2	2	3	4	2	2	3	1	3	2	2	1	3	39.00	.49
90	3	2	4	2	2	3	3	1	1	2	2	3	3	2	3	1	4	2	3	1	3	38.00	.48
91	3	1	4	3	2	3	3	1	4	2	1	4	3	2	3	1	3	3	2	1	4	39.00	.49
92	3	1	3	1	2	1	1	3	2	3	2	3	3	2	4	2	4	2	3	1	3	42.00	.53
95	3	1	4	1	2	3	3	2	3	1	2	3	2	2	3	2	3	4	4	1	4	37.00	.46
97	3	1	4	1	2	4	4	3	2	1	1	3	4	2	4	1	3	4	3	1	4	31.00	.39
99	3	1	3	1	2	3	3	1	3	2	2	4	4	2	3	2	3	4	3	1	3	34.00	.43
121	3	4	1	3	3	1	1	3	2	4	4	1	2	3	1	4	1	1	1	1	1	70.00	.88
122	3	2	4	2	2	4	2	1	1	2	1	3	3	2	4	1	3	2	2	1	4	37.00	.46
125	3	2	4	2	2	4	3	1	2	2	1	4	4	2	4	1	4	3	3	1	4	32.00	.40
127	3	2	4	2	2	3	3	1	1	3	2	3	3	1	4	3	2	3	2	1	3	41.00	.51
128	3	1	4	1	2	3	2	1	2	3	2	4	3	1	4	1	3	2	2	1	4	37.00	.46
131	3	4	1	3	4	1	1	3	2	3	4	1	1	3	1	3	1	1	1	3	1	72.00	.90
143	3	2	4	1	2	4	2	1	2	3	1	3	2	1	3	2	3	2	3	1	4	39.00	.49
144	3	2	4	1	2	3	2	1	2	2	1	3	4	1	3	1	3	3	2	1	4	36.00	.45
145	3	2	2	1	3	4	3	1	3	4	2	3	3	2	4	2	3	2	3	1	3	41.00	.51
148	3	1	4	2	2	4	2	1	2	1	3	4	4	2	3	2	4	3	2	1	4	36.00	.45
149	3	4	2	4	3	1	1	3	2	2	3	1	1	2	1	4	1	2	1	3	1	68.00	.85
153	3	3	1	2	3	1	1	2	3	2	3	1	1	3	1	4	1	2	1	2	2	65.00	.81

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

090177e1803f22f8\Approved\Approved On: 11-Nov-2002 20:34

FCE 20124/706 i

Placebo Treatment Group
Day 28

Pat. No.	Ctr. No.	Items:															Total Score	Index Score						
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5			6	7	8	9	0	
33	2	3	1	2	3	1	2	3	1	3	3	1	1	3	1	3	1	1	1	1	2	63.00	.79	
34	2	1	1	1	1	4	4	1	1	1	4	4	1	4	4	1	4	4	1	4	1	4	32.00	.40
35	2	2	1	2	2	4	4	1	1	2	2	2	2	2	3	2	2	3	1	1	2	43.00	.54	
82	3	4	1	4	4	1	1	3	2	4	4	1	1	4	1	4	2	1	1	3	1	75.00	.94	
83	3	2	1	4	3	2	3	1	1	2	3	3	2	2	3	2	3	1	3	2	2	49.00	.61	
85	3	4	2	4	4	1	1	1	3	4	4	1	2	1	1	4	2	1	1	4	1	70.00	.88	
87	3	4	1	4	4	1	1	3	2	4	3	1	1	4	1	4	2	1	1	3	1	74.00	.93	
88	3	3	1	3	3	2	2	1	3	3	4	2	3	2	2	4	2	1	2	2	3	58.00	.73	
93	3	1	3	1	2	4	3	1	3	2	2	3	4	3	4	2	3	4	3	1	3	34.00	.43	
94	3	4	3	4	4	1	1	1	4	4	4	1	1	4	1	3	2	1	1	4	1	73.00	.91	
96	3	3	3	2	3	1	3	1	2	2	3	1	3	2	2	3	3	2	2	1	3	49.00	.61	
99	3	4	2	4	4	1	1	4	3	3	4	1	2	4	1	4	1	2	1	4	1	75.00	.94	
100	3	1	4	3	3	1	1	4	3	3	4	1	2	3	1	4	1	1	1	4	1	71.00	.89	
123	3	2	4	3	2	3	2	1	2	3	3	2	3	2	2	3	2	1	3	1	3	50.00	.63	
124	3	4	1	3	4	1	1	2	2	4	4	1	1	1	3	1	1	1	3	1	3	70.00	.88	
126	3	2	4	2	2	4	2	1	3	3	2	4	3	1	3	3	2	3	2	1	4	42.00	.53	
129	3	4	2	3	4	1	1	3	1	4	2	3	2	2	1	3	1	1	1	3	1	65.00	.81	
130	3	4	1	3	4	1	1	4	3	3	4	1	1	2	1	3	1	1	1	3	1	73.00	.91	
133	3	4	2	2	4	1	1	2	3	3	3	2	1	4	1	4	1	1	1	3	1	70.00	.88	
141	3	2	3	2	3	4	3	1	2	2	3	2	3	2	2	3	1	2	2	1	2	47.00	.59	
142	3	4	1	4	4	1	1	3	2	2	4	1	2	3	1	4	1	1	1	3	1	72.00	.90	
146	3	4	1	4	4	1	1	2	3	4	4	1	1	3	1	4	2	1	1	2	1	73.00	.91	
147	3	4	1	3	4	1	1	2	2	3	3	2	1	2	1	3	1	1	1	3	2	67.00	.84	
150	3	2	3	1	2	3	1	1	2	3	1	4	4	1	3	2	3	3	2	1	4	36.00	.45	
151	3	4	3	4	4	1	1	4	3	4	3	1	1	2	1	4	1	1	2	3	1	72.00	.90	

1 Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

Reboxetine Treatment Group
Day 35

Pat. No.	Ctr. No.	Items:																		Total Score	Index Score		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8			9	0
1	1	3	1	2	4	4	1	1	4	3	3	2	2	4	1	4	2	1	2	4	2	64.00	.80
31	2	2	2	2	2	3	2	1	1	2	2	3	2	1	2	2	2	3	2	1	2	43.00	.54
32	2	1	4	2	4	4	4	4	1	4	2	4	4	4	4	2	3	4	4	1	4	39.00	.49
46	2	3	1	4	4	2	2	2	2	3	3	2	1	3	3	4	2	2	1	2	1	63.00	.79
47	2	1	2	1	2	4	4	1	1	1	1	4	3	1	3	1	3	3	3	1	3	29.00	.36
81	3	1	3	2	2	4	4	1	2	2	2	4	3	1	4	2	3	2	3	1	3	33.00	.41
84	3	2	3	1	2	3	3	1	1	2	3	4	4	2	4	1	4	3	3	1	3	32.00	.40
86	3	2	3	1	2	4	3	1	2	2	4	3	2	2	4	3	4	3	2	1	4	38.00	.48
89	3	2	4	2	1	3	4	1	2	3	2	3	4	2	3	2	3	2	3	1	3	39.00	.49
90	3	2	4	1	3	1	3	1	1	2	1	4	3	1	3	4	4	3	4	1	4	37.00	.46
91	3	1	4	2	2	4	3	1	4	2	2	3	3	2	4	1	3	3	3	1	4	37.00	.46
92	3	1	4	2	2	2	1	3	2	2	1	3	4	2	3	2	4	3	3	1	3	41.00	.51
95	3	1	4	1	2	3	2	1	2	2	3	4	3	2	3	1	3	4	4	1	4	35.00	.44
97	3	1	4	1	2	4	3	1	2	1	3	4	3	1	4	1	3	2	3	1	4	33.00	.41
98	3	1	3	1	2	4	4	1	3	2	2	3	4	1	3	2	3	4	3	1	4	31.00	.39
121	3	4	1	2	3	1	1	4	3	3	3	1	1	2	1	3	1	1	1	1	2	67.00	.84
122	3	2	3	1	2	3	2	1	1	2	2	3	4	2	4	1	3	2	3	1	4	34.00	.43
125	3	1	3	2	2	4	3	1	2	3	2	4	4	1	3	2	2	3	3	1	3	35.00	.44
127	3	2	3	3	2	2	2	1	2	3	3	2	3	1	4	3	2	2	3	1	3	45.00	.56
128	3	1	3	1	2	3	3	1	3	2	1	3	3	1	4	3	4	3	2	1	3	35.00	.44
131	3	4	1	3	4	1	1	3	2	3	4	1	1	3	1	3	1	1	1	3	1	72.00	.90
143	3	2	3	2	2	3	3	1	2	3	2	4	2	1	3	3	4	3	2	1	4	38.00	.48
144	3	2	4	1	1	3	1	1	3	2	1	3	2	1	3	1	4	3	3	1	4	37.00	.46
145	3	2	2	1	2	3	3	1	4	3	3	3	4	3	3	4	1	2	2	1	3	48.00	.60
148	3	1	3	2	2	4	3	1	3	2	2	4	4	3	3	1	3	2	2	1	3	37.00	.46
149	3	4	2	4	4	1	2	3	2	3	4	1	1	2	1	3	1	1	1	3	1	70.00	.88
153	3	3	1	4	2	1	1	1	2	4	3	2	2	3	1	3	1	2	1	1	2	62.00	.78

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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Placebo Treatment Group
Day 35

Pat. No.	Ctr. No.	Items:										Total Score	Index Score										
		1	2	3	4	5	6	7	8	9	0												
33	2	3	1	2	3	1	2	3	1	3	3	1	1	3	1	1	1	1	1	2	63.00	.79	
34	2	1	1	1	1	4	4	1	1	1	4	4	1	4	4	1	4	4	1	4	32.00	.40	
35	2	2	1	2	2	4	4	1	1	2	2	2	2	2	3	2	2	3	1	1	2	43.00	.54
82	3	4	1	4	4	1	1	3	2	4	4	1	1	4	1	4	2	1	1	3	1	75.00	.94
83	3	3	2	2	3	3	1	1	1	3	4	3	2	2	3	4	3	1	2	2	3	52.00	.65
85	3	4	2	4	4	1	1	1	3	4	4	1	2	1	1	4	2	1	1	4	1	70.00	.88
87	3	4	1	4	4	1	1	3	2	4	3	1	1	4	1	4	2	1	1	3	1	74.00	.93
88	3	3	1	2	3	2	3	1	4	2	2	3	2	1	3	2	4	2	1	2	3	48.00	.60
93	3	1	4	2	2	3	4	1	3	2	3	3	2	1	3	3	4	3	3	1	4	39.00	.49
94	3	4	3	4	4	1	1	1	4	4	4	1	1	4	1	3	2	1	1	4	1	73.00	.91
96	3	2	3	1	2	3	2	1	4	3	2	4	3	3	4	1	3	2	2	1	4	40.00	.50
99	3	4	2	4	4	1	1	4	3	3	4	1	2	4	1	4	1	2	1	4	1	75.00	.94
100	3	1	4	3	3	1	1	4	3	3	4	1	2	3	1	4	1	1	1	4	1	71.00	.89
123	3	2	2	3	3	3	1	1	3	3	2	4	3	2	3	2	3	3	2	1	4	44.00	.55
124	3	4	2	3	4	2	1	2	2	1	4	1	1	2	1	3	1	1	1	2	1	65.00	.81
126	3	2	4	1	2	4	3	1	2	2	2	4	3	2	4	2	3	2	3	1	4	36.00	.45
129	3	4	2	3	4	1	1	3	1	4	2	3	2	2	1	3	1	1	1	3	1	65.00	.81
130	3	4	1	3	4	1	1	4	3	3	4	1	1	2	1	3	1	1	1	3	1	73.00	.91
133	3	4	2	2	4	1	1	2	3	3	3	2	1	4	1	4	1	1	1	3	1	70.00	.88
141	3	3	2	2	4	3	1	1	1	3	3	1	2	2	1	3	1	2	2	1	1	57.00	.71
142	3	4	1	4	4	1	1	3	2	2	4	1	2	3	1	4	1	1	1	3	1	72.00	.90
146	3	4	1	4	4	1	1	2	3	4	4	1	1	3	1	4	2	1	1	2	1	73.00	.91
147	3	4	1	3	4	1	1	2	2	3	3	2	1	2	1	3	1	1	1	3	2	67.00	.84
150	3	2	4	1	2	3	1	1	2	3	1	4	3	1	4	3	3	3	2	1	4	39.00	.49
151	3	4	3	4	4	1	1	4	3	4	3	1	1	2	1	4	1	1	2	3	1	72.00	.90

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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Reboxetine Treatment Group
Day 42

Pat. No.	Ctr. No.	Items:																		Total Score	Index Score		
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8			9	0
1	1	3	1	2	4	4	1	1	4	3	3	2	2	4	1	4	2	1	2	4	2	64.00	.80
31	2	2	2	2	2	2	1	1	1	2	2	3	2	2	2	2	2	2	2	2	2	48.00	.60
32	2	1	4	2	4	4	4	4	1	4	2	4	4	4	4	2	3	4	4	1	4	39.00	.49
46	2	3	1	4	4	2	2	2	2	3	3	2	1	3	3	4	2	2	1	2	1	63.00	.79
47	2	3	1	3	2	3	2	1	1	1	4	2	2	2	1	3	3	1	2	4	2	55.00	.69
81	3	1	4	1	2	3	3	1	2	3	2	3	4	2	3	1	4	4	3	1	4	34.00	.43
84	3	1	4	2	2	4	3	1	1	2	2	4	4	1	3	2	4	3	3	1	4	32.00	.40
86	3	2	3	1	2	4	4	1	3	3	3	4	2	1	3	2	3	3	2	1	3	38.00	.48
89	3	1	3	1	1	3	4	1	2	3	1	3	4	1	4	2	4	2	3	1	4	30.00	.38
90	3	1	4	1	2	4	4	2	1	2	2	4	4	2	3	1	4	3	4	1	3	31.00	.39
91	3	1	4	2	2	4	4	3	2	3	2	4	2	1	3	1	4	4	3	1	3	36.00	.45
92	3	1	3	1	2	2	2	1	3	2	3	4	4	1	4	2	2	3	3	1	4	36.00	.45
95	3	1	4	1	2	3	4	1	2	3	3	4	4	2	3	1	4	4	4	1	4	32.00	.40
97	3	1	4	1	1	3	4	1	2	1	1	4	3	1	3	1	4	3	4	1	4	28.00	.35
98	3	1	3	1	2	4	4	1	2	2	1	3	3	1	4	2	3	4	3	1	4	29.00	.36
121	3	3	1	3	3	1	2	4	3	3	3	1	2	2	1	4	2	1	1	2	1	67.00	.84
122	3	1	3	1	2	3	3	1	2	3	2	4	2	1	4	3	2	3	3	1	4	36.00	.45
125	3	1	2	1	2	3	2	1	2	3	1	3	4	2	4	2	3	4	3	1	4	34.00	.43
127	3	1	4	1	2	4	3	1	2	2	1	4	4	1	4	4	1	3	4	1	1	37.00	.46
128	3	1	4	1	2	2	3	1	2	2	1	4	3	1	3	2	3	2	2	1	4	37.00	.46
131	3	4	1	3	4	1	1	3	2	3	4	1	1	3	1	3	1	1	1	3	1	72.00	.90
143	3	2	4	2	2	4	4	1	2	3	2	4	4	1	4	3	2	3	2	1	4	37.00	.46
144	3	1	4	1	2	3	2	1	2	3	1	3	3	4	1	4	4	3	1	3	36.00	.45	
145	3	2	3	2	2	3	2	1	3	4	3	3	2	2	3	3	2	2	2	1	4	47.00	.59
148	3	1	2	1	3	4	3	1	2	2	1	4	4	1	3	2	4	3	3	1	4	31.00	.39
149	3	4	1	4	4	1	2	3	2	3	4	1	1	3	1	4	1	1	1	3	1	73.00	.91
153	3	2	1	3	2	1	1	1	3	2	3	3	2	3	2	3	3	2	1	1	3	54.00	.68

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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Placebo Treatment Group
Day 42

Pat. No.	Ctr. No.	Items:																	Total Score	Index Score				
		1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7			8	9	0	
33	2	3	1	2	3	1	2	3	1	3	3	1	1	3	1	3	1	1	1	1	2	63.00	.79	
34	2	1	1	1	1	4	4	1	1	1	4	4	1	4	4	1	4	4	1	4	1	4	32.00	.40
35	2	2	1	2	2	4	4	1	1	2	2	2	2	2	3	2	2	3	1	1	2	43.00	.54	
82	3	4	1	4	4	1	1	3	2	4	4	1	1	4	1	4	2	1	1	3	1	75.00	.94	
83	3	3	1	2	3	3	2	1	1	2	3	3	2	2	3	3	2	3	2	2	3	48.00	.60	
85	3	4	2	4	4	1	1	1	3	4	4	1	2	1	1	4	2	1	1	4	1	70.00	.88	
87	3	4	1	4	4	1	1	3	2	4	3	1	1	4	1	4	2	1	1	3	1	74.00	.93	
88	3	3	2	2	3	3	2	1	3	2	2	4	3	2	3	3	4	2	3	2	2	45.00	.56	
93	3	1	3	1	3	3	3	1	3	3	1	3	4	2	3	2	3	4	3	1	3	36.00	.45	
94	3	4	3	4	4	1	1	1	4	4	4	1	1	4	1	3	2	1	1	4	1	73.00	.91	
96	3	2	4	3	2	4	4	1	2	3	2	4	2	3	4	1	3	3	3	1	4	38.00	.48	
99	3	4	2	4	4	1	1	4	3	3	4	1	2	4	1	4	1	2	1	4	1	75.00	.94	
100	3	1	4	3	3	1	1	4	3	3	4	1	2	3	1	4	1	1	1	4	1	71.00	.89	
123	3	2	4	2	3	4	3	1	3	2	3	4	3	1	4	1	2	3	2	1	4	39.00	.49	
124	3	3	1	2	3	2	1	2	2	1	4	2	2	1	1	2	2	1	1	2	1	58.00	.73	
126	3	1	3	1	2	3	3	1	3	2	2	3	4	3	4	2	3	2	2	1	4	37.00	.46	
129	3	4	2	3	4	1	1	3	1	4	2	3	2	2	1	3	1	1	1	3	1	65.00	.81	
130	3	4	1	3	4	1	1	4	3	3	4	1	1	2	1	3	1	1	1	3	1	73.00	.91	
133	3	4	2	2	4	1	1	2	3	3	3	2	1	4	1	4	1	1	1	3	1	70.00	.88	
141	3	3	1	2	4	1	2	2	2	1	3	1	2	1	1	3	1	2	2	1	1	58.00	.73	
142	3	4	1	4	4	1	1	3	2	2	4	1	2	3	1	4	1	1	1	3	1	72.00	.90	
146	3	4	1	4	4	1	1	2	3	4	4	1	1	3	1	4	2	1	1	2	1	73.00	.91	
147	3	4	1	3	4	1	1	2	2	3	3	2	1	2	1	3	1	1	1	3	2	67.00	.84	
150	3	1	4	1	2	3	2	1	2	3	2	4	3	1	3	2	4	3	2	1	4	37.00	.46	
151	3	4	3	4	4	1	1	4	3	4	3	1	1	2	1	4	1	1	2	3	1	72.00	.90	

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

FCE 20124/706 i

ENCLOSURE 24

**Analytic Cohort:
CGI-SI in the Two Treatment Groups**

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FCE 20124/706 i

		Reboxetine Treatment Group Day 0 to Day 42								
Pat. No.	Ctr. ¹ No.	Rater ² No.	Day:							
			0	7	14	21	28	35	42	
1	1	1	5	5	5	4	5	5	5	
31	2	2	5	5	5	4	4	3	3	
32	2	2	5	3	5	4	3	2	2	
46	2	3	6	5	5	5	5	5	5	
47	2	3	6	1	1	1	2	1	1	
81	3	4	5	5	4	2	1	1	1	
84	3	4	6	4	3	3	2	2	1	
86	3	4	6	6	4	3	3	2	2	
89	3	4	6	6	4	3	3	2	2	
90	3	4	6	4	4	3	2	1	1	
91	3	4	6	4	2	2	1	1	1	
92	3	4	6	5	3	2	1	1	1	
95	3	4	6	6	3	2	1	1	1	
97	3	4	6	5	3	1	1	1	1	
98	3	4	6	5	4	3	1	1	1	
121	3	4	5	5	4	4	4	4	4	
122	3	4	5	5	3	2	1	1	1	
125	3	4	6	6	3	2	1	1	1	
127	3	4	6	5	4	3	3	2	1	
128	3	4	5	4	2	1	1	1	1	
131	3	4	6	6	6	6	6	6	6	
143	3	4	6	5	4	3	2	1	1	
144	3	4	6	5	3	2	2	2	1	
145	3	4	6	5	3	3	3	2	2	
148	3	4	6	5	4	2	1	1	1	
149	3	4	6	6	6	6	6	6	6	
153	3	4	6	6	5	5	5	3	3	

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Rater 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi

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Pat. No.	Ctr. ¹ No.	Rater ² No.	Placebo Treatment Group Day 0 to Day 42						
			Day: 0	7	14	21	28	35	42
33	2	2	6	6	5	5	5	5	5
34	2	3	6	4	4	4	4	4	4
35	2	3	5	5	4	6	3	3	3
82	3	4	5	5	5	5	5	5	5
83	3	4	5	4	4	3	3	3	3
85	3	4	5	5	5	5	5	5	5
87	3	4	6	6	6	6	6	6	6
88	3	4	5	5	4	4	3	3	3
93	3	4	5	5	2	2	1	1	1
94	3	4	6	6	6	6	6	6	6
96	3	4	6	6	4	4	3	2	1
99	3	4	5	5	5	5	5	5	5
100	3	4	6	6	6	6	6	6	6
123	3	4	5	4	3	3	2	2	2
124	3	4	5	5	5	6	6	6	6
126	3	4	5	4	2	2	1	1	1
129	3	4	6	6	6	6	6	6	6
130	3	4	6	5	5	6	6	6	6
133	3	4	6	5	6	6	6	6	6
141	3	4	5	4	3	3	2	2	3
142	3	4	5	5	5	6	6	6	6
146	3	4	4	4	4	4	4	4	4
147	3	4	5	5	6	6	6	6	6
150	3	4	6	5	3	3	2	2	1
151	3	4	6	6	6	6	6	6	6

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Rater 1 = Beauclair 2 = Mimiran 3 = Song 4 = Nardi

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ENCLOSURE 25

**Analytic Cohort:
CGI-QI in the Two Treatment Groups**

301

180

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Pat. No.	Ctr. ¹ No.	Rater ² No.	Reboxetine Treatment Group Day 7 to Day 42					
			Day: 7	14	21	28	35	42
1	1	1	4	3	3	4	.	.
31	2	2	4	3	3	2	2	2
32	2	2	2	3	3	1	1	.
46	2	3	3
47	2	3	1	1	1	1	1	.
81	3	4	4	2	2	1	1	1
84	3	4	3	2	2	2	1	1
86	3	4	4	3	2	2	1	1
89	3	4	4	2	2	2	1	1
90	3	4	3	2	2	1	1	1
91	3	4	3	1	1	1	1	1
92	3	4	3	2	1	1	1	1
95	3	4	4	2	1	1	1	1
97	3	4	3	2	1	1	1	1
98	3	4	3	2	2	1	1	1
121	3	4	4	3	3	3	3	3
122	3	4	4	2	1	1	1	1
125	3	4	4	2	1	1	1	1
127	3	4	3	3	2	2	1	1
128	3	4	3	1	1	1	1	1
131	3	4	4	4	4	.	.	.
143	3	4	3	3	2	1	1	1
144	3	4	3	2	1	1	1	1
145	3	4	3	2	2	2	1	1
148	3	4	3	3	1	1	1	1
149	3	4	4	4	4	4	4	4
153	3	4	4	3	3	3	3	2

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Rater 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi

FCE 20124/706 i

Pat. No.	Ctr. ¹ No.	Rater ² No.	Placebo Treatment Group Day 7 to Day 42					
			Day:					
			7	14	21	28	35	42
33	2	2	4	3	3	.	.	.
34	2	3	3	3
35	2	3	4	4	5	6	.	.
82	3	4	4	4	4	.	.	.
83	3	4	3	3	3	2	2	2
85	3	4	4	4	4	.	.	.
87	3	4	4	4	5	.	.	.
88	3	4	4	3	3	3	2	2
93	3	4	4	1	1	1	1	1
94	3	4	4	4	4	.	.	.
96	3	4	4	2	2	2	1	1
99	3	4	4	4	4	.	.	.
100	3	4	4	4	4	.	.	.
123	3	4	3	2	2	1	1	1
124	3	4	4	4	5	5	5	5
126	3	4	3	2	2	1	1	1
129	3	4	4	4	4	.	.	.
130	3	4	3	3	5	.	.	.
133	3	4	3	4	4	.	.	.
141	3	4	3	3	3	2	2	3
142	3	4	4	4	5	.	.	.
146	3	4	4	4	4	.	.	.
147	3	4	4	4	4	.	.	.
150	3	4	3	2	2	1	1	1
151	3	4	4	4	5	.	.	.

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Rater 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi

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ENCLOSURE 26

**Experimental Cohort:
NOSS - Day 0**

304

183

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Reboxetine Treatment Group
Day 0

Pat. No.	Ctr. ¹ No.	Rater ² No.	Adverse Effect	Severity ³	Report ⁴
1	1	1	headache	0	0
1	1	1	dizziness	0	0

Placebo Treatment Group

Pat. No.	Ctr. ¹ No.	Rater ² No.	Adverse Effect	Severity ³	Report ⁴
2	1	1	dizziness	0	1
16	1	1	insomnia	1	1
16	1	1	dizziness	2	1
16	1	1	constipation	0	0
34	2	3	sexual disturbance	1	1
34	2	3	agitation	2	0

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Rater 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nandi
³ Severity 0 = Mild 1 = Moderate 2 = Severe
⁴ Report 0 = Spontaneously 1 = Upon Inquiry

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ENCLOSURE 27

**Analytic Cohort:
NOSS in the Two Treatment Groups**

306

185

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FCE 20124/706 i

Reboxetine Treatment Group
Day 4

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
1	1	1	dry mouth	0	1	12 08 89	4	0	1	.	3	1
1	1	1	insomnia	0	0	12 05 89	4	1	0	.	0	1
1	1	1	sweating	0	0	12 05 89	4	0	1	.	1	1
1	1	1	urinary retention	0	1	12 05 89	4	2	1	.	3	1
17	1	1	dizziness	0	1	8 21 90	4	1	1	.	1	1
32	2	2	dry mouth	0	1	12 1 90	1	0	1	.	2	1
32	2	2	cold-extremities	0	1	12 1 90	1	1	1	.	2	1
47	2	3	dizziness	1	1	10 21 90	2	0	0	.	0	1
84	3	4	dry mouth	1	1	10 09 89	2	0	1	.	3	1
86	3	4	insomnia	1	0	10 08 89	2	2	0	.	3	1
89	3	4	tremor	0	1	10 07 89	3	1	1	.	3	3
91	3	4	dry mouth	0	1	11 15 89	3	0	1	.	3	1
98	3	4	dry mouth	1	1	11 17 89	1	0	1	.	3	1
122	3	4	dry mouth	0	1	4 16 89	2	0	0	.	2	1
125	3	4	dry mouth	0	1	4 17 89	1	1	0	.	3	1
125	3	4	insomnia	0	1	4 17 89	1	0	0	.	2	1
125	3	4	constipation	1	1	4 16 89	2	0	0	.	3	1
143	3	4	dry mouth	1	1	4 17 89	1	0	0	.	2	1
143	3	4	tremor	0	1	4 17 89	1	0	0	.	2	1
144	3	4	dry mouth	1	1	5 19 89	2	0	0	.	2	1
144	3	4	vomiting	0	1	5 20 89	2	1	1	.	2	3
145	3	4	dry mouth	0	1	5 19 89	2	1	0	.	2	1
145	3	4	insomnia	0	0	5 19 89	2	2	0	.	1	1
149	3	4	dry mouth	0	1	5 19 89	2	0	0	.	2	1

1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
 5 Dur (Duration of Symptom in days)
 6 Severity 0 = Mild 1 = Moderate 2 = Severe
 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
 10 course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
 4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

FCE 20124/706 i

Placebo Treatment Group
Day 4

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
16	1	1	agitation	1	1	2 12 90	1	1	1	.	1	1
16	1	1	urinary incont.	1	1	2 10 90	3	1	1	.	1	1
48	2	3	headache	1	1	11 14 90	.	0	0	.	2	1
48	2	3	lassitude	1	1	11 15 90	.	0	0	.	2	1
83	3	4	dry mouth	0	1	10 08 89	3	0	1	.	3	1
93	3	4	tremor	0	1	11 15 89	3	0	1	.	3	1
94	3	4	sexual disturb.	0	1	11 15 89	3	0	1	.	3	1
124	3	4	constipation	0	1	4 17 89	1	0	0	.	1	1
126	3	4	dry mouth	0	1	4 16 89	3	0	0	.	3	1
126	3	4	headache	0	1	4 17 89	1	1	0	0	1	0
130	3	4	dry mouth	0	1	5 18 89	4	0	0	.	2	1
130	3	4	headache	0	1	5 18 89	4	1	0	0	1	0
141	3	4	headache	0	1	4 16 89	3	1	0	.	1	1
141	3	4	tremor	1	1	4 17 89	2	0	0	.	2	1
150	3	4	diarrhea	0	1	6 02 89	2	1	0	.	2	1

- 1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
- 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
- 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
- 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
- 5 Dur (Duration of Symptom in days)
- 6 Severity 0 = Mild 1 = Moderate 2 = Severe
- 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
- 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
- 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
- 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

FCE 20124/706 i

Reboxetine Treatment Group
Day 7

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
1	1	1	dry mouth	0	1	12 08 89	4	0	1	.	3	0
1	1	1	insomnia	0	0	12 05 89	6	1	0	.	0	1
1	1	1	sweating	0	0	12 05 89	6	0	1	.	1	1
1	1	1	urinary retention	0	1	12 05 89	6	2	1	.	3	1
17	1	1	hypotension	0	1	8 25 90	2	2	1	.	2	5
17	1	1	dizziness	0	1	8 25 90	2	2	1	.	2	5
31	2	2	drowsiness	1	1	11 24 89	4	0	1	.	1	1
31	2	2	sweating	0	1	11 26 89	3	1	1	.	2	1
31	2	2	headache	0	0	11 27 89	1	1	0	0	1	0
31	2	2	blurred vision	1	1	11 27 89	1	0	1	.	1	1
32	2	2	dry mouth	0	1	1 21 90	5	0	1	.	2	1
32	2	2	insomnia	0	1	1 25 90	1	1	1	.	2	1
32	2	2	decr. appetite	1	1	1 24 90	2	1	1	.	2	1
46	2	3	agitation	0	1	7 21 90	3	1	1	.	2	1
47	2	3	hypotension	0	1	10 19 90	1	1	0	.	3	1
81	3	4	dry mouth	0	1	10 11 89	3	1	1	.	3	1
84	3	4	dry mouth	1	1	10 08 89	5	0	1	.	3	1
84	3	4	tremor	0	1	10 11 89	3	0	1	.	2	1
86	3	4	insomnia	1	0	10 08 89	5	0	0	.	3	1
89	3	4	tremor	0	1	10 07 89	6	0	1	.	3	1
91	3	4	dry mouth	0	1	11 15 89	6	0	1	.	3	1
91	3	4	blurred vision	0	1	11 19 89	2	0	1	.	3	1
92	3	4	sexual disturb.	1	1	11 19 89	2	0	1	.	3	1
97	3	4	vomiting	0	1	11 19 89	2	0	1	0	2	0
98	3	4	dry mouth	1	1	11 17 89	4	1	1	.	3	1
98	3	4	blurred vision	1	1	11 19 89	2	0	1	.	3	1
121	3	4	sweating	1	1	4 17 89	3	0	0	.	2	1
122	3	4	dry mouth	0	1	4 16 89	5	0	0	.	3	1
122	3	4	headache	0	1	4 17 89	4	0	0	.	2	1
122	3	4	constipation	0	1	4 18 89	3	0	0	.	3	1

- 1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
5 Dur (Duration of Symptom in days)
6 Severity 0 = Mild 1 = Moderate 2 = Severe
7 Req.Rx (Required Treatment) 0 = No 1 = Yes
8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Reboxetine Treatment Group
Day 7 (cont.)

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
125	3	4	dry mouth	0	1	4 17 89	4	0	0	.	3	1
125	3	4	insomnia	0	1	4 17 89	4	0	0	.	2	1
125	3	4	constipation	1	1	4 16 89	5	1	0	.	3	1
125	3	4	vomiting	0	1	4 19 89	2	1	0	0	1	0
128	3	4	dry mouth	0	1	5 22 89	2	0	0	.	3	1
143	3	4	dry mouth	1	1	4 17 89	4	0	0	.	3	1
143	3	4	tremor	0	1	4 17 89	4	0	0	.	3	1
144	3	4	dry mouth	1	1	5 19 89	5	0	0	.	3	1
144	3	4	vomiting	0	1	5 20 89	4	0	0	.	3	3
145	3	4	dry mouth	0	1	5 19 89	5	1	0	.	2	1
145	3	4	insomnia	0	0	5 19 89	5	1	0	.	1	1
149	3	4	dry mouth	0	1	5 19 89	5	0	0	.	3	1

1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
 5 Dur (Duration of Symptom in days)
 6 Severity 0 = Mild 1 = Moderate 2 = Severe
 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
 4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

FCE 20124/706 i

Placebo Treatment Group
Day 7

Pat. No.	Ctr. No.	Rater ² No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
16	1	1	agitation	1	1	2 12 90	3	1	1	.	1	5
16	1	1	urinary incont.	1	1	2 10 90	5	1	1	.	1	5
33	2	2	dry mouth	1	1	3 09 90	7	0	1	.	1	1
33	2	2	headache	0	1	3 13 90	1	1	0	1	.	.
34	2	3	drowsiness	0	1	7 14 90	2	2	1	.	1	1
34	2	3	diarrhea	0	1	7 13 90	3	1	1	.	1	1
34	2	3	dizziness	0	1	7 13 90	3	0	1	.	0	1
34	2	3	vomiting	0	1	7 13 90	3	0	1	.	1	1
83	3	4	dry mouth	0	1	10 08 89	6	0	1	.	3	1
83	3	4	constipation	0	1	10 10 89	4	0	1	.	2	1
93	3	4	dry mouth	0	1	11 19 89	2	0	1	.	3	1
93	3	4	tremor	0	1	11 15 89	6	0	1	.	3	1
94	3	4	sexual disturb.	1	1	11 15 89	4	0	1	0	3	0
124	3	4	constipation	0	1	4 17 89	5	1	0	.	2	1
126	3	4	dry mouth	0	1	4 16 89	6	0	0	.	3	1
130	3	4	dry mouth	0	1	5 18 89	7	0	0	.	3	1
141	3	4	dry mouth	1	1	4 19 89	3	0	0	.	3	1
141	3	4	headache	0	1	4 16 89	4	1	0	0	1	0
141	3	4	tremor	1	1	4 17 89	3	0	0	0	2	0
150	3	4	diarrhea	0	1	6 02 89	4	1	0	0	1	0
150	3	4	tremor	1	1	6 05 89	2	0	0	.	2	1

- 1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
- 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
- 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
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- 5 Dur (Duration of Symptom in days)
- 6 Severity 0 = Mild 1 = Moderate 2 = Severe
- 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
- 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
- 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
- 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

FCE 20124/706 i

Reboxetine Treatment Group
Day 10

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
1	1	1	insomnia	0	0	12 05 89	8	1	0	.	0	1
1	1	1	sweating	0	0	12 05 89	8	0	1	.	2	1
1	1	1	constipation	0	1	12 12 89	1	0	0	.	2	.
1	1	1	urinary retention	0	1	12 05 89	8	2	1	.	3	1
81	3	4	dry mouth	0	1	10 11 89	6	0	1	.	3	1
84	3	4	dry mouth	1	1	10 09 89	8	0	1	.	3	1
84	3	4	tremor	0	1	10 11 89	6	0	1	.	3	1
86	3	4	insomnia	.	0	10 08 89	7	0	0	0	3	0
89	3	4	tremor	0	1	10 07 89	9	0	1	.	3	1
91	3	4	dry mouth	0	1	11 15 89	9	0	1	.	3	1
91	3	4	constipation	0	1	11 21 89	3	0	1	.	3	1
91	3	4	blurred vision	0	1	11 19 89	5	0	1	.	3	1
92	3	4	sexual disturb.	1	1	11 19 89	5	0	1	.	3	1
97	3	4	tremor	0	1	11 22 89	2	0	1	.	2	1
98	3	4	dry mouth	1	1	11 17 89	7	0	1	.	3	1
98	3	4	blurred vision	1	1	11 19 89	5	0	1	.	3	1
121	3	4	sweating	1	1	4 17 89	6	0	0	.	3	1
121	3	4	decr. appetite	1	1	4 21 89	2	1	0	.	1	1
121	3	4	sexual disturb.	1	1	4 20 89	3	0	0	.	2	1
122	3	4	dry mouth	0	1	4 16 89	8	0	0	.	3	1
122	3	4	headache	0	1	4 17 89	5	0	0	0	2	0
122	3	4	constipation	0	1	4 18 89	6	0	0	.	3	1
125	3	4	dry mouth	0	1	4 17 89	7	0	0	.	3	1
125	3	4	constipation	1	1	4 16 89	8	0	0	.	3	1
125	3	4	insomnia	0	1	4 17 89	7	0	0	.	3	1
127	3	4	dry mouth	0	1	4 22 89	2	0	0	.	3	1
127	3	4	blurred vision	0	1	4 22 89	2	0	0	.	3	1
128	3	4	dry mouth	0	1	5 22 89	5	0	0	.	3	1

- 1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
- 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
- 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
- 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
- 5 Dur (Duration of Symptom in days)
- 6 Severity 0 = Mild 1 = Moderate 2 = Severe
- 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
- 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
- 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
- 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

FCE 20124/706 i

Reboxetine Treatment Group
Day 10 (cont.)

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
143	3	4	dry mouth	1	1	4 17 89	7	0	0	.	3	1
143	3	4	tremor	0	1	4 17 89	7	0	0	.	3	1
144	3	4	dry mouth	1	1	5 19 89	8	0	0	.	3	1
144	3	4	vomiting	0	1	5 20 89	7	0	0	0	3	0
145	3	4	dry mouth	0	1	5 19 89	8	0	0	.	3	1
145	3	4	insomnia	0	0	5 19 89	7	0	0	1	0	
149	3	4	dry mouth	0	1	5 19 89	8	0	0	.	3	1

1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
 5 Dur (Duration of Symptom in days)
 6 Severity 0 = Mild 1 = Moderate 2 = Severe
 7 Req. Rx (Required Treatment) 0 = No 1 = Yes
 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
 9 Rel. To Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
 4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Placebo Treatment Group
Day 10

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
34	2	3	dizziness	0	1	7 13 90	6	1	1	.	1	1
83	3	4	dry mouth	0	1	10 08 89	9	0	1	.	3	1
89	3	4	constipation	0	1	10 10 89	7	0	1	.	2	1
93	3	4	tremor	0	1	11 15 89	9	0	1	.	3	1
93	3	4	dry mouth	0	1	11 19 89	5	0	1	.	3	1
124	3	4	constipation	0	1	4 17 89	8	0	0	0	2	1
126	3	4	dry mouth	0	1	4 16 89	9	0	0	0	3	1
130	3	4	dry mouth	0	1	5 18 89	10	0	0	0	3	0
141	3	4	dry mouth	1	1	4 19 89	6	0	0	0	3	1
150	3	4	tremor	1	1	6 05 89	5	0	0	.	2	1

- 1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
- 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
- 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
- 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
- 5 Dur (Duration of Symptom in days)
- 6 Severity 0 = Mild 1 = Moderate 2 = Severe
- 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
- 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
- 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
- 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Reboxetine Treatment Group
Day 14

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
1	1	1	insomnia	0	0	12 05 89	13	2	0	.	0	1
1	1	1	urinary retention	0	1	12 05 89	13	2	0	.	3	3
1	1	1	constipation	0	1	12 12 89	6	0	0	.	2	1
1	1	1	sweating	0	0	12 05 89	14	0	1	.	2	1
32	2	2	vomiting	1	1	2 01 90	2	0	1	.	1	0
32	2	2	sweating	1	2	1 31 90	2	0	1	.	1	1
81	3	4	dry mouth	0	1	10 11 89	1	0	1	.	3	1
84	3	4	dry mouth	1	1	10 09 89	12	0	1	.	3	1
84	3	4	tremor	0	1	10 11 89	10	0	1	.	3	1
89	3	4	tremor	0	1	10 07 89	13	0	1	.	3	1
89	3	4	insomnia	0	0	10 17 89	3	1	1	.	2	3
91	3	4	dry mouth	0	1	11 15 89	13	0	1	.	3	1
91	3	4	blurred vision	0	1	11 19 89	9	0	1	.	3	1
91	3	4	constipation	0	1	11 21 89	7	0	1	.	3	1
92	3	4	sexual disturb.	1	1	11 19 89	9	0	1	.	3	1
92	3	4	decr.appetite	1	1	11 24 89	4	0	1	.	3	1
97	3	4	tremor	0	1	11 22 89	6	0	1	.	2	1
98	3	4	dry mouth	1	1	11 17 89	11	0	1	.	3	1
98	3	4	blurred vision	1	1	11 19 89	9	0	1	.	3	1
98	3	4	sweating	1	1	11 25 89	3	0	1	.	3	1
121	3	4	sweating	1	1	4 17 89	10	0	0	.	3	1
121	3	4	decr.appetite	1	1	4 21 89	6	1	0	.	2	1
121	3	4	sexual disturb.	0	1	4 16 89	11	1	0	.	3	1
122	3	4	dry mouth	0	1	4 16 89	12	0	0	.	3	1
122	3	4	constipation	0	1	4 17 89	10	0	0	0	3	0
125	3	4	dry mouth	0	1	4 17 89	11	0	0	.	3	1
125	3	4	constipation	1	1	4 16 89	12	0	0	.	3	1
125	3	4	insomnia	0	1	4 17 89	9	0	0	0	2	0

1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
 5 Dur (Duration of Symptom in days)
 6 Severity 0 = Mild 1 = Moderate 2 = Severe
 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
 4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Reboxetine Treatment Group
Day 14 (cont.)

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ¹	Pre-Std. ⁴	Onset		Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out- come ⁸	Rel. Course ¹⁰	
						Date dy mo yr						To Meds. ⁹	
127	3	4	dry mouth	0	1	4	22	89	6	0	.	3	1
127	3	4	blurred vision	0	1	4	22	89	6	0	.	3	1
128	3	4	dry mouth	0	1	5	22	89	9	0	.	3	1
143	3	4	dry mouth	1	1	4	17	89	11	0	0	3	0
143	3	4	tremor	0	1	4	17	89	11	0	0	3	1
144	3	4	dry mouth	1	1	5	19	89	12	0	.	3	1
145	3	4	dry mouth	0	1	5	19	89	12	0	.	3	1
149	3	4	dry mouth	0	1	5	19	89	12	0	.	3	1

1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
 5 Dur (Duration of Symptom in days)
 6 Severity 0 = Mild 1 = Moderate 2 = Severe
 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
 4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Placebo Treatment Group
Day 14

Pat. No.	Ctr. ¹ No.	Rater ² No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
34	2	3	drowsiness	0	1	1	1	.	2	1
35	2	3	blurred vision	0	1	9 04 90	.	0	1	.	1	1
83	3	4	dry mouth	0	1	10 08 89	10	0	1	0	3	0
83	3	4	constipation	0	1	10 10 89	9	0	1	0	2	0
93	3	4	tremor	0	1	11 15 89	11	0	1	0	3	0
93	3	4	dry mouth	0	1	11 19 89	8	0	1	0	3	0
150	3	4	tremor	1	1	6 05 89	9	0	0	0	2	0

1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
 5 Dur (Duration of Symptom in days)
 6 Severity 0 = Mild 1 = Moderate 2 = Severe
 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
 4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Reboxetine Treatment Group
Day 21

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ¹	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
1	1	1	insomnia	0	0	12 05 89	22	2	0	.	1	3
1	1	1	urinary retention	0	1	12 05 89	22	2	0	.	3	3
1	1	1	pruritis	0	1	12 20 89	7	0	1	.	1	3
1	1	1	hypotension	.	1	12 24 89	3	1	1	.	2	3
31	2	2	dry mouth	0	1	12 06 89	6	0	1	.	1	1
31	2	2	drowsiness	1	1	12 07 89	5	0	1	.	2	1
47	2	3	insomnia	0	1		1	1	1	.	2	.
81	3	4	dry mouth	0	1	10 11 89	15	0	1	0	3	1
84	3	4	dry mouth	1	1	10 09 89	16	0	1	0	3	0
84	3	4	tremor	0	1	10 11 89	17	0	1	.	3	1
89	3	4	tremor	0	1	10 07 89	20	0	1	.	3	1
89	3	4	insomnia	0	0	10 17 89	10	0	1	.	3	1
91	3	4	dry mouth	0	1	11 15 89	20	0	1	.	3	1
91	3	4	blurred vision	0	1	11 19 89	16	0	1	.	3	1
91	3	4	constipation	0	1	11 21 89	14	0	1	.	3	1
92	3	4	sexual disturb.	1	1	11 19 89	16	0	1	.	3	1
92	3	4	decr.appetite	1	1	11 24 89	11	0	1	.	3	1
97	3	4	tremor	0	1	11 22 89	12	0	1	0	2	0
97	3	4	dry mouth	0	1	12 01 89	5	1	1	.	2	1
98	3	4	dry mouth	1	1	11 17 89	18	0	1	0	3	0
98	3	4	blurred vision	1	1	11 19 89	16	0	1	.	3	1
98	3	4	sweating	1	1	11 25 89	10	0	1	.	3	1
121	3	4	sweating	1	1	4 17 89	17	0	0	.	3	1
121	3	4	decr.appetite	1	1	4 21 89	13	0	0	.	2	1
121	3	4	sexual disturb.	0	1	4 16 89	18	0	0	.	3	1
122	3	4	dry mouth	0	1	4 16 89	19	0	0	.	3	1

- ¹ Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
- ² Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
- ³ Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
- ⁴ Pre-Std. (Pre-Study) 0 = No 1 = Yes
- ⁵ Dur (Duration of Symptom in days)
- ⁶ Severity 0 = Mild 1 = Moderate 2 = Severe
- ⁷ Req.Rx (Required Treatment) 0 = No 1 = Yes
- ⁸ Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
- ⁹ Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
- ¹⁰ Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Reboxetine Treatment Group
Day 21 (cont.)

Pat. No.	Ctr. ¹ No.	Rater ² No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
125	3	4	dry mouth	0	1	4 17 89	15	0	0	0	3	0
125	3	4	constipation	0	1	4 16 89	16	0	0	0	3	0
127	3	4	dry mouth	0	1	4 22 89	10	0	0	0	3	0
127	3	4	blurred vision	0	1	4 22 89	10	0	0	0	3	0
128	3	4	dry mouth	0	1	5 22 89	14	0	0	0	3	0
144	3	4	dry mouth	1	1	5 19 89	19	0	0	.	3	1
145	3	4	dry mouth	0	1	5 19 89	19	0	0	.	3	1
149	3	4	dry mouth	0	1	5 19 89	15	0	0	0	3	0

- 1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
 2 Rater (Assessor) 1 = Beaucclair 2 = Mirmiran 3 = Song 4 = Nardi
 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
 5 Dur (Duration of Symptom in days)
 6 Severity 0 = Mild 1 = Moderate 2 = Severe
 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
 4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Placebo Treatment Group
Day 21

Pat. No.	Ctr. ¹ No.	Rater ² No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
48	2	3	lassitude	0	1	11 29 90	5	0	0	.	1	1

- 1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
- 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
- 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
- 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
- 5 Dur (Duration of Symptom in days)
- 6 Severity 0 = Mild 1 = Moderate 2 = Severe
- 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
- 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
- 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
- 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Reboxetine Treatment Group
Day 28

Pat. No.	Ctr. ¹	Rater ²	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
1	1	1	urinary retention	0	1	12 05 89	29	2	0	.	3	5
1	1	1	constipation	0	1	12 12 89	22	1	0	.	2	5
1	1	1	sweating	0	0	12 05 89	29	0	1	.	2	5
31	2	2	dry mouth	1	1	12 06 89	13	0	1	.	1	1
32	2	2	hypomania	0	1	2 15 90	2	0	1	.	2	1
84	3	4	tremor	0	1	10 11 89	24	0	1	.	3	1
84	3	4	blurred vision	0	1	10 31 89	4	0	1	.	2	1
89	3	4	tremor	0	1	10 07 89	27	0	1	.	3	1
89	3	4	insomnia	0	0	10 17 89	13	0	1	0	3	0
91	3	4	dry mouth	0	1	11 15 89	25	0	1	0	3	0
91	3	4	blurred vision	0	1	11 19 89	23	0	1	.	3	1
91	3	4	constipation	0	1	11 21 89	21	0	1	.	3	1
92	3	4	sexual disturb.	1	1	11 19 89	23	0	1	.	3	1
92	3	4	decr.appetite	1	1	11 24 89	18	0	1	.	3	1
97	3	4	dry mouth	0	1	12 01 89	12	0	1	.	3	1
98	3	4	blurred vision	1	1	11 19 89	23	0	1	.	3	1
98	3	4	sweating	1	1	11 25 89	17	0	1	.	3	1
121	3	4	sweating	1	1	4 17 89	24	0	0	.	3	1
121	3	4	decr.appetite	1	1	4 21 89	21	1	0	.	3	1
121	3	4	sexual disturb.	0	1	4 16 89	25	1	0	.	3	1
122	3	4	dry mouth	0	1	4 16 89	26	0	0	0	3	0
144	3	4	dry mouth	1	1	5 19 89	24	0	0	0	3	0
145	3	4	dry mouth	0	1	5 19 89	23	0	0	.	3	1

1 Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
 2 Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
 3 Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
 4 Pre-Std. (Pre-Study) 0 = No 1 = Yes
 5 Dur (Duration of Symptom in days)
 6 Severity 0 = Mild 1 = Moderate 2 = Severe
 7 Req.Rx (Required Treatment) 0 = No 1 = Yes
 8 Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
 9 Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
 10 Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
 4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Placebo Treatment Group
Day 28

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. Rpt.	Pre-Std.	Onset Date	Dur. (dys)	Sev.	Req. Rx.	Out-come	Rel. To Meds.	Course
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No newly observed signs and symptoms reported for PBO patients at Day 28.

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Reboxetine Treatment Group
Day 35

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date dy mo yr	Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
31	2	2	sexual disturb.	0	1	12 24 89	1	0	1	.	2	1
32	2	2	hypomania	.	1	2 17 90	3	2	0	.	2	5
84	3	4	tremor	0	1	10 11 89	26	0	1	0	3	0
84	3	4	blurred vision	0	1	10 31 89	11	0	1	.	3	1
89	3	4	tremor	0	1	10 07 89	30	0	1	0	3	1
91	3	4	blurred vision	0	1	11 19 89	25	0	1	0	3	0
91	3	4	constipation	0	1	11 21 89	28	0	1	.	3	1
92	3	4	sexual disturb.	1	1	11 19 89	30	0	1	.	3	1
92	3	4	decr.appetite	1	1	11 24 89	20	0	1	0	3	0
97	3	4	dry mouth	0	1	12 01 89	19	0	1	0	3	0
98	3	4	blurred vision	1	1	11 19 89	28	0	1	0	3	0
98	3	4	sweating	1	1	11 25 89	22	0	1	0	3	0
121	3	4	decr.appetite	1	1	4 21 89	28	0	0	.	2	1
121	3	4	sweating	1	1	4 17 89	31	0	0	.	3	1
121	3	4	sexual disturb.	0	1	4 16 89	32	0	0	.	3	1

Placebo Treatment Group
Day 35

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Severity ³	Report ⁴
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No newly observed signs and symptoms reported for PBO patients at Day 35.

- ¹ Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
- ² Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
- ³ Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
- ⁴ Pre-Std. (Pre-Study) 0 = No 1 = Yes
- ⁵ Dur (Duration of Symptom in days)
- ⁶ Severity 0 = Mild 1 = Moderate 2 = Severe
- ⁷ Req.Rx (Required Treatment) 0 = No 1 = Yes
- ⁸ Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
- ⁹ Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
- ¹⁰ Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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Reboxetine Treatment Group
Day 42

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Rpt. ³	Pre-Std. ⁴	Onset Date		Dur. ⁵ (dys)	Sev. ⁶	Req. Rx. ⁷	Out-come ⁸	Rel. To Meds. ⁹	Course ¹⁰
						dy	mo yr						
31	2	2	sexual disturb.	.	.	12	24 89	7	0	1	.	2	1
84	3	4	blurred vision	0	1	10	31 89	18	0	1	0	3	1
91	3	4	constipation	0	1	11	21 89	30	0	1	0	3	0
92	3	4	sexual disturb.	1	1	11	19 89	37	0	1	0	3	5
121	3	4	sexual disturb.	0	1	4	16 89	39	0	0	.	3	.
121	3	4	decr.appetite	1	1	4	21 89	35	0	0	.	2	.
121	3	4	sweating	1	1	4	17 89	38	0	0	.	3	.

Placebo Treatment Group
Day 42

Pat. No.	Ctr. No.	Rater No.	Adverse Effect	Severity ³	Report ⁴
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No newly observed signs and symptoms reported for PBO patients at Day 42.

- ¹ Ctr. (Center) 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
- ² Rater (Assessor) 1 = Beauclair 2 = Mirmiran 3 = Song 4 = Nardi
- ³ Rpt. (Reported) 0 = Spontaneously 1 = Upon Inquiry
- ⁴ Pre-Std. (Pre-Study) 0 = No 1 = Yes
- ⁵ Dur (Duration of Symptom in days)
- ⁶ Severity 0 = Mild 1 = Moderate 2 = Severe
- ⁷ Req.Rx (Required Treatment) 0 = No 1 = Yes
- ⁸ Outcome 0 = Fully Recovered 1 = Recovered with Sequelae
- ⁹ Rel.To.Meds. (Relationship to Medication) 0 = Unknown 1 = Possible/Doubtful 2 = Probable 3 = Certain
- ¹⁰ Course 0 = Cleared 1 = Persisted 2 = Cleared/Dose Lowered 3 = Persisted/Dose Lowered
4 = Trial Drug Temporarily Stop 5 = Trial Drug Permanently Stopped

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ENCLOSURE 28

**Experimental Cohort:
Vital Signs in the Two Treatment Groups**

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Reboxetine Treatment Group
Baseline (Period 00)

Pat. No.	Per. (dy)	Prior to Morning Dose:					
		Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
1	00	160	80	111	152	76	95
17	00	108	62	66	106	58	70
31	00	148	102	110	140	108	114
32	00	114	58	60	100	74	78
46	00	106	66	84	104	64	120
47	00	130	80	100	120	82	120
81	00	130	80	74	130	75	72
84	00	135	85	72	130	80	70
86	00	120	80	64	120	75	66
89	00	115	75	62	110	70	60
90	00	115	75	60	120	75	62
91	00	130	90	72	125	80	75
92	00	115	75	64	120	80	60
95	00	120	80	72	120	70	74
97	00	120	75	74	115	75	72
98	00	105	65	62	100	60	64
121	00	120	85	72	120	80	74
122	00	130	90	80	130	85	82
125	00	130	85	78	130	85	80
127	00	135	85	76	130	80	77
128	00	140	100	83	140	95	82
131	00	130	85	78	130	80	81
143	00	135	90	74	130	90	76
144	00	120	75	74	120	70	76
145	00	110	65	64	105	60	65
148	00	110	70	66	115	65	68
149	00	100	70	62	105	65	64
153	00	130	80	82	130	75	80

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Reboxetine Treatment Group
Period (Day 01)

Pat. No.	(dy)	Prior to Morning Dose:						Prior to Evening Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart			Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
1	01	158	76	97	160	82	95	170	90	100	150	100	.
17	01	122	72	76	116	64	72	140	96	80	110	70	76
31	01	146	102	100	132	110	110	150	106	100	134	108	108
32	01	116	60	60	104	72	76	126	56	60	110	74	90
46	01	112	60	96	110	64	120	110	60	90	106	64	120
47	01	130	80	100	128	82	120	130	78	100	134	86	120
81	01	130	85	72	125	85	70	135	85	74	130	85	73
84	01	135	90	70	130	80	74	130	85	76	130	80	78
86	01	120	85	72	115	80	74	125	85	68	120	80	70
89	01	115	75	72	120	80	76	115	80	74	120	80	76
90	01	115	75	64	120	75	66	115	75	60	115	70	61
91	01	130	80	68	120	80	70	130	85	64	125	85	62
92	01	120	80	68	115	75	66	125	80	72	120	70	72
95	01	125	75	66	120	70	70	120	80	74	110	75	76
97	01	115	70	64	110	60	66	120	70	68	110	60	70
98	01	105	60	72	110	60	70	105	65	74	110	60	72
121	01	125	85	72	125	75	72	120	82	75	115	75	74
122	01	125	85	76	115	75	74	125	90	72	120	85	70
125	01	120	80	76	115	75	80	115	80	74	120	75	78
127	01	130	85	78	130	80	77	130	85	72	125	85	74
128	01	140	95	80	135	85	82	135	90	78	125	85	81
131	01	140	90	68	135	85	70	130	80	66	120	75	68
143	01	140	90	72	140	85	73	140	85	78	135	85	80
144	01	120	80	72	115	75	73	115	75	74	115	80	76
145	01	115	65	72	115	70	76	115	60	73	110	55	71
148	01	110	70	62	105	60	62	105	70	64	105	60	65
149	01	110	75	66	110	70	68	110	75	70	105	70	67
153	01	135	80	72	125	70	70	130	75	76	120	70	76

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Reboxetine Treatment Group
Period (Day 02)

Pat. No.	(dy)	Prior to Morning Dose:						Prior to Evening Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart			Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
1	02	168	84	92	158	90	96	162	94	84	158	90	88
17	02	138	82	84	118	74	92	120	60	76	112	60	60
31	02	144	108	100	130	108	110	140	102	96	130	100	108
32	02	130	60	60	108	76	92	126	80	58	106	84	100
46	02	104	62	90	100	70	120	110	62	90	100	70	123
47	02	130	84	90	100	80	110	134	80	91	110	80	110
81	02	135	85	74	135	80	75	135	80	76	130	75	78
84	02	130	90	74	135	85	72	130	85	72	130	80	73
86	02	115	80	74	115	75	76	120	80	66	125	80	66
89	02	120	75	66	115	70	68	120	80	72	120	75	70
90	02	120	75	64	115	70	66	115	75	62	110	70	60
91	02	125	85	67	130	90	69	130	85	69	120	75	71
92	02	120	85	74	110	80	72	125	85	76	120	80	74
95	02	120	80	76	110	70	78	115	75	78	115	70	74
97	02	115	75	72	110	70	74	120	70	76	110	75	75
98	02	110	60	72	105	65	71	110	65	66	110	60	64
121	02	120	75	76	125	70	74	125	80	68	115	70	66
122	02	130	85	70	120	80	68	125	80	68	120	75	68
125	02	115	75	72	110	65	73	115	80	70	115	75	72
127	02	125	85	70	125	85	72	125	80	74	125	75	72
128	02	135	95	77	130	90	79	140	90	84	130	85	82
131	02	125	85	72	120	80	70	125	85	70	125	75	74
143	02	130	85	80	130	80	78	130	90	84	125	85	84
144	02	120	75	72	115	70	76	120	75	72	115	75	70
145	02	115	60	66	115	65	68	120	70	66	115	65	67
148	02	110	65	64	100	60	66	115	75	60	105	70	62
149	02	115	75	61	110	70	63	110	75	59	100	70	61
153	02	130	80	66	120	75	68	120	75	68	115	70	65

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Reboxetine Treatment Group
Period (Day 03)

Pat. No.	(dy)	Prior to Morning Dose:						Prior to Evening Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart			Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
1	03	150	82	96	140	80	82	150	100	112	130	90	.
17	03	128	66	88	104	72	94	130	100	80	110	70	80
31	03	152	112	100	130	108	116	148	110	94	130	108	110
32	03	112	60	66	96	76	100	132	60	60	108	76	98
46	03	108	60	105	100	70	125	110	68	90	90	60	125
47	03	146	90	100	90	58	110	166	96	100	90	70	112
81	03	130	85	74	125	80	72	125	80	74	130	80	74
84	03	130	85	74	135	80	72	130	90	72	125	85	75
86	03	125	85	72	115	80	72	120	85	76	120	80	78
89	03	120	75	70	115	70	68	120	80	72	125	80	72
90	03	120	80	62	110	75	66	115	75	64	115	70	66
91	03	130	85	74	125	80	78	125	85	70	130	90	76
92	03	120	80	72	115	70	76	115	75	68	120	70	72
95	03	120	75	72	115	75	74	120	80	78	115	70	76
97	03	115	75	72	120	70	74	115	80	74	110	70	72
98	03	110	65	64	105	65	62	105	65	66	110	65	66
121	03	120	75	70	115	65	66	120	75	74	115	70	74
122	03	125	85	74	120	75	70	125	80	70	125	70	69
125	03	115	70	76	110	65	76	115	75	74	110	65	72
127	03	130	90	72	125	80	72	130	85	74	125	80	72
128	03	135	85	76	125	90	79	135	90	72	135	90	75
131	03	135	85	74	130	80	72	130	90	76	120	82	77
143	03	135	85	74	130	85	74	130	80	78	130	85	80
144	03	125	75	68	120	70	70	100	80	66	100	75	70
145	03	120	65	62	115	60	64	115	65	67	120	65	69
148	03	110	70	60	100	65	62	105	70	58	100	65	62
149	03	115	75	70	105	65	68	110	75	62	100	70	60
153	03	125	75	68	120	70	67	120	75	60	110	70	64

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Reboxetine Treatment Group
Period (Day 04)

Pat. No.	(dy)	Prior to Morning Dose:						Prior to Evening Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart			Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
1	04	142	94	96	124	80	108	150	90	84	130	80	.
17	04	128	82	84	102	64	76	140	100	80	140	90	80
31	04	148	112	100	128	108	108	150	110	100	130	110	110
32	04	130	66	74	112	76	110	126	80	58	106	84	100
46	04	106	64	100	100	70	120
47	04	150	110	100	110	50	110	110	84	93	80	50	107
81	04	125	85	78	120	85	76	125	80	74	130	80	76
84	04	130	85	72	125	85	74	130	85	74	125	80	76
86	04	120	80	72	120	85	74	125	85	64	120	80	66
89	04	115	75	66	115	70	67	115	80	74	115	75	72
90	04	120	75	72	115	70	68	115	70	66	110	70	68
91	04	125	85	82	130	90	80	130	85	74	125	80	76
92	04	125	80	70	120	70	68	120	80	66	115	75	70
95	04	110	70	78	115	75	80	115	75	68	120	85	72
97	04	110	70	80	110	60	76	115	70	78	110	60	80
98	04	105	65	68	110	65	65	110	70	64	105	65	62
121	04	115	75	66	110	70	68	115	80	70	110	70	73
122	04	120	80	75	115	75	80	120	85	77	120	80	80
125	04	120	75	72	110	65	70	115	75	74	115	65	76
127	04	125	85	74	120	80	76	130	90	72	125	85	74
128	04	140	90	78	130	80	76	140	90	81	135	80	80
131	04	130	80	72	120	75	75	125	85	78	120	80	80
143	04	135	90	76	130	90	79	130	85	76	125	80	74
144	04	125	80	70	120	75	73	100	85	71	120	80	73
145	04	115	65	69	110	60	70	120	70	70	115	75	68
148	04	110	75	62	100	65	60	105	75	60	100	70	61
149	04	115	75	68	110	70	66	110	75	60	105	70	58
153	04	130	75	72	125	70	69	125	75	66	120	70	68

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Reboxetine Treatment Group
Period (Day 05)

Pat. No.	Per. (dy)	Prior to Morning Dose:					
		Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
1	05	130	98	100	122	98	.
17	05	138	70	96	120	90	108
31	05	150	108	98	132	110	114
32	05	112	70	60	106	80	102
46	05
47	05	124	80	96	96	80	118
81	05	130	80	68	125	80	72
84	05	125	85	74	130	85	72
86	05	125	85	70	120	80	68
89	05	115	80	74	120	80	76
90	05	115	75	68	110	70	70
91	05	125	85	76	120	85	72
92	05	120	80	76	120	70	75
95	05	120	80	80	120	80	76
97	05	120	75	78	115	70	80
98	05	110	70	72	100	60	70
121	05	120	70	70	110	65	74
122	05	125	85	73	120	75	76
125	05	115	75	74	105	65	70
127	05	115	75	70	105	65	68
128	05	140	90	82	135	80	84
131	05	125	85	70	120	80	72
143	05	130	90	82	125	85	80
144	05	120	70	70	110	60	72
145	05	120	70	72	110	60	68
148	05	105	70	64	100	60	63
149	05	110	75	64	105	65	62
153	05	120	70	66	110	60	64

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Reboxetine Treatment Group
Period (Day 06)

Pat. No.	Per. (dy)	Prior to Morning Dose:					
		Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
1	06	148	80	104	138	80	.
17	06	140	90	104	90	70	120
31	06	152	110	100	130	108	112
32	06	112	70	58	106	80	102
46	06
47	06	150	90	84	96	72	118
81	06	130	75	74	125	75	76
84	06	130	85	76	125	85	74
86	06	120	80	62	125	80	64
89	06	120	80	68	115	75	70
90	06	115	75	66	120	80	66
91	06	130	85	74	125	85	72
92	06	125	85	80	130	80	76
95	06	120	80	72	115	80	70
97	06	115	70	76	110	60	78
98	06	110	65	70	105	60	72
121	06	115	70	68	110	65	69
122	06	130	85	66	125	80	68
125	06	110	70	72	105	65	70
127	06	115	70	68	105	65	70
128	06	135	85	80	130	80	76
131	06	125	80	76	125	75	78
143	06	130	85	74	125	85	78
144	06	115	75	70	110	70	73
145	06	115	70	68	110	60	66
148	06	105	70	68	100	60	65
149	06	110	75	65	100	65	63
153	06	115	70	72	110	65	68

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Reboxetine Treatment Group
Period (Day 07)

Pat. No.	Per. (dy)	Prior to Morning Dose:					
		Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
1	07	158	86	102	144	82	108
17	07	106	62	92	88	60	104
31	07	152	110	102	134	108	118
32	07	120	62	58	104	80	94
46	07	110	62	96	100	70	120
47	07	154	90	72	106	76	110
81	07	130	80	72	120	75	74
84	07	130	85	74	125	80	78
86	07	120	75	73	120	80	75
89	07	120	75	68	115	70	66
90	07	125	75	74	120	70	72
91	07	125	85	74	130	80	70
92	07	120	80	74	110	80	72
95	07	125	80	76	120	85	78
97	07	110	75	72	120	70	74
98	07	105	65	60	100	65	58
121	07	115	75	72	110	70	70
122	07	125	80	70	120	75	68
125	07	110	75	72	100	70	70
127	07	115	80	74	110	75	72
128	07	140	85	74	130	80	78
131	07	130	80	74	125	75	70
143	07	130	80	70	125	80	72
144	07	115	75	70	110	70	73
145	07	110	65	66	105	60	65
148	07	105	65	62	100	60	63
149	07	115	75	62	110	75	64
153	07	120	70	62	115	60	64

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Reboxetine Treatment Group
Period (Day 10)

Pat. No.	Per. (dy)	Prior to Morning Dose:			Standing Blood		
		Lying Blood Pressure/Heart Rate			Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
1	10	120	66	60	110	80	92
17	10
31	10	150	105	96	130	110	122
32	10	120	66	60	110	80	92
46	10	108	60	93	100	70	120
47	10	108	78	100	100	76	120
81	10	125	85	74	120	80	72
84	10	130	90	72	125	80	74
86	10	120	75	64	125	75	62
89	10	120	75	76	120	70	78
90	10	130	75	72	125	75	68
91	10	120	75	81	130	80	80
92	10	120	75	68	110	70	66
95	10	120	80	72	110	75	76
97	10	120	80	74	125	75	76
98	10	105	65	64	110	70	60
121	10	120	70	64	110	65	66
122	10	125	85	66	115	75	68
125	10	115	80	76	110	70	76
127	10	110	80	72	105	70	74
128	10	140	95	84	130	85	82
131	10	125	80	76	115	70	74
143	10	130	90	72	125	85	68
144	10	120	80	66	110	70	67
145	10	110	70	62	105	60	63
148	10	110	75	64	100	65	60
149	10	110	70	72	100	60	68
153	10	120	75	74	115	65	77

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Reboxetine Treatment Group
Period (Day 14)

Pat. No.	Per. (dy)	Prior to Morning Dose: Lying Blood			Standing Blood		
		Pressure/Heart Sys Dia Rate	Pressure/Heart Sys Dia Rate	Pressure/Heart Sys Dia Rate			
1	14	158	64	90	150	72	91
17	14
31	14	155	110	96	130	102	120
32	14	118	60	68	102	84	100
46	14	106	58	93	100	70	123
47	14	124	90	90	112	80	90
81	14	130	80	74	125	75	77
84	14	125	85	68	125	80	71
86	14	125	75	74	120	70	72
89	14	120	80	70	115	70	74
90	14	120	75	68	115	70	70
91	14	125	85	76	130	80	74
92	14	125	75	64	120	80	60
95	14	115	70	74	115	75	72
97	14	125	75	74	120	75	72
98	14	105	65	62	100	65	64
121	14	115	75	74	115	70	75
122	14	120	80	68	115	70	72
125	14	120	75	68	115	70	70
127	14	115	75	70	105	65	72
128	14	140	90	78	135	80	79
131	14	130	85	71	120	75	80
143	14	130	85	80	125	80	82
144	14	115	70	72	105	65	75
145	14	120	70	72	110	60	68
148	14	110	75	66	105	70	64
149	14	110	70	63	105	65	61
153	14	115	75	70	110	70	67

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Reboxetine Treatment Group
Period (Day 21)

Pat. No.	Per. (dy)	Prior to Morning Dose: Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate
1	21	140	78	100	138	80	94
17	21
31	21	150	100	84	120	100	112
32	21	108	56	74	106	82	114
46	21
47	21	150	80	87	102	80	110
81	21	130	90	74	125	85	72
84	21	130	85	72	135	90	70
86	21	120	80	76	115	80	78
89	21	120	75	64	115	70	62
90	21	120	75	72	115	70	74
91	21	125	80	64	120	80	68
92	21	120	80	74	110	70	72
95	21	120	80	76	115	75	78
97	21	120	75	70	130	75	74
98	21	115	75	64	110	70	66
121	21	115	80	70	110	75	68
122	21	125	80	68	125	75	66
125	21	120	85	70	115	75	68
127	21	115	80	78	110	75	76
128	21	140	95	83	135	85	85
131	21	130	80	74	120	75	76
143	21	130	90	70	125	85	74
144	21	110	70	72	100	60	68
145	21	115	75	70	105	70	67
148	21	110	75	62	105	65	60
149	21	105	65	60	95	60	58
153	21	115	70	64	105	60	65

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Reboxetine Treatment Group
Period (Day 28)

Pat. No.	Per. (dy)	Prior to Morning Dose:			Standing Blood		
		Lying Blood Pressure/Heart Rate			Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
1	28	148	76	94	134	74	108
17	28
31	28	150	110	100	130	105	110
32	28	118	66	68	116	84	100
46	28
47	28	140	90	81	96	70	105
81	28	130	90	74	125	85	76
84	28	135	85	66	130	85	65
86	28	125	85	76	125	80	78
89	28	120	75	68	115	70	66
90	28	125	85	76	115	80	78
91	28	120	80	72	130	75	68
92	28	120	80	82	115	75	78
95	28	115	75	70	115	80	74
97	28	120	80	76	120	80	78
98	28	105	65	70	105	60	68
121	28	115	75	68	115	70	70
122	28	130	75	70	125	75	74
125	28	115	80	72	105	70	68
127	28	115	75	72	110	70	70
128	28	140	90	83	135	85	84
131	28
143	28	125	85	76	120	85	80
144	28	110	75	66	105	65	64
145	28	110	65	72	105	55	70
148	28	110	75	62	100	65	60
149	28	105	70	65	100	60	61
153	28	115	75	62	105	65	65

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Reboxetine Treatment Group
Period (Day 35)

Pat. No.	Per. (dy)	Prior to Morning Dose:			Standing Blood		
		Lying Blood Pressure/Heart Rate			Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
1	35
17	35
31	35	130	92	98	120	102	120
32	35
46	35
47	35	156	86	80	110	80	112
81	35
84	35	130	90	74	125	85	76
86	35	130	80	74	120	80	76
89	35	120	75	66	115	70	64
90	35	120	80	72	120	70	74
91	35	130	80	62	125	80	64
92	35	120	75	74	115	80	72
95	35	120	80	72	115	75	76
97	35	120	75	68	110	75	72
98	35	105	65	64	110	65	62
121	35	120	75	76	115	70	80
122	35	125	85	74	120	80	76
125	35	120	75	78	115	70	79
127	35	110	75	74	105	70	78
128	35	145	95	86	135	90	88
131	35
143	35	125	90	72	120	85	76
144	35	110	75	70	105	70	66
145	35	115	80	72	110	70	71
148	35	115	80	64	110	70	60
149	35	110	70	60	105	60	63
153	35	120	75	73	110	70	71

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Reboxetine Treatment Group
Period (Day 42)

Pat. No.	Per. (dy)	Prior to Morning Dose:					
		Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
1	42
17	42
31	42	142	102	94	134	110	110
32	42
46	42
47	42
81	42	130	90	76	125	85	74
84	42	135	80	76	130	80	78
86	42	125	85	74	125	85	76
89	42	120	75	72	125	70	70
90	42	125	75	68	115	70	72
91	42	125	75	68	130	75	72
92	42	120	80	82	115	70	80
95	42	120	80	76	125	70	80
97	42	120	80	78	115	75	76
98	42	110	65	70	100	65	68
121	42	125	75	68	115	70	73
122	42	130	80	66	125	75	70
125	42	115	80	78	105	70	80
127	42	115	75	72	110	65	70
128	42	140	95	77	135	90	80
131	42
143	42	130	90	80	125	90	78
144	42	115	75	68	110	65	70
145	42	110	70	74	100	60	74
148	42	110	70	60	100	60	61
149	42	110	70	72	100	60	70
153	42	115	70	64	105	60	66

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Vital Signs
Reboxetine Treatment Group
Screening Period

Pat. No.	Per. (dy)	Body Temperature	Weight
1	sc	37.0	87.80
17	sc	37.2	44.00
31	sc	36.7	110.80
32	sc	36.8	80.20
46	sc	37.0	48.60
47	sc	37.2	53.10
81	sc	36.4	50.00
84	sc	36.6	42.00
86	sc	36.6	74.00
89	sc	36.4	75.00
90	sc	36.4	52.00
91	sc	36.5	62.00
92	sc	36.6	55.00
95	sc	36.5	63.00
97	sc	36.5	58.00
98	sc	36.5	51.00
121	sc	36.6	75.00
122	sc	36.7	82.00
125	sc	36.5	70.00
127	sc	36.8	63.00
128	sc	36.6	77.00
131	sc	36.8	55.00
143	sc	36.5	52.00
144	sc	36.7	68.00
145	sc	36.7	71.00
148	sc	36.6	60.00
149	sc	36.5	60.00
153	sc	36.6	45.00

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Reboxetine Treatment Group
Baseline (Period 00)

Pat. No.	Per. (dy)	Body Temperature	Weight
1	00	37.0	86.10
17	00	36.8	44.00
31	00	36.7	110.50
32	00	36.8	80.40
46	00	37.0	48.40
47	00	37.2	52.60
81	00	36.6	50.00
84	00	36.6	42.00
86	00	36.6	73.00
89	00	36.4	74.00
90	00	36.6	52.00
91	00	36.6	61.00
92	00	36.6	55.00
95	00	36.6	63.00
97	00	36.6	56.00
98	00	36.4	50.00
121	00	36.5	74.00
122	00	36.6	80.00
125	00	36.7	70.00
127	00	36.8	63.00
128	00	36.6	77.00
131	00	36.5	55.00
143	00	36.6	51.00
144	00	36.6	68.00
145	00	36.6	70.00
148	00	36.6	60.00
149	00	36.6	60.00
153	00	36.5	45.00

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Reboxetine Treatment Group
Period Day 07

Pat. No.	Per. (dy)	Body Temperature	Weight
1	07	36.8	85.80
17	07	36.8	44.00
31	07	36.7	109.00
32	07	36.6	78.20
46	07	37.2	47.40
47	07	37.1	52.40
81	07	36.5	50.00
84	07	36.6	43.00
86	07	36.5	72.00
89	07	36.5	75.00
90	07	36.5	52.00
91	07	36.5	60.00
92	07	36.5	55.00
95	07	36.6	63.00
97	07	36.7	56.00
98	07	36.7	50.00
121	07	36.6	73.00
122	07	36.6	78.00
125	07	36.7	69.00
127	07	36.5	62.00
128	07	36.5	77.00
131	07	36.5	53.00
143	07	36.6	51.00
144	07	36.5	68.00
145	07	36.6	68.00
148	07	36.6	60.00
149	07	36.5	60.00
153	07	36.5	43.00

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Reboxetine Treatment Group
Period Day 14

Pat. No.	Per. (dy)	Body Temperature	Weight
1	14	36.8	85.00
17	14	.	.
31	14	36.8	107.80
32	14	36.7	78.30
46	14	37.1	48.30
47	14	37.2	52.00
81	14	36.5	51.00
84	14	36.5	44.00
86	14	36.5	72.00
89	14	36.6	75.00
90	14	36.5	53.00
91	14	36.5	61.00
92	14	36.5	54.00
95	14	36.4	64.00
97	14	36.4	57.00
98	14	36.6	51.00
121	14	36.6	72.00
122	14	36.5	79.00
125	14	36.8	71.00
127	14	36.4	61.00
128	14	36.5	78.00
131	14	36.5	52.00
143	14	36.6	52.00
144	14	36.6	69.00
145	14	36.6	68.00
148	14	36.6	61.00
149	14	36.5	58.00
153	14	36.5	42.00

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Reboxetine Treatment Group
Period Day 21

Pat. No.	Per. (dy)	Body Temperature	Weight
1	21	36.8	84.50
17	21	.	.
31	21	36.8	108.50
32	21	36.6	78.70
46	21	.	.
47	21	37.0	52.60
81	21	36.4	51.00
84	21	36.5	44.00
86	21	36.4	73.00
89	21	36.5	75.00
90	21	36.4	54.00
91	21	36.5	62.00
92	21	36.6	52.50
95	21	36.5	63.50
97	21	36.6	57.00
98	21	36.5	52.00
121	21	36.6	71.00
122	21	36.5	80.00
125	21	36.8	72.00
127	21	36.6	62.00
128	21	36.5	79.00
131	21	36.6	52.00
143	21	36.6	53.00
144	21	36.5	69.00
145	21	36.6	69.00
148	21	36.6	62.00
149	21	36.6	57.00
153	21	36.6	43.00

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Reboxetine Treatment Group
Period Day 28

Pat. No.	Per. (dy)	Body Temperature	Weight
1	28	37.0	85.50
17	28	.	.
31	28	36.7	109.00
32	28	36.6	75.80
46	28	.	.
47	28	37.0	53.60
81	28	36.4	51.00
84	28	36.5	45.00
86	28	36.3	73.00
89	28	36.5	76.00
90	28	36.6	54.00
91	28	36.6	63.00
92	28	36.3	51.00
95	28	36.7	63.00
97	28	36.5	58.00
98	28	36.6	52.00
121	28	36.7	70.00
122	28	36.6	80.00
125	28	36.7	72.00
127	28	36.5	62.00
128	28	36.5	79.00
131	28	.	.
143	28	36.5	53.00
144	28	36.6	70.00
145	28	36.6	70.00
148	28	36.5	62.00
149	28	36.6	57.00
153	28	36.5	44.00

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Reboxetine Treatment Group
Period Day 35

Pat. No.	Per. (dy)	Body Temperature	Weight
1	35	.	.
17	35	.	.
31	35	36.8	110.30
32	35	.	.
46	35	.	.
47	35	37.0	53.80
81	35	.	.
84	35	36.6	45.00
86	35	36.5	74.00
89	35	36.5	76.00
90	35	36.5	54.00
91	35	36.7	63.00
92	35	36.5	51.00
95	35	36.5	63.50
97	35	36.5	58.00
98	35	36.5	52.00
121	35	36.7	69.00
122	35	36.7	81.00
125	35	36.8	73.00
127	35	36.5	63.00
128	35	36.5	80.00
131	35	.	.
143	35	36.5	53.00
144	35	36.6	70.00
145	35	36.6	70.00
148	35	36.5	62.00
149	35	36.5	56.00
153	35	36.6	45.00

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Reboxetine Treatment Group
Period Day 42

Pat. No.	Per. (dy)	Body Temperature	Weight
1	42	.	.
17	42	.	.
31	42	36.7	111.70
32	42	.	.
46	42	.	.
47	42	.	.
81	42	36.4	52.00
84	42	36.5	45.00
86	42	36.4	74.00
89	42	36.6	76.00
90	42	36.5	55.00
91	42	36.5	63.00
92	42	36.3	52.00
95	42	36.6	64.00
97	42	36.5	58.00
98	42	36.5	52.00
121	42	36.6	68.00
122	42	36.6	82.00
125	42	36.7	73.00
127	42	36.6	63.00
128	42	36.5	80.00
131	42	.	.
143	42	36.6	53.00
144	42	36.5	71.00
145	42	36.6	71.00
148	42	36.5	62.00
149	42	36.5	57.00
153	42	36.6	45.00

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Vital Signs
 Placebo Treatment Group
 Screening Period

Pat. No.	Per. (dy)	Prior to Morning Dose:			Standing Blood		
		Lying Blood Pressure/Heart			Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate
2	sc	165	88	112	166	90	106
16	sc	118	70	105	105	70	103
33	sc	116	66	72	114	80	88
34	sc	116	88	84	122	94	90
35	sc	156	88	90	150	100	100
48	sc	120	60	70	94	58	90
82	sc	120	75	80	175	70	78
83	sc	110	70	64	110	60	66
85	sc	110	75	62	110	70	64
87	sc	110	70	72	105	65	69
88	sc	115	75	76	110	70	74
93	sc	125	75	80	130	80	78
94	sc	110	70	64	110	65	66
96	sc	110	70	68	100	60	66
99	sc	120	70	68	120	60	66
100	sc	120	75	72	110	65	68
123	sc	130	80	74	125	80	75
124	sc	120	85	74	115	80	78
126	sc	115	75	84	120	85	86
129	sc	120	80	72	120	70	74
130	sc	125	85	68	120	75	72
133	sc	130	75	78	130	80	80
141	sc	110	70	68	115	75	71
142	sc	125	75	76	120	75	78
146	sc	115	75	90	110	75	86
147	sc	100	65	64	100	60	66
150	sc	115	75	60	115	70	64
151	sc	125	80	72	120	75	70

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Placebo Treatment Group
Baseline (Period 00)

Pat. No.	Per. (dy)	Prior to Morning Dose:			Standing Blood		
		Lying Blood Pressure/Heart			Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate
2	00	170	90	99	154	80	98
16	00	112	62	96	108	60	95
33	00	124	76	62	118	60	78
34	00	120	88	84	122	94	90
35	00	182	90	90	182	100	96
48	00	112	56	78	100	66	80
82	00	120	80	78	115	80	76
83	00	110	70	64	110	65	66
85	00	110	70	60	110	65	62
87	00	110	75	76	105	65	78
88	00	110	70	64	110	70	66
93	00	130	80	84	130	75	86
94	00	105	70	62	100	60	64
96	00	110	70	64	115	80	66
99	00	120	70	68	120	75	66
100	00	115	75	72	120	80	70
123	00	130	90	86	130	85	88
124	00	120	80	76	120	75	74
126	00	125	90	86	125	85	90
129	00	120	75	70	115	75	71
130	00	120	80	66	115	75	68
133	00	130	80	72	125	75	76
141	00	110	70	74	110	75	72
142	00	120	75	82	115	80	84
146	00	110	70	88	110	75	87
147	00	100	60	70	100	65	68
150	00	120	80	60	115	80	62
151	00	115	75	60	125	75	62

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Placebo Treatment Group
Period Day (01)

Pat. No.	(dy)	Prior to Morning Dose:						Prior to Evening Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart			Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
2	01	160	88	130	.	.	.	140	82	96	124	80	104
16	01	128	74	124	108	78	.	120	75	88	120	80	92
33	01	124	76	62	118	60	78	122	76	68	114	62	74
34	01	134	88	84	140	94	90	120	84	84	130	90	90
35	01	172	90	80	164	100	95	170	90	81	160	100	93
48	01	110	70	62	118	80	90	120	80	62	120	88	90
82	01	125	80	76	120	75	80	120	80	82	120	75	74
83	01	105	65	60	110	65	63	110	65	62	110	60	64
85	01	115	75	62	110	75	64	110	75	60	110	75	58
87	01	115	75	78	110	75	76	115	75	74	115	70	76
88	01	105	70	62	105	65	64	110	70	58	105	65	60
93	01	110	70	86	120	80	82	120	75	84	125	80	84
94	01	125	85	76	130	85	74	115	75	76	120	80	78
96	01	110	75	60	105	70	62	110	65	72	115	70	72
99	01	120	70	72	125	70	74	115	70	68	120	70	70
100	01	120	75	60	115	75	64	120	75	68	120	70	66
123	01	125	85	82	125	80	84	120	80	78	120	80	79
124	01	125	85	72	120	85	75	125	80	73	120	75	75
126	01	130	90	85	125	85	83	125	85	79	125	80	82
129	01	120	80	70	120	70	74	120	80	68	120	80	67
130	01	120	85	70	120	90	68	120	80	84	115	80	82
133	01	130	85	60	130	80	63	130	80	64	135	85	62
141	01	120	80	70	115	75	74	115	80	68	115	75	73
142	01	115	75	80	120	70	84	115	70	76	115	75	79
146	01	115	75	84	110	70	86	115	75	82	110	75	83
147	01	105	65	72	100	60	74	105	60	66	110	60	64
150	01	125	85	64	120	80	66	120	85	62	115	80	61
151	01	115	80	70	115	85	72	120	75	62	120	70	63

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Placebo Treatment Group
Period Day (02)

Pat. No.	(dy)	Prior to Morning Dose:						Prior to Evening Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart			Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
2	02	184	100	98	180	105	103	140	82	96	124	80	104
16	02	120	80	112	106	78	.	130	80	100	120	80	.
33	02	122	74	72	118	80	100	118	74	68	112	78	96
34	02	132	88	84	136	92	90	126	86	82	134	94	93
35	02	160	90	81	150	96	100	170	92	78	162	96	96
48	02	120	76	66	118	80	90	110	62	63	114	84	90
82	02	125	85	78	120	85	80	120	75	84	120	80	84
83	02	110	60	64	115	60	66	105	65	68	105	60	67
85	02	110	70	64	115	70	62	110	70	58	110	75	60
87	02	110	75	76	110	70	74	115	75	80	110	70	78
88	02	110	70	62	105	70	64	110	65	64	110	60	66
93	02	125	80	80	130	85	79	125	85	81	130	90	77
94	02	110	75	66	115	75	64	115	75	62	110	70	64
96	02	115	75	62	110	70	62	120	70	64	110	60	66
99	02	125	75	72	120	70	70	115	75	70	120	80	72
100	02	115	75	72	115	70	72	120	75	76	125	70	78
123	02	130	85	76	130	80	74	125	80	81	130	85	84
124	02	125	80	70	120	75	72	120	75	68	120	80	71
126	02	125	80	78	120	85	83	125	85	78	130	85	80
129	02	120	80	73	115	80	71	120	75	72	120	80	74
130	02	120	75	78	115	70	82	115	75	76	120	80	77
133	02	135	85	60	130	80	62	130	85	61	125	85	60
141	02	120	75	73	115	80	76	120	80	66	120	75	70
142	02	120	80	78	120	85	81	115	80	75	120	85	80
146	02	110	70	80	115	70	82	115	75	79	120	70	81
147	02	110	65	70	100	60	68	105	60	62	105	55	63
150	02	120	80	64	115	75	62	125	85	66	125	80	68
151	02	120	75	58	120	80	60	115	75	62	115	80	61

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Placebo Treatment Group
Period Day (03)

Pat. No.	(dy)	Prior to Morning Dose:						Prior to Evening Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart			Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
2	03	175	90	97	160	80	96
16	03	122	60	120	118	80	.	115	85	88	115	85	.
33	03	124	68	76	118	78	100	118	68	68	116	76	90
34	03	130	80	84	134	88	96	140	96	84	142	100	90
35	03	174	88	86	150	98	101	156	90	84	156	100	93
48	03	124	60	66	110	76	90	120	70	87	132	90	100
82	03	120	75	82	120	70	80	125	80	82	120	80	84
83	03	110	60	64	115	60	62	115	65	62	110	60	63
85	03	110	70	62	115	70	64	115	70	64	110	65	60
87	03	110	75	76	115	75	74	115	75	76	110	75	78
88	03	110	70	70	110	60	68	110	70	62	110	65	63
93	03	130	85	82	135	85	80	130	80	84	130	85	82
94	03	115	70	68	110	75	66	110	75	62	110	70	64
96	03	125	75	70	120	70	71	115	75	68	115	80	70
99	03	115	75	68	120	75	70	115	75	72	120	80	74
100	03	120	80	78	110	75	76	115	75	76	110	70	78
123	03	130	85	81	130	80	85	125	80	88	120	75	89
124	03	120	85	70	120	80	73	120	75	71	115	80	74
126	03	125	80	72	120	75	76	120	85	78	120	80	79
129	03	120	75	76	120	80	78	120	80	75	115	75	78
130	03	120	80	70	115	80	73	115	80	74	115	75	72
133	03	140	85	62	140	80	63	135	90	66	135	85	68
141	03	125	80	75	120	85	80	120	85	70	125	80	74
142	03	125	90	74	120	85	76	120	80	79	120	85	81
146	03	115	80	78	115	70	82	120	80	86	125	85	89
147	03	110	65	74	100	60	73	105	65	72	100	60	70
150	03	120	80	66	115	80	64	125	80	62	125	75	63
151	03	115	80	62	120	80	63	120	80	62	115	75	64

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Placebo Treatment Group
Period Day (04)

Pat. No.	(dy)	Prior to Morning Dose:						Prior to Evening Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart			Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
2	04	146	94	91	140	86	104	140	88	96	130	88	96
16	04	132	78	85	128	74	90	115	80	.	110	75	.
33	04	120	70	68	116	76	92	118	68	70	114	76	92
34	04	140	86	82	142	90	89	140	80	86	142	84	90
35	04
48	04
82	04	125	75	82	120	80	84	120	75	83	120	80	84
83	04	110	60	64	110	65	66	105	65	60	110	60	62
85	04	110	75	68	110	70	66	115	75	62	110	70	60
87	04	110	70	72	105	65	74	110	75	74	110	70	74
88	04	110	70	72	105	65	69	115	75	64	110	70	62
93	04	125	85	84	125	90	82	130	85	78	125	80	80
94	04	120	75	66	110	70	64	115	75	64	110	70	65
96	04	125	80	72	120	80	69	120	70	66	115	65	68
99	04	120	80	72	110	70	76	115	75	70	120	80	68
100	04	115	80	78	120	75	76	125	75	80	120	80	78
123	04	135	85	86	135	80	88	135	80	84	130	75	85
124	04	120	75	72	115	70	75	125	75	68	120	70	72
126	04	125	75	72	130	80	76	130	90	84	125	85	85
129	04	115	75	78	110	70	80	120	75	74	115	70	78
130	04	120	70	70	125	65	68	125	75	74	120	75	76
133	04	130	90	66	135	90	70	135	85	72	135	80	68
141	04	120	85	78	115	80	80	125	80	75	120	85	76
142	04	120	75	86	120	80	87	120	80	75	120	75	72
146	04	115	80	80	115	75	81	125	85	84	120	80	86
147	04	100	70	70	90	60	71	105	70	68	105	60	70
150	04	125	85	64	120	85	65	120	80	62	120	75	63
151	04	120	75	66	120	70	68	120	75	72	115	80	73

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Placebo Treatment Group
Period (Day 05)

Pat. No.	Per. (dy)	Prior to Morning Dose: Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
2	05
16	05	124	60	97	110	64	100
33	05	122	72	68	116	78	94
34	05	122	80	82	130	86	90
35	05
48	05
82	05	125	85	82	120	85	84
83	05	110	70	64	110	60	66
85	05	115	75	60	110	75	58
87	05	115	75	70	110	70	72
88	05	110	70	74	115	70	74
93	05	125	85	82	130	90	82
94	05	110	75	62	110	70	64
96	05	110	70	64	105	75	66
99	05	120	70	74	115	75	72
100	05	120	75	76	115	80	78
123	05	130	85	70	125	80	74
124	05	120	80	73	115	75	75
126	05	130	85	88	130	80	90
129	05	120	75	80	115	65	76
130	05	120	75	72	115	70	72
133	05	130	90	65	125	85	67
141	05	120	75	68	125	80	73
142	05	120	75	81	120	80	84
146	05	120	85	82	115	75	84
147	05	105	70	62	100	65	60
150	05	120	80	60	115	75	58
151	05	120	75	54	115	70	58

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Placebo Treatment Group
Period (Day 06)

Pat. No.	Per. (dy)	Prior to Morning Dose:			Standing Blood		
		Lying Blood Pressure/Heart			Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate
2	06
16	06	110	58	88	.	.	.
33	06	118	70	70	114	76	92
34	06	130	80	89	128	90	96
35	06
48	06	110	60	66	120	82	90
82	06	120	80	80	125	75	84
83	06	110	65	66	105	60	63
85	06	120	70	64	110	70	60
87	06	110	75	72	105	75	70
88	06	110	75	72	110	70	70
93	06	130	90	84	130	85	82
94	06	110	70	64	115	75	62
96	06	110	70	64	115	65	62
99	06	120	70	66	115	70	68
100	06	115	80	76	110	70	78
123	06	140	90	78	140	85	80
124	06	125	80	66	125	85	70
126	06	125	85	80	125	80	84
129	06	120	70	78	115	65	76
130	06	120	80	68	115	75	70
133	06	140	90	72	145	85	72
141	06	125	85	80	120	85	78
142	06	125	85	82	125	80	83
146	06	120	75	78	120	80	79
147	06	105	70	66	105	65	68
150	06	120	75	62	120	70	63
151	06	115	75	56	115	70	58

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Placebo Treatment Group
Period (Day 07)

Pat. No.	Per. (dy)	Prior to Morning Dose:			Dose:		
		Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
2	07
16	07	110	58	88	.	.	.
33	07	110	76	74	116	80	88
34	07	128	78	78	120	97	93
35	07	144	86	78	150	96	99
48	07	120	66	60	116	82	90
82	07	125	75	76	120	75	78
83	07	115	65	64	110	65	62
85	07	110	65	62	110	60	64
87	07	110	70	74	110	65	72
88	07	115	75	67	110	70	69
93	07	130	75	84	135	80	82
94	07	110	70	60	105	70	58
96	07	115	70	62	110	70	60
99	07	120	70	76	115	75	78
100	07	115	80	76	115	75	80
123	07	125	85	78	125	90	82
124	07	115	75	74	115	70	75
126	07	135	90	80	130	90	78
129	07	125	80	76	125	75	74
130	07	115	75	80	115	70	82
133	07	130	85	70	135	85	72
141	07	130	80	70	125	80	71
142	07	120	80	86	120	75	82
146	07	115	75	84	110	70	85
147	07	110	60	76	100	65	78
150	07	120	75	68	115	70	71
151	07	115	70	56	110	70	57

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Placebo Treatment Group.
Period (Day 10)

Pat. No.	Per. (dy)	Prior to Morning Lying Blood			Dose: Standing Blood		
		Pressure/Sys	Heart/Dia	Rate	Pressure/Sys	Heart/Dia	Rate
2	10
16	10
33	10	116	72	70	118	82	88
34	10	120	80	75	112	90	78
35	10	160	80	90	150	90	108
48	10	104	60	70	106	80	100
82	10	120	80	72	125	75	74
83	10	110	70	72	105	60	70
85	10	110	70	72	110	65	70
87	10	115	80	70	110	80	74
88	10	110	75	62	110	70	64
93	10	130	90	84	125	80	86
94	10	115	75	62	110	70	60
96	10	115	75	66	110	70	65
99	10	120	70	64	110	65	66
100	10	120	80	82	110	70	78
123	10	130	80	82	130	75	84
124	10	115	80	74	120	80	72
126	10	135	85	78	130	80	85
129	10	120	75	74	120	65	72
130	10	125	80	70	120	75	69
133	10	130	80	64	130	75	66
141	10	125	75	76	120	80	74
142	10	125	85	82	125	90	84
146	10	115	80	83	110	80	85
147	10	110	70	60	100	60	64
150	10	120	70	64	115	70	60
151	10	120	75	56	110	80	54

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Placebo Treatment Group
Period (Day 14)

Pat. No.	Per. (dy)	Prior to Morning Dose:					
		Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
2	14
16	14
33	14	130	85	80	120	80	100
34	14	124	88	75	132	88	90
35	14	150	88	84	148	100	102
48	14	108	60	70	118	78	90
82	14	120	75	78	120	70	80
83	14	115	65	60	110	60	64
85	14	110	70	68	110	65	66
87	14	115	75	72	115	70	70
88	14	110	70	72	105	65	74
93	14	130	85	88	125	90	86
94	14	115	75	64	110	70	62
96	14	115	75	60	110	70	60
99	14	115	75	64	110	70	62
100	14	125	80	76	120	75	74
123	14	125	85	84	125	90	85
124	14	120	80	74	120	75	76
126	14	130	85	80	130	80	81
129	14	125	75	78	120	70	79
130	14	120	80	79	115	70	84
133	14	140	75	70	135	80	74
141	14	120	70	72	125	70	75
142	14	120	80	70	125	75	68
146	14	110	70	72	110	75	74
147	14	110	70	65	105	65	67
150	14	110	75	68	115	75	72
151	14	110	75	58	115	75	60

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Placebo Treatment Group
Period (Day 21)

Pat. No.	Per. (dy)	Prior to Morning Dose:			Lying Blood			Standing Blood		
		Pressure/Sys	Heart/Dia	Rate	Pressure/Sys	Heart/Dia	Rate	Pressure/Sys	Heart/Dia	Rate
2	21
16	21
33	21
34	21
35	21	148	84	96	146	96	102			
48	21	112	70	66	114	88	81			
82	21	120	75	80	115	80	82			
83	21	115	75	72	110	70	70			
85	21	110	70	64	110	60	66			
87	21	115	80	72	120	80	68			
88	21	110	70	64	115	70	62			
93	21	130	85	76	125	85	80			
94	21	105	70	62	110	65	60			
96	21	110	70	58	105	60	60			
99	21	115	80	64	120	75	60			
100	21	120	75	72	115	75	74			
123	21	130	85	78	130	80	82			
124	21	125	75	80	120	75	86			
126	21	130	80	75	125	80	76			
129	21	120	75	70	120	70	72			
130	21	125	80	68	115	75	73			
133	21	130	85	70	125	80	72			
141	21	130	80	82	125	75	86			
142	21	115	75	82	120	75	83			
146	21	125	85	72	125	80	76			
147	21	110	70	66	105	65	68			
150	21	120	80	66	115	75	68			
151	21	115	75	58	115	70	60			

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Placebo Treatment Group
Period (Day 28)

Pat. No.	Per. (dy)	Prior to Morning Dose:					
		Lying Blood Pressure/Heart Rate			Standing Blood Pressure/Heart Rate		
		Sys	Dia	Rate	Sys	Dia	Rate
2	28
16	28
33	28
34	28
35	28
48	28	112	66	64	118	80	81
82	28
83	28	115	75	66	110	75	68
85	28
87	28
88	28	115	75	60	110	70	62
93	28	130	85	84	125	80	82
94	28
96	28	120	70	68	115	75	70
99	28
100	28
123	28	125	90	84	125	85	86
124	28	115	80	82	115	75	85
126	28	130	85	88	120	80	92
129	28
130	28
133	28
141	28	120	75	70	115	70	76
142	28
146	28
147	28
150	28	125	85	68	120	85	71
151	28

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Placebo Treatment Group
Period (Day 35)

Pat. No.	Per. (dy)	Prior to Morning Dose:					
		Lying Blood Pressure/Heart			Standing Blood Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate
2	35
16	35
33	35
34	35
35	35
48	35	110	62	70	100	76	78
82	35
83	35	115	70	62	110	65	64
85	35
87	35
88	35	110	75	64	115	70	66
93	35	130	90	76	120	80	82
94	35
96	35	115	80	72	105	70	72
99	35
100	35
123	35	125	85	84	120	80	86
124	35	120	85	66	125	80	70
126	35	125	85	82	125	80	83
129	35
130	35
133	35
141	35	120	75	70	110	70	76
142	35
146	35
147	35
150	35	125	85	72	125	90	70
151	35

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Placebo Treatment Group
Period (Day 42)

Pat. No.	Per. (dy)	Prior to Morning Dose:			Lying Blood			Standing Blood		
		Pressure/Heart			Pressure/Heart			Pressure/Heart		
		Sys	Dia	Rate	Sys	Dia	Rate	Sys	Dia	Rate
2	4
16	42
33	42
34	42
35	4
48	42	108	60	70	100	72	76	.	.	.
82	42
83	42	115	75	64	115	70	65	.	.	.
85	42
87	42
88	42	115	75	62	110	70	64	.	.	.
93	42	135	85	84	130	90	86	.	.	.
94	42
96	42	120	70	66	110	70	64	.	.	.
99	42
100	42
123	42	130	85	76	135	80	79	.	.	.
124	42	120	75	78	115	70	80	.	.	.
126	42	130	80	76	125	75	80	.	.	.
129	42
130	42
133	42
141	42	125	80	76	120	85	80	.	.	.
142	42
146	42
147	42
150	42	120	85	66	120	80	67	.	.	.
151	42

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Vital Signs
Placebo Treatment Group
Screening Period

Pat. No.	Per. (dy)	Body Temperature	Weight
2	sc	36.4	64.30
16	sc	36.6	37.50
33	sc	36.6	85.00
34	sc	37.0	80.40
35	sc	37.0	73.00
48	sc	37.2	57.50
82	sc	36.5	78.00
83	sc	36.4	58.00
85	sc	36.6	59.00
87	sc	36.4	51.00
88	sc	36.4	59.00
93	sc	36.4	72.00
94	sc	36.5	60.00
96	sc	36.5	48.00
99	sc	36.5	47.00
100	sc	36.5	62.00
123	sc	36.5	61.00
124	sc	36.7	72.00
126	sc	36.4	66.00
129	sc	36.7	77.00
130	sc	36.7	80.00
133	sc	36.8	72.00
141	sc	36.6	70.00
142	sc	36.6	56.00
146	sc	36.7	44.00
147	sc	36.5	55.00
150	sc	36.6	68.00
151	sc	36.6	58.00

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Placebo Treatment Group
Baseline (Period 00)

Pat. No.	Per. (dy)	Body Temperature	Weight
2	00	36.8	62.27
16	00	37.7	37.00
33	00	36.7	84.00
34	00	37.2	80.00
35	00	37.1	73.10
48	00	37.1	58.00
82	00	36.6	77.00
83	00	36.4	57.00
85	00	36.6	59.00
87	00	36.5	51.00
88	00	36.5	59.00
93	00	36.6	72.00
94	00	36.6	58.00
96	00	36.4	48.00
99	00	36.6	47.00
100	00	36.5	62.00
123	00	36.8	60.00
124	00	36.7	71.00
126	00	36.8	65.00
129	00	36.6	77.00
130	00	36.5	79.00
133	00	36.6	72.00
141	00	36.7	70.00
142	00	36.5	56.00
146	00	36.6	44.00
147	00	36.5	53.00
150	00	36.5	68.00
151	00	36.7	58.00

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Placebo Treatment Group
Period Day 07

Pat. No.	Per. (dy)	Body Temperature	Weight
2	07	.	.
16	07	37.0	35.70
33	07	36.6	84.50
34	07	36.8	80.10
35	07	37.6	72.40
48	07	36.8	58.80
82	07	36.5	76.00
83	07	36.5	57.00
85	07	36.4	59.00
87	07	36.5	50.00
88	07	36.5	58.00
93	07	36.5	72.00
94	07	36.4	57.00
96	07	36.5	47.00
99	07	36.5	46.00
100	07	36.7	61.00
123	07	.	.
124	07	36.7	71.00
126	07	36.8	65.00
129	07	36.6	75.00
130	07	36.6	78.00
133	07	36.7	72.00
141	07	36.8	71.00
142	07	36.8	55.00
146	07	36.6	42.00
147	07	36.5	53.00
150	07	36.6	66.00
151	07	36.6	58.00

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Placebo Treatment Group
Period Day 14

Pat. No.	Per. (dy)	Body Temperature	Weight
2	14	.	.
16	14	.	.
33	14	36.8	83.00
34	14	36.9	80.60
35	14	37.1	73.10
48	14	37.0	58.70
82	14	36.5	75.00
83	14	36.3	54.00
85	14	36.5	59.00
87	14	36.4	49.00
88	14	36.5	59.00
93	14	36.5	72.00
94	14	36.5	57.00
96	14	36.5	48.00
99	14	36.5	45.00
100	14	36.7	60.00
123	14	36.8	60.00
124	14	36.9	71.00
126	14	36.7	67.20
129	14	36.6	74.00
130	14	36.7	76.00
133	14	36.6	72.00
141	14	36.8	71.00
142	14	36.8	54.00
146	14	36.6	43.00
147	14	36.6	53.00
150	14	36.5	67.00
151	14	36.6	58.00

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Placebo Treatment Group
Period Day 21

Pat. No.	Per. (dy)	Body Temperature	Weight
2	21	.	.
16	21	.	.
33	21	.	.
34	21	.	.
35	21	37.1	73.30
48	21	37.0	58.40
82	21	36.6	75.00
83	21	36.4	57.00
85	21	36.4	59.00
87	21	36.4	48.00
88	21	36.5	60.00
93	21	36.5	73.00
94	21	36.7	57.00
96	21	36.5	48.00
99	21	36.5	45.00
100	21	36.6	59.00
123	21	36.8	61.00
124	21	36.6	71.00
126	21	36.8	68.00
129	21	36.6	73.00
130	21	36.6	76.00
133	21	36.6	72.00
141	21	36.7	72.00
142	21	36.9	53.50
146	21	36.5	43.00
147	21	36.5	53.00
150	21	36.6	68.00
151	21	36.6	56.60

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Placebo Treatment Group
Period Day 28

Pat. No.	Per. (dy)	Body Temperature	Weight
2	28	.	.
16	28	.	.
33	28	.	.
34	28	.	.
35	28	.	.
48	28	37.0	58.00
82	28	.	.
83	28	36.5	57.00
85	28	.	.
87	28	.	.
88	28	36.4	60.00
93	28	36.7	73.00
94	28	.	.
96	28	36.6	48.00
99	28	.	.
100	28	.	.
123	28	36.7	61.00
124	28	36.7	71.00
126	28	36.8	68.00
129	28	.	.
130	28	.	.
133	28	.	.
141	28	36.7	73.00
142	28	.	.
146	28	.	.
147	28	.	.
150	28	36.6	68.00
151	28	.	.

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Placebo Treatment Group
Period Day 35

Pat. No.	Per. (dy)	Body Temperature	Weight
2	35	.	.
16	35	.	.
33	35	.	.
34	35	.	.
35	35	.	.
48	35	37.0	57.50
82	35	.	.
83	35	36.4	57.00
85	35	.	.
87	35	.	.
88	35	36.5	61.00
93	35	36.6	73.00
94	35	.	.
96	35	36.5	48.00
99	35	.	.
100	35	.	.
123	35	36.6	62.00
124	35	36.7	71.00
126	35	36.6	69.00
129	35	.	.
130	35	.	.
133	35	.	.
141	35	36.6	73.00
142	35	.	.
146	35	.	.
147	35	.	.
150	35	36.6	68.00
151	35	.	.

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Placebo Treatment Group.
Period Day 42

Pat. No.	Per. (dy)	Body Temperature	Weight
2	42	.	.
16	42	.	.
33	42	.	.
34	42	.	.
35	42	.	.
48	42	37.0	57.60
82	42	.	.
83	42	36.5	57.00
85	42	.	.
87	42	.	.
88	42	36.5	61.00
93	42	36.6	73.00
94	42	.	.
96	42	36.5	48.00
99	42	.	.
100	42	.	.
123	42	36.7	62.00
124	42	36.7	71.00
126	42	36.7	69.00
129	42	.	.
130	42	.	.
133	42	.	.
141	42	36.7	72.00
142	42	.	.
146	42	.	.
147	42	.	.
150	42	36.5	68.00
151	42	.	.

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ENCLOSURE 29

**Experimental Cohort:
Laboratory Tests in the Two Treatment Groups**

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Laboratory Characteristics
Day 0 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	HGB	HCT	RBC	WBC	NEUT.	LYMP.	EOS.	MONO.
1	1	1	15.70	47.50	4.93	12.90	72.00	20.00	.00	7.00
17	1	1	12.10	33.50	3.28	6.30	62.00	24.00	1.00	3.00
31	2	1	16.00	47.40	5.10	8.90	75.00	19.00	1.00	1.00
32	2	1	15.30	45.30	4.75	4.90	65.00	31.00	1.00	1.00
46	2	1	14.10	41.80	4.69	7.70	69.00	23.00	3.00	1.00
47	2	1	13.70	41.90	4.45	8.30	63.00	32.00	.	.50
81	3	1	13.10	40.00	4.56	5.00	58.00	36.00	1.00	5.00
84	3	1	14.00	42.00	4.70	10.40	53.00	43.00	2.00	2.00
86	3	1	14.10	42.00	4.70	3.50	45.00	42.00	2.00	7.00
89	3	1	14.10	43.00	4.81	8.10	72.00	20.00	4.00	4.00
90	3	1	13.60	40.00	4.35	7.00	72.00	22.00	1.00	5.00
91	3	1	12.50	38.00	4.30	5.80	55.00	33.00	3.00	8.00
92	3	1	11.20	36.00	4.16	5.20	66.00	26.00	2.00	5.00
95	3	1	13.00	38.00	4.32	5.40	63.00	29.00	2.00	6.00
97	3	1	11.80	38.00	4.01	19.50	80.00	8.00	.00	2.00
98	3	1	13.40	42.00	4.75	7.20	65.00	25.00	3.00	3.00
121	3	1	16.00	49.00	5.40	4.70	56.00	29.00	8.00	6.00
122	3	1	13.90	43.00	4.80	6.40	67.00	26.00	4.00	3.00
125	3	1	14.00	43.00	4.80	4.30	51.00	42.00	3.00	3.00
127	3	1	15.20	45.00	5.10	6.40	40.00	53.00	4.00	2.00
128	3	1	15.00	45.00	5.20	8.70	65.00	31.00	1.00	3.00
131	3	1	14.40	43.00	4.90	5.20	59.00	36.00	2.00	3.00
143	3	1	13.60	40.00	4.50	4.60	62.00	34.00	2.00	2.00
144	3	1	14.50	43.00	5.10	6.00	63.00	33.00	1.00	2.00
145	3	1	15.50	45.00	5.20	5.90	53.00	41.00	4.00	1.00
148	3	1	12.50	38.00	4.60	4.20	69.00	29.00	1.00	1.00
149	3	1	13.00	38.00	4.60	7.30	65.00	32.00	1.00	2.00
153	3	1	14.00	42.00	4.90	6.90	66.00	30.00	1.00	3.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:
HGB Hemoglobin WBC White Blood Cells EOS. Eosinophils
HCT Hematocrit NEUT. Neutrophils MONO. Monocytes
RBC Red Blood Cells LYMP. Lymphocytes

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Laboratory Characteristics
Day 0 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	BASO	PLATE.	NA+	K+	CL-	CA++	PO4	SGOT
1	1	1	1.00	387.00	141.00	4.30	103.00	2.61	1.01	42.00
17	1	1	.00	323.00	141.00	4.20	106.00	2.27	1.04	14.00
31	2	1	1.00	263.00	141.00	4.20	104.00	2.21	.84	17.00
32	2	1	.00	203.00	144.00	4.10	109.00	2.31	1.07	12.00
46	2	1	.00	303.00	143.00	4.30	105.00	2.45	1.00	14.00
47	2	1	.	360.00	139.00	4.60	104.00	2.22	1.18	15.00
81	3	1	.00	295.00	136.00	4.10	98.00	9.00	4.00	10.00
84	3	1	.00	240.00	140.00	4.50	102.00	8.80	2.80	7.00
86	3	1	.00	205.00	140.00	4.60	105.00	9.40	2.90	25.00
89	3	1	.00	239.00	139.00	3.60	100.00	8.80	3.00	15.00
90	3	1	.00	215.00	135.00	3.80	100.00	8.80	2.50	13.00
91	3	1	1.00	225.00	135.00	3.70	99.00	8.80	2.50	15.00
92	3	1	1.00	210.00	138.00	4.00	100.00	9.00	2.70	10.00
95	3	1	.00	208.00	140.00	4.10	102.00	8.90	2.70	5.00
97	3	1	.00	285.00	135.00	5.10	102.00	8.80	2.50	40.00
98	3	1	.00	230.00	138.00	3.80	100.00	8.80	2.50	10.00
121	3	1	1.00	248.00	137.00	3.50	94.00	9.10	3.50	12.00
122	3	1	.00	229.00	135.00	3.90	93.00	8.90	4.00	14.00
125	3	1	1.00	246.00	142.00	4.40	102.00	8.90	2.90	20.00
127	3	1	1.00	226.00	142.00	4.60	100.00	8.80	2.70	13.00
128	3	1	.00	260.00	139.00	4.70	97.00	8.80	2.70	15.00
131	3	1	.00	236.00	140.00	4.40	100.00	9.50	3.70	12.00
143	3	1	.00	237.00	143.00	4.20	105.00	8.90	4.50	27.00
144	3	1	1.00	230.00	138.00	4.40	102.00	9.20	3.20	12.00
145	3	1	1.00	256.00	139.00	4.30	98.00	10.20	5.00	12.00
148	3	1	.00	238.00	140.00	3.80	98.00	9.00	3.00	11.00
149	3	1	.00	320.00	141.00	4.50	102.00	8.80	2.50	8.00
153	3	1	.00	236.00	137.00	4.60	100.00	8.80	2.60	12.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
BASO Basophils K+ Phosphorous PO4
PLATE Platelet Count CL- Chlorine SGOT Aspartate Amino
NA+ Sodium CA++ Calcium Transferase

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Laboratory Characteristics
Day 0 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	SGPT	τ GT	BLOOD SUGAR	ALK. PHOS.	BUN	CREAT.	URIC ACID	TOT. BILI.
1	1	1	57.00	62.00	5.30	87.00	7.00	81.00	457.00	11.00
17	1	1	11.00	41.00	4.70	51.00	4.80	74.00	274.00	7.90
31	2	1	17.00	24.00	5.10	125.00	3.70	83.00	361.00	6.00
32	2	1	7.00	4.00	4.30	76.00	4.50	102.00	256.00	5.00
46	2	1	7.00	6.00	5.40	.	6.80	75.00	187.00	10.00
47	2	1	8.00	16.00	5.60	61.00	3.30	95.00	236.00	4.90
81	3	1	9.00	5.00	100.00	22.00	22.00	.90	3.60	.70
84	3	1	5.00	8.00	87.00	24.00	8.00	.70	3.50	.50
86	3	1	38.00	25.00	56.00	34.00	5.00	.90	4.10	.50
89	3	1	19.00	20.00	84.00	26.00	23.00	.50	2.60	.70
90	3	1	23.00	18.00	87.00	24.00	4.00	.70	5.60	.70
91	3	1	17.00	11.00	81.00	28.00	22.00	.80	5.40	.60
92	3	1	12.00	18.00	91.00	36.00	4.00	.80	3.20	.60
95	3	1	10.00	9.00	95.00	22.00	30.00	.90	3.50	.70
97	3	1	16.00	44.00	103.00	37.00	21.00	.70	3.20	.80
98	3	1	13.00	11.00	95.00	25.00	0.00	.80	3.40	.60
121	3	1	35.00	38.00	88.00	28.00	34.00	.90	5.00	1.00
122	3	1	22.00	39.00	82.00	34.00	7.00	.90	6.40	.50
125	3	1	28.00	11.00	82.00	25.00	32.00	.90	3.80	.90
127	3	1	14.00	13.00	96.00	28.00	28.00	.80	3.30	.50
128	3	1	33.00	43.00	89.00	25.00	8.00	1.00	6.20	.60
131	3	1	13.00	10.00	93.00	25.00	39.00	.90	4.40	.90
143	3	1	27.00	5.00	83.00	46.00	19.00	.50	2.50	.70
144	3	1	15.00	8.00	101.00	20.00	6.00	1.00	3.90	.60
145	3	1	12.00	10.00	84.00	33.00	38.00	.80	3.70	.80
148	3	1	13.00	22.00	89.00	28.00	6.00	.90	3.10	.70
149	3	1	9.00	8.00	91.00	38.00	17.00	.50	3.30	1.10
153	3	1	15.00	20.00	96.00	25.00	8.00	.60	3.50	1.40

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:

SGPT Alanine Aminotransferase
ALK. Alkaline Phosphatase
PHOS. Phosphatase
τ GT Urea Nitrogen
BUN Urea Nitrogen
CREAT. Creatinine
TOT. Total
BILI. Bilirubin

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Laboratory Characteristics
Day 0 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	DIR. BILI.	TOT. PROT.	BLOOD ALBU.	CHOL.	TRIG.	GLOBULINS:		
								α-1	α-2	β
1	1	1	.00	71.00	41.00	5.64	.95	3.00	16.00	13.00
17	1	1	.00	59.90	38.00	6.39	1.68	.	.	.
31	2	1	.00	70.00	42.00	6.00	.05	3.00	7.00	8.00
32	2	1	.	59.00	42.00	5.01	.78	3.00	4.00	7.00
46	2	1	.	71.00	45.00	5.30	1.26	4.00	4.00	6.00
47	2	1	.	67.00	46.00	7.49	1.74	3.00	8.00	10.00
81	3	1	.20	7.20	4.20	100.00	38.00	4.00	7.00	12.00
84	3	1	.10	8.10	4.40	150.00	66.00	9.00	7.00	12.00
86	3	1	.30	7.20	4.60	159.00	90.00	4.00	7.00	12.00
89	3	1	.20	7.80	4.20	282.00	89.00	4.00	7.00	13.00
90	3	1	.30	7.10	4.10	201.00	105.00	5.00	7.00	12.00
91	3	1	.10	6.80	3.50	138.00	58.00	4.00	7.00	12.00
92	3	1	.10	6.90	4.30	183.00	91.00	4.00	7.00	12.00
95	3	1	.20	7.10	4.30	174.00	44.00	4.00	7.00	12.00
97	3	1	.20	7.20	4.80	161.00	76.00	5.00	7.00	13.00
98	3	1	.20	6.80	4.20	167.00	60.00	5.00	7.00	12.00
121	3	1	.40	6.60	4.40	191.00	60.00	4.00	8.00	12.00
122	3	1	.10	8.30	4.60	231.00	296.00	6.00	9.00	14.00
125	3	1	.20	7.10	3.60	184.00	89.00	7.00	11.00	14.00
127	3	1	1.00	6.80	3.50	195.00	148.00	4.00	7.00	12.00
128	3	1	.10	6.60	3.80	262.00	133.00	4.00	7.00	13.00
131	3	1	.20	6.50	4.10	200.00	44.00	5.00	8.00	13.00
143	3	1	.10	6.50	3.80	219.00	67.00	4.00	7.00	12.00
144	3	1	.20	7.00	3.80	332.00	115.00	7.00	10.00	13.00
145	3	1	.20	7.00	3.80	276.00	142.00	4.00	7.00	12.00
148	3	1	.20	7.50	4.20	184.00	84.00	4.00	7.00	12.00
149	3	1	.30	6.70	3.60	253.00	97.00	4.00	7.00	12.00
153	3	1	.30	7.50	4.30	296.10	106.00	6.00	11.00	14.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:
DIR. Direct TOT. Total BLOOD Blood
BILI. Bilirubin PROT. Protein ALBU. Albumin
CHOL. Cholesterol TRIG. Triglycerides

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Laboratory Characteristics
Day 0 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	Globulins: τ	T3	T4	TSH	HBS Ag ³	AIDS ³	ALT/AST Non-HEP. ³
1	1	1	13.00	.26	75.00	1.50	1	1	.
17	1	1
31	2	1	11.00	.96	77.00	.56	1	1	.
32	2	1	7.00	.79	96.00	2.17	.	.	.
46	2	1	7.00	.87	107.00	.77	1	1	1
47	2	1	6.00	.28	118.00	1.30	1	1	1
81	3	1	15.00	1.30	7.00	1.10	1	1	1
84	3	1	15.00	1.20	6.20	3.20	1	1	1
86	3	1	15.00	1.45	7.00	3.20	1	1	1
89	3	1	15.00	1.20	8.00	2.90	1	1	1
90	3	1	15.00	1.15	5.80	2.60	1	1	1
91	3	1	15.00	1.10	6.40	.22	1	1	1
92	3	1	16.00	1.30	7.00	1.10	1	1	1
95	3	1	15.00	1.40	9.00	.22	1	1	1
97	3	1	16.00	1.30	11.00	.50	1	1	1
98	3	1	17.00	2.00	9.00	5.20	1	1	1
121	3	1	17.00	1.15	6.40	1.80	1	1	1
122	3	1	17.00	1.80	7.70	5.30	1	1	1
125	3	1	22.00	1.20	8.50	5.00	1	1	1
127	3	1	15.00	1.35	8.50	2.40	1	1	1
128	3	1	15.00	1.00	7.70	13.00	1	1	1
131	3	1	19.00	1.30	9.00	2.00	1	1	1
143	3	1	16.00	1.20	8.80	5.50	1	1	1
144	3	1	20.00	1.20	7.70	2.00	1	1	1
145	3	1	15.00	1.10	8.50	1.20	1	1	1
148	3	1	15.00	1.30	8.00	2.70	1	1	1
149	3	1	16.00	1.90	11.50	.30	1	1	1
153	3	1	21.00	1.55	10.00	.10	1	1	1

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Tx Group 1 = RBX 2 = PBO

³ HBS ag/AIDS/Non-HEP 1 = Negative 0 = Positive

Abbreviations:

T3 HBS AG

ALT/AST

T4 Thyroxine AIDS

NON-HEP.

TSH Thyrotropin (Thyroid-stimulating Hormone)

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Laboratory Characteristics
Day 0 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	Specific Gravity	Albumin	Sugar	RBC	WBC
1	1	1	1.014	-	-	-	0-3
17	1	1	1.030	-	-	-	0-3
31	2	1	1.020	-	-	-	-
32	2	1	1.025	-	-	-	0-1
46	2	1	.				
47	2	1	1.015	0001+	neg	trace	55-60
81	3	1	1.010	++	-	2a4	35a40
84	3	1	1.020	+	-	2a4	2a4
86	3	1	1.020	+	-	=0	=0
89	3	1	1.022	+	-	=0	1a2
90	3	1	1.016	+	-	-	1a2
91	3	1	1.022	+	-	=0	1a2
92	3	1	1.025	+	-	=0	=0
95	3	1	1.012	+	-	=0	1a2
97	3	1	1.011	+	-	=0	=0
98	3	1	1.014	+	-	=0	2a4
121	3	1	1.028	+	-	-	-
122	3	1	1.015	+	-	-	-
125	3	1	1.010	+	-	-	-
127	3	1	1.015	+	-	-	-
128	3	1	1.018	+	-	-	-
131	3	1	1.019	+	-	1a2	-
143	3	1	1.020	+	-	-	-
144	3	1	1.012	+	-	-	-
145	3	1	1.013	+	-	1a2	-
148	3	1	1.022	+	-	2a4	-
149	3	1	1.010	+	-	-	-
153	3	1	1.021	+	-	-	-

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
RBC Red Blood Cells WBC White Blood Cells

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Laboratory Characteristics
Day 0 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	HGB	HCT	RBC	WBC	NEUT.	LYMP.	EOS.	MONO.
2	1	2	16.20	47.20	5.15	7.20	83.00	14.00	.00	3.00
16	1	2	14.80	44.70	5.08	9.70	88.00	11.00	.00	1.00
33	2	2	15.60	47.50	5.07	6.40	67.00	27.00	.00	2.00
34	2	2	16.50	48.90	5.30	14.00	74.50	20.80	.00	4.70
35	2	2	14.00	41.40	4.77	12.10	65.00	30.20	4.80	1.00
48	2	2	13.20	37.30	3.94	6.80	60.00	36.00	1.00	1.00
82	3	2	14.50	44.00	4.32	5.50	64.00	28.00	1.00	7.00
83	3	2	14.70	45.00	5.06	6.50	67.00	26.00	3.00	4.00
85	3	2	14.00	43.00	4.80	7.60	56.00	38.00	2.00	4.00
87	3	2	14.10	43.00	4.89	7.50	70.00	24.00	4.00	2.00
88	3	2	13.10	39.00	4.41	10.00	66.00	27.00	2.00	5.00
93	3	2	15.30	46.00	5.16	6.20	53.00	35.00	7.00	4.00
94	3	2	15.60	47.00	5.28	3.30	66.00	27.00	2.00	5.00
96	3	2	13.40	42.00	4.73	4.50	62.00	31.00	4.00	3.00
99	3	2	13.60	40.00	4.55	6.40	36.00	50.00	12.00	2.00
100	3	2	13.50	42.00	4.73	6.50	65.00	29.00	2.00	4.00
123	3	2	14.50	44.00	4.90	4.70	63.00	31.00	4.00	2.00
124	3	2	14.30	43.00	4.80	5.20	62.00	33.00	4.00	1.00
126	3	2	16.00	49.00	5.40	9.70	71.00	27.00	1.00	1.00
129	3	2	14.90	44.00	5.20	6.00	52.00	44.00	1.00	3.00
130	3	2	14.40	43.00	5.00	7.60	62.00	34.00	2.00	2.00
133	3	2	13.80	42.00	4.90	7.90	61.00	33.00	2.00	4.00
141	3	2	14.30	42.00	4.80	6.50	60.00	37.00	2.00	1.00
142	3	2	14.50	44.00	4.90	5.20	81.00	17.00	1.00	1.00
146	3	2	12.00	36.00	4.10	7.10	76.00	18.00	2.00	4.00
147	3	2	14.40	45.00	4.70	5.90	55.00	41.00	1.00	3.00
150	3	2	13.70	40.00	4.70	5.80	57.00	41.00	1.00	1.00
151	3	2	14.00	41.00	4.60	7.10	70.00	28.00	1.00	1.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:

HGB Hemoglobin WBC White Blood Cells EOS. Eosinophils
HCT Hematocrit NEUT. Neutrophils MONO. Monocytes
RBC Red Blood Cells LYMP. Lymphocytes

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Laboratory Characteristics
Day 0 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	BASO	PLATE.	NA+	K+	CL-	CA++	PO4	SGOT
2	1	2	.00	405.00	137.00	4.20	99.00	2.42	1.02	16.00
16	1	2	.00	391.00	140.00	4.60	102.00	2.39	1.23	23.00
33	2	2	.00	194.00	143.00	4.00	105.00	2.26	.90	11.00
34	2	2	.20	245.00	144.00	4.40	105.00	2.38	1.11	19.00
35	2	2	.20	251.00	143.00	3.50	105.00	2.24	.79	14.00
48	2	2	.	319.00	142.00	4.20	105.00	2.22	1.35	12.00
82	3	2	.00	241.00	140.00	3.80	102.00	8.80	3.00	14.00
83	3	2	.00	262.00	143.00	4.50	95.00	9.00	2.50	25.00
85	3	2	.00	230.00	140.00	4.30	100.00	8.80	2.50	19.00
87	3	2	.00	305.00	136.00	3.80	102.00	9.00	3.00	11.00
88	3	2	.00	445.00	136.00	4.70	94.00	9.10	3.70	15.00
93	3	2	1.00	225.00	140.00	4.10	98.00	8.00	2.60	8.00
94	3	2	.00	255.00	136.00	4.10	103.00	12.10	3.70	12.00
96	3	2	.00	240.00	141.00	4.20	103.00	8.50	3.20	12.00
99	3	2	.00	245.00	135.00	4.10	105.00	9.00	2.70	11.00
100	3	2	.00	235.00	138.00	4.20	96.00	8.90	2.50	18.00
123	3	2	.00	225.00	140.00	3.80	97.00	8.90	2.70	18.00
124	3	2	.00	240.00	141.00	4.10	100.00	8.80	2.80	10.00
126	3	2	.00	225.00	134.00	3.90	90.00	10.10	3.90	25.00
129	3	2	.00	250.00	142.00	3.90	100.00	9.50	4.10	12.00
130	3	2	.00	228.00	139.00	4.40	100.00	9.10	4.10	17.00
133	3	2	.00	236.00	141.00	4.20	92.00	8.80	2.90	14.00
141	3	2	.00	238.00	138.00	4.00	95.00	9.10	3.30	9.00
142	3	2	.00	240.00	136.00	3.60	96.00	9.60	4.20	18.00
146	3	2	.00	240.00	140.00	3.90	100.00	9.90	3.90	15.00
147	3	2	.00	242.00	139.00	4.50	97.00	8.90	4.10	17.00
150	3	2	.00	340.00	142.00	4.50	103.00	9.30	3.30	10.00
151	3	2	.00	290.00	142.00	4.60	102.00	10.20	5.00	19.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
 BASO Basophils K+ Phosphorous PO4
 PLATE Platelet Count CL- Chlorine SGOT Aspartate Amino
 NA+ Sodium CA++ Calcium Transferase

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FCE 20124/706 i

Laboratory Characteristics
Day 0 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	SGPT	τ GT	BLOOD SUGAR	ALK. PHOS.	BUN	CREAT.	URIC ACID	TOT. BILI.
2	1	2	14.00	32.00	8.80	90.00	4.10	72.00	299.00	9.90
16	1	2	26.00	16.00	4.70	71.00	7.40	61.00	274.00	10.90
33	2	2	8.00	.	4.60	85.00	4.50	93.00	396.00	14.00
34	2	2	29.00	.	5.80	.	6.60	127.00	495.00	5.00
35	2	2	7.00	10.00	5.00	15.00	6.40	131.00	437.00	9.00
48	2	2	5.00	.	10.50	86.00	4.90	101.00	196.00	6.00
82	3	2	25.00	26.00	75.00	50.00	5.00	.80	5.60	.70
83	3	2	27.00	24.00	93.00	39.00	31.00	.50	7.30	.70
85	3	2	18.00	8.00	86.00	34.00	18.00	.60	3.30	.90
87	3	2	38.00	4.00	76.00	20.00	23.00	.70	4.60	.60
88	3	2	35.00	20.00	55.00	27.00	8.00	.50	4.80	.70
93	3	2	32.00	47.00	178.00	37.00	38.00	.50	6.20	2.00
94	3	2	10.00	17.00	89.00	27.00	2.00	1.10	4.00	1.20
96	3	2	15.00	26.00	50.00	47.00	5.00	.80	3.70	.20
99	3	2	12.00	35.00	85.00	33.00	15.00	.80	4.40	.40
100	3	2	26.00	38.00	85.00	38.00	1.00	1.00	4.80	.20
123	3	2	22.00	28.00	84.00	28.00	25.00	.80	6.00	1.00
124	3	2	13.00	12.00	73.00	34.00	0.00	1.20	4.80	1.20
126	3	2	33.00	4.00	83.00	33.00	6.00	.90	3.00	.60
129	3	2	13.00	8.00	89.00	30.00	40.00	.90	4.40	.60
130	3	2	13.00	12.00	78.00	20.00	7.00	.90	3.80	1.10
133	3	2	31.00	21.00	79.00	19.00	0.00	.80	5.80	.60
141	3	2	13.00	10.00	95.00	23.00	13.00	.50	3.00	1.20
142	3	2	9.00	6.00	82.00	32.00	6.00	.60	3.20	.80
146	3	2	16.00	8.00	87.00	32.00	1.00	.90	3.00	.60
147	3	2	26.00	40.00	79.00	24.00	24.00	.60	4.10	1.10
150	3	2	13.00	7.00	78.00	28.00	4.00	.90	3.20	.90
151	3	2	19.00	13.00	77.00	34.00	37.00	1.10	4.90	1.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PEO

Abbreviations:

SGPT Alanine Aminotransferase
ALK. Alkaline Phosphatase
PHOS. Phosphatase
τ GT Urea Nitrogen
BUN Urea Nitrogen
CREAT. Creatinine
TOT. Total
BILI. Bilirubin

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Laboratory Characteristics
Day 0 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	DIR. BILI.	TOT. PROT.	BLOOD ALEU.	CHOL.	TRIG.	GLOBULINS:		B
								α-1	α-2	
2	1	2	1.20	70.00	38.00	6.54	3.09	3.00	13.00	12.00
16	1	2	.50	72.00	39.00	5.53	1.13	.	.	.
33	2	2	.	66.00	43.00	5.33	1.04	3.00	4.00	7.00
34	2	2	.	75.00	45.00	5.33	3.31	4.00	7.00	9.00
35	2	2	.	74.00	48.00	6.02	1.25	3.00	4.00	8.00
48	2	2	.	61.00	35.00	4.84	1.00	3.00	5.00	8.00
82	3	2	.20	6.40	3.50	166.00	82.00	5.00	7.00	12.00
83	3	2	.20	6.90	3.70	272.00	181.00	3.00	10.00	14.00
85	3	2	.20	6.60	3.60	208.00	73.00	4.00	7.00	12.00
87	3	2	.20	7.50	4.20	135.00	38.00	6.00	8.00	13.00
88	3	2	.20	7.40	4.00	177.00	39.00	6.00	9.00	13.00
93	3	2	.80	8.00	4.00	180.00	141.00	4.00	7.00	14.00
94	3	2	.40	8.10	5.00	130.00	39.00	4.00	7.00	12.00
96	3	2	.50	7.30	4.50	168.00	60.00	5.00	7.00	12.00
99	3	2	1.80	7.60	4.80	158.00	106.00	7.00	11.00	15.00
100	3	2	.60	7.50	4.30	191.00	70.00	5.00	7.00	15.00
123	3	2	.30	7.10	3.70	293.00	120.00	5.00	7.00	13.00
124	3	2	.40	7.10	4.40	186.00	97.00	4.00	7.00	13.00
126	3	2	.10	7.50	4.20	215.00	145.00	6.00	8.00	14.00
129	3	2	.20	7.60	4.10	140.00	36.00	4.00	8.00	13.00
130	3	2	.40	7.00	3.60	173.00	74.00	6.00	9.00	14.00
133	3	2	.10	6.80	4.50	254.00	195.00	4.00	7.00	12.00
141	3	2	.30	7.00	3.80	213.00	80.00	6.00	8.00	12.00
142	3	2	.20	7.10	4.00	166.00	79.00	4.00	7.00	13.00
146	3	2	.10	6.10	3.40	206.00	116.00	7.00	11.00	13.00
147	3	2	.40	7.60	3.80	229.00	71.00	4.00	8.00	13.00
150	3	2	.30	7.40	3.90	196.00	99.00	5.00	7.00	13.00
151	3	2	.30	6.30	3.20	227.00	106.00	7.00	12.00	15.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:

DIR. Direct TOT. Total BLOOD Blood
BILI. Bilirubin PROT. Protein ALEU. Albumin
CHOL. Cholesterol TRIG. Triglycerides

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Laboratory Characteristics
Day 0 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	Globulins: τ	TSH			HBS Ag ³	AIDS ³	ALT/AST Non-HEP. ³
				T3	T4	TSH			
2	1	2	14.00	.28	112.00	.50	1	1	1
16	1	2	.	.26	135.00	.30	1	.	.
33	2	2	5.00	.81	85.00	.84	1	.	.
34	2	2	13.00	1.10	136.00	1.89	0	1	1
35	2	2	11.00	.90	105.00	2.30	0	1	1
48	2	2	10.00	.	.	.	1	1	1
82	3	2	15.00	1.05	6.00	.50	1	1	1
83	3	2	16.00	1.30	10.20	.48	1	1	1
85	3	2	15.00	1.55	7.00	2.50	1	1	1
87	3	2	15.00	1.10	9.00	2.80	1	1	1
88	3	2	17.00	1.30	8.50	.22	1	1	1
93	3	2	15.00	1.60	8.00	1.70	1	1	1
94	3	2	15.00	1.40	6.40	1.80	1	1	1
96	3	2	16.00	1.20	10.00	.48	1	1	1
99	3	2	21.00	1.15	8.00	4.50	1	1	1
100	3	2	16.00	1.30	12.50	2.00	1	1	1
123	3	2	21.00	1.30	9.50	5.20	1	1	1
124	3	2	16.00	1.50	8.50	2.70	1	1	1
126	3	2	20.00	1.70	7.20	5.20	1	1	1
129	3	2	15.00	.	.	.	1	1	1
130	3	2	17.00	1.30	7.80	.30	1	1	1
133	3	2	16.00	1.00	5.60	3.40	1	1	1
141	3	2	16.00	1.50	7.50	1.00	1	1	1
142	3	2	15.00	1.45	7.20	5.00	1	1	1
146	3	2	19.00	.85	6.20	.60	1	1	1
147	3	2	15.00	1.70	12.00	1.20	1	1	1
150	3	2	16.00	.88	5.40	1.50	1	1	1
151	3	2	22.00	.75	6.50	2.00	1	1	1

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO
³ HBS ag/AIDS/Non-HEP 1 = Negative 0 = Positive

Abbreviations:

T3 HBS AG ALT/AST
T4 Thyroxine AIDS NON-HEP.
TSH Thyrotropin (Thyroid-stimulating Hormone)

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Laboratory Characteristics
Day 0 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	Specific Gravity	Albumin	Sugar	RBC	WBC
2	1	2	1.020	-	-	3-5	0-3
16	1	2	1.015	-	-	-	0-3
33	2	2	1.020	0	0	0-1	0-1
34	2	2	1.010	-	-	-	-
35	2	2	1.020	-	-	-	-
48	2	2	1.015	00000	00000	20-30	00-03
82	3	2	1.028	+	-	1a2	1a2
83	3	2	1.022	+	-	1a2	1a3
85	3	2	1.017	+	-	-	2a4
87	3	2	1.020	+	-	1a2	2a4
88	3	2	1.025	+	-	1a2	3a5
93	3	2	1.020	+	-	=0	2a4
94	3	2	1.025	++	-	1a3	15a20
96	3	2	1.016	+	-	4a6	1a2
99	3	2	1.010	+	-	1a2	2a4
100	3	2	1.013	+	-	1a2	=0
123	3	2	1.021	+	-	1a2	-
124	3	2	1.017	+	-	-	-
126	3	2	1.019	+	-	-	-
129	3	2	1.023	+	-	1a2	-
130	3	2	1.013	+	-	1a2	-
133	3	2	1.015	+	-	-	-
141	3	2	1.006	+	-	1a2	-
142	3	2	1.021	+	-	-	-
146	3	2	1.012	+	-	-	-
147	3	2	1.010	+	-	1a3	8a10
150	3	2	1.007	+	-	-	-
151	3	2	1.024	+	-	-	-

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
RBC Red Blood Cells WBC White Blood Cells

3 b 3

FCE 20124/706 i

Laboratory Characteristics
Day 21 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	HGB	HCT	RBC	WBC	NEUT.	LYMP.	EOS.	MONO.
1	1	1	15.70	47.50	4.93	12.90	72.00	20.00	.00	7.00
1	1	1	15.30	47.10	4.97	16.90	68.00	28.00	1.00	3.00
17	1	1	14.20	43.80	5.02	6.30	73.00	19.00	.00	8.00
31	2	1	16.70	49.00	5.27	7.90	60.00	34.00	2.00	1.00
32	2	1	15.10	43.50	4.59	10.20	68.00	28.00	.00	2.00
46	2	1
47	2	1
81	3	1	13.10	45.00	4.50	5.00	55.00	35.00	1.00	4.00
84	3	1	13.60	42.00	4.73	8.60	63.00	31.00	1.00	5.00
86	3	1	15.00	46.00	5.15	5.10	72.00	22.00	3.00	2.00
89	3	1	14.10	42.00	4.77	7.10	66.00	27.00	4.00	3.00
90	3	1	13.40	39.00	4.45	6.10	66.00	24.00	2.00	8.00
91	3	1	13.50	40.00	4.50	5.60	64.00	26.00	6.00	4.00
92	3	1	11.00	36.00	4.10	5.20	66.00	25.00	3.00	6.00
95	3	1	13.60	40.00	4.55	6.50	71.00	25.00	2.00	2.00
97	3	1	13.50	41.00	4.64	14.30	79.00	15.00	2.00	4.00
98	3	1	13.10	42.00	4.73	6.00	65.00	25.00	7.00	3.00
121	3	1	15.70	47.00	5.31	3.60	56.00	21.00	7.00	5.00
122	3	1	13.40	40.00	4.90	5.10	60.00	38.00	1.00	1.00
125	3	1	15.70	47.00	5.60	6.40	67.00	30.00	1.00	2.00
127	3	1	15.10	45.00	4.80	6.40	53.00	43.00	1.00	3.00
128	3	1	15.20	45.00	5.05	8.60	65.00	29.00	1.00	5.00
131	3	1	15.60	46.00	5.10	5.50	61.00	35.00	3.00	1.00
143	3	1	14.00	42.00	5.00	4.60	67.00	30.00	2.00	1.00
144	3	1	14.40	43.00	5.00	6.20	54.00	42.00	2.00	2.00
145	3	1	15.20	45.00	5.10	7.20	70.00	24.00	2.00	4.00
148	3	1	13.20	41.00	4.60	2.70	60.00	38.00	1.00	1.00
149	3	1	13.60	41.00	4.30	5.80	55.00	38.00	5.00	2.00
153	3	1	13.90	42.00	4.40	5.20	54.00	38.00	1.00	6.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:
HGB Hemoglobin WBC White Blood Cells EOS. Eosinophils
HCT Hematocrit NEUT. Neutrophils MONO. Monocytes
RBC Red Blood Cells LYMP. Lymphocytes

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Laboratory Characteristics
Day 21 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	EASO	PLATE.	NA+	K+	CL-	CA++	PO4	SGOT
1	1	1	.00	442.00	138.00	4.00	102.00	2.45	1.09	24.00
17	1	1	.00	586.00	138.00	4.50	98.00	2.41	1.23	25.00
31	2	1	.00	190.00	142.00	4.80	105.00	2.15	.82	13.00
32	2	1	.00	241.00	141.00	4.20	107.00	2.13	.81	11.00
46	2	1
47	2	1
81	3	1	.00	280.00	137.00	4.30	100.00	8.90	3.70	10.00
84	3	1	.00	352.00	139.00	4.20	102.00	8.80	2.70	15.00
86	3	1	1.00	210.00	138.00	4.70	102.00	8.80	2.50	17.00
89	3	1	.00	259.00	139.00	4.20	57.00	8.40	2.90	10.00
90	3	1	.00	245.00	137.00	4.30	98.00	8.90	2.70	13.00
91	3	1	.00	220.00	140.00	3.30	100.00	8.90	2.70	9.00
92	3	1	.00	210.00	137.00	4.10	100.00	9.00	2.90	10.00
95	3	1	.00	252.00	139.00	4.00	102.00	8.90	2.90	15.00
97	3	1	.00	215.00	135.00	4.80	93.00	3.00	2.50	16.00
98	3	1	.00	232.00	132.00	4.00	100.00	8.90	2.70	10.00
121	3	1	1.00	242.00	137.00	4.00	98.00	10.10	3.70	16.00
122	3	1	.00	420.00	139.00	3.90	95.00	8.90	3.90	9.00
125	3	1	.00	235.00	140.00	4.80	102.00	8.80	3.10	12.00
127	3	1	.00	238.00	141.00	4.70	98.00	8.40	2.90	8.00
128	3	1	.00	249.00	139.00	4.40	97.00	8.80	2.90	16.00
131	3	1	.00	256.00	138.00	4.30	98.00	9.60	3.90	14.00
143	3	1	.00	230.00	141.00	4.00	102.00	9.10	4.00	13.00
144	3	1	.00	270.00	139.00	4.00	95.00	8.90	3.10	12.00
145	3	1	.00	280.00	138.00	4.70	92.00	10.00	4.50	13.00
148	3	1	.00	250.00	140.00	4.70	102.00	9.00	3.10	10.00
149	3	1	.00	230.00	140.00	4.60	98.00	8.40	2.70	8.00
153	3	1	1.00	238.00	140.00	3.60	102.00	8.90	2.50	16.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:
 EASO Basophils K+ Phosphorous PO4
 PLATE Platelet Count CL- Chlorine SGOT Aspartate Amino
 NA+ Sodium CA++ Calcium Transferase

FCE 20124/706 i

Laboratory Characteristics
Day 21 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	SGPT	τ GT	BLOOD SUGAR	ALK. PHOS.	BUN	CREAT.	URIC ACID	TOT. BILI.
2	1	2	14.00	32.00	8.80	90.00	4.10	72.00	299.00	9.90
1	1	1	23.00	28.00	4.90	73.00	4.30	82.00	534.00	14.90
17	1	1	24.00	15.00	4.70	61.00	4.60	57.00	239.00	12.70
31	2	1	16.00	16.00	4.70	126.00	2.60	98.00	421.00	10.00
32	2	1	8.00	3.00	4.50	95.00	4.40	98.00	204.00	18.00
46	2	1
47	2	1	5.00
81	3	1	9.00	6.00	100.00	23.00	20.00	.60	3.60	.70
84	3	1	5.00	15.00	87.00	23.00	33.00	.80	3.00	.80
86	3	1	19.00	40.00	92.00	25.00	28.00	.50	3.60	1.10
89	3	1	9.00	31.00	86.00	23.00	19.00	1.10	2.40	1.10
90	3	1	15.00	35.00	95.00	27.00	15.00	.80	2.60	.20
91	3	1	10.00	6.00	77.00	28.00	15.00	.70	3.00	.20
92	3	1	13.00	20.00	99.00	60.00	24.00	.80	3.20	.60
95	3	1	19.00	10.00	98.00	25.00	30.00	1.00	4.00	.90
97	3	1	10.00	28.00	56.00	40.00	23.00	.70	3.00	1.10
98	3	1	12.00	14.00	53.00	28.00	14.00	.70	5.10	.30
121	3	1	16.00	38.00	87.00	31.00	41.00	.90	4.60	.90
122	3	1	18.00	20.00	85.00	25.00	20.00	.80	4.90	.50
125	3	1	13.00	7.00	91.00	24.00	25.00	1.00	3.40	1.10
127	3	1	15.00	22.00	90.00	23.00	23.00	.90	3.70	.80
128	3	1	7.00	52.00	113.00	30.00	33.00	.80	6.50	.70
131	3	1	15.00	8.00	88.00	24.00	28.00	.80	3.30	.80
143	3	1	16.00	7.00	78.00	62.00	23.00	.70	3.10	.70
144	3	1	16.00	7.00	105.00	25.00	30.00	.70	3.50	.90
145	3	1	16.00	15.00	88.00	34.00	34.00	.80	3.80	.60
148	3	1	10.00	11.00	82.00	24.00	23.00	.80	3.30	1.00
149	3	1	14.00	7.00	83.00	34.00	16.00	.80	3.50	.90
153	3	1	12.00	9.00	99.00	20.00	18.00	.80	7.00	1.50

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:

SGPT Alanine Aminotransferase
ALK. Alkaline Phosphatase
PHOS. Phosphatase
τ GT Urea Nitrogen
BUN Urea Nitrogen
CREAT. Creatinine
TOT. Total
BILI. Bilirubin

FCE 20124/706 i

Laboratory Characteristics
Day 21 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	DIR. BILI.	TOT. PROT.	BLOOD ALBU.	CHOL.	TRIG.	GLOBULINS:		
								α-1	α-2	β
1	1	1	.00	67.00	41.00	4.88	2.43	.	.	.
17	1	1	.70	74.00	41.00	6.07	1.13	5.00	14.00	11.00
31	2	1	.	71.00	42.00	5.62	2.99	2.00	4.00	8.00
32	2	1	.	61.00	40.00	4.98	.58	2.00	5.00	7.00
46	2	1
47	2	1	.	71.00	43.00	.	.	3.00	7.00	8.00
81	3	1	6.20	8.10	4.20	138.00	36.00	4.00	7.00	14.00
84	3	1	.20	7.20	4.50	155.00	113.00	5.00	7.00	13.00
86	3	1	.40	8.50	4.10	228.00	80.00	4.00	7.00	12.00
89	3	1	.40	7.20	4.00	235.00	108.00	4.00	7.00	13.00
90	3	1	.80	7.90	4.70	188.00	87.00	6.00	8.00	12.00
91	3	1	.80	6.80	3.70	171.00	61.00	5.00	7.00	13.00
92	3	1	.20	6.50	4.30	180.00	91.00	4.00	7.00	13.00
95	3	1	.30	7.30	4.60	142.00	35.00	5.00	8.00	12.00
97	3	1	.40	6.50	4.40	126.00	66.00	5.00	7.00	12.00
98	3	1	.50	7.60	5.00	126.00	66.00	5.00	7.00	12.00
121	3	1	.30	7.30	4.20	213.00	42.00	5.00	8.00	12.00
122	3	1	.10	8.00	4.80	189.00	292.00	6.00	9.00	15.00
125	3	1	.40	7.00	4.20	158.00	117.00	6.00	11.00	12.00
127	3	1	.20	6.80	3.90	212.00	184.00	6.00	7.00	13.00
128	3	1	.20	7.00	4.50	194.00	69.00	4.00	7.00	13.00
131	3	1	.20	6.70	4.50	239.00	48.00	6.00	8.00	13.00
143	3	1	.20	6.30	3.70	242.00	125.00	6.00	7.00	13.00
144	3	1	.20	7.10	4.00	374.00	121.00	7.00	10.00	14.00
145	3	1	.10	7.20	3.70	309.00	138.00	5.00	7.00	15.00
148	3	1	.20	7.70	4.50	179.00	70.00	5.00	7.00	12.00
149	3	1	.20	7.70	4.20	254.00	107.00	5.00	7.00	13.00
153	3	1	.60	7.40	4.30	274.00	99.00	7.00	11.00	13.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Tx Group 1 = REX 2 = PBO

Abbreviations:

DIR.	Direct	TOT.	Total	BLOOD	Blood
BILI.	Bilirubin	PROT.	Protein	ALBU.	Albumin
CHOL.	Cholesterol	TRIG.	Triglycerides		

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Laboratory Characteristics
Day 21 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ¹ Group	Globulins: τ	Specific Gravity	Albumin	Sugar	RBC	WBC
1	1	1	.	1.019	-	-	-	0-3
17	1	1	18.00	.				
31	2	1	12.00	1.025	-	-	-	-
32	2	1	7.00	1.020	-	-	-	0-3
46	2	1
47	2	1	7.00	1.025	00010	00000	00000	00-05
81	3	1	16.00	1.012	+	-	2a4	25a35
84	3	1	15.00	1.027	++	-	2a4	10a15
86	3	1	15.00	1.019	+	-	1a2	1a2
89	3	1	16.00	1.015	+	-	=0	2a4
90	3	1	15.00	1.010	+	-	=0	1a2
91	3	1	16.00	1.025	+	-	3a5	6a8
92	3	1	15.00	1.020	+	-	=0	=0
95	3	1	15.00	1.010	+	-	=0	=0
97	3	1	15.00	1.024	+	-	1a2	=0
98	3	1	17.00	1.012	+	-	=0	1a2
121	3	1	16.00	1.026	+	-	-	-
122	3	1	18.00	1.032	++	-	-	-
125	3	1	21.00	1.012	+	-	-	-
127	3	1	15.00	1.025	+	-	1a2	-
128	3	1	16.00	1.025	+	-	-	-
131	3	1	20.00	1.016	+	-	-	-
143	3	1	16.00	1.008	+	-	1a3	-
144	3	1	21.00	1.010	+	-	-	-
145	3	1	15.00	1.015	+	-	-	-
148	3	1	16.00	1.019	+	-	-	-
149	3	1	15.00	1.010	+	-	1a2	-
153	3	1	19.00	1.014	+	-	1a2	-

Number of cases read = 28 Number of cases listed = 28

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Laboratory Characteristics
Day 42 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	HGB	HCT	RBC	WBC	NEUT.	LYMP.	EOS.	MONO.
1	1	1	15.60	45.40	4.77	11.80	69.00	23.00	1.00	6.00
17	1	1
31	2	1	17.20	51.80	5.56	10.80	79.00	17.00	.00	1.00
32	2	1
46	2	1
47	2	1	13.80	40.70	4.39	7.20	56.60	39.40	4.00	.50
81	3	1	13.10	40.00	4.60	5.00	55.00	35.00	1.00	5.00
84	3	1	14.20	44.00	4.58	8.00	61.00	28.00	2.00	5.00
86	3	1	13.30	42.00	4.73	3.60	57.00	33.00	6.00	4.00
89	3	1	14.90	45.00	5.07	6.60	65.00	31.00	2.00	2.00
90	3	1	13.60	40.00	4.35	7.00	72.00	22.00	1.00	5.00
91	3	1	12.40	37.00	4.23	6.10	68.00	25.00	6.00	3.00
92	3	1	12.00	35.00	4.00	5.00	65.00	25.00	2.00	7.00
95	3	1	11.60	35.00	4.02	4.70	60.00	35.00	4.00	1.00
97	3	1	13.50	35.00	4.40	13.80	65.00	30.00	2.00	3.00
98	3	1	15.10	45.00	5.14	7.80	60.00	32.00	5.00	3.00
121	3	1	16.60	49.00	5.70	6.00	47.00	40.00	8.00	5.00
122	3	1	14.00	40.00	5.00	7.80	74.00	24.00	1.00	1.00
125	3	1	15.00	45.00	5.40	5.30	59.00	39.00	1.00	1.00
127	3	1	15.10	46.00	5.10	7.00	67.00	29.00	2.00	2.00
128	3	1	14.70	45.00	5.11	6.90	66.00	25.00	1.00	8.00
131	3	1
143	3	1	12.90	40.00	4.50	4.60	50.00	44.00	1.00	5.00
144	3	1	14.30	43.00	4.60	6.50	57.00	40.00	2.00	1.00
145	3	1	14.10	42.00	4.50	5.60	77.00	17.00	3.00	3.00
148	3	1	13.40	42.00	4.70	3.00	57.00	41.00	1.00	1.00
149	3	1	13.00	41.00	4.60	5.30	66.00	30.00	2.00	2.00
153	3	1	14.40	43.00	4.80	5.90	73.00	25.00	1.00	1.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
HGB Hemoglobin WBC White Blood Cells EOS. Eosinophils
HCT Hematocrit NEUT. Neutrophils MONO. Monocytes
RBC Red Blood Cells LYMP. Lymphocytes

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Laboratory Characteristics
Day 42 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	BASO	PLATE.	NA+	K+	CL-	CA++	PO4	SGOT
1	1	1	1.00	411.00	144.00	4.30	105.00	2.55	.88	27.00
17	1	1
31	2	1	.00	213.00	139.00	4.30	102.00	2.33	1.06	13.00
32	2	1
46	2	1
47	2	1	1.00	324.00	143.00	4.50	106.00	.	.	.
81	3	1	.00	295.00	137.00	4.30	100.00	8.90	3.70	10.00
84	3	1	.00	226.00	141.00	4.20	100.00	10.20	4.20	11.00
86	3	1	.00	225.00	138.00	4.60	100.00	9.70	2.70	15.00
89	3	1	.00	315.00	143.00	4.10	103.00	9.00	3.10	18.00
90	3	1	.00	215.00	139.00	3.90	100.00	8.50	2.50	13.00
91	3	1	.00	350.00	144.00	4.00	103.00	9.00	2.50	8.00
92	3	1	.00	210.00	137.00	4.00	100.00	9.10	3.00	10.00
95	3	1	.00	300.00	140.00	4.30	102.00	10.00	4.30	13.00
97	3	1	.00	355.00	137.00	4.80	98.00	9.00	3.00	12.00
98	3	1	.00	250.00	136.00	3.60	102.00	9.00	2.70	17.00
121	3	1	.00	230.00	139.00	4.20	96.00	9.50	3.90	13.00
122	3	1	.00	235.00	138.00	4.10	98.00	8.40	3.90	22.00
125	3	1	.00	240.00	140.00	4.40	102.00	8.90	3.50	11.00
127	3	1	.00	278.00	136.00	4.50	94.00	9.00	3.00	7.00
128	3	1	.00	235.00	138.00	4.50	97.00	9.10	2.80	11.00
131	3	1
143	3	1	.00	320.00	142.00	4.00	98.00	9.00	4.10	10.00
144	3	1	.00	234.00	139.00	4.00	96.00	9.00	3.10	17.00
145	3	1	.00	220.00	137.00	5.00	95.00	10.00	4.90	12.00
148	3	1	.00	238.00	140.00	5.00	98.00	9.20	3.20	12.00
149	3	1	.00	230.00	140.00	4.30	102.00	8.80	2.60	7.00
153	3	1	.00	238.00	138.00	4.60	103.00	9.10	3.20	13.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:

BASO Basophils K+ Phosphorous PO4
 PLATE Platelet Count CL- Chlorine SGOT Aspartate Amino
 NA+ Sodium CA++ Calcium Transferase

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Laboratory Characteristics
Day 42 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	SGPT	τ GT	BLOOD SUGAR	ALK. PHOS.	BUN	CREAT.	URIC ACID	TOT. BILI.
1	1	1	25.00	29.00	5.10	83.00	4.30	81.00	517.00	18.10
17	1	1
31	2	1	15.00	.	4.80	169.00	4.30	93.00	424.00	7.00
32	2	1
46	2	1
47	2	1	.	.	5.60	82.00	5.80	76.00	345.00	5.00
81	3	1	8.00	7.00	110.00	23.00	20.00	.60	3.60	.70
84	3	1	12.00	14.00	80.00	27.00	28.00	.50	4.50	.50
86	3	1	16.00	28.00	73.00	30.00	27.00	.50	3.60	1.10
89	3	1	16.00	28.00	50.00	27.00	32.00	.90	3.20	1.10
90	3	1	23.00	18.00	87.00	24.00	14.00	.70	5.60	.70
91	3	1	11.00	14.00	85.00	38.00	27.00	1.10	5.80	.20
92	3	1	13.00	20.00	100.00	60.00	24.00	.80	3.50	.80
95	3	1	14.00	11.00	98.00	27.00	26.00	.70	3.80	.30
97	3	1	11.00	96.00	94.00	36.00	23.00	.70	4.00	1.10
98	3	1	19.00	19.00	52.00	27.00	18.00	.80	3.60	.20
121	3	1	15.00	18.00	82.00	34.00	27.00	.80	4.50	.70
122	3	1	25.00	32.00	96.00	38.00	19.00	.70	6.10	.60
125	3	1	11.00	24.00	96.00	28.00	28.00	.60	3.60	1.40
127	3	1	13.00	43.00	95.00	30.00	29.00	.70	3.30	.50
128	3	1	7.00	56.00	112.00	24.00	33.00	.80	6.90	1.00
131	3	1
143	3	1	11.00	24.00	88.00	60.00	27.00	.50	3.00	.70
144	3	1	26.00	8.00	101.00	24.00	23.00	.80	4.10	1.00
145	3	1	13.00	14.00	91.00	28.00	18.00	.70	3.90	.70
148	3	1	20.00	17.00	100.00	32.00	28.00	.70	3.20	.60
149	3	1	8.00	23.00	88.00	34.00	23.00	.90	3.40	.70
153	3	1	12.00	6.00	107.00	18.00	30.00	1.00	2.50	1.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:

SGPT Alanine Aminotransferase ALK. Alkaline Phosphatase CREAT. Creatinine
τ GT BUN Urea Nitrogen PHOS. Phosphatase TOT. Total
BILI. Bilirubin

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Laboratory Characteristics
Day 42 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	DIR. BILI.	TOT. PROT.	BLOOD ALBU.	CHOL.	TRIG.	GLOBULINS:		
								α-1	α-2	β
1	1	1	1.40	71.00	43.00	5.29	2.42	3.00	12.00	15.00
17	1	1
31	2	1	.	74.00	48.00	6.36	3.14	3.00	6.00	9.00
32	2	1
46	2	1
47	2	1	.	63.00	39.00	6.59	.76	.	.	.
81	3	1	.20	8.10	4.20	138.00	36.00	4.00	7.00	14.00
84	3	1	.10	6.80	4.50	137.00	69.00	5.00	7.00	12.00
86	3	1	.40	7.40	4.80	166.00	79.00	5.00	7.00	13.00
89	3	1	.40	7.80	4.50	302.00	164.00	4.00	7.00	13.00
90	3	1	.30	7.10	4.10	201.00	105.00	6.00	7.00	13.00
91	3	1	.70	7.50	4.10	135.00	72.00	5.00	7.00	12.00
92	3	1	.10	7.20	4.30	180.00	50.00	5.00	7.00	12.00
95	3	1	.90	7.90	5.00	171.00	46.00	6.00	8.00	13.00
97	3	1	.40	6.40	4.70	124.00	64.00	4.00	7.00	12.00
98	3	1	.70	7.30	4.30	159.00	71.00	4.00	7.00	12.00
121	3	1	.20	7.30	3.70	194.00	61.00	4.00	8.00	13.00
122	3	1	.10	7.50	4.00	200.00	272.00	7.00	9.00	15.00
125	3	1	.20	7.00	3.70	197.00	118.00	7.00	12.00	14.00
127	3	1	.10	6.50	4.50	234.00	283.00	6.00	7.00	12.00
128	3	1	.40	6.50	3.70	214.00	124.00	6.00	8.00	13.00
131	3	1
143	3	1	.20	7.30	3.90	234.00	96.00	5.00	8.00	13.00
144	3	1	.20	7.50	4.10	306.00	119.00	5.00	10.00	13.00
145	3	1	.20	6.80	3.80	260.00	142.00	7.00	10.00	13.00
148	3	1	.10	7.70	5.00	203.00	82.00	5.00	8.00	13.00
149	3	1	.20	6.70	4.70	230.00	97.00	6.00	7.00	13.00
153	3	1	.20	6.80	4.70	251.00	103.00	7.00	12.00	14.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:
DIR. Direct TOT. Total BLOOD Blood
BILI. Bilirubin PROT. Protein ALBU. Albumin
CHOL. Cholesterol TRIG. Triglycerides

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Laboratory Characteristics
Day 42 - Reboxetine

Pat. No.	Ctr. ¹ No.	Tx ² Group	Globulins: τ	Specific Gravity	Albumin	Sugar	RBC	WBC
1	1	1	13.00	1.006	-	-	-	0-3
17	1	1
31	2	1	13.00	1.015	-	-	-	.
32	2	1
46	1	1
47	2	1	.	1.025	00000	00000	00000	60-80
81	3	1	16.00	1.010	+	-	2a4	20a30
84	3	1	15.00	1.020	+	-	1a3	4a6
86	3	1	16.00	1.024	+	-	=0	=0
89	3	1	15.00	1.020	+	-	1a2	6a8
90	3	1	15.00	1.016	+	-	=0	1a2
91	3	1	15.00	1.025	++	-	6a8	8a10
92	3	1	15.00	1.010	+	-	1a2	1a2
95	3	1	15.00	1.022	+	-	=0	1a2
97	3	1	15.00	1.027	+	-	=0	1a2
98	3	1	15.00	1.011	+	-	1a2	1a2
121	3	1	17.00	1.025	+	-	-	-
122	3	1	20.00	1.017	+	-	-	-
125	3	1	20.00	1.011	+	-	-	-
127	3	1	16.00	1.020	+	-	-	-
128	3	1	16.00	1.022	+	-	1a2	-
131	3	1
143	3	1	17.00	1.011	+	-	2a4	-
144	3	1	20.00	1.013	+	-	1a2	-
145	3	1	16.00	1.016	+	-	-	-
148	3	1	16.00	1.023	++	-	2a4	0
149	3	1	17.00	1.010	+	-	-	-
153	3	1	20.00	1.016	+	-	1a2	8a10

Number of cases read = 28 Number of cases listed = 28

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Laboratory Characteristics
Day 21 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	HGB	HCT	RBC	WBC	NEUT.	LYMP.	EOS.	MONO.
2	1	2	49.90	5.41	7.50	86.00	12.00	.00	2.00	
16	1	2	43.80	5.02	6.30	73.00	19.00	.00	8.00	
33	2	2	45.20	4.84	7.60	65.00	32.00	1.00	1.00	
34	2	2	
35	2	2	37.50	4.36	12.30	69.00	27.00	4.00	.00	
48	2	2	37.90	3.93	6.40	
82	3	2	41.00	4.00	7.80	58.00	34.00	6.00	2.00	
83	3	2	45.00	5.00	6.90	65.00	25.00	3.00	4.00	
85	3	2	40.00	4.60	4.50	44.00	41.00	8.00	7.00	
87	3	2	40.00	4.56	7.10	67.00	27.00	1.00	5.00	
88	3	2	39.00	4.42	8.70	74.00	20.00	3.00	3.00	
93	3	2	47.00	5.22	7.50	51.00	38.00	3.00	7.00	
94	3	2	43.00	4.51	3.70	55.00	20.00	5.00	10.00	
96	3	2	42.00	4.75	4.50	80.00	17.00	2.00	1.00	
99	3	2	38.00	4.30	7.50	55.00	24.00	18.00	1.00	
100	3	2	40.00	4.52	6.50	66.00	26.00	4.00	4.00	
123	3	2	44.00	5.00	4.80	70.00	25.00	1.00	4.00	
124	3	2	42.00	4.80	5.20	54.00	39.00	3.00	3.00	
126	3	2	47.00	5.70	5.70	63.00	33.00	1.00	3.00	
129	3	2	45.00	5.14	5.40	53.00	36.00	2.00	9.00	
130	3	2	42.00	4.30	7.60	53.00	38.00	3.00	6.00	
133	3	2	42.00	4.74	5.20	45.00	35.00	9.00	11.00	
141	3	2	45.00	5.20	6.30	57.00	40.00	1.00	2.00	
142	3	2	39.00	4.40	4.50	54.00	42.00	3.00	1.00	
146	3	2	37.00	4.10	6.50	65.00	31.00	2.00	2.00	
147	3	2	37.00	4.30	5.90	61.00	35.00	1.00	3.00	
150	3	2	40.00	4.60	6.50	63.00	33.00	1.00	3.00	
151	3	2	40.00	4.40	6.70	45.00	49.00	2.00	4.00	

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:
HGB Hemoglobin WBC White Blood Cells EOS. Eosinophils
HCT Hematocrit NEUT. Neutrophils MONO. Monocytes
RBC Red Blood Cells LYMP. Lymphocytes

FCB 20124/706 i

Laboratory Characteristics
Day 21 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	Laboratory:							
			BASO	PLATE.	NA+	K+	CL-	CA++	PO4	SGOT
2	1	2	.00	427.00	136.00	4.10	99.00	2.32	1.00	28.00
16	1	2	.00	586.00	138.00	4.50	98.00	2.41	1.23	25.00
33	2	2	.00	201.00	146.00	4.20	109.00	2.22	.89	10.00
34	2	2
35	2	2	.00	204.00	143.00	3.70	106.00	2.09	.89	14.00
48	2	2	.	232.00	142.00	4.50	108.00	.	.	.
82	3	2	.00	265.00	141.00	4.00	103.00	8.90	3.20	19.00
83	3	2	.00	260.00	143.00	4.50	99.00	8.80	2.70	25.00
85	3	2	.00	240.00	140.00	4.20	102.00	9.00	3.00	13.00
87	3	2	.00	246.00	138.00	4.00	105.00	9.10	3.10	20.00
88	3	2	.00	239.00	136.00	4.60	100.00	9.10	3.00	8.00
93	3	2	1.00	302.00	138.00	4.10	96.00	8.80	2.50	10.00
94	3	2	.00	275.00	142.00	4.00	101.00	9.00	2.70	14.00
96	3	2	.00	263.00	140.00	4.80	102.00	4.30	3.30	16.00
99	3	2	2.00	210.00	140.00	4.00	100.00	8.80	2.60	9.00
100	3	2	.00	275.00	140.00	4.40	102.00	8.80	2.50	11.00
123	3	2	.00	231.00	140.00	4.00	100.00	8.80	2.70	19.00
124	3	2	1.00	245.00	142.00	3.90	100.00	9.00	3.10	8.00
126	3	2	.00	220.22	140.00	4.20	97.00	8.90	4.00	35.00
129	3	2	.00	216.00	140.00	4.30	102.00	9.10	3.50	12.00
130	3	2	.00	246.00	139.00	5.00	102.00	9.00	3.00	14.00
133	3	2	.00	249.00	142.00	4.10	97.00	8.90	2.70	20.00
141	3	2	.00	290.00	137.00	4.00	96.00	9.00	3.10	14.00
142	3	2	.00	325.00	134.00	4.50	98.00	9.50	4.00	12.00
146	3	2	.00	260.00	138.00	4.20	100.00	9.50	3.50	14.00
147	3	2	.00	240.00	137.00	4.10	102.00	8.90	3.50	14.00
150	3	2	.00	238.00	140.00	4.70	100.00	9.00	3.70	12.00
151	3	2	.00	268.00	145.00	4.20	105.00	10.00	4.70	14.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:
 BASO Basophils K+ Phosphorous PO4
 PLATE Platelet Count CL- Chlorine SGOT Aspartate Amino
 NA+ Sodium CA++ Calcium Transferase

FCE 20124/706 i

Laboratory Characteristics
Day 21 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	Laboratory: SGPT	τ GT	BLOOD SUGAR	ALK. PHOS.	BUN	CREAT.	URIC ACID	TOT. BILI.
2	1	2	16.00	33.00	11.30	99.00	6.00	89.00	350.00	8.20
16	1	2	24.00	15.00	4.70	61.00	4.60	57.00	239.00	12.70
33	2	2	14.00	5.00	4.70	82.00	4.50	98.00	465.00	11.00
34	2	2
35	2	2	9.00	11.00	4.40	133.00	8.50	145.00	478.00	11.00
48	2	2	.	8.00	4.70	.	6.00	88.00	.	.
82	3	2	28.00	30.00	100.00	39.00	32.00	.90	5.00	.50
83	3	2	27.00	28.00	98.00	39.00	31.00	.90	7.10	.80
85	3	2	10.00	7.00	57.00	38.00	31.00	.80	3.30	.60
87	3	2	8.00	5.00	80.00	17.00	15.00	.70	4.00	1.00
88	3	2	13.00	16.00	97.00	24.00	25.00	.90	3.10	.80
93	3	2	18.00	47.00	153.00	34.00	36.00	6.90	5.80	.90
94	3	2	15.00	20.00	52.00	24.00	28.00	1.10	4.70	.80
96	3	2	10.00	40.00	56.00	35.00	24.00	.70	4.50	.20
99	3	2	12.00	48.00	50.00	33.00	16.00	.70	5.40	.70
100	3	2	19.00	27.00	92.00	40.00	26.00	.50	4.10	.20
123	3	2	23.00	29.00	91.00	30.00	23.00	1.10	5.60	.80
124	3	2	9.00	17.00	72.00	35.00	37.00	1.00	3.60	1.20
126	3	2	45.00	17.00	89.00	30.00	28.00	1.00	3.50	.60
129	3	2	12.00	9.00	96.00	32.00	26.00	.70	3.60	.70
130	3	2	15.00	30.00	76.00	26.00	28.00	.50	3.00	.60
133	3	2	20.00	26.00	85.00	24.00	15.00	.60	5.70	.50
141	3	2	18.00	8.00	84.00	20.00	25.00	.70	3.70	1.40
142	3	2	12.00	42.00	83.00	22.00	15.00	.50	3.40	.70
146	3	2	11.00	13.00	86.00	34.00	38.00	.80	3.00	.60
147	3	2	16.00	19.00	87.00	24.00	39.00	.70	4.10	.60
150	3	2	13.00	13.00	85.00	36.00	36.00	.60	3.40	.80
151	3	2	10.00	26.00	85.00	34.00	19.00	.50	5.70	.70

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:
SGPT Alanine Aminotransferase
τ GT
ALK. Alkaline Phosphatase
PHOS. Phosphatase
BUN Urea Nitrogen
CREAT. Creatinine
TOT. Total
BILI. Bilirubin

FCE 20124/706 i

Laboratory Characteristics
Day 21 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	DIR. BILI.	TOT. PROT.	BLOOD			GLOBULINS:		
					ALBU.	CHOL.	TRIG.	α-1	α-2	β
2	1	2	.00	70.00	38.00	5.22	3.03	2.00	9.00	10.00
16	1	2	.70	74.00	41.00	6.07	1.13	5.00	14.00	11.00
33	2	2	.	66.00	44.00	5.87	1.24	3.00	5.00	7.00
34	2	2
35	2	2	.	65.00	38.00	4.93	.94	2.00	3.00	7.00
48	2	2	.	60.00	34.00	.	.	3.00	6.00	9.00
82	3	2	.10	6.80	4.10	163.00	68.00	4.00	7.00	12.00
83	3	2	.20	6.90	3.90	270.00	170.00	4.00	7.00	12.00
85	3	2	.20	7.30	4.70	151.00	54.00	6.00	8.00	14.00
87	3	2	.30	6.80	4.50	153.00	35.00	4.00	7.00	12.00
88	3	2	.20	7.10	4.40	213.00	68.00	6.00	8.00	13.00
93	3	2	.20	7.40	5.00	196.00	155.00	4.00	7.00	12.00
94	3	2	.20	7.00	4.10	125.00	35.00	5.00	8.00	13.00
96	3	2	.80	7.40	3.80	195.00	61.00	5.00	7.00	12.00
99	3	2	1.60	7.80	4.80	162.00	124.00	6.00	11.00	14.00
100	3	2	.80	6.70	4.00	203.00	113.00	4.00	7.00	12.00
123	3	2	.20	7.00	3.60	312.00	171.00	5.00	8.00	15.00
124	3	2	.40	6.50	3.60	151.00	92.00	5.00	7.00	13.00
126	3	2	.10	7.30	4.20	202.00	130.00	6.00	7.00	14.00
129	3	2	.10	6.90	3.70	140.00	50.00	5.00	7.00	13.00
130	3	2	.20	6.20	4.01	60.00	74.00	6.00	9.00	13.00
133	3	2	.10	6.50	3.80	260.00	172.00	4.00	8.00	13.00
141	3	2	.20	7.00	4.40	271.00	93.00	7.00	8.00	13.00
142	3	2	.20	7.30	3.80	153.00	83.00	5.00	7.00	13.00
146	3	2	.10	6.40	4.20	236.00	85.00	7.00	11.00	14.00
147	3	2	.10	6.70	3.60	169.00	40.00	5.00	9.00	14.00
150	3	2	.10	7.00	3.50	218.00	75.00	5.00	7.00	13.00
151	3	2	.20	6.90	3.80	230.00	218.00	7.00	12.00	15.00

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Tx Group 1 = RBX 2 = PBO

Abbreviations:

DIR.	Direct	TOT.	Total	BLOOD	Blood
BILI.	Bilirubin	PROT.	Protein	ALBU.	Albumin
CHOL.	Cholesterol	TRIG.	Triglycerides		

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Laboratory Characteristics
Day 21 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ¹ Group	Globulins: τ	Specific Gravity	Albumin	Sugar	RBC	WBC
2	1	1	25.00	1.025	0.3	5.5	-	0-3
16	1	1	18.00	.				
33	2	1	7.00	1.025	0	0	0	0
34	2	1
35	2	1	11.00	1.010				
48	2	1	8.00	1.025	00000	00000	00000	00000
82	3	1	15.00	1.030	+	-	=0	=0
83	3	1	15.00	1.020	+	-	1a2	1a2
85	3	1	16.00	1.019	+	-	1a3	10a15
87	3	1	15.00	1.014	+	-	1a3	8a10
88	3	1	17.00	1.020	++	-	=0	10a15
93	3	1	15.00	1.024	+	++++	=0	2a4
94	3	1	16.00	1.026	+	-	1a2	1a3
96	3	1	15.00	1.012	+	-	1a3	1a2
99	3	1	21.00	1.013	+	-	1a2	1a2
100	3	1	15.00	1.010	+	-	=0	=0
123	3	1	15.00	1.025	++	-	1a2	-
124	3	1	16.00	1.017	+	-	-	-
126	3	1	19.00	1.024	+	-	-	-
129	3	1	15.00	1.020	+	-	1a2	-
130	3	1	19.00	1.011	+	-	-	-
133	3	1	15.00	1.007	+	-	-	-
141	3	1	16.00	1.018	+	-	2a4	15a20
142	3	1	16.00	1.020	+	-	2a4	-
146	3	1	20.00	1.010	+	-	1a2	-
147	3	1	15.00	1.016	+	-	-	-
150	3	1	15.00	1.015	+	-	1a3	-
151	3	1	20.00	1.010	+	-	-	-

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Laboratory Characteristics
Day 42 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	HGB	HCT	RBC	WBC	NEUT.	LYMP.	EOS.	MONO.
2	1	2
16	1	2
33	2	2
34	2	2
35	2	2
48	2	2	13.70	40.10	4.25	6.50	69.00	28.00	3.00	.00
82	3	2
83	3	2	13.20	45.00	5.00	6.80	66.00	27.00	3.00	4.00
85	3	2
87	3	2
88	3	2	12.60	39.00	4.45	5.50	56.00	32.00	4.00	8.00
93	3	2	15.20	47.00	5.25	7.40	38.00	51.00	6.00	4.00
94	3	2
96	3	2	13.50	42.00	4.73	4.50	62.00	30.00	4.00	3.00
99	3	2
100	3	2
123	3	2	15.00	45.00	5.14	4.86	69.00	27.00	1.00	3.00
124	3	2	14.30	43.00	5.10	4.30	59.00	36.00	3.00	2.00
126	3	2	14.10	45.00	5.40	6.90	54.00	42.00	2.00	2.00
129	3	2
130	3	2
133	3	2
141	3	2	13.90	41.00	4.68	5.60	63.00	26.00	7.00	3.00
142	3	2
146	3	2
147	3	2
150	3	2	13.40	40.00	4.60	5.10	68.00	28.00	2.00	2.00
151	3	2

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = REX 2 = PBO

Abbreviations:
HGB Hemoglobin WBC White Blood Cells EOS. Eosinophils
HCT Hematocrit NEUT. Neutrophils MONO. Monocytes
RBC Red Blood Cells LYMP. Lymphocytes

FCE 20124/706 i

Laboratory Characteristics
Day 42 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	BASO	PLATE.	NA+	K+	CL-	CA++	PO4	SGOT
2	1	2
16	1	2
33	2	2
34	2	2
35	2	2
48	2	2	.00	237.00	145.00	4.40	107.00	2.36	1.26	14.00
82	3	2
83	3	2	.00	262.00	140.00	4.50	99.00	8.80	2.70	25.00
85	3	2
87	3	2
88	3	2	.00	201.00	135.00	4.40	94.00	9.20	3.40	12.00
93	3	2	1.00	270.00	142.00	4.00	105.00	10.10	3.20	21.00
94	3	2
96	3	2	.00	290.00	141.00	4.20	103.00	8.80	3.00	12.00
99	3	2
100	3	2
123	3	2	.00	242.00	140.00	4.00	98.00	8.80	2.70	17.00
124	3	2	.00	253.00	140.00	4.50	100.00	9.10	2.70	12.00
126	3	2	.00	230.00	138.00	4.50	97.00	9.50	4.10	16.00
129	3	2
130	3	2
133	3	2
141	3	2	1.00	215.00	140.00	4.20	102.00	9.20	3.50	11.00
142	3	2
146	3	2
147	3	2
150	3	2	.00	235.00	142.00	4.70	103.00	9.50	3.50	6.00
151	3	2

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:

BASO Basophils K+ Phosphorous PO4
PLATE Platelet Count CL- Chlorine SGOT Aspartate Amino
NA+ Sodium CA++ Calcium Transferase

FCE 20124/706 i

Laboratory Characteristics
Day 42 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	SGPT	τ GT	BLOOD SUGAR	ALK. PHOS.	BUN	CREAT.	URIC ACID	TOT. BILI.
2	1	2
16	1	2
33	2	2
34	2	2
35	2	2
48	2	2	7.00	.	5.20	78.00	5.60	88.00	225.00	10.00
82	3	2
83	3	2	28.00	22.00	99.00	39.00	37.00	.90	7.10	.80
85	3	2
87	3	2
88	3	2	11.00	15.00	52.00	23.00	31.00	.50	4.00	1.00
93	3	2	32.00	55.00	286.00	40.00	30.00	1.20	4.50	1.00
94	3	2
96	3	2	15.00	25.00	90.00	47.00	25.00	.80	3.70	.20
99	3	2
100	3	2
123	3	2	22.00	27.00	86.00	30.00	24.00	.70	6.10	1.00
124	3	2	16.00	17.00	85.00	18.00	36.00	1.00	4.80	.90
126	3	2	21.00	18.00	92.00	44.00	14.00	.60	3.30	.60
129	3	2
130	3	2
133	3	2
141	3	2	12.00	6.00	104.00	25.00	15.00	.60	3.40	1.60
142	3	2
146	3	2
147	3	2
150	3	2	7.00	10.00	88.00	34.00	38.00	.70	4.00	.70
151	3	2

¹ Ctr. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Tx Group 1 = RBX 2 = PBO

Abbreviations:

SGPT Alanine Aminotransferase
ALK. Alkaline Phosphatase
PHOS. Phosphatase
τ GT Urea Nitrogen
BUN Urea Nitrogen
CREAT. Creatinine
TOT. Total
BILI. Bilirubin

4 0 1

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Laboratory Characteristics
Day 42 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	DIR. BILI.	TOT. PROT.	BLOOD ALBU.	CHOL.	TRIG.	GLOBULINS:		β
								α-1	α-2	
2	1	2
16	1	2
33	2	2
34	2	2
35	2	2
48	2	2	.	72.00	46.00	5.01	1.23	8.50	6.00	8.00
82	3	2
83	3	2	.20	7.10	3.90	270.00	150.00	4.00	7.00	15.00
85	3	2
87	3	2
88	3	2	.30	7.80	4.60	188.00	62.00	5.00	8.00	13.00
93	3	2	.30	7.50	4.80	172.00	224.00	5.00	7.00	13.00
94	3	2
96	3	2	.50	7.30	4.50	168.00	60.00	5.00	8.00	12.00
99	3	2
100	3	2
123	3	2	.30	6.90	3.70	315.00	187.00	4.00	8.00	15.00
124	3	2	.30	7.40	4.40	157.00	82.00	5.00	7.00	13.00
126	3	2	.10	6.50	3.70	206.00	119.00	5.00	7.00	13.00
129	3	2
130	3	2
133	3	2
141	3	2	.50	7.20	3.90	210.00	88.00	6.00	7.00	13.00
142	3	2
146	3	2
147	3	2
150	3	2	.20	7.30	4.30	208.00	63.00	4.00	8.00	13.00
151	3

Number of cases read = 28 Number of cases listed = 28

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Laboratory Characteristics
Day 42 - Placebo

Pat. No.	Ctr. ¹ No.	Tx ² Group	Globulins: τ	Specific Gravity	Albumin	Sugar	RBC	WBC
2	1	2
16	1	2
33	2	2
34	2	2
35	2	2
48	2	1	9.00	1.025	00000	00000	00000	000
82	3	2
83	3	2	16.00	1.020	+	-	1a2	1a2
85	3	2
87	3	2
88	3	2	15.00	1.020	+	-	3a5	2a4
93	3	2	16.00	1.030	+	37g1	=0	=0
94	3	2
96	3	2	17.00	1.010	+	-	1a2	1a2
99	3	2
100	3	2
123	3	2	16.00	1.022	+	-	1a2	-
124	3	2	20.00	1.020	+	-	-	-
126	3	2	19.00	1.018	+	-	1a2	-
129	3	2
130	3	2
133	3	2
141	3	2	16.00	1.014	+	-	6a8	-
142	3	2
146	3	2
147	3	2
150	3	2
151	3	2

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ENCLOSURE 30

**Experimental Cohort:
Electrophysiologic Tests
in the Two Treatment Groups**

404

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FCE 20124/706 i

Reboxetine Treatment Group
Electrocardiogram and Electroencephalogram

Pat. No.	Ctr. ¹ No.	ECG: ²			EEG:	
		Day 0	Day 21	Day 42	Day 0	Day 42
1	1	0	0	0	0	0
17	1	1	-	1	0	-
31	2	0	0	0	0	0
32	2	0	0	-	0	-
46	2	0	-	-	0	-
47	2	0	0	0	0	0
81	3	1	1	1	0	0
84	3	0	0	0	0	0
86	3	1	1	1	0	0
89	3	1	1	1	0	0
90	3	0	0	0	0	0
91	3	0	0	0	0	0
92	3	1	1	1	0	0
95	3	0	0	0	0	0
97	3	0	0	0	0	0
98	3	0	0	0	0	0
121	3	0	0	0	0	0
122	3	0	0	0	0	0
125	3	0	0	0	0	0
127	3	0	0	0	0	0
128	3	0	0	0	0	0
131	3	0	0	-	0	-
143	3	0	0	0	0	0
144	3	0	0	0	0	0
145	3	0	0	0	0	0
148	3	0	0	0	0	0
149	3	0	0	0	0	0
153	3	0	0	0	0	0

¹ Ctr. No. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² E.C.G./E.E.G. 1 = Abnormal 0 = Normal

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Placebo Treatment Group
Electrocardiogram and Electroencephalogram

Pat. No.	Ctr. No. ¹	ECG: ²			EEG:	
		Day 0	Day 21	Day 42	Day 0	Day 42
2	1	1	-	1	0	0
16	1	1	-	-	0	-
33	2	0	0	-	0	0
34	2	0	-	-	0	-
35	2	0	-	-	0	-
48	2	0	0	0	0	0
82	3	0	0	-	0	0
83	3	0	0	0	0	0
85	3	0	0	-	0	0
87	3	0	0	-	0	0
88	3	0	0	0	0	0
93	3	1	1	1	0	0
94	3	1	1	-	0	0
96	3	0	0	0	0	0
99	3	0	0	-	0	0
100	3	0	0	-	0	0
123	3	0	0	0	0	0
124	3	0	0	0	0	0
126	3	0	0	0	0	0
129	3	0	0	-	0	0
130	3	0	0	-	0	-
133	3	0	0	-	0	-
141	3	0	0	0	-	-
142	3	0	-	-	0	-
146	3	1	1	-	0	0
147	3	0	0	-	0	0
150	3	0	0	0	0	0
151	3	0	0	-	0	0

¹ Ctr. No. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² E.C.G./E.E.G. 1 = Abnormal 0 = Normal

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ENCLOSURE 31

**Analytic Cohort:
Benefit/Risk Ratio in the Two Treatment Groups**

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Efficacy Index
Reboxetine Treatment Group

Pat. No.	Ctr. No. ¹	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
1	1	14	10	10	15	.	.
17	1	8
31	2	14	9	10	6	6	6
32	2	6	10	9	3	4	.
46	2	10
47	2	2	1	2	1	1	.
81	3	15	6	6	1	1	1
84	3	10	6	6	6	2	2
86	3	14	9	5	5	1	1
89	3	14	7	6	6	2	1
90	3	9	5	5	1	2	1
91	3	10	2	2	2	2	2
92	3	10	6	2	2	2	2
95	3	13	5	1	1	1	1
97	3	10	6	3	2	1	1
98	3	11	6	6	2	2	1
121	3	14	10	10	10	10	10
122	3	14	6	2	1	1	1
125	3	15	6	1	1	1	1
127	3	9	10	6	5	1	1
128	3	10	2	2	1	1	1
131	3	13	13	13	.	.	.
143	3	10	10	5	1	1	1
144	3	10	6	2	2	1	1
145	3	10	6	6	6	1	1
148	3	9	9	1	1	1	1
149	3	14	14	14	13	13	13
153	3	13	14	9	9	9	5

¹ Ctr. No.: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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		Efficacy Index Placebo Treatment Group					
Pat. No.	Ctr. No. ¹	Day 7	Day 14	Day 21	Day 28	Day 35	Day 42
2	1	13
16	1	13
33	2	14	9	9	.	.	.
34	2	11	11
35	2	13	14	13	51	.	.
48	2	5	9	6	5	1	1
82	3	13	13	13	.	.	.
83	3	10	10	9	5	5	5
85	3	13	13	13	.	.	.
87	3	13	13	13	.	.	.
88	3	13	9	9	9	5	5
93	3	10	2	1	1	1	1
94	3	14	13	13	.	.	.
96	3	13	5	5	5	1	1
99	3	13	13	13	.	.	.
100	3	13	13	13	.	.	.
123	3	9	5	5	5	5	5
124	3	14	13	13	13	13	13
126	3	10	5	5	1	1	1
129	3	13	13	13	.	.	.
130	3	10	9	13	.	.	.
133	3	9	13	13	.	.	.
141	3	10	5	5	5	5	9
142	3	13	13	13	.	.	.
146	3	13	13	13	.	.	.
147	3	13	13	13	.	.	.
150	3	11	6	5	1	1	1
151	3	13	13	13	.	.	.

¹ Ctr. No.: 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

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ENCLOSURE 32

**Analytic Cohort:
Indirect Indicators of Efficacy
in the Two Treatment Groups at Termination**

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Pat. No.	Ctr. ¹ No.	Total Days in Trial	Reboxetine Group	
			Disposition ² at Termination	Disposition ³ with Medication
1	1	30	1	1
17	1	7	1	1
31	2	42	2	3
32	2	30	2	.
46	2	14	1	1
47	2	42	.	.
81	3	42	2	4
84	3	42	2	4
86	3	42	2	4
89	3	42	2	4
90	3	42	2	4
91	3	42	2	4
92	3	42	2	4
95	3	42	2	4
97	3	42	2	4
98	3	42	2	4
121	3	42	1	1
122	3	42	1	2
125	3	42	1	2
127	3	42	1	2
128	3	42	1	2
131	3	21	1	1
143	3	42	1	2
144	3	42	1	2
145	3	42	1	2
148	3	42	2	4
149	3	42	1	1
153	3	42	1	2

¹ Ctr.No. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Disposition at Termination: 1 = Hospitalized 2 = Discharged
³ Disposition with Medicaiton: 1 = Hospitalized with Medication
 2 = Hospitalized without Medication
 3 = Discharged with Medication
 4 = Discharged without Medication

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Pat. No.	Ctr. ¹ No.	Total Days in Trial	Placebo Group	
			Disposition ² at Termination	Disposition ³ with Medication
2	1	4	.	.
16	1	7	1	1
33	2	15	1	1
34	2	17	1	1
35	2	21	1	1
48	2	43	2	4
82	3	21	1	1
83	3	42	2	4
85	3	21	1	1
87	3	21	1	1
88	3	42	2	3
93	3	42	.	.
94	3	21	1	1
96	3	42	2	4
99	3	21	1	1
100	3	21	1	1
123	3	42	1	2
124	3	42	1	1
126	3	42	1	2
129	3	21	1	1
130	3	21	1	1
133	3	21	1	1
141	3	42	1	2
142	3	21	1	1
146	3	21	1	1
147	3	21	1	1
150	3	42	1	2
151	3	21	1	1

¹ Ctr.No. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro
² Disposition at Termination: 1 = Hospitalized 2 = Discharged
³ Disposition with Medicaiton: 1 = Hospitalized with Medication
2 = Hospitalized without Medication
3 = Discharged with Medication
4 = Discharged without Medication

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ENCLOSURE 33

**Total Population:
Indirect Indicators of Efficacy
in the Two Treatment Groups at Follow-up**

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Pat. No.	Ctr. ¹ No.	New Sign/ Symptom	Reboxetine Group					
			Pres. ² Meds.	Meds	Dose	Eff. ³	Tol. ⁴	Disp. ⁵
1	1	SUICIDE	0		.	.	.	0
17	1		1	Desipramine	50.000	1	1	1
31	2		1	Imip/Chlrdiaz	60.000	1	1	0
32	2	
46	2	
47	2		0		.	.	.	1
81	3		0		.	.	.	2
84	3		0		.	.	.	2
86	3		0		.	.	.	0
89	3		0		.	.	.	0
90	3		0		.	.	.	2
91	3		0		.	.	.	0
92	3		0		.	.	.	0
95	3		0		.	.	.	0
97	3		0		.	.	.	0
98	3		0		.	.	.	0
121	3		1	IMIPRAMINE	300.000	1	3	0
122	3		0		.	.	.	0
125	3		0		.	.	.	0
127	3		0		.	.	.	0
128	3		0		.	.	.	0
131	3		1	IMIPRAMINE	300.000	1	1	0
143	3		0		.	.	.	0
144	3		0		.	.	.	0
145	3		1	IMIPRAMINE	200.000	1	1	0
148	3		0		.	.	.	0
149	3		1	IMIPRAMINE	300.000	1	1	0
153	3		0		.	.	.	0

¹ Ctr.No. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Pres.Meds (Prescribed Medication) 0 = No 1 = Yes

³ Eff. (Efficacy) 0=None 1=Good 2=Very Good 3=Fair 4=Poor 5=Bad

⁴ Tol. (Tolerability) 0=None 1=Good 2=Very Good 3=Fair 4=Poor 5=Bad

⁵ Disp. (Disposition) 0=Outpatient 1=Inpatient 2=Discharged

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Pat. No.	Ctr. ¹ No.	New Sign/ Symptom	Placebo Group					
			Pres. ² Meds.	Meds	Dose	Eff. ³	Tol. ⁴	Disp. ⁵
2	1		0		.	.	.	2
16	1		1	Chl1rhyd/Amitr	100.000	1	3	1
33	2	
34	2	
35	2		0		.	.	.	1
48	2		0		.	.	.	1
82	3		1	Imipramine	300.000	1	1	0
83	3		1	Imipramine	.	1	4	0
85	3		1	Imipramine	200.000	1	1	0
87	3		1	Imipramine	250.000	1	1	0
88	3		1	Imipramine	300.000	1	1	0
93	3	DM/LIA/MR/SI	1	Imipramine	300.000	1	4	0
94	3		1	Imipramine	250.000	1	1	0
96	3		0		.	.	.	0
99	3		1	Imipramine	200.000	4	4	1
100	3		1	Imipramine	275.000	1	1	0
123	3		0		.	.	.	0
124	3		1	IMIPRAMINE	250.000	1	1	0
126	3		0		.	.	.	0
129	3		1	IMIPRAMINE	300.000	1	1	0
130	3		1	IMIPRAMINE	250.000	1	1	0
133	3		1	IMIPRAMINE	250.000	1	1	0
141	3		1	IMIPRAMINE	150.000	1	4	0
142	3		1	IMIPRAMINE	300.000	1	1	0
146	3		1	IMIPRAMINE	250.000	1	1	0
147	3		1	IMIPRAMINE	250.000	1	1	0
150	3		0		.	.	.	0
151	3		1	IMIPRAMINE	300.000	1	1	0

¹ Ctr.No. 1 = Montreal 2 = Pointe Claire 3 = Rio de Janeiro

² Pres.Meds (Prescribed Medication) 0 = No 1 = Yes

³ Eff. (Efficacy) 0=None 1=Good 2=Very Good 3=Fair 4=Poor 5=Bad

⁴ Tol. (Tolerability) 0=None 1=Good 2=Very Good 3=Fair 4=Poor 5=Bad

⁵ Disp. (Disposition) 0=Outpatient 1=Inpatient 2=Discharged

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ENCLOSURE 34

Data Base Listings

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Addendum:

Data regarding the results of ECG and EEG tracings (i.e., normal or abnormal and specifics of any abnormality) was recorded on the Day 0 and Day 21 Vital Signs Forms -- ECG both days; EEG on Day 0 -- and on the Day 42 Physical Examination form -- both ECG and EEG. Because of this, for data analysis purposes a specially designed form was created at the time of data entry. This form consisted only of ECG and EEG data and was set up as follows:

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PATIENT IDENTIFICATION

Column No.	Contents
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-16	Patient Initials (2)
17	Sex: 0=Female 1=Male
18-19	Age
20-22	Weight (in kilograms)
23-25	Height (in centimeters)
26-31	Hospitalization Date

RECORD: 1

01001001-0111 PR150088177111689112789
 01002001-0112 GB160064170030290030790
 01016001-0112 PJ053038155012990020290
 01017001-0111 LB050044152081090081690
 04031001-0111 HB146111178110789111589
 04032001-0111 CG130080172111190011290
 04033001-0112 SS153085180021390030290
 04034001-0112 MD146080165070290070490
 04035001-0112 YL154074166071590081590
 04046001-0111 LB042049158071090071090
 04047001-0111 DP038053162101690101090
 04048001-0112 CG020058168110290110690
 07121001-0111 SF138075173040489040689
 07122001-0111 PC134082180040789040789
 07123001-0112 AC141061164040789040789
 07124001-0112 IG141072172040789040789
 07125001-0111 CS139070186040789040789
 07126001-0112 OF132066174040789040789
 07127001-0111 AJ147063180040789040789
 07128001-0111 JA142077169050989051089
 07129001-0112 RA126077178050989051089
 07130001-0112 CV140080180051089051089
 07131001-0111 MP125055166052489052489
 07133001-0112 CM147072178052489052489
 07141001-0112 EB043070173040789040789
 07142001-0112 CC025056167040589040789
 07143001-0111 RR058052160040589040789
 07144001-0111 MM050068165051089051089
 07145001-0111 ML052071157051089051089
 07146001-0112 LP058044150050989051089
 07147001-0112 JN040055150061389061489
 07148001-0111 VG050060158051089051089

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07149001-0111 ES058060161051089051089
07150001-0112 CF052068168052489052489
07151001-0112 BS048058163052489052489
07153001-0111 AC057045158052489052489
07081001-7211 MC134050156092889092989
07082001-7212 CS133078176092789092989
07083001-7212 CC120058156092889092989
07084001-7211 AM133042150092789092989
07085001-7212 SP147059159092789092989
07086001-7211 EP138074169092889092989
07087001-7212 MC127051160092889092989
07088001-7212 AL137059160092989092989
07089001-7211 NM149075160092989092989
07090001-7211 DC124052162092989092989
07091001-7211 MA037062165110689110789
07092001-7211 LZ043055160110689110789
07093001-7212 JM051072170110689110789
07094001-7212 SF029060174110689110789
07095001-7211 MA048063164110689110789
07096001-7212 AC055048163110789110789
07097001-7211 CO030058163110689110789
07098001-7211 RL026051169110789110789
07099001-7212 LM018047160110789110789
07100001-7212 AR034062166110789110789

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CHECKLIST OF ELIGIBILITY FOR PLACEBO WASHOUT

Column No.	Contents		
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro		
3-5	Patient Number		
6-8	Form Number		
9-11	Assessment Day		
12	Record Number		
13	Treatment Group: 1=Reboxetine 2=Placebo		
14	Women at risk of pregnancy who are using.....	0=No	1=Yes
15	Age 18-65	0=No	1=Yes
16	DSM-III-R diagnosis.....	0=No	1=Yes
17	HAMD Score.....	0=No	1=Yes
18	Signed written	0=No	1=Yes
20	Women at risk of pregnancy who are not using.	0=No	1=Yes
21	Presence and/or history of schizophrenia.....	0=No	1=Yes
22	Presence and/or history of substance abuse...	0=No	1=Yes
23	Presence of non-psychiatric medical.....	0=No	1=Yes
24	Chronic use of medications.....	0=No	1=Yes
25	Presence of neurological disorder.....	0=No	1=Yes
26	History or presence of glaucoma.....	0=No	1=Yes
27	Pregnancy or breast feeding.....	0=No	1=Yes
28	History of hypersensitivity.....	0=No	1=Yes
29	Participation in clinical trial.....	0=No	1=Yes
30	Clinically meaningful abnormal finding.....	0=No	1=Yes
31	Patients who are at suicidal risk.....	0=No	1=Yes
32	Patients treated with ECT.....	0=No	1=Yes
33	History or presence of hematitis.....	0=No	1=Yes

01001002-0111 11111000000000000000112789
 01002002-0112 1111100000000000000030790
 01016002-0112 1111100000000000000020290
 01017002-0111 11111000000000000000081690
 04031002-0111 11111000000000000000111589
 04032002-0111 1111100000000000000011290
 04033002-0112 1111100000000000000030290
 04034002-0112 11111000000000000000070490
 04035002-0112 11111000000000000000081590
 04046002-0111 11111000000000000000071090
 04047002-0111 11111000000000000000101090
 04048002-0112 11111000000000000000061190
 07081002-7211 11111000000000000000092989
 07082002-7212 11111000000000000000092989
 07083002-7212 11111000000000000000092989
 07084002-7211 11111000000000000000092989
 07085002-7212 11111000000000000000092989
 07086002-7211 11111000000000000000092989
 07087002-7212 11111000000000000000092989
 07088002-7212 11111000000000000000092989

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07089002-7211 111110000000000000092989
07090002-7211 111110000000000000092989
07091002-7211 1111100000000000000110789
07092002-7211 1111100000000000000110789
07093002-7212 1111100000000000000110789
07094002-7212 1111100000000000000110789
07095002-7211 1111100000000000000110789
07096002-7212 1111100000000000000110789
07097002-7211 1111100000000000000110789
07098002-7211 1111100000000000000110789
07099002-7212 1111100000000000000110789
07100002-7212 1111100000000000000110789
07121002-0111 111110000000000000040689
07122002-0111 111110000000000000040789
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07124002-0112 111110000000000000040789
07125002-0111 111110000000000000040789
07126002-0112 111110000000000000040789
07127002-0111 111110000000000000040789
07128002-0111 111110000000000000051089
07129002-0112 111110000000000000051089
07130002-0112 111110000000000000051089
07131002-0111 111110000000000000052489
07133002-0112 111110000000000000052489
07141002-0112 111110000000000000040789
07142002-0112 111110000000000000040789
07143002-0111 111110000000000000040789
07144002-0111 111110000000000000051089
07145002-0111 111110000000000000051089
07146002-0112 111110000000000000051089
07147002-0112 111110000000000000061489
07148002-0111 111110000000000000051089
07149002-0111 111110000000000000051089
07150002-0112 111110000000000000052489
07151002-0112 111110000000000000052489
07153002-0111 111110000000000000052489

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DIAGNOSIS

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-19	DSM-III-R (Axis I) Code Number
20-49	DSM-III-R Diagnosis
50	History of mental disorder known 0=No 1=Yes
51-52	Age at onset
53-54	Number of previous episodes
55-56	Approximate duration of last episode: weeks
57-58	Approximate duration of last episode: months
59-60	Approximate duration of last episode: years
61-62	Approximate duration at time of admission to study: days
63-64	Approximate duration at time of admission to study: weeks
65-66	Approximate duration at time of admission to study: months
67-68	Approximate duration at time of admission to study: years
69	Present episode is best characterized as: 1=Exacerbation 2=Recurrence 3=Significantly different 4=First occurrence
70	Onset of present episode was: 1=Acute (< 2weeks) 2=Subacute (≥ 2weeks) 3=Insidious (≥ 3months)
71	Precipitating external stress was: 1=Absent 2=Probably present 3=Definitely present
07121005-0111	29630Major Depression 1360100080000000400211040689
07122005-0111	29620Major Depression 1340000000000000300411040789
07123005-0112	29630Major Depression 1300500070000000300211040789
07124005-0112	29630Major Depression 1280800120000000100211040789
07125005-0111	29630Major Depression 1300100000200000600221040789
07126005-0112	29620Major Depression 1320000000000000300411040789
07127005-0111	29620Major Depression 1470000000000000900421040789
07129005-0111	29630Major Depression 1350600180000000200211051089
07129005-0112	29620Major Depression 1260000000000000300411051089
07130005-0112	29630Major Depression 1250600040000000500231051089
07131005-0111	29630Major Depression 1190500030000000200211052489
07133005-0112	29620Major Depression 1460000000000000400421052489
07141005-0112	29630Major Depression 1320200050000000200222040789
07142005-0112	29620Major Depression 12400000000000001000413040789
07143005-0111	29620Major Depression 1580000000000000200412040789
07144005-0111	29630Major Depression 1351000180000000500211051089
07145005-0111	29620Major Depression 1520000000000000400411051089
07146005-0112	29620Major Depression 1580000000000000900421051089
07147005-0112	29620Major Depression 1400000000000000300411061489
07148005-0111	29620Major Depression 15000000000000001200431051089

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07149005-0111	29630Major	Depression	1300800080000000400231051089
07150005-0112	29630Major	Depression	1401000100000000900231052489
07151005-0112	29620Major	Depression	1480000000000000100413052489
07153005-0111	29620Major	Depression	1570000000000000400421052489
07081005-7211	29620Major	Depression	1340000000000000400421092989
07082005-7212	29620Major	Depression	1330000000000000500411092989
07083005-7212	29620Major	Depression	12000000000000200411092989
07084005-7211	29630Major	Depression	1270200080000000300221092989
07085005-7212	29630Major	Depression	1400300100000000400221092989
07086005-7211	29620Major	Depression	1380000000000000600422092989
07087005-7212	29620Major	Depression	127000000000001000412092989
07088005-7212	29620Major	Depression	1320200000200000800211092989
07089005-7211	29620Major	Depression	1490000000000000800421092989
07090005-7211	29620Major	Depression	1240000000000000300412092989
07091005-7211	29620Major	Depression	1370000000000000400421110789
07092005-7211	29630Major	Depression	1300500000100000400231110789
07093005-7212	29630Major	Depression	1400400080000000400221110789
07094005-7212	29620Major	Depression	1290000000000000800413110789
07095005-7211	29620Major	Depression	1480000000000000100431110789
07096005-7212	29630Major	Depression	1420700060000000200221110789
07097005-7211	29620Major	Depression	1300000000000000100411110789
07098005-7211	29620Major	Depression	126000000000001000421110789
07099005-7212	29620Major	Depression	1180000000000000400413110789
07100005-7212	29630Major	Depression	1340200070000001200231110789
01001005-0111	29633Maj.	Depression,rec.Sev.W/op.F.	1500100030000000300232112789
01002005-0112	29633Maj.	Depression,rec.Sev.W/op.F.	1420806000000000200221030790
01016005-0112	29633Maj.	Depression,rec.Sev.W/op.F.	1430100000100000200221020290
01017005-0111	29634Maj.	Depression,rec.W/psy.Feat.	1310100040000000100232081690
04031005-0111	29633Maj.	Depression,recur.Sev.W/pf	1440400030000000300222111569
04032005-0111	29632Maj.	Depression,recur.Mod.	12301 00000800231011290
04033005-0112	29630Maj.	Depression,Recurr.Unspec.	1250500050000000600221030290
04034005-0112	29630Maj.	Depression,recurr.Unspec.	1321000070000000200211070490
04035005-0112	29630Maj.	Depression,recurr.Unspec.	1250600050000000900232081590
04046005-0111	29630Maj.	Depression,recurr.Unspec.	134 00000200221071090
04047005-0111	29630Maj.	Depression	1072000020000000200222101090
04048005-0112	29630Maj.	Depression	1111000030000000200212110690

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PREVIOUS MEDICATION TREATMENTS FOR PSYCHIATRIC DISORDERS

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-34	Medication name
35-40	From date
41-46	To date
47	Efficacy 0=Very Poor 1=Poor 2=Fair 3=Good 4=Very Good
48-65	Side effects (detail)
07121006-0111	tranylcypromine 04 8701 883dizziness 040689
07121006-0121	bromazepam 04 8701 882sleepiness 040689
07122006-0111	
07123006-0112	imipramine 0715771030832dry mouth 040789
07123006-0122	chlordiazepoxide 0715770620801sedation 040789
07123006-0132	diazepam 0620800518861none 040789
07123006-0142	amitryptiline 0518861215861sedation 040789
07124006-0112	imipramine 03 7904 844dry mouth 040789
07124006-0122	amitryptiline 04 8408 864sleepiness 040789
07124006-0132	diazepam 03 7908 862none 040789
07124006-0142	trazodone 08 8610 872none 040789
07124006-0152	triazolan 04 3402 893none 040789
07125006-0111	clomipramine 03 8012 823constipation 040789
07125006-0121	bromazepam 03 8010 843none 040789
07126006-0112	
07127006-0111	
07128006-0111	amitryptiline 02 8510 862sleepiness 051089
07128006-0121	chlordiazepoxide 02 8510 861none 051089
07129006-0112	
07130006-0112	diazepam 06 8612 802sleepiness 051089
07130006-0122	bromazepam 07 8710 802none 051089
07130006-0132	clomipramine 07 8710 883dry mouth 051089
07131006-0111	imipramine 10 8611 883constipation 052489
07131006-0121	diazepam 10 860420893none 052489
07132006-0112	
07141006-0112	amitryptiline 09 7709 803anticholinergic 040789
07141006-0122	clomipramine 02 8206 833sleepiness 040789
07141006-0132	diazepam 09 7709 802sleepiness 040789
07141006-0142	bromazepam 02 8206 833none 040789
07142006-0112	clomipramine 0810880330891dry mouth/sleepy 040789
07142006-0122	diazepam 0810880112891none 040789
07142006-0132	alprazolam 0112690330891none
07143006-0111	

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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07144006-0111	imipramine	04	8306	853	dry mouth	051089
07144006-0121	amitryptiline	03	8602	883	constipation	051089
07144006-0131	diazepam	10	850905893	none		051089
07145006-0111						
07146006-0112						
07147006-0122	imipramine	0320890613891	none			061489
07147006-0112	diazepam	0320890613891	none			061489
07148006-0111						
07149006-0111	alprazolam	06	880501892	none		051089
07149006-0121	imipramine	03	8712	893	dry mouth/constip.	051089
07150006-0132	bromazepam	03	8502	892	none	052489
07150006-0132	haloperidol	04	8605	871	none	052489
07150006-0112	clomipramine	05	8708	883	none	052489
07151006-0112						
07153006-0111						
07081006-7211						
07082006-7212						
07083006-7212						
07084006-7211	imipramine	01	8708	873	dry mouth	092989
07084006-7221	diazepam	01	8708	872	sleepiness	092989
07084006-7231	clonazepam	07	8804	892	sleepiness	
07085006-7212	clomipramine	02	8510	852	sleepiness	
07085006-7222	alprazolam	06	8603	872	none	
07086006-7211						
07087006-7212						
07088006-7212	alprazolam	10	8610	882	sleepiness	092989
07089006-7211						
07090006-7211						
07091006-7211						
07092006-7211	imipramine	10	8310	843	dry mouth	110789
07092006-7221	trazodone	07	8607	873	sleepiness	110789
07093006-7212	trazodone	05	8610	883	none	110789
07093006-7222	amitryptiline	10	8812	881	sleepiness	110789
07094006-7212						
07095006-7211						
07096006-7212	clomipramine	10	8506	873	sexual problems	110789
07096006-7222	alprazolam	06	8703	891	sleepiness	110789
07097006-7211						
07098006-7211						
07099006-7212						
07100006-7212	clomipramine	06	8701	883	sexual problems	110789
01001006-0111	flurazepam	1118291123891	none			112789
01001006-0121	flurazepam	1127891127891	none			112789
01001006-0131	doxepine	0207881126891	none			112789
01001006-0141	alprazolam	0207881126891	sleepiness			112789
01002006-0112						
01016006-0112	clonazepam	0201900202901	none			002090
01016006-0122	flurazepam	0201900202901	none			002090
01016006-0132	lorazepam	0129900191901	none			002090
01017006-0111	prozac	0210900816901	none			011290
01017006-0121	dalmane	0210900816902	none			011290
01017006-0131	chlonal hydrate	0215900816902	none			011290
01017006-0141	ativan	0210900816901	none			011290

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04031006-0111	fluoxetine	0913891107392	none	111589
04031006-0121	haloperidol	1107891108891	none	111589
04031006-0131	benztropin	1108891108891	none	111589
04031006-0141	chloral hydrate	1108891115892	none	111589
04031006-0151	chlorpromazine	1025891107891	none	111589
04031006-0161	lorazepam	0126871107892	none	111589
04032006-0111	imipramine	0109900112901	none	011290
04032006-0121	diazepam	0109900112901	none	011290
04033006-0112	perphenazine	1212890214901	none	030290
04033006-0122	maprotiline	0523890214901	none	030290
04033006-0132	flurazepam	0315890214901	none	030290
04033006-0142	methylphenidate	0303890512892	none	030290
04033006-0152	desipramine	0303890523891	none	030290
04033006-0162	amitriptyline	0221890315891	none	030290
04034006-0112	carbamazepine	0110900702902	none	070490
04034006-0122	clomipramine hcl	0110900702902	none	070490
04034006-0132	lithium carbonate	12 77030190	none	070490
04034006-0142	clonazepam	05 810307902	none	070490
04034006-0152	haloperidol	07 770905892	none	070490
04034006-0162	chlorpromazine	082889090589	none	070490
04034006-0172	amitriptyline hcl	05 8106 892	none	070490
04035006-0112	maprotiline hcl	0418900815901	none	081590
04035006-0122	maprotiline hcl	0102900306901	none	081590
04035006-0132	diazepam	0818890815902	none	081590
04035006-0142	clomipramine hcl	0510880517891	none	081590
04035006-0152	clomipramine hcl	0427850527872	none	081590
04035006-0162	flupenthixol hcl	0225870527872	none	081590
04035006-0172	clomipramine hcl	0213791209812	none	081590
04046006-0111	doxepin hcl	0704900710901	none	071090
04046006-0121	triazolam	0619900710901	none	071090
04046006-0131	methotrimeprazine	1121890515902	none	071090
04046006-0141	amitriptyline	0515900619901	fatigue	071090
04046006-0151	flurazepam	0829890515901	none	071090
04046006-0161	hydroxyzine	0912891029891	none	071090
04046006-0171	imipramine	0619900710901	none	071090
04047006-0111	fluoxetine HCl	0619900918902	nausea/vomiting	101090
04047006-0121	flurazepam Cl	0913900918902	none	101090
04047006-0131	amitriptyline	0827870612902	none	101090
04047006-0141	lithium	0202870523892	none	101090
04047006-0151	isocarboxazid	0826860619872	none	101090
04047006-0161	clonazepam	0323870420087	none	101090
04047006-0171	chlordiazepoxide	1126850420872	none	101090
04048006-0112	alprazolam	1101902	none	110690

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CONCOMITANT DRUGS

Column No.	Contents
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-34	Drug name
35-41	Dose
42-47	From date
48-53	Stop date
54-74	Reason for administration

0712100942211
0712200942211
0712300942212
0712400942212
0712500942211
0712600942212
0712700942211
0712800942211
0712900921212
0713000921212
0713100921211
0713300921212
0714100942212
0714200921212
0714300942211
0714400942211
0714500942211
0714600921212
0714700921212
0714800942211
0714900942211
0715000942212
0715100921212
0715300942211
0708100942211
0708200942212
0708300942212
0708400942211
0708600942211 Diazepam 0005.00100989101508 Insomnia
0708500942212
0708700942212
0708800942212
0708900942211

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0709000942211			
0709100942211			
0709200942211			
0709300942212			
0709400921212			
0709500942211			
0709600921212			
0709700942211			
0709800942211			
0709900921212			
0710000921212			
0100100928211	ACETAMINOPHEN	1300.00	112789010390 ARTHRITIS
0100100928221	INDOMETHACINE	0050.00	112689010390 ARTHRITIS
0100100928231	CHLORAL HYDRATE		prn insomnia
0100100928241	SURFAK		2wks constipation
0100100928251	chlorine de hethan.		qid urinary ret.
0100100928261	URECHOLINE		bid urinary hes.
0100100928271	ACETAMINOPHEN		prn headache
0100200904212			
0101600921212			
0101700921212	CHLORAL HYDRATE	0500.00	008159002790 INSOMNIA
0101700921221	PREMARIN	0000.63	86022790POST.HYSTERECTOMY
0101700921231	PROVERAN	0005.00	86082790POST.HYSTERECTOMY
0403100921211	CHLORAL HYDRATE		110889112189AGITATION/INSOMNIA
0403100921221	CHLORAL HYDRATE	1000.00	112189010290 INSOMNIA
0403100921231	ACETAMINOPHEN	1000.00	111489111489HEADACHE
0403100921241	ACETAMINOPHEN	0500.00	112789112789HEADACHE
0403200921211	CHLORAL HYDRATE	0500.00	11390011390 INSOMNIA
0403200921221	CHLORAL HYDRATE	0500.00	12190012190 INSOMNIA/AGITATION
0403200921231	CHLORAL HYDRATE	1000.00	20190020190 AGITATION
0403200921241	CHLORAL HYDRATE	0500.00	21090021090 AGITATION
0403200921251	CHLORAL HYDRATE	1000.00	21390021390 AGITATION
0403200921261	CHLORAL HYDRATE	1000.00	21590021590 AGITATION
0403200921271	CHLORAL HYDRATE	0500.00	21690021690 AGITATION
0403200921291	KETOCONAZOLE CREAM	02%	020890021590 SKIN INFECTION
0403300921212	CHLORAL HYDRATE	1000.00	30130032690 AGITATION/ANXIETY
0403300921222	ACETAMINOPHEN	0500.00	31590031590 HEADACHE
0403400921212			
0403500921212			
0404600910211			
04047009-0711	MINI-ORAL	0150.00	1030112890 BIRTHCONTROL
0404700921211	CHLORAL HYDRATE		INSOMNIA
0404800904212			

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HAMILTON DEPRESSION RATING SCALE (HAM-D)

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	Item 1: depressed mood 0 = Absent 0=Absent 1=Only on questioning 2=Spontaneously reported 3=Communicates non-verbally 4=Patient reports
16	Item 2: feelings of guilt 0=Absent 1=Self reproach 2=ideas of guilt 3=Present illness punishment 4=Hears accusatory voices
17	Item 3: suicide 0=Absent 1=Life not worth 2=Wishes were dead 3=Suicide ideas 4=Attempts
18	Item 4: insomnia-early 0=No difficulty 1=Complains of occasional 2=Complains of nightly
19	Item 5: insomnia-middle 0=No difficulty 1=Patient complains 2=Waking during the night
20	Item 6: insomnia-late 0=No difficulty 1=Waking in early hours 2=Unable to fall asleep again
21	Item 7: work and activities 0=No difficulty 1=Thoughts of incapacity 2=Loss of interest 3=Decrease in time 4=Stopped working
22	Item 8: retardation 0=Normal speech/thought 1=Slight retardation 2=Obvious retardation 3=Interview difficult 4=Complete stupor
23	Item 9: agitation 0=None 1=Fidgetiness 2=Playing with hands 3=Moving about 4=Handwringing...
24	Item 10: anxiety-psychic 0=No difficulty 1=Subjective tension 2=Worrying about minor matters 3=Apprehensive attitude 4=Fears expressed
25	Item 11: anxiety-somatic 0=Absent 1=Mild 2=Moderate 3=Severe 4=Incapacitating
26	Item 12: somatic symptoms gastrointestinal 0=None 1=Loss of appetite 2=Difficulty eating

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HAMILTON DEPRESSION RATING SCALE (HAM-D) (cont.)

Column No.	Contents	
RECORD: 1 (cont.)		
27	Item 13: somatic symptoms general 0=None 2=Any clear-cut symptom	1=Heaviness in limbs
28	Item 14: genital symptoms 0=Absent 1=Mild 2=Severe	
29	Item 15: hypochondriasis 0=Not present 2=Preoccupation with health 4=Hypochondriacal delusions	1=Self-absorption (bodil) 3=Frequent complaints
30	Item 16: weight loss 0=No 2=Greater than 2 lb.	1=Greater than 1 lb.
31	Item 17: insight 0=Acknowledges being ill 2=Denies being ill	1=Attributes cause
32	Item 18a: Diurnal variation 0=No variation 1=worse in a.m. 2=worse in p.m.	
33	Item 18b: Diurnal variation-when present 0=None 1=mild 2=severe	
34	Item 19: depersonalization and derealization 0=Absent 1=Mild 2=Moderate 3=Severe 4=Incapacitating	
35	Item 20: paranoid symptoms 0=None 1=Suspicious 2=Ideas of reference 3=delusions	
36	Item 21: obsessional and compulsive symptoms 0=Absent 1=Mild 2=Severe	

01001049-0111 4222123122212222011001112789
 01002049-0112 4320113114212002022101030790
 01010049-0112 4212004313222212000110020290
 01017049-0111 4432223103222202012001081690
 04021049-0111 3112014013111201111001111589
 04032049-0111 4210124102111112011000011290
 04033049-0112 4210124034922122012020030290
 04034049-0112 3132224031211100000001070490
 04035049-0112 4222204044311201111101001590
 04040049-0111 4122224034211212000000071090
 04047049-0111 410201302221202000000101090
 04048049-0112 414210401110100000000110690
 07081049-0011 4212223203322010011001092909
 07082049-0012 3212223023322121112000022909
 07083049-0012 4221123303322121112000022909
 07084049-0011 3202223303322121011201092909
 07085049-0012 4022124303322021100211032909
 07086049-0011 421222403322121100000022909
 07087049-0012 3211224034322121100211092909

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07088049-0012 4112224303322121112100092989
07089049-0011 4222224303322221112211092989
07090049-0011 4212223303322221012201092989
07091049-0011 3022123033322221112311110789
07092049-0011 4232024303422212211300110789
07093049-0012 3012223304322232112000110789
07094049-0012 4202224303322200121202110789
07095049-0011 4012223033422212200200110789
07096049-0012 4222223303322231112000110789
07097049-0011 4000004304422202200300110789
07098049-0011 3212224204322202212000110789
07099049-0012 3212223303322232200300110789
07100049-0012 4212023103322202211002110789
07121049-0011 4202204303302202112200040689
07122049-0011 3022024303202202212300040789
07123049-0012 300202430222220020000040789
07124049-0012 4002024302322202012000040789
07125049-0011 302022410322222212000040789
07126049-0012 3202024302222132200000040789
07127049-0011 420122420322222112310040789
07128049-0011 3202224204322232112002051089
07129049-0012 3022124033322132211200051089
07130049-0012 3202024303222102221200051089
07131049-0011 322122420332222100300052489
07133049-0012 4022124023222102000201052489
07141049-0012 3102114203202120011100040789
07142049-0012 2112224033212232100200040789
07143049-0011 4220224203322122121000040789
07144049-0011 4222124303222232021302051089
07145049-0011 3201124303222232100220051089
07146049-0012 3001224303322101112210051089
07147049-0012 3112213302322102111200061489
07148049-0011 4220224303212102100201051089
07149049-0011 320221420332222100210051089
07150049-0012 3212024102322120112201052489
07151049-0012 3021223203222201022201052489
07153049-0011 3231223032222201211200052489
0100104900011 4222223022302222021000120489
0100104904211 3212113122202222021001120033
0100104907211 42222230222202220021001111289
0100104910211 3012113012202223021001121389
0100104914211 32220203022202221021101121889
0100104921211 2212211002031220021101122789
0100104928211 4212223012302220021001010390
0100104935211
0100104942211
0100204900012 4222213113112202122101030990
0100204904212 3221113022012200021010031490
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0100204910212
0100204914212
0100204921212
0100204928212

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0100204935212
0100204942212
0101604900012 4002224314322200112000020790
0101604904212 3222104323221222212010021390
0101604907212 4422224423022222212030021590
0101604910212
0101604914212
0101604921212
0101604928212
0101604935212
0101604942212
0101704900011 4442223113121212011002082090
0101704904211 3222213010212200021001082490
0101704907211 2211003002211000021001082790
0101704910211
0101704914211
0101704921211
0101704928211
0101704935211
0101704942211
0403104900011 3122124012111201012000112189
0403104904211 422111403421121011110112589
0403104907211 4112224014211212011101112889
0403104910211 4112224014211210011101120189
0403104914211 4112124034111212012110051289
0403104921211 3002224022101200011000121299
0403104928211 3111013000100100011000121989
0403104935211 3102121013101100011100122689
0403104942211 210211101110111000000010290
0403204900011 4222104103101201111000011890
0403204904211 210000401110110000000012290
0403204907211 0000023001110102011000012690
0403204910211 0000023001110100011000012990
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PHYSICAL EXAMINATION

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	Physical examination: 0=Normal 1=Abnormal
16-18	Systolic: lying
19-21	Diastolic: lying
22-24	Heart rate: lying
25-27	Systolic: standing
28-30	Diastolic: standing
31-33	Heart rate: standing
34-39	Temperature (xxx.xx)
40-45	Weight (xxx.xx)
46	ECG (DAY 42 ONLY) 0=Normal 1=Abnormal
47	EEG (DAY 42 ONLY) 0=Normal 1=Abnormal
48	Chest x-ray: 0=Normal 1=Abnormal
49-54	Chest x-ray date
55-60	Assessment date
RECORD: 2	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-65	Abnormality details
RECORD: 3	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-65	Previous important diseases

01001003-0111 0165085102150030090037.00037.30 0100499110780
 01001003-0121
 01001003-0131 H.B.F./ARTHRITIS/SCUT
 01002003-0112 016508811210090106036.40064.30 0030990030790

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01002003-0122
 01002003-0132 HEMICOLECTOMY-'87
 01016003-0112 0118070105105070103036.60037.50 0020690020290
 01016003-0122
 01016003-0132 APPENDECTOMY/HYSTERECTOMY
 01017003-0111 0138078070122068072037.20044.00 0081590081690
 01017003-0121
 01017003-0131 APPENDECTOMY/HYSTERECTOMY/GEN.SURGERY
 04031003-0111 0144092070142094084036.70110.80 0111589111509
 04031003-0121
 04031003-0131
 04032003-0111 0112052060110078078036.80080.20 0011790011290
 04032003-0121
 04032003-0131
 04033003-0112 011606607211408038036.60085.00 0030190030290
 04033003-0122
 04033003-0132
 04034003-0112 1116088084122094090037.00080.40 0 070490
 04034003-0122 Abn.PE due to fall in ER
 04034003-0132 Malaria-age 10
 04035003-0112 0156088090150100100037.00073.000082190 081590
 04035003-0122
 04035003-0132 High B.P.
 04046003-0111 0130080076120070079037.00048.60 0071190071090
 04046003-0121
 04046003-0131
 04047003-0111 0120080100122086115037.20053.10 0092490101090
 04047003-0121
 04047003-0131 '77 C-Sect; 35 Tuba1 Lig.
 04048003-0112 0120080070094058090037.20057.50 0 001100
 04048003-0122
 04048003-0132 '77 C-Sect; 65 Tuba1 Lig.
 07081003-7211 0130080076125080078036.40050.60 0520890092989
 07081003-7221
 07081003-7231
 07082003-7212 0120075080175070078036.50078.00 0920890092989
 07082003-7222
 07082003-7232
 07083003-7212 0110070064110660086036.40058.00 0927890092989
 07083003-7222
 07083003-7232
 07084003-7211 010500066125075068036.60042.00 0623890092989
 07084003-7221
 07084003-7231
 07085003-7212 0110075062110070004036.60059.00 0927890092989
 07085003-7222
 07085003-7232
 07086003-7211 0120080074120070072036.60074.00 0027090092989
 07086003-7221
 07086003-7231
 07087003-7212 0110070072105060000000.40051.00 0927290092989
 07087003-7222
 07087003-7232

4 4 4

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07088003-7212	0115075076110070074036.40059.00	0712890092989
07088003-7222		
07088003-7332		
07089003-7211	0110070064105065066036.40075.00	0927890092989
07089003-7221		
07089003-7231		
07090003-7211	0115075064115070066036.40052.00	0821890092989
07090003-7221		
07090003-7231		
07091003-7211	0130080072105080074036.50062.00	1010890110789
07091003-7221		
07091003-7231		
07092003-7211	0120080076115085074036.60055.00	1101890110789
07092003-7221		
07092003-7231		
07093003-7212	0125075080130090078036.40072.00	1106890110789
07093003-7222		
07093003-7332		
07094003-7212	0110070064110065066036.50060.00	0703890110789
07094003-7222		
07094003-7332		
07095003-7211	0120075066115070066036.50063.00	0826890110789
07095003-7221		
07095003-7231		
07096003-7212	0110070036100060066036.50048.00	1106890110789
07096003-7222		
07096003-7332		
07097003-7211	0115075064110070066036.50058.00	0916890110789
07097003-7221		
07097003-7231		
07098003-7211	0105065064110065066036.50051.00	1106890110789
07098003-7221		
07098003-7231		
07099003-7212	0120070068120060066036.50047.00	0615890110789
07099003-7322		
07099003-7232		
07100003-7212	0120075072110065068036.50062.00	0830890110789
07100003-7222		
07100003-7332		
07121003-0111	0120085070125090062036.60075.00	0012089040009
07121003-0121		
07121003-0131		
07122003-0111	0100090002135085085036.70092.00	0040139040789
07122003-0121		
07122003-0131		
07123003-0112	0100060074110000075036.50061.00	0122088040789
07123003-0122		
07123003-0132		
07124003-0112	0120065074115080078036.70072.00	0040139040789
07124003-0122		
07124003-0132		
07125003-0111	0110080069115075072036.50070.00	0031039040789
07125003-0121		

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07125003-0131		
07126003-0112	0115075084120085086036.40066.00	0040189040789
07126003-0122		
07126003-0132		
07127003-0111	0135090086135085090036.80063.00	0040289040789
07127003-0121		
07127003-0131		
07128003-0111	0140095086135090087036.60077.00	0050989051089
07128003-0121		
07128003-0131		
07129003-0112	0120080072120070074036.70077.00	0030389051089
07129003-0122		
07129003-0132		
07130003-0112	0125085068120075072036.70080.00	0011089051039
07130003-0122		
07130003-0132		
07131003-0111	0130080074135075076036.60055.00	0050489052489
07131003-0121		
07131003-0131		
07133003-0112	0130075078130080080036.80072.00	0031089052489
07133003-0122		
07133003-0132		
07141003-0112	0110070068115075071036.60070.00	0121289040789
07141003-0122		
07141003-0132		
07142003-0112	0125075076120075078036.60056.00	0022089040789
07142003-0122		
07142003-0132		
07143003-0111	0140095070135090074036.50052.00	0031089040789
07143003-0121		
07143003-0131		
07144003-0111	0120070070115065072036.70068.00	0050989051089
07144003-0121		
07144003-0131		
07145003-0111	0110060054105080066036.70071.00	0033089051089
07145003-0121		
07145003-0131		
07146003-0112	0115075090110075086036.70044.00	0050989051089
07146003-0122		
07146003-0132		
07147003-0112	0100065064100060066036.50055.00	0041489051489
07147003-0122		
07147003-0132		
07148003-0111	0110070000110075067036.60080.00	0102089051089
07148003-0121		
07148003-0131		
07149003-0111	0110075004105070066036.80080.00	0050989051089
07149003-0121		
07149003-0131		
07150003-0112	0115075000115070054036.60060.00	0042089052489
07150003-0122		
07150003-0132		
07151003-0112	0125090072120075070036.60058.00	0021289052489

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07151003-0122		
07151003-0132		
07153003-0111	0125075078120070081036.60045.00	0052389052489
07153003-0121		
07153003-0131		
0100100328211	0148076094134074108037.00085.0000	010390
0100100328221		
0100100328231		
0100200304212	0165088112166090106036.40064.30	0030990030790
0100200304222		
0100200304232	HEMICOLECTOMY- '87	
0101600342212		
0101600342222		
0101600342232		
0101700307211	0158072086132070094	082990
0101700307221		
0101700307231	ECG/EEG NOT DONE	
0403100342211	0142102094134110110036.70111.70	00010290
0403100342221		
0403100342231		
0403200332211	0118084076116088098030.60075.70	022090
0403200332221	EEG/EKG not done	
0403200332231		
0403300315212	0130082082122000098036.60082.9000	032390
0403300315222		
0403300315232		
0403400342212		
0403400342222		
0403400342232		
0403500322212	0148034096146096102037.10073.30	00091990
0403500322222		
0403500322232		
0404600342211		
0404600342221		
0404600342231		
0404700342211		
0404700342221		
0404700342231		
0404800342212	0108060070100072076037.00057.60	00122690
0404800342222		
0404800342232		
0708100342211	0130090076125085074036.40052.0010	111789
0708100342221	ECG: ABN-Lft.Vent.Hypertrophy	
0708100342231		
0708200342212		
0708200342222		
0708200342232		
0708300342212	0115075094115076065036.50057.0000	111789
0708300342222		
0708300342232		
0708400342211	0135090076130080078030.50045.0000	111789
0708400342221		
0708400342231		

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0708500342212		
0708500342222		
0708500342332		
0708600342211	0125085074125085076036.40074.0010	111789
0708600342221	ECG:ABN-Lft.Ant.Div.Block	
0708600342231		
0708700342212		
0708700342222		
0708700342332		
0708800342212	0115075062110070064036.50061.0000	111789
0708800342222		
0708800342332		
0708900342211	0120075072125070070036.60076.0010	111789
0708900342221	ECG:ABN-Lft.Atr.Enlargement	
0708900342231		
0709000342211	0125075068115070072036.50055.0000	111789
0709000342221		
0709000342231		
0709100342211	0125075068130075072036.50063.0000	122689
0709100342221		
0709100342231		
0709200342211	0120080082115070080036.30052.0010	122689
0709200342221	ECG:ABN-Unspec.Repolar.Alter.QT Prolong.	
0709200342231		
0709300342212	0135085084130090086036.60073.0010	122689
0709300342222	ECG ABN-Lft.Axis Dev.-1st Deg.A-V block	
0709300342332		
0709400342212		
0709400342222		
0709400342332		
0709500342211	0120080076125070080036.60064.0000	122689
0709500342221		
0709500342231		
0709600342212	0120070066110070064036.50048.0000	122689
0709600342222		
0709600342332		
0709700342211	0120080078115075076036.50058.0000	122689
0709700342221		
0709700342231		
0709800342211	011006507010005000036.50052.0000	122689
0709800342221		
0709800342231		
0709900342212		
0709900342222		
0709900342332		
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0710000342222		
0710000342332		
0712100342211	0125075068115070073036.60068.0000	052589
0712100342221		
0712100342231		
0712200342211	0130080006125075070036.60062.0000	052689
0712200342221		

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0712200342231		
0712300342212	0130085076135080079036,70062,0000	052689
0712300342222		
0712300342232		
0712400342212	0120075078115070080036,70071,0000	052689
0712400342222		
0712400342232		
0712500342211	0115080078105070080036,70073,0000	052689
0712500342221		
0712500342231		
0712600342212	0130080076125075080036,70069,0000	052689
0712600342222		
0712600342232		
0712700342211	0115075072110065070036,60063,0000	052689
0712700342221		
0712700342231		
0712800342211	0140095077135090080036,50080,0000	062889
0712800342221		
0712800342231		
0712900342212		
0712900342222		
0712900342232		
0713000342212		
0713000342222		
0713000342232		
0713100342211		
0713100342221		
0713100342231		
0713300342212		
0713300342222		
0713300342232		
0714100342212	0125080076120085000036,70072,0000	052689
0714100342222		
0714100342232		
0714200342212		
0714200342222		
0714200342232		
0714300342211	0120090080125090078036,60053,0000	052689
0714300342221		
0714300342231		
0714400342211	0115075068110065070036,50071,0000	062889
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0714400342231		
0714500342211	0110070074100060074036,60071,0000	062889
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0714500342231		
0714600342212		
0714600342222		
0714600342232		
0714700342212		
0714700342222		
0714700342232		
0714800342211	0110070069100060061036,50062,0000	062689

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0714800342221		
0714800342231		
0714900342211	0110070072100060070036.50057.0000	062889
0714900342221		
0714900342231		
0715000342212	0120085066120080067036.50068.0000	071289
0715000342222		
0715000342232		
0715100342212		
0715100342222		
0715100342232		
0715300342211	0115070064105060066036.60045.0000	071289
0715300342221		
0715300342231		

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0712100104211 00000
0712200104211 00000
0712300104212 00000
0712400104212 00000
0712500104211 00001EEG: More α rythm w/greater topograph.distribut.N.C.S.
0712600104212 00000
0712700104211 00000
0712800104211 00000
0712900104212 00 00Final:Day 21
0713000104212 00 0 Final:Day 21
0713100104211 00 0 Final:Day 21
0713300104212 00 0 Final:Day 21
0714100104212 000
0714200104212 0 0 Final:Day 21
0714300104211 00000
0714400104211 00000
0714500104211 00000
0714600104212 11 00ECG: Heart Block 1st Grade Final:Day 21
0714700104212 00 00Final:Day 21
0714800104211 00000
0714900104211 00000
0715000104212 00000
0715100104212 00 00Final:Day 21
0715300104211 00000

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TREATMENT PERIOD MEDICATION RECORD

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	Morning dose number of capsules: Day 1
16	Morning dose number of capsules: Day 2
17	Morning dose number of capsules: Day 3
18	Morning dose number of capsules: Day 4
19	Morning dose number of capsules: Day 5
20	Morning dose number of capsules: Day 6
21	Morning dose number of capsules: Day 7
22	Morning dose number of capsules: Day 8
23	Morning dose number of capsules: Day 9
24	Morning dose number of capsules: Day 10
25	Morning dose number of capsules: Day 11
26	Morning dose number of capsules: Day 12
27	Morning dose number of capsules: Day 13
28	Morning dose number of capsules: Day 14
29	Morning dose number of capsules: Day 15
30	Morning dose number of capsules: Day 16
31	Morning dose number of capsules: Day 17
32	Morning dose number of capsules: Day 18
33	Morning dose number of capsules: Day 19
34	Morning dose number of capsules: Day 20
35	Morning dose number of capsules: Day 21
36	Morning dose number of capsules: Day 22
37	Morning dose number of capsules: Day 23
38	Morning dose number of capsules: Day 24
39	Morning dose number of capsules: Day 25
40	Morning dose number of capsules: Day 26
41	Morning dose number of capsules: Day 27
42	Morning dose number of capsules: Day 28
43	Morning dose number of capsules: Day 29
44	Morning dose number of capsules: Day 30
45	Morning dose number of capsules: Day 31
46	Morning dose number of capsules: Day 32
47	Morning dose number of capsules: Day 33
48	Morning dose number of capsules: Day 34
49	Morning dose number of capsules: Day 35
50	Morning dose number of capsules: Day 36
51	Morning dose number of capsules: Day 37
52	Morning dose number of capsules: Day 38
53	Morning dose number of capsules: Day 39
54	Morning dose number of capsules: Day 40

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TREATMENT PERIOD MEDICATION RECORD (cont.)

Column No.	Contents
RECORD: 1 (cont.)	
55	Morning dose number of capsules: Day 41
56	Morning dose number of capsules: Day 42
RECORD: 2	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	Evening dose number of capsules: Day 1
16	Evening dose number of capsules: Day 2
17	Evening dose number of capsules: Day 3
18	Evening dose number of capsules: Day 4
19	Evening dose number of capsules: Day 5
20	Evening dose number of capsules: Day 6
21	Evening dose number of capsules: Day 7
22	Evening dose number of capsules: Day 8
23	Evening dose number of capsules: Day 9
24	Evening dose number of capsules: Day 10
25	Evening dose number of capsules: Day 11
26	Evening dose number of capsules: Day 12
27	Evening dose number of capsules: Day 13
28	Evening dose number of capsules: Day 14
29	Evening dose number of capsules: Day 15
30	Evening dose number of capsules: Day 16
31	Evening dose number of capsules: Day 17
32	Evening dose number of capsules: Day 18
33	Evening dose number of capsules: Day 19
34	Evening dose number of capsules: Day 20
35	Evening dose number of capsules: Day 21
36	Evening dose number of capsules: Day 22
37	Evening dose number of capsules: Day 23
38	Evening dose number of capsules: Day 24
39	Evening dose number of capsules: Day 25
40	Evening dose number of capsules: Day 26
41	Evening dose number of capsules: Day 27
42	Evening dose number of capsules: Day 28
43	Evening dose number of capsules: Day 29
44	Evening dose number of capsules: Day 30
45	Evening dose number of capsules: Day 31
46	Evening dose number of capsules: Day 32
47	Evening dose number of capsules: Day 33
48	Evening dose number of capsules: Day 34
49	Evening dose number of capsules: Day 35

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TREATMENT PERIOD MEDICATION RECORD (cont.)

Column No.	Contents
RECORD: 2 (cont.)	
50	Evening dose number of capsules: Day 36
51	Evening dose number of capsules: Day 37
52	Evening dose number of capsules: Day 38
53	Evening dose number of capsules: Day 39
54	Evening dose number of capsules: Day 40
55	Evening dose number of capsules: Day 41
56	Evening dose number of capsules: Day 42
RECORD: 3	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-80	Comments

0100101800011 122222222222222222222222222222222222
 0100101800021 223333333333222222222222222222222222
 0100101800031 DROPPED DAY 30/DOSE REDUC: URINARY RETENTION
 0100201800012 1222
 0100201800022 223
 0100201800032 DROPPED DAY 4/NO COOPERATION
 0101601800012 1222222
 0101601800022 2233333
 0101601800032 DROPPED DAY 7
 0101701800011 1222201
 0101701800021 223311
 0101701800031 DROPPED DAY 7/MED.REDOC:LOW B.P.
 0403101800011 122222222222222222222222222222222222
 0403101800021 223333333333333333333333333333333333
 0403101800031 Dn,Error/W.O. eve meds.
 0403201800011 122222222222222222222222222222222222
 0403201800021 223333333333333333333333333333333333
 0403201800031 DROPPED DAY 30/DAY ADV.EFF:HYPMANIA
 0403301800012 1222222222222222
 0403301800022 22333333333333
 0403301800032 DROPPED DAY 14/DAY
 0403401800012 12222222222222222222
 0403401800022 2233333333333333333333
 0403401800032 DROPPED DAY 20
 0403501800012 1222222222222222222222
 0403501800022 22333333333333333333333333333333
 0403501800032 DROPPED DAY 21

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VITAL SIGNS

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-17	Morning lying systolic (Days 0,1,2,3,4,5,6,7,10,14,21,28,35,42)
18-20	Morning lying diastolic (Days 0,1,2,3,4,5,6,7,10,14,21,28,35,42)
21-23	Morning lying heart rate (Days 0,1,2,3,4,5,6,7,10,14,21,28,35,42)
24-26	Morning standing systolic (Days 0,1,2,3,4,5,6,7,10,14,21,28,35,42)
27-29	Morning standing diastolic (Days 0,1,2,3,4,5,6,7,10,14,21,28,35,42)
30-32	Morning standing heart rate (Days 0,1,2,3,4,5,6,7,10,14,21,28,35,42)
33-35	Evening lying systolic (Days 0,1,2,3,4,5,6,7,10,14,21,28,35,42)
36-38	Evening lying diastolic (Days 1,2,3,4)
39-41	Evening lying heart rate (Days 1,2,3,4)
42-44	Evening standing systolic (Days 1,2,3,4)
45-47	Evening standing diastolic (Days 1,2,3,4)
48-50	Evening standing heart rate (Days 1,2,3,4)
51-54	Temperature (xx.x) (Days 0,7,14,21,28,35,42)
55-60	Weight (xxx.xx) (Days 0,7,14,21,28,35,42)

01001010-0111	165205102150068098	37.0087.80
0100101000011	160080111152076095	37.0086.10
0100101001211	158376097160082095170095100150100	
0100101002211	168084092158090096162094084158090080	
0100101003211	150082096140080082150100112100090	
0100101004211	142094696124080108150090084130080	
0100101005211	130098100122098	
0100101006211	148080104138080	
0100101007211	158086102144082108	36.6085.00
0100101010211	120866000110030082	
0100101014211	158064090100072087	36.8085.00
0100101021211	140078100138080094	36.8084.50
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0100201004212	145094091140080104140080096130088096	
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0100201007212		

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0100201010212		
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0403501010212	130080093150090109	

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0404701001211	130080100128082120130078100134086120	
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0404701035211	156086080110080112	37.0053.80
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0708101021211	130090074125085072	36.4051.00
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0708101035211		
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0709601007212	115070062110070060	36.5047.00
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0714900342211	110070072100060070	36.5057.00
07150003-0112	115075060115070064	36.5066.00
0715001000012	120000060115080062	36.5066.00
0715001001212	125085064120080066120085062115080001	
0715001002212	120080064115075062125085066125080068	
0715001003212	120080060115080064125080062125075063	
0715001004212	125085064120085065120080062120075003	
0715001005212	120080060115075058	
0715001006212	120075002120070063	
0715001007212	120075068115070071	36.6060.00
0715001010212	120070064113070060115075060115080069	
0715001014212	110075068115075072	36.5067.00
0715001021212	120080060115075060	36.6068.00
0715001028212	125085068120080071	36.6060.00
0715001035212	125085072125090070	36.6066.00
0715000342212	120085066120080067	36.5068.00
07151003-0112	125080072120075070	36.6058.00
0715101000012	115075060125075062	36.7056.00
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0715101003212	11508006012008006312008006115070064	
0715101004212	1200750601200700601120070072115080073	
0715101005212	120075064115070058	
0715101006212	115075063115070058	
0715101007212	115070066110070067	36.6056.00

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0715101010212	120075056110080054	
0715101014212	110075058115075060	36.6058.00
0715101021212	115075058115070060	36.6056.00
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0715101035212		
0715100342212		
07153003-0111	125075078120070081	36.6045.00
0715301000011	130080082130075080	36.5045.00
0715301001211	135080072125070070130075076120070076	
0715301002211	130080066120075068120075068115070065	
0715301003211	125075068120070067120075060110070064	
0715301004211	130075072125070069125075066120070068	
0715301005211	120070066110060064	
0715301006211	115070072110065068	
0715301007211	120070062115060064	36.5043.00
0715301010211	120075074115065077	
0715301014211	115075070110070067	36.5042.00
0715301021211	115070064105060065	36.6043.00
0715301028211	115075062105065065	36.5044.00
0715301035211	120075073110070071	36.6045.00
0715300342211	115070064105060065	36.6045.00

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NEWLY OBSERVED SIGNS AND SYMPTOMS

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-16	Symptom number:
	00=None 10=Constipation 32=Agitation
	01=Hypotension 12=Dizziness 34=Tremor
	02=Dry mouth 19=Diarrhea 38=Decreased appetite
	03=Drowsiness 21=Vomiting 44=Urinary retention
	04=Insomnia 22=Blurred vision 46=Sexual disturbance
	07=Sweating 26=Pruritus 50=Hypomania
	08=Headache 28=Lassitude 51=Urinary incontinence
	93=Cold extremities
17	Reported: 0=Spontaneously 1=Upon inquiry
18	Present before start of study: 0=Yes 1=No 2=Unknown
19-24	Date of onset
25-26	Duration in days
31	Severity: 0=Mild 1=Moderate 2=Severe
32	Required treatment: 0=Yes 1=No
33-35	Specific treatment
53-60	Dose of treatment
61	Route of administration: 0=p.o. 1=i.m.
62-63	Treatment duration
64	Outcome: 0=Fully recovered 1=Recovered with sequelae
65	Relationship: 0=Unknown 1=Possible/Doubtful 2=Probable 3=Certain
66-77	Details of relationship to medication
78	Course: 0=Cleared 1=Persisted/drug cont. 2=Cleared/dose lowered 3=Persisted/dose lowered 4=Temporarily stopped 5=Permanently stopped
79-80	Follow-up duration (days)

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0100101404241	020012058904			3	1
0100101404251	070012058904			1	1
0100101407201	040012058900	10CHLORAL HYDRATE	0500.000000	0	1
0100101407201	440012058900			3	1
0100101407241	020012088504			3	0
0100101407251	070012058900			1	1
0100101410221	040012058900	10CHLORAL HYDRATE	0500.000000	0	1

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

FCE 20124/706 i

0100101410231	440112058908	21		3	1
0100101410241	100112128901	00SURFAK	2 CAPS 001	2	
0100101410251	070012058908	01		2	1
0100101414221	040012058913	20CHLORAL HYDRATE	0500.0000	0	1
0100101414231	440112058913	20URECHOLINE	0020.0000	3	3
0100101414241	100112128906	00SURFAK	2 CAPS 0	2	1
0100101414251	070012058914	01		2	1
0100101421221	040012058922	20CHLORAL HYDRATE	1000.000010	1	3
0100101421231	440112058922	20URECHOLINE	0030.000006	3	3
0100101421241	260112208907	01		1	3
0100101421261	01 112248903	11		2	3
0100101428221	440112058929	20URECHOLINE	0040.000014	3	5
0100101428241	100112128922	10SURFAK	2 CAPS 002	2	5
0100101428251	070012058929	01		2	5
0100101435211					
0100101442211					
0100201400012	121103099001	01			
0100201404212	00				
0100201407212					
0100201410212					
0100201414212					
0100201421212					
0100201428212					
0100201435212					
0100201442212					
0101601400012	100102079003	00RECTAL INJECTION	1 101		
0101601400022	041002029007	10CHLORAL HYDRATE	500.000004		
0101601400032	121002029007	21			
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0101601404222	511102109003	11		1	1
0101601407212	321102129003	11		1	5
0101601407222	511102109005	11		1	5
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0101601414212					
0101601421212					
0101601428212					
0101601435212					
0101601442212					
0101701400011	00				
0101701404211	120108219004	11		1	1
0101701407211	010108259002	21		2	5
0101701407221	120108259002	21		2	5
0101701410211					
0101701414211					
0101701421211					
0101701428211					
0101701435211					
0101701442211					
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0403101407221	001111245904	01		1	1
0403101407231	221111278901	01		1	1

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0403101407241	030011278901	10Acetaminophen	0325.00000101	0
0403101410211	00			
0403101414211	00			
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0403101428211	021112068913	01	1	1
0403101435211	460112248901	01	2	1
0403101442211	46 12248907	01	2	1
0403201400011	00			
0403201404211	020101219001	01	2	1
0403201404221	930101219001	11	2	1
0403201407211	020101219005	01	2	1
0403201407221	381101249002	11	2	1
0403201407231	040101258001	11	2	1
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0403201414211	211102019002	01	1	0
0403201414221	071201319002	01	1	1
0403201421211	00			
0403201428211	500102159002	01	2	1
0403201435211	50 102179003	20 termination	2	5
0403201442211	00			
0403301400012	00			
0403301404212	00			
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0403301407222	030103139001	10ACETAMINOPHEN	0500.0000031	0
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0403301414212	00			
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0403301421212	00			
0403301428212	00			
0403301435212	00			
0403301442212	00			
0403401400012	4610	11		
0403401406022	320107109001	21		
0403401404221	00			
0403401407212	130107139003	11	1	1
0403401407222	210107139003	01	1	1
0403401407232	120107139003	01	0	1
0403401407242	030107140002	01	1	1
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0403501407212	00			
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0403501428212	00			
0403501435212	00			

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

FCE 20124/706 i

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0404601407211	320107219003	11		2	1
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0404601414211					
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0404601421211					
0404601428211					
0404601435211					
0404601442211					
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0404701414211	00				
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0404801442212	00				
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0708101414211	020110118901	01		3	1
0708101421211	020110118915	01		03	1
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0708201404212	00				
0708201407212	00				
0708201410212	00				
0708201414212	00				
0708201421212	00				
0708201428212	00				
0708201435212	00				
0708201442212	00				
0708301400012	00				
0708301404212	020110088903	01		3	1
0708301407212	020110088906	01		0	1
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0708301410222	100110108907	01		2	1
0708301414212	020110088910	01		03	0
0708301414222	100110108909	01		02	0
0708301421212	00				
0708301428212	00				
0708301435122	00				
0708301442212	00				
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0708401407211	021110098905	01		3	1
0708401407221	340110118903	01		2	1
0708401410211	021110098908	01		3	1
0708401410221	340110118906	01		3	1
0708401414211	021110098912	01		3	1
0708401414221	340110118910	01		3	1
0708401421211	021110098916	01		03	0
0708401421221	340110118917	01		3	1
0708401428211	340110118924	01		3	1
0708401428221	220110318904	01		2	1
0708401435211	340110118926	01		03	0
0708401435221	220110318911	01		3	1
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0708501404212	00				
0708501407212	00				
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0708501421212	00				
0708501428212	00				
0708501435212	00				
0708501442212	00				
0708601400011	00				
0708601404211	041010088902	00Diazepam	0005.000 07 3Worse		1
0708601407211	041010088905	00Diazepam	0005.000 05 3		1
0708601410211	04 010088907	00Diazepam	0005.000 0703		0
0708601414211	00				
0708601421211	00				
0708601428211	00				
0708601435211	00				
0708601442211	00				
0708701400012	00				
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0708701407212	00				
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0708701421212	00				
0708701428212	00				
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0708701442212	00				
0708801400012	00				
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0708801410212	00				

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0708801414212	00				
0708801421212	00				
0708801428212	00				
0708601435212	00				
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0708901400011	00				
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0708901407211	340110078906	01	3	1	
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0708901414211	340110078913	01	3	1	
0708901414221	040010178903	11	2	3	
0708901421211	340110078920	01	3	1	
0708901421221	040010178910	01	3	1	
0708901428211	340110078927	01	3	1	
0708901428221	040010178913	01	03	0	
0708901435211	340110078930	01	03	1	
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0709001410211	00				
0709001414211	00				
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0709001428211	00				
0709001435211	00				
0709001442211	00				
0709101400011	00				
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0709101407211	020111158906	01	3	1	
0709101407221	220111198902	01	0	1	
0709101410211	020111158909	01	3	1	
0709101410221	220111198905	01	3	1	
0709101410231	100111218903	01	3	1	
0709101414211	020111158913	01	3	1	
0709101414221	220111198909	01	3	1	
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0709101421211	020111158920	01	3	1	
0709101421221	220111198916	01	3	1	
0709101421231	100111218914	01	3	1	
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0709101435211	220111198925	01	03	0	
0709101435221	100111218920	01	3	1	
0709101442231	100111218930	01	03	0	
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0709201407211	461111198902	01	3	1	
0709201410211	461111198905	01	3	1	
0709201414211	461111198909	01	3	1	
0709201414221	381111248904	01	3	1	
0709201421211	461111198916	01	0	1	
0709201421221	381111248911	01	3	1	

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0709201428211	461111198923	01		
0709201428221	361111248918	01	3	1
0709201435211	461111198930	01	3	1
0709201435221	361111248920	01	3	1
0709201442231	461111198937	01	03	0
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0709301407212	340111158906	01	3	1
0709301407222	020111198902	01	3	1
0709301410212	340111158909	01	3	1
0709301410222	020111198905	01	3	1
0709301414212	340111158911	01		
0709301414222	020111198908	01	03	0
0709301421212	00		03	0
0709301428212	00			
0709301435212	00			
0709301442212	00			
0709401400012	00			
0709401404212	460111158903	01	3	1
0709401407212	461111158904	01	03	0
0709401410212	00			
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0709501404211	00			
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0709701414211	340111228900	01	2	1
0709701421211	340111228912	01	02	0
0709701421221	020112018905	11	2	1
0709701428211	020112010912	01	3	1
0709701435211	020112010910	01	03	0

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0709701442231	00			
0709801400011	00			
0709801404211	0211111178901	01	3	1
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0709801407221	2211111198902	01	3	1
0709801410211	0211111178907	01	3	1
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0709801414211	0211111178911	01	3	1
0709801414221	2211111198909	01	3	1
0709801414231	071111258903	01	3	1
0709801421211	0211111178918	01	03	0
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0709801428211	2211111198923	01	3	1
0709801428221	071111258917	01	3	1
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0709801435221	071111258922	01	03	0
0709801442231	00			
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0709901404212	00			
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0709901410212	00			
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0710001414212	00			
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0710001428212				
0710001435212				
0710001442212				
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0712101435211	381104218928	00	2	1
0712101435221	071104178931	00	0	1

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0712101435231	460104168932	00	3	1
0712101442211	071104178938	00	3	03
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0712201407211	020104168905	00	3	1
0712201407221	080104178904	00	2	1
0712201407231	100104188903	00	3	1
0712201410211	020104168908	00	3	1
0712201410221	080104178905	00	02	0
0712201410231	100104188906	00	3	1
0712201414211	020104168912	00	3	1
0712201414221	100104178910	00	03	0
0712201421211	020104168919	00	3	1
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0712201442211	00			
0712301400012	00			
0712301404212	00			
0712301407212	00			
0712301410212	00			
0712301414212	00			
0712301421212	00			
0712301428212	00			
0712301435212	00			
0712301442212	00			
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0712401404212	100104178901	00	1	1
0712401407212	100104178905	10	2	1
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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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CLINICAL GLOBAL IMPRESSION (CGI)

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	Severity of illness: 1=Normal 2=Borderline 3=Mildly depressed 4=Moderately depressed 5=Markedly depressed 6=Severely depressed 7=Amongst the most extremely depressed patients
16	Global improvement: (NOT DONE AT DAY 0) 1=Very much improved 2=Much improved 3=Minimally improved 4=No change 5=Minimally worse 6=Much worse 7=Very much worse
17-18	Efficacy index: (NOT DONE AT DAY 0) 01=Marked activity/no side effects 02=Marked activity/side effects do not significantly interfere 03=Marked activity/side effects interfere with functioning 04=Marked activity/side effects outweigh therapeutic effects 05=Moderate activity/no side effects 06=Moderate activity/side effects do not signif. interfere 07=Moderate activity/side effects interfere with functioning 08=Moderate activity/side effects outweigh therapeutic effects 09=Minimal activity/no side effects 10=Minimal activity/side effects do not signif. interfere 11=Minimal activity/side effects interfere with functioning 12=Minimal activity/side effects outweigh therapeutic effects 13=Unchanged activity/no side effects 14=Unchanged activity/side effects do not signif. interfere 15=Unchanged activity/side effects interfere with functioning 16=Unchanged activity/side effects outweigh therapeutic effects
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ZUNG - SDS

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	Item 1: feel downhearted 1=None 2=Some 3=Good part 4=Most
16	Item 2: morning feel best 1=None 2=Some 3=Good part 4=Most
17	Item 3: crying spells 1=None 2=Some 3=Good part 4=Most
18	Item 4: trouble sleeping 1=None 2=Some 3=Good part 4=Most
19	Item 5: eat as much 1=None 2=Some 3=Good part 4=Most
20	Item 6: still enjoy sex 1=None 2=Some 3=Good part 4=Most
21	Item 7: losing weight 1=None 2=Some 3=Good part 4=Most
22	Item 8: constipation 1=None 2=Some 3=Good part 4=Most
23	Item 9: heart beats faste 1=None 2=Some 3=Good part 4=Most
24	Item 10: get tired 1=None 2=Some 3=Good part 4=Most
25	Item 11: mind is clear 1=None 2=Some 3=Good part 4=Most
26	Item 12: easy to do things 1=None 2=Some 3=Good part 4=Most
27	Item 13: restless 1=None 2=Some 3=Good part 4=Most
28	Item 14: hopeful 1=None 2=Some 3=Good part 4=Most
29	Item 15: more irritable 1=None 2=Some 3=Good part 4=Most
30	Item 16: easy to decide 1=None 2=Some 3=Good part 4=Most
31	Item 17: feel useful 1=None 2=Some 3=Good part 4=Most
32	Item 18: life is pretty full 1=None 2=Some 3=Good part 4=Most
33	Item 19: others better off 1=None 2=Some 3=Good part 4=Most
34	Item 20: still enjoy things 1=None 2=Some 3=Good part 4=Most

0100107300011 41343131441141411121120489
 0100107307211 41444143441141411131121189
 0100107314211 33344133331231311143121889
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LABORATORY DATA

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-20	Hemoglobin (xxx.xx)
21-26	Hematocrit (xxx.xx)
27-32	Red Blood Cells (xxx.xx)
33-38	White Blood Cells (xxx.xx)
39-44	Neutrophils (xxx.xx)
45-50	Lymphocytes (xxx.xx)
51-56	Eosinophils (xxx.xx)
57-62	Monocytes (xxx.xx)
63-68	Basophils (xxx.xx)
69-74	Platelets (xxx.xx)
75-80	NA+ (xxx.xx)
RECORD: 2	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-20	K+ (xxx.xx)
21-26	CL- (xxx.xx)
27-32	CA++ (xxx.xx)
33-38	PO4 (xxx.xx)
39-44	SGOT (xxx.xx)
45-50	SGPT (xxx.xx)
51-56	t GT (xxx.xx)
57-62	Blood Sugar (xxx.xx)
63-68	Alkaline Phosphatase (xxx.xx)
69-74	BUN (xxx.xx)
75-80	Creatinine (xxx.xx)
RECORD: 3	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo

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LABORATORY DATA (cont.)

Column
No. Contents

RECORD: 3 (cont.)

15-20 Uric Acid (xxx.xx)
21-26 Total Bilirubin (xxx.xx)
27-32 Direct Bilirubin (xxx.xx)
33-38 Total Protein (xxx.xx)
39-44 Blood Albumin (xxx.xx)
45-50 Cholesterol (xxx.xx)
51-56 Triglycerides (xxx.xx)
57-62 Globulins α-1 (xxx.xx)
63-68 Globulins α-2 (xxx.xx)
69-74 Globulins β (xxx.xx)
75-80 Globulins τ (xxx.xx)

RECORD: 4

1-2 Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5 Patient Number
6-8 Form Number
9-11 Assessment Day
12 Record Number
13 Treatment Group: 1=Reboxetine 2=Placebo
15-20 T3 (xxx.xx)
21-26 T4 (xxx.xx)
27-32 TSH (xxx.xx)
33 HBS Ag, ANTi-HEC for Hepatitis B 0=Positive 1=Negative
34 ELISA HIV for AIDS 0=Positive 1=Negative
35 ALT, AST for non-A, non-B Hepatitis 0=Positive 1=Negative
36-40 Specific Gravity (x.xxx)
41-45 Albumin-urine
46-50 Sugar-urine
51-55 RBC-urine
56-60 WBC-urine

0100100400011 015.70047.50004.99012.90072.00020.00000.00007.00001.00387.00141.00
0100100400021 004.30103.00002.61001.01042.00057.00062.00000.00007.00007.00081.00
0100100400031 457.00011.00000.00071.00041.00005.64000.00003.00016.00010.00010.00
0100100400041 000.26075.00001.5011 1.014 - - - 0-3 120489
0100100421211 015.60045.40004.77011.00060.00020.00001.00006.00001.00411.00144.00
0100100421221 004.30103.00002.55000.68027.00025.00029.00005.10003.00004.30081.00
0100100421231 517.00010.10001.40071.00040.00005.10002.42003.00012.00015.00013.00
0100100421241 1.006 - - - 0-3 122789
0100100428211 015.30047.10004.97016.90068.00020.00001.00003.00000.00442.00136.00
0100100428221 004.00102.00002.45001.09024.00023.00028.00004.90073.00004.30082.00
0100100428231 004.00014.00000.00067.00041.00004.08002.43
0100100428241 1.019 - - - 0-3 010490

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0100200400012	016.20047.20005.15007.20083.00014.00000.00003.00000.00405.00137.00
0100200400022	004.20099.00002.42001.02016.00014.00032.00008.80090.00004.10072.00
0100200400032	299.00009.90001.20070.00038.00006.54003.09003.00013.00012.00014.00
0100200400042	000.26112.00000.501111.020 - - 3-5 0-3 030990
0100200405212	014.80049.90005.41007.50086.00012.00000.00002.00000.00427.00136.00
0100200405222	004.10099.00002.32001.00028.00016.00033.00011.30099.00006.00089.00
0100200405232	350.00008.20000.00070.00038.00005.22003.03002.00009.00010.00025.00
0100200405242	1.025 0.3 5.5 - 0-3 031490
0100200428212	
0100200428222	
0100200428232	
0100200428242	
0101600400012	014.80044.70005.08009.70088.00011.00000.00001.00000.00391.00140.00
0101600400022	004.60102.00002.39001.23023.00026.00016.00004.70071.00007.40061.00
0101600400032	274.00010.90000.50072.00039.00005.53001.13
0101600400042	000.26135.00000.301 1.015 - - - 0-3 020790
0101600407212	014.20043.80005.02006.30073.00019.00000.00008.00000.00586.00138.00
0101600407222	004.50098.00002.41001.23025.00024.00015.00004.70061.00004.60057.00
0101600407232	239.00012.70000.70074.00041.00006.07001.13005.00014.00011.00018.00
0101600407242	
0101600428212	
0101600428222	
0101600428232	
0101600428242	
0101700400011	012.10033.50003.28006.30062.00024.00001.00003.00000.00323.00141.00
0101700400021	004.20106.00002.27001.04014.00011.00041.00004.70051.00004.80074.00
0101700400031	274.00007.90000.00059.90038.00006.39001.68
0101700400041	1.030 - - - 0-3 082090
0101700407211	014.20043.80005.02006.30073.00019.00000.00008.00000.00586.00138.00
0101700407221	004.50098.00002.41001.23025.00024.00015.00004.70061.00004.60057.00
0101700407231	239.00012.70000.70074.00041.00006.07001.13005.00014.00011.00018.00
0101700407241	
0101700428211	
0101700428221	
0101700428231	
0101700428241	
0403100400011	016.00047.40005.10008.90075.00019.00001.00001.00001.00253.00141.00
0403100400021	004.20104.00002.21000.84017.00017.00024.00005.10125.00035.70033.00
0403100400031	367.00006.00 070.03042.00006.05 003.00007.00000.00011.00
0403100400041	000.96077.00000.5611 1.020 - - - - 111628
0403100407211	016.70049.90005.27007.90060.00034.00002.00001.00000.00160.00142.00
0403100407221	004.80105.00002.15000.82013.00016.00016.00004.70126.00002.60098.00
0403100407231	421.00010.00 071.00042.00005.62002.99002.00004.00009.00012.00
0403100407241	1.025 - - - - 121289
0403100442211	017.20051.80005.50070.60078.00017.00009.00001.00000.00210.00139.00
0403100442221	004.60102.00002.03001.06013.00015.00 004.80169.00004.50069.00
0403100442231	424.00007.00 074.00046.00006.30003.14003.00006.00009.00013.00
0403100442241	1.015 - - - - 010290
0403200400011	015.30049.90004.75004.00005.00031.00001.00001.00000.00200.00144.00
0403200400021	004.10105.00002.21001.07012.00007.00004.00004.30076.00004.50102.00
0403200400031	256.00005.00 000.00041.00005.01000.78003.00004.00007.00007.00
0403200400041	000.79096.00002.17 1.025 - - - 0-1 011830
0403200407211	015.10043.50004.00010.20063.00028.00000.00002.00000.00241.00141.00

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(6.3) Frequency Distribution of Height at Time of Recruitment by Country

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	150	3	6.8	6.8	6.8
	156	2	4.5	4.5	11.4
	157	1	2.3	2.3	13.6
	158	2	4.5	4.5	18.2
	159	1	2.3	2.3	20.5
	160	6	13.6	13.6	34.1
	161	1	2.3	2.3	36.4
	162	1	2.3	2.3	38.6
	163	3	6.8	6.8	45.5
	164	2	4.5	4.5	50.0
	165	2	4.5	4.5	54.5
	166	2	4.5	4.5	59.1
	167	1	2.3	2.3	61.4
	168	1	2.3	2.3	63.6
	169	3	6.8	6.8	70.5
	170	1	2.3	2.3	72.7
	172	1	2.3	2.3	75.0
	173	2	4.5	4.5	79.5
	174	2	4.5	4.5	84.1
	176	1	2.3	2.3	86.4
	178	2	4.5	4.5	90.9
	180	3	6.8	6.8	97.7
	186	1	2.3	2.3	100.0
	Total	44	100.0	100.0	
Mean	165.727	Median	164.500	Std dev	8.630

547

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0403200421221	004.20107.00002.13000.81011.00008.00003.00004.50095.00004.40098.00
0403200421231	204.00018.00 061.00040.00004.98000.58002.00005.00007.00007.00
0403200421241	1.020 - - - 0-3 020990
0403200442211	
0403200442221	
0403200442231	
0403200442241	
0403300400012	015.60047.50005.07006.40067.00027.00000.00002.00000.00194.00143.00
0403300400022	004.00105.00002.26000.90011.00008.00 004.60085.00004.50093.00
0403300400032	396.00014.00 066.00043.00005.33001.04003.00004.00007.00005.00
0403300400042	000.81085.00000.841 1.020 0 0 0-1 0-1 030890
0403300415212	015.50045.20004.84007.60065.00032.00001.00001.00000.00201.00146.00
0403300415222	004.20109.00002.22000.89010.00014.00005.00004.70082.00004.50098.00
0403300415232	465.00011.00 066.00044.00005.87001.24003.00005.00007.00007.00
0403300415242	1.025 0 0 0 0 032390
0403300442212	
0403300442222	
0403300442232	
0403300442242	
0403400400012	016.50048.90005.30014.00074.50020.80000.00004.70000.20245.00144.00
0403400400022	004.40105.00002.38001.11019.00029.00 005.80 006.60127.00
0403400400032	495.00005.00 075.00045.00005.33003.31004.00007.00009.00013.00
0403400400042	001.10136.00001.89011.010 - - - - 071090
0403400421212	
0403400421222	
0403400421232	
0403400421242	
0403400442212	
0403400442222	
0403400442232	
0403400442242	
0403500400012	014.00041.40004.77012.10365.00030.20004.80001.00000.20251.00149.00
0403500400022	003.50105.00002.24000.79014.00007.00010.00005.00015.00006.40131.00
0403500400032	437.00009.00 074.00048.00006.02001.25003.00004.00008.00011.00
0403500400042	000.00105.00002.300111.020 - - - - 011890
0403500421212	013.00037.50004.00012.30069.00027.00004.00000.00000.00204.00143.00
0403500421222	003.70106.00002.09000.89014.00009.00011.00004.40133.00008.50145.00
0403500421232	478.00011.00 005.00038.00004.93000.94002.00003.00007.00011.00
0403500421242	1.010 - - - - 091890
0403500442212	
0403500442222	
0403500442232	
0403500442242	
0404600400011	014.10041.00004.60007.70069.00020.00003.00001.00000.00303.00149.00
0404600400021	004.30105.00002.45001.00014.00007.00006.00005.40 006.80075.00
0404600400031	187.00010.00 071.00040.00005.30001.26004.00004.00006.00007.00
0404600400041	000.87107.00000.77111 071790
0404600421211	
0404600421221	
0404600421231	
0404600421241	
0404600442211	
0404600442221	

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0404600442231
 0404600442241
 0404700400011 013.70041.90004.45008.30063.00032.00 000.50 360.00139.00
 0404700400021 004.60104.00002.22001.18015.00008.00016.00005.60061.00003.30095.00
 0404700400031 236.00004.90 067.00046.00007.49001.74003.00008.00010.00006.00
 0404700400041 000.28116.00001.301111.0150001+ neg trace55-60101790
 0404700421211
 0404700421221
 0404700421231 005.00 071.00043.00 003.00007.00006.00007.00
 0404700421241 1.02500010000000000000-05110710
 0404700442211 013.80040.70004.39007.20056.60039.40004.00000.50001.00324.00143.00
 0404700442221 004.50106.00 005.60082.00005.80076.00
 0404700442231 345.00005.00 063.00039.00006.59000.76
 0404700442241 1.02500000000000000000-80112810
 0404800400012 013.20037.50003.94006.80060.00036.00001.00001.00 319.00142.00
 0404800400022 004.20105.00002.22001.35012.00005.00 010.50086.00004.90101.00
 0404800400032 196.00006.00 061.00035.00004.8-001.00003.00005.00008.00010.00
 0404800400042 1111.01500000000000-3000-03111390
 0404800421212 012.60037.90003.93006.40 232.00142.00
 0404800421222 004.50108.00 008.00004.70 006.00088.00
 0404800421232 060.00034.00 003.00006.00009.00008.00
 0404800421242 1.02500000000000000000120990
 0404800442212 013.70040.10004.25006.50069.00028.00003.00000.00000.00237.00145.00
 0404800442222 004.40107.00002.36001.26014.00007.00 005.20078.00005.60088.00
 0404800442232 225.00010.00 072.00046.00005.01001.23008.50006.00008.00009.00
 0404800442242 1.02500000000000000000000122090
 0708100400011 013.10040.00004.56005.00056.00036.00001.00005.00000.00295.00136.00
 0708100400021 004.10098.00009.00004.00010.00009.00005.00103.00022.00022.00000.90
 0708100400031 003.60000.70000.20007.20004.20100.00038.00004.00007.00012.00015.00
 0708100400041 001.30007.00001.101111.010 ++ - 2a4 35a4010099
 0708100421211 013.10045.00004.50005.00055.00035.00001.00004.00000.00200.00137.00
 0708100421221 004.30100.00008.90003.70010.00009.00005.00100.00023.00020.00000.60
 0708100421231 003.60000.70006.20008.10004.20138.00036.00004.00007.00014.00016.00
 0708100421241 1.012 + - 2a4 25a35102789
 0708100442211 013.10040.00004.60005.00055.00035.00001.00005.00000.00295.00136.00
 0708100442221 004.30100.00008.90003.70010.00009.00005.00110.00023.00020.00000.60
 0708100442231 003.60000.70000.20008.10004.20138.00036.00004.00007.00014.00016.00
 0708100442241 1.010 + - 2a4 20a30111789
 0708200400012 014.50044.00004.02005.50004.00020.00001.00007.00000.00241.00140.00
 0708200400022 003.60102.00008.80003.00014.00025.00020.00075.00050.00025.00000.80
 0708200400032 003.60000.70000.20008.10004.20138.00036.00004.00007.00014.00016.00
 0708200400042 001.05000.00000.501111.026 + - 1a2 1a2 100789
 0708200421212 014.00041.00004.00007.50003.00001.00000.00002.00000.00265.00141.00
 0708200421222 004.00100.00008.90003.70019.00029.00030.00100.00039.00032.00000.90
 0708200421232 003.60000.70000.20008.10004.20138.00036.00004.00007.00014.00016.00
 0708200421242 1.030 + - 00 00 100739
 0708200442212
 0708200442222
 0708200442232
 0708200442242
 0708300400012 014.70045.00005.06006.50007.00020.00003.00004.00000.00262.00143.00
 0708300400022 004.50095.00009.00002.50025.00027.00024.00039.00039.00001.00000.50
 0708300400032 007.30000.70000.20008.10004.20138.00036.00004.00007.00014.00016.00

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0708300400042	001.30010.20000.481111.022	+	-	1a2	1a3	100689
0708300421212	013.00045.00005.00006.90065.00025.00003.00004.00000.00260.00143.00					
0708300421222	004.50099.00008.80002.70025.00027.00028.00098.00039.00031.00000.90					
0708300421232	007.10000.80000.20006.90003.90270.00170.00004.00007.00012.00015.00					
0708300421242	1.020	+	-	1a2	1a2	102789
0708300442212	013.20045.00005.00006.80066.00027.00003.00004.00000.00262.00140.00					
0708300442222	004.50099.00008.80002.70025.00028.00022.00099.00039.00037.00000.90					
0708300442232	007.10000.80000.20007.10003.90270.00150.00004.00007.00015.00016.00					
0708300442242	1.020	+	-	1a2	1a2	111789
0708400400011	014.00042.00004.70010.40053.00043.00002.00002.00000.00240.00140.00					
0708400400021	004.50102.00008.80002.80007.00005.00008.00067.00024.00018.00000.70					
0708400400031	003.50000.50000.10008.10004.40150.00066.00009.00007.00012.00015.00					
0708400400041	001.20006.20003.201111.020	+	-	2a4	2a4	100689
0708400421211	013.60042.00004.73008.60063.00031.00001.00005.00000.00352.00139.00					
0708400421221	004.20102.00008.80002.70015.00005.00015.00067.00023.00033.00000.80					
0708400421231	003.00000.80000.20007.20004.50155.00113.00005.00007.00013.00015.00					
0708400421241	1.027	++	-	2a4	10a15	102789
0708400442211	014.20044.00004.58008.00061.00028.00002.00005.00000.00226.00141.00					
0708400442221	004.20100.00010.20004.20011.00012.00014.00030.00027.00028.00000.50					
0708400442231	004.50000.50000.10006.80004.50137.00069.00005.00007.00012.00015.00					
0708400442241	1.020	+	-	1a3	4a6	111789
0708500400012	014.00043.00004.80007.60056.00038.00002.00004.00000.00230.00140.00					
0708500400022	004.30100.00008.80002.50019.00018.00008.00066.00034.00018.00000.60					
0708500400032	003.30000.30000.20006.60003.60208.00073.00004.00007.00012.00015.00					
0708500400042	001.55007.00002.501111.017	+	-	-	2a4	100689
0708500421212	013.70040.00004.60004.50044.00041.00008.00007.00000.00240.00140.00					
0708500421222	004.20102.00009.00003.00013.00010.00007.00057.00038.00031.00000.80					
0708500421232	003.30000.60000.20007.30004.70151.00054.00006.00008.00014.00016.00					
0708500421242	1.013	+	-	1a3	10a15	102789
0708500442212						
0708500442222						
0708500442232						
0708500442242						
0708600400011	014.10042.00004.70003.50045.00042.00002.00007.00000.00205.00140.00					
0708600400021	004.60105.00009.40002.90025.00038.00025.00056.00034.00025.00000.90					
0708600400031	004.10000.50000.30007.20004.60159.00090.00004.00007.00012.00015.00					
0708600400041	001.45007.00003.201111.020	+	-	=0	=0	100689
0708600421211	015.00046.00005.15005.10072.00022.00000.00002.00001.00210.00139.00					
0708600421221	004.70102.00005.80002.50017.00019.00040.00092.00025.00028.00000.50					
0708600421231	003.30001.30000.40008.50004.10229.00080.00004.00007.00012.00015.00					
0708600421241	1.013	+	-	1a2	1a2	102789
0708600442211	013.30042.00004.73003.60057.00033.00003.00004.00000.00225.00139.00					
0708600442221	004.60100.00009.70002.70015.00010.00020.00073.00030.00027.00000.50					
0708600442231	003.60001.10003.40007.40004.60130.00079.00005.00007.00019.00010.00					
0708600442241	1.024	+	-	=0	=0	111789
0708700400012	014.10043.00004.89007.50070.00024.00004.00002.00000.00305.00136.00					
0708700400022	003.80102.00009.00003.00011.00038.00034.00070.00020.00023.00000.70					
0708700400032	004.60000.60000.20007.50004.20125.00038.00006.00006.00010.00015.00					
0708700400042	001.10008.00000.801111.020	+	-	1a2	2a4	100789
0708700421212	013.40040.00004.56007.10067.00027.00001.00005.00000.00246.00136.00					
0708700421222	004.60105.00009.10000.10020.00000.00005.00080.00017.00015.00000.70					
0708700421232	004.00001.00000.30006.80004.50135.00035.00004.00007.00012.00015.00					
0708700421242	1.014	+	-	1a3	8a10	100789

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0708700442212
 0708700442222
 0708700442232
 0708700442242
 0708800400012 013.10039.00004.41010.00066.00027.00002.00005.00000.00445.00136.00
 0708800400022 004.70094.00009.10003.70015.00035.00020.00055.00027.00038.00000.50
 0708800400032 004.80000.70000.20007.40004.00177.00039.00006.00009.00013.00017.00
 0708800400042 001.30008.50000.221111.025 + - 1a2 3a5 100689
 0708800421212 012.50039.00004.42008.70074.00020.00003.00003.00000.00239.00136.00
 0708800421222 004.60100.00009.10003.00008.00013.00016.00097.00024.00025.00000.90
 0708800421232 003.10000.80000.20007.10004.40213.00068.00006.00008.00013.00017.00
 0708800421242 1.020 ++ - =0 10a15100789
 0708800442212 012.60039.00004.45005.50056.00032.00004.00008.00000.00201.00135.00
 0708800442222 004.40094.00009.20003.40012.00011.00015.00052.00023.00031.00000.50
 0708800442232 004.00001.00000.30007.80004.60188.00062.00005.00008.00013.00015.00
 0708800442242 1.020 + - 3a5 2a4 111789
 0708900400011 014.10043.00004.81000.10072.00020.00004.00004.00000.00239.00139.00
 0708900400021 003.60100.00008.60003.00015.00019.00020.00084.00026.00023.00000.50
 0708900400031 002.60000.70000.20007.80004.20282.00089.00004.00007.00013.00015.00
 0708900400041 001.20008.00002.301111.022 + - =0 1a2 100689
 0708900421211 014.10042.00004.77007.10066.00027.00004.00002.00000.00250.00139.00
 0708900421221 004.20057.00008.40002.90010.00009.00031.00086.00023.00019.00001.10
 0708900421231 002.40001.10000.40007.20004.60235.00108.00004.00007.00013.00016.00
 0708900421241 1.015 + - =0 2a4 102789
 0708900442211 014.90045.00005.07000.60065.00031.00002.00002.00000.00315.00143.00
 0708900442221 004.10103.00009.00003.10016.00016.00028.00050.00027.00032.00000.90
 0708900442231 003.20001.10000.40007.80004.50332.00164.00004.00007.00013.00015.00
 0708900442241 1.020 + - 1a2 6a8 111789
 0709000400011 013.60040.00004.35007.00072.00022.00001.00005.00000.00215.00135.00
 0709000400021 003.80100.00006.80002.50013.00023.00018.00087.00024.00014.00000.70
 0709000400031 005.60000.70000.30007.10004.10201.00105.00035.00007.00012.00015.00
 0709000400041 001.15005.80002.601111.016 + - - 1a2 100689
 0709000421211 013.40039.00004.40000.10060.00024.00002.00008.00000.00245.00137.00
 0709000421221 004.30098.00008.90002.70013.00015.00035.00095.00027.00015.00000.80
 0709000421231 002.60000.20000.80007.90004.70188.00067.00036.00008.00012.00015.00
 0709000421241 1.010 + - =0 1a2 102789
 0709000442211 015.60040.00004.35007.00072.00022.00001.00005.00000.00215.00139.00
 0709000442221 003.90100.00006.80002.50013.00023.00018.00087.00024.00014.00000.70
 0709000442231 005.60000.70000.30007.10004.10201.00105.00035.00007.00012.00015.00
 0709000442241 1.010 + - =0 1a2 111789
 0709100400011 012.50039.00004.40000.70005.00035.00003.00008.00001.00220.00135.00
 0709100400021 003.70099.00008.80002.50015.00017.00011.00061.00028.00022.00000.80
 0709100400031 005.40000.60000.10006.00003.50128.00035.00004.00007.00012.00015.00
 0709100400041 001.10006.40000.221111.022 + - =0 1a2 111439
 0709100421211 012.60039.00004.45005.50056.00032.00004.00008.00000.00201.00135.00
 0709100421221 003.30100.00008.90002.70013.00015.00035.00095.00027.00015.00000.70
 0709100421231 002.60000.20000.80007.90004.70188.00067.00036.00008.00012.00015.00
 0709100421241 1.020 + - 3a5 8a8 100689
 0709100442211 012.40037.00004.23000.10060.00025.00006.00008.00000.00150.00144.00
 0709100442221 004.00103.00009.00003.50008.00011.00014.00085.00038.00027.00001.10
 0709100442231 005.60000.70000.30007.10004.10195.00072.00005.00067.00012.00015.00
 0709100442241 1.020 ++ - 6a8 8a10122603
 0709200400011 011.20039.00004.10000.20000.00020.00002.00005.00001.00210.00138.00

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0708700442212
 0708700442222
 0708700442232
 0708700442242
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 0708800400022 004.70094.00009.10003.70015.00035.00020.00055.00027.00038.00000.50
 0708800400032 004.80000.70000.20007.40004.00177.00039.00006.00009.00013.00017.00
 0708800400042 001.30008.50000.221111.025 + - 1a2 3a5 100689
 0708800421212 012.50039.00004.42008.70074.00020.00003.00003.00000.00239.00136.00
 0708800421222 004.60100.00009.10003.00008.00013.00016.00097.00024.00025.00000.90
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 0708800421242 1.020 ++ - =0 10a15100789
 0708800442212 012.60039.00004.45005.50056.00032.00004.00008.00000.00201.00135.00
 0708800442222 004.40094.00009.20003.40012.00011.00015.00052.00023.00031.00000.50
 0708800442232 004.00001.00000.30007.80004.60188.00062.00005.00008.00013.00015.00
 0708800442242 1.020 + - 3a5 2a4 111789
 0708900400011 014.10043.00004.81000.10072.00020.00004.00004.00000.00239.00139.00
 0708900400021 003.60100.00008.60003.00015.00019.00020.00084.00026.00023.00000.50
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 0708900421211 014.10042.00004.77007.10066.00027.00004.00002.00000.00250.00139.00
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 0708900421241 1.015 + - =0 2a4 102789
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 0708900442221 004.10103.00009.00003.10016.00016.00028.00050.00027.00032.00000.90
 0708900442231 003.20001.10000.40007.80004.50002.00164.00004.00007.00013.00015.00
 0708900442241 1.020 + - 1a2 6a8 111789
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 0709000421221 004.30098.00008.90002.70013.00015.00035.00095.00027.00015.00000.80
 0709000421231 002.60000.20000.80007.90004.70188.00067.00036.00008.00012.00015.00
 0709000421241 1.010 + - =0 1a2 102789
 0709000442211 015.60040.00004.35007.00072.00022.00001.00005.00000.00215.00139.00
 0709000442221 003.90100.00006.80002.50013.00023.00018.00087.00024.00014.00000.70
 0709000442231 005.60000.70000.30007.10004.10201.00105.00035.00007.00012.00015.00
 0709000442241 1.010 + - =0 1a2 111789
 0709100400011 012.50039.00004.40000.70000.00020.00003.00003.00000.00239.00139.00
 0709100400021 003.70099.00008.80002.50015.00017.00011.00061.00028.00022.00000.80
 0709100400031 005.40000.60000.30007.10004.10201.00105.00035.00007.00012.00015.00
 0709100400041 001.10006.40000.221111.022 + - =0 1a2 111439
 0709100421211 012.50039.00004.40000.70000.00020.00003.00003.00000.00239.00139.00
 0709100421221 003.30100.00008.90002.70013.00015.00035.00095.00027.00015.00000.70
 0709100421231 002.60000.20000.80007.90004.70188.00067.00036.00008.00012.00015.00
 0709100421241 1.020 + - 3a5 8a8 100689
 0709100442211 012.40037.00004.23000.10060.00020.00006.00008.00000.00150.00144.00
 0709100442221 004.00103.00009.00002.50008.00011.00014.00085.00038.00027.00001.10
 0709100442231 005.60000.70000.30007.10004.10201.00105.00035.00007.00012.00015.00
 0709100442241 1.020 ++ - 6a8 8a10122603
 0709200400011 011.20039.00004.10000.20000.00020.00002.00005.00001.00210.00138.00

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0709600421232 004.50000.20000.80007.40003.80195.00061.00005.00007.00012.00015.00
 0709600421242 1.012 + - 1a3 1a2 120589
 0709600442212 013.50042.00004.73004.50062.00030.00004.00003.00000.00230.00141.00
 0709600442222 004.20103.00008.00003.00012.00015.00025.00090.00047.00025.00000.80
 0709600442232 003.70000.20000.50007.30004.50165.00060.00005.00008.00012.00017.00
 0709600442242 1.010 + - 1a2 1a2 122689
 0709700400011 011.80038.00004.01019.50080.00008.00000.00002.00000.00285.00135.00
 0709700400021 005.10102.00008.80002.50040.00016.00044.00103.00037.00021.00000.70
 0709700400031 003.20000.80000.20007.20004.80161.00076.00005.00007.00013.00016.00
 0709700400041 001.30.11.00000.501111.011 + - =0 111489
 0709700421211 013.50041.00004.64014.30079.00015.00002.00004.00000.00215.00135.00
 0709700421221 004.60093.00003.00002.50016.00010.00026.00056.00040.00023.00000.70
 0709700421231 003.00001.10000.40006.50004.40120.00000.00005.00007.00012.00015.00
 0709700421241 1.024 + - 1a2 =0 120589
 0709700442211 013.50035.00004.40013.80065.00030.00002.00003.00000.00355.00137.00
 0709700442221 004.80098.00009.00003.00012.00017.00096.00094.00036.00023.00000.70
 0709700442231 004.00001.10000.40006.40004.70124.00064.00004.00007.00012.00015.00
 0709700442241 1.027 + - =0 1a2 122689
 0709800400011 013.70042.00004.75007.20065.00025.00003.00003.00000.00230.00138.00
 0709800400021 003.80100.00009.80002.50010.00013.00011.00095.00025.00020.00000.80
 0709800400031 003.40000.80000.20006.80004.20107.00060.00005.00007.00012.00017.00
 0709800400041 002.00009.00005.201111.014 + - =0 2a4 111489
 0709800421211 013.10042.00004.73006.00065.00025.00007.00003.00000.00232.00132.00
 0709800421221 004.00100.00008.90002.70010.00012.00014.00053.00028.00014.00000.70
 0709800421231 003.10000.30000.50007.60005.00126.00066.00005.00007.00012.00017.00
 0709800421241 1.012 + - =0 1a2 120589
 0709800442211 015.10045.00005.14007.80060.00032.00005.00003.00000.00250.00136.00
 0709800442221 003.60102.00009.00002.70017.00019.00019.00052.00027.00018.00000.80
 0709800442231 003.00000.20000.70007.30004.80155.00071.00004.00007.00012.00015.00
 0709800442241 1.011 + - 1a2 1a2 122689
 0709900400012 013.60040.00004.55006.40030.00050.00012.00002.00000.00245.00135.00
 0709900400022 004.10105.00008.00002.70011.00012.00025.00085.00033.00015.00000.80
 0709900400032 004.40000.40001.80007.60004.80150.00100.00007.00011.00015.00021.00
 0709900400042 001.10000.00004.501111.010 + - 1a2 2a4 111489
 0709900421212 013.00035.00004.30007.50055.00024.00018.00001.00002.00210.00140.00
 0709900421222 004.00100.00008.80002.60003.00010.00040.00050.00033.00016.00000.70
 0709900421232 003.40000.70001.60007.80004.80102.00124.00000.00011.00014.00021.00
 0709900421242 1.013 + - 1a2 1a2 120589
 0709900442211
 0709900442222
 0709900442232
 0709900442242
 0710000400012 013.50042.00004.70000.50005.00008.00002.00004.00000.00235.00138.00
 0710000400021 004.10000.00000.00002.50016.00020.00030.00085.00030.00021.00001.00
 0710000400032 003.00000.20000.70007.30004.80155.00071.00004.00007.00012.00015.00
 0710000400042 001.30012.50002.001111.013 + - 1a2 =0 111489
 0710000421212 013.30040.00004.50006.50006.00026.00004.00004.00000.00270.00130.00
 0710000421222 004.40102.00001.00002.50011.00019.00019.00052.00027.00018.00000.80
 0710000421232 004.10000.00000.00000.70004.80102.00124.00000.00011.00014.00021.00
 0710000421242 1.010 + - =0 =0 120589
 0710000442211
 0710000442222
 0710000442232

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0710000442242	
0712100400011	016.00049.00005.40004.70056.00029.00008.00006.00001.00248.00137.00
0712100400021	003.50094.00009.10003.50012.00035.00038.00088.00028.00034.00000.90
0712100400031	005.00001.00000.40006.60004.40191.00060.00004.00008.00012.00017.00
0712100400041	001.15006.40001.801111.028 + - - - 041389
0712100421211	015.70047.00005.31003.60056.00021.00007.00005.00001.00242.00137.00
0712100421221	004.00098.00010.10003.70016.00016.00038.00087.00031.00041.00000.90
0712100421231	004.60000.90000.30007.30004.20213.00042.00005.00008.00012.00016.00
0712100421241	1.026 + - - - 050489
0712100442211	016.60049.00005.70006.00047.00040.00008.00005.00000.00230.00139.00
0712100442221	004.20096.00009.50003.90013.00015.00018.00082.00034.00027.00000.80
0712100442231	004.50000.70000.20007.30003.70194.00001.00004.00002.00013.00017.00
0712100442241	1.025 + - - - 052589
0712200400011	013.90043.00004.80006.40067.00026.00004.00003.00000.00229.00135.00
0712200400021	003.90093.00008.90004.00014.00022.00039.00082.00034.00027.00000.90
0712200400031	006.40000.50000.10009.30004.60231.00296.00006.00009.00014.00017.00
0712200400041	001.80007.70005.301111.015 + - - - 041489
0712200421211	013.40040.00004.00005.10060.00038.00031.00001.00000.00420.00139.00
0712200421221	003.90035.00003.90003.90009.00018.00020.00085.00023.00020.00000.80
0712200421231	004.90000.50000.10008.00004.80189.00292.00006.00009.00015.00018.00
0712200421241	1.032 ++ - - - 050589
0712200442211	014.00040.00005.00007.80074.00024.00001.00001.00000.00235.00139.00
0712200442221	004.10098.00008.40003.90022.00025.00032.00096.00038.00019.00000.70
0712200442231	006.10000.80000.10007.50004.00200.00272.00007.00009.00015.00020.00
0712200442241	1.017 + - - - 052689
0712300400012	014.50044.00004.90004.70063.00031.00004.00002.00000.00225.00140.00
0712300400022	003.80097.00008.90002.70018.00022.00028.00084.00028.00025.00000.80
0712300400032	006.00001.00000.30007.10009.70293.00120.00005.00007.00018.00021.00
0712300400042	001.30009.50005.201111.021 + - 1a2 - 041489
0712300421212	014.40044.00005.00004.80070.00025.00001.00004.00000.00231.00140.00
0712300421222	004.00100.00008.80002.70019.00023.00029.00091.00030.00023.00001.10
0712300421232	005.60000.80000.20007.00003.60312.00171.00005.00008.00015.00015.00
0712300421242	1.025 ++ - 1a2 - 050589
0712300442212	015.00040.00005.10004.90068.00027.00001.00003.00000.00242.00140.00
0712300442222	004.00098.00008.80002.70017.00022.00027.00086.00030.00024.00000.70
0712300442232	006.10001.00000.30006.90003.70315.00187.00004.00008.00015.00016.00
0712300442242	1.022 + - 1a2 - 050689
0712400400012	014.80040.00004.80005.20062.00030.00004.00001.00000.00240.00141.00
0712400400022	004.90193.00003.60002.90010.00013.00018.00073.00034.00030.00001.20
0712400400032	004.60001.00000.40007.10004.60190.00097.00004.00007.00013.00016.00
0712400400042	001.30008.00002.701111.017 + - - - 041489
0712400421212	014.00040.00004.80005.20054.00030.00003.00000.00001.00240.00142.00
0712400421222	003.90100.00009.00003.10038.00009.00017.00072.00035.00037.00001.00
0712400421232	005.00001.00000.40006.80003.00151.00050.00005.00007.00013.00010.00
0712400421242	1.017 + - - - 050589
0712400442212	014.00040.00005.10004.90068.00027.00001.00003.00000.00242.00140.00
0712400442222	004.00098.00008.80002.70017.00022.00027.00086.00030.00024.00000.70
0712400442232	006.10001.00000.30006.90003.70315.00187.00004.00008.00015.00016.00
0712400442242	1.022 + - 1a2 - 050689
0712500400011	013.90043.00004.80006.40067.00026.00004.00003.00000.00229.00135.00
0712500400021	003.40102.00008.90002.90020.00028.00011.00082.00025.00032.00000.90
0712500400031	006.80000.50000.10009.30004.60231.00296.00006.00009.00014.00017.00
0712500400041	001.20009.50005.201111.010 + - - - 041489

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

FCE 20124/706 i

0712900442222
 0712900442232
 0712900442242
 0713000400012 014.40043.00005.00007.60062.00034.00002.00002.00000.00228.00139.00
 0713000400022 004.40100.00009.10004.10017.00013.00012.00078.00020.00327.00000.90
 0713000400032 003.80001.10000.40007.00009.60173.00074.00000.00000.00014.00017.00
 0713000400042 001.30007.80000.301111.013 + - 1a2 - 051789
 0713000421212 013.40042.00004.30007.60053.00036.00009.00006.00000.00246.00139.00
 0713000421222 005.00102.00009.00003.00014.00015.00030.00076.00026.00029.00000.50
 0713000421232 003.00000.60000.20006.20004.0160.00074.00006.00009.00013.00019.00
 0713000421242 1.011 + - - - 060789
 0713000442212
 0713000442222
 0713000442232
 0713000442242
 0713100400011 014.40043.00004.90005.20059.00036.00002.00009.00000.00236.00146.00
 0713100400021 004.40100.00009.50003.70012.00013.00010.00093.00025.00039.00000.90
 0713100400031 004.40000.90009.20006.50004.10200.00044.00005.00008.00013.00019.00
 0713100400041 001.30009.00002.001111.013 + - 1a2 - 053168
 0713100421211 015.60046.00005.10005.50061.00005.00009.00001.00000.00256.00138.00
 0713100421221 004.90096.00003.00003.00014.00015.00006.00008.00024.00028.00000.80
 0713100421231 003.30000.60000.20006.70004.50239.00048.00000.00008.00013.00020.00
 0713100421241 1.010 + - - - 062189
 0713100442211
 0713100442221
 0713100442231
 0713100442241
 0713300400012 013.60042.00004.90007.90061.00009.00002.00004.00000.00260.00141.00
 0713300400022 004.20092.00008.90002.90014.00031.00021.00079.00019.00020.00000.80
 0713300400032 005.80009.00003.10006.80004.50254.00195.00004.00007.00012.00016.00
 0713300400042 001.00005.60003.401111.015 + - - 052169
 0713300421212 013.70042.00004.74005.20045.00009.00011.00000.00249.00142.00
 0713300421222 004.10097.00008.90002.70020.00020.00026.00065.00024.00015.00000.60
 0713300421232 005.70009.50000.10006.50003.80260.00172.00004.00009.00010.00015.00
 0713300421242 1.007 + - - - 062189
 0713300442212
 0713300442222
 0713300442232
 0713300442242
 0714100400012 014.00042.00004.90000.90000.00007.00002.00001.00000.00238.00138.00
 0714100400022 004.00096.00009.10002.00000.00016.00010.00095.00020.00010.00000.90
 0714100400032 003.00001.20000.30007.00002.00219.00000.00000.00008.00012.00016.00
 0714100400042 001.50007.50003.001111.015 + - 1a2 - 041499
 0714100421212 015.00045.00005.20006.00057.00012.00001.00002.00000.00290.00137.00
 0714100421222 004.00096.00009.00003.10014.00016.00009.00004.00020.00025.00000.70
 0714100421232 003.70001.00000.20007.00009.40277.00009.00007.00009.00010.00016.00
 0714100421242 1.010 + - - 2a 15a2100000
 0714100442212 013.80041.00004.90007.90000.00002.00007.00009.00001.00215.00140.00
 0714100442222 004.20102.00009.20003.00011.00012.00000.00104.00010.00010.00000.90
 0714100442232 003.40001.00000.50007.00003.00210.00008.00006.00007.00013.00016.00
 0714100442242 1.010 + - - 6a0 - 052680
 0714200400012 014.00042.00004.90000.90000.00007.00002.00001.00000.00240.00138.00
 0714200400022 003.60096.00009.00004.20010.00009.00006.00002.00001.00010.00000.90

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0714200400032	003.20000.80000.20007.10004.00166.00079.00004.00007.00013.00015.00
0714200400042	001.45007.20005.001111.021 + - - - 041489
0714200421212	012.70039.00004.40004.50054.00042.00003.00001.00000.00325.00134.00
0714200421222	004.50098.00009.50004.00012.00012.00042.00083.00022.00015.00000.50
0714200421232	003.40000.70000.20007.30003.80153.00083.00005.00007.00013.00016.00
0714200421242	1.020 + - 2a4 - 050589
0714200442212	
0714200442222	
0714200442232	
0714200442242	
0714300400011	013.60040.00004.50004.60062.00034.00002.00002.00000.00237.00143.00
0714300400021	004.20105.00008.90004.50027.00027.00005.00003.00046.00019.00000.50
0714300400031	002.50000.70000.10006.50003.80219.00067.00004.00007.00012.00016.00
0714300400041	001.20008.80005.501111.020 + - - - 041489
0714300421211	014.00042.00005.00004.60007.00000.00002.00001.00000.00230.00141.00
0714300421221	004.00102.00009.10004.00013.00016.00007.00078.00062.00023.00000.70
0714300421231	003.10003.70000.20007.30003.70242.00125.00006.00007.00013.00016.00
0714300421241	1.008 + - 1a3 - 050589
0714300442211	012.90040.00034.50004.60030.00044.00001.00005.00000.00320.00142.00
0714300442221	004.00098.00009.00004.10010.00011.00024.00088.00060.00027.00000.50
0714300442231	003.00000.70000.20007.30003.90234.00096.00005.00008.00013.00017.00
0714300442241	1.011 + - 2a4 - 052689
0714400400011	014.50043.00005.10006.00063.00030.00001.00002.00001.00230.00138.00
0714400400021	004.40102.00009.20003.20012.00015.00008.00101.00020.00036.00001.00
0714400400031	003.90000.60000.20007.00003.80332.00115.00007.00010.00013.00020.00
0714400400041	001.20007.70002.001111.012 + - - - 051789
0714400421211	014.40040.00005.00006.20054.00042.00002.00002.00000.00270.00139.00
0714400421221	004.00095.00008.90003.10012.00016.00007.00105.00025.00030.00000.70
0714400421231	003.50000.90000.20007.10004.00074.00121.00007.00010.00014.00021.00
0714400421241	1.010 + - - - 000789
0714400442211	014.30040.00004.60036.50057.00040.00002.00001.00000.00234.00139.00
0714400442221	004.00096.00009.00003.10017.00026.00008.00101.00024.00023.00000.80
0714400442231	004.10001.00000.20007.50004.10308.00119.00005.00010.00013.00020.00
0714400442241	1.013 + - 1a2 - 062889
0714500400011	015.50045.00005.20005.90050.00041.00004.00001.00001.00256.00139.00
0714500400021	004.30098.00010.20005.00012.00012.00010.00064.00033.00038.00000.80
0714500400031	003.70000.80000.20007.00003.80276.00142.00004.00007.00012.00015.00
0714500400041	001.10003.50001.201111.013 + - 1a2 - 051789
0714500421211	015.20045.00005.10007.20070.00024.00002.00004.00000.00280.00138.00
0714500421221	004.70092.00010.00004.50013.00010.00015.00088.00034.00004.00000.80
0714500421231	003.00000.90000.20007.10003.70308.00138.00005.00007.00015.00015.00
0714500421241	1.015 - - - 060789
0714500442211	014.10042.00005.50005.00077.00017.00003.00003.00000.00220.00107.00
0714500442221	005.00095.00010.00004.90012.00010.00010.00091.00028.00010.00000.70
0714500442231	003.00000.70000.20007.60003.80260.00142.00007.00010.00013.00016.00
0714500442241	1.019 + - - - 062389
0714600400010	012.00000.00004.10007.10076.00018.00002.00004.00000.00240.00140.00
0714600400020	003.80100.00003.90003.90018.00010.00000.00007.00002.00041.00000.60
0714600400030	003.80000.00000.10000.10000.40206.00116.00007.00011.00013.00019.00
0714600400040	003.80000.00000.20007.601111.012 + - - - 051789
0714600421210	012.20007.00004.10006.50065.00031.00002.00002.00000.00200.00100.00
0714600421220	004.20105.00008.90003.50014.00011.00013.00030.00034.00000.70
0714600421230	003.00000.90000.20007.40004.20236.00065.00007.00011.00014.00020.00

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0714600421242		1.010	+	-	1a2	-	060789
0714600442212							
0714600442222							
0714600442232							
0714600442242							
0714700400012	014.40045.00004.70005.90055.00041.00001.00003.00000.00242.00139.00						
0714700400022	004.50097.00008.90004.10017.00026.00040.00079.00024.00024.00000.60						
0714700400032	004.10001.10000.40007.60003.80229.00071.00004.00008.00013.00015.00						
0714700400042	001.70012.00001.201111.010	+	-	1a3	8a10062189		
0714700421212	012.30037.00004.30005.90061.00035.00001.00003.00000.00240.00137.00						
0714700421222	004.10102.00008.90003.50014.00016.00019.00067.00024.00039.00000.70						
0714700421232	004.10000.60000.10006.70003.60169.00040.00005.00009.00014.00015.00						
0714700421242		1.016	+	-	-	-	071289
0714700442212							
0714700442222							
0714700442232							
0714700442242							
0714800400011	012.50009.00004.60004.20069.00029.00001.00001.00000.00238.00140.00						
0714800400021	003.80098.00009.00003.00011.00013.00022.00039.00026.00026.00000.90						
0714800400031	003.10000.70000.20007.50004.20184.00084.00004.00007.00012.00015.00						
0714800400041	001.30003.00002.701111.022	+	-	2a4	-	051799	
0714900421211	013.20041.00004.60002.70060.00038.00001.00001.00000.00250.00140.00						
0714900421221	004.70102.00009.00003.10010.00010.00011.00082.00024.00023.00000.80						
0714900421231	003.30001.00000.20007.70004.50179.00070.00005.00007.00012.00016.00						
0714900421241		1.019	+	-	-	-	060789
0714900442211	013.40042.00004.70003.00057.00041.00001.00001.00000.00138.00140.00						
0714900442221	005.00098.00009.20003.20012.00020.00017.00100.00032.00028.00000.70						
0714900442231	003.20000.60000.10007.70005.00203.00082.00005.00006.00013.00016.00						
0714900442241		1.023	++	-	2a4	0	002009
0714900400011	013.00039.00004.60007.00005.00001.00001.00001.00000.00130.00141.00						
0714900400021	004.50102.00003.80001.50009.00009.00008.00091.00038.00017.00000.50						
0714900400031	003.30001.10000.30006.70003.60253.00097.00004.00007.00012.00016.00						
0714900400041	001.90011.50000.301111.010	+	-	-	-	051789	
0714900421211	013.60041.00004.30005.80055.00036.00005.00002.00000.00230.00140.00						
0714900421221	004.60098.00008.40002.70009.00014.00007.00033.00034.00018.00000.80						
0714900421231	003.50000.90000.20007.70004.20254.00107.00005.00007.00013.00015.00						
0714900421241		1.010	+	-	1a2	-	060789
0714900442211	013.00041.00004.60005.30066.00030.00002.00002.00000.00230.00140.00						
0714900442221	004.30102.00008.80002.60007.00008.00023.00038.00034.00023.00000.60						
0714900442231	003.40000.70000.20006.70004.70200.00097.00006.00007.00013.00017.00						
0714900442241		1.010	+	-	-	-	062889
0715000400012	013.70040.00004.70005.00037.00041.00001.00001.00000.00240.00142.00						
0715000400022	004.50103.00008.30008.30010.00013.00007.00076.00026.00004.00000.60						
0715000400032	003.20000.90000.30007.40003.20100.00000.00003.00007.00010.00016.00						
0715000400042	003.90005.00001.501111.007	+	-	-	-	052189	
0715000421212	012.40040.00004.30006.00000.00000.00001.00003.00000.00239.00140.00						
0715000421222	004.70103.00009.00009.70012.00019.00018.00005.00036.00036.00000.70						
0715000421232	003.40000.90000.20007.70004.20254.00107.00005.00007.00013.00015.00						
0715000421242		1.015	+	-	1a3	-	062189
0715000442212	013.40040.00004.60005.30066.00030.00002.00002.00000.00230.00140.00						
0715000442222	004.70103.00009.50009.50010.00007.00010.00008.00034.00038.00000.70						
0715000442232	004.60000.70000.20007.00001.20100.00001.00004.00001.00010.00015.00						
0715000442242		1.020	+	-	2a4	-	071289

Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0715100400012 014.00041.00004.60007.10070.00026.00001.00001.00000.00290.00142.00
 0715100400022 004.60102.00010.20005.00019.00019.00019.00077.00054.00037.00001.10
 0715100400032 004.90001.00000.30006.30003.20227.00106.00007.00012.00015.00022.00
 0715100400042 000.75006.50002.001111.024 + - - - 053189
 0715100421212 013.80040.00004.40006.70045.00049.00002.00004.00000.00268.00145.00
 0715100421222 004.20105.00010.00004.70014.00016.00026.00025.00034.00019.00000.50
 0715100421232 005.70000.70000.20006.90003.80230.00218.00007.00012.00015.00020.00
 0715100421242 1.010 + - - - 062189
 0715100442212
 0715100442222
 0715100442232
 0715100442242
 0715300400011 014.00042.00004.90006.90066.00030.00001.00003.00000.00236.00137.00
 0715300400021 004.60100.00008.80002.60012.00015.00020.00096.00025.00028.00000.60
 0715300400031 003.50001.40000.30007.50004.30296.10106.00006.00011.00014.00021.00
 0715300400041 001.55010.00009.101111.021 + - - - 053189
 0715300421211 013.80042.00004.40005.20054.00038.00001.00006.00001.00236.00140.00
 0715300421221 003.60102.00009.90002.50016.00012.00009.00099.00020.00018.00000.80
 0715300421231 007.00001.50000.60007.40004.30274.00099.00007.00011.00013.00019.00
 0715300421241 1.014 + - 1a2 - 062189
 0715300442211 014.40049.00004.80005.90079.00015.00001.00001.00000.00236.00138.00
 0715300442221 004.60100.00009.10003.20013.00012.00006.00107.00018.00039.00001.00
 0715300442231 002.50001.00000.20006.80004.70251.00103.00007.00012.00014.00020.00
 0715300442241 1.016 + - 1a2 8a10071269

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TREATMENT TERMINATION RECORD

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15-16	Treatment duration (days)
17	Premature discontinuation: 0=No 1=Yes
18-23	Discontinuation date
24	Nonresponse: 0=No 1=Yes
25-26	HAMD score at discontinuation
27	Adverse reaction: 0=No 1=Yes
28-42	Adverse reaction details
43	Intercurrent illness: 0=No 1=Yes
44-58	Intercurrent illness details
59	Withdrawn consent: 0=No 1=Yes
60-69	Withdrawn consent details
70	Administrative reasons: 0=No 1=Yes
71-80	Administrative reasons details
RECORD: 2	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	Significant events: 0=No 1=Yes
16	Negative event: 0=No 1=Yes
17-18	Negative event details
19	Positive event: 0=No 1=Yes
20-27	Positive event details
28	Non-pharmacological treatment: 0=No 1=Yes
29-31	Non-pharmacological treatment details
32	TCM study medication as prescribed: 0=No 1=Yes
33-39	Suspected irregularities details
40	Final conclusions: 0=Definitely no 3=Inclined yes 1=Inclined to no 4=Definitely yes 2=Undecided 5=Not assessed
RECORD: 3	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number

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TREATMENT TERMINATION RECORD (cont.)

Column
No. Contents

RECORD 3: (cont.)

- 9-11 Assessment Day
- 12 Record Number
- 13 Treatment Group: 1=Reboxetine 2=Placebo
- 15 Remains hospitalized: 0=No 1=Yes
- 16 Prescribed medication: 0=No 1=Yes
- 17-31 Medication prescribed
- 32 Patient discharged: 0=No 1=Yes
- 33 Patient discharged with medication: 0=No 1=Yes
- 34-48 Medication prescribed
- 49 Other: 0=No 1=Yes
- 50-65 Other details

0100101528211	3010103901320		0		0	
0100101528221	0		0	1	0010390	
0100101528231	11FLUCKETINE					
0100201505212	0410315900	0	0		11left hosp.	0
0100201505222	0		0	0refusal	2031690	
0100201505232	0		0	1		
0101601305212	0710215901470		0	0	0	0
0101601505222	0		0	0	0threw away	0021000
0101601505232	11FLUCKETINE					
0101701307211	0710827900	11HYPOTEN/DIZZY	0		0	0
0101701507221	0		0	1	4082990	
0101701507231	11DESPRAMINE					
0403101521211	420	0 0		0	0	0
0403101521221	0			1MilieuTher.	2010290	
0403101521231	0			11		
0403201521211	3010217900	11Hypomania	0		0	0
0403201521221	0		0	1	022030	
0403201521231	0		1			
0403301515212	1510323901260		0	0	0	0
0403301515222	0		0	1	1032390	
0403301515232	11LIL, July/Sep1.	0				
0403401307212	0710727900	11Agitation	0		0	0
0403401521222	0		0	1	1073190	
0403401521232	11Ativan					
0403501521212	2110919001900		0	0	0	0
0403501521222	0		0	1	2091900	
0403501521232	11Clonopin	0				
0404001521211	1410731901000		0	0	0	0
0404001521221	0		0	1	1073190	
0404001521231	11Ativan					
0404701521211	420	0 0		0	0	0
0404701521221	0		0	1	9112690	
0404701521231	0		0	1	1refused treatment	

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Anhang: Dokumentation der Stellungnahmen zum Vorbericht A05-20C. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)

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0404801521212	430	0	0				0	0
0404801521222	0			0		1	2122030	
0404801521232	0		10			0		
0708101542211	420	0	0			0	0	0
0708101542221	00	0				1	4111789	
0708101542231	00		10					
0708201521212	2111027891430					0	0	0
0708201521222	00					1	1102789	
0708201521232	11Imipramine							
0708301542212	420	0	0			0	0	0
0708301542222	00	0				1	3111789	
0708301542232	00		10					
0708401542211	420	0	0			0	0	0
0708401542221	00	0				1	4111789	
0708401542231	00		10					
0708501521212	2111027891400					0	0	0
0708501521222	00					1	0102789	
0708501521232	11Imipramine							
0708601542211	420	0	0			0	0	0
0708601542221	00	0				1	4111789	
0708601542231	00		10					
0708701521212	2111027891460					0	0	0
0708701521222	00					1	0102789	
0708701521232	11Imipramine							
0708801521222	00					1	1111789	
0708801521232	00		11Imipramine					
0708901542212	420	0	0			0	0	0
0708901542211	420	0	0			0	0	0
0708901542221	00	0				1	4111789	
0708901542231	00		10					
0709001542211	420	0	0			0	0	0
0709001542221	00	0				1	4111789	
0709001542231	00		10					
0709101542211	420	0	0			0	0	0
0709101542221	00	0				1	4122689	
0709101542231	00		10					
0709201542211	420	0	0			0	0	0
0709201542221	00	0				1	4122689	
0709201542231	00		10					
0709301521212	420	0	0			0	0	0
0709301521222	00	0				1	4122689	
0709301521232	00		10					
0709401521212	21110205001400					0	0	0
0709401521222	00					1	0120589	
0709401521232	11Imipramine							
0709501542211	420	0	0			0	0	0
0709501542221	00	0				1	4122689	
0709501542231	00		10					
0709601521212	420	0	0			0	0	0
0709601521222	00	0				1	4122689	
0709601521232	00		10					
0709701542211	420	0	0			0	0	0
0709701542221	00	0				1	4122689	

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0709701542231			10				0	0
0709801542211	420	0 0		0	0	1	4122689	
0709801542221	00	0						0
0709801542231			10				0	0
0709901521212	2111205891410			0	0	1	0122689	
0709901521222	00	0						0
0709901521232	111MIPRAMINE						0	0
0710001521212	2111205891440			0	0	1	0122689	
0710001521222	00	0						0
0710001521232	111MIPRAMINE						0	0
0712101542211	420	0 0		0	0	1	1052589	
0712101542221	0							0
0712101542231	111MIPRAMINE						0	0
0712201542211	420	0 0		0	0	1	4052689	
0712201542221	0							0
0712201542231	10						0	0
0712301542212	420	0 0		0	0	1	3052689	
0712301542222	0							0
0712301542232	10						0	0
0712401542212	420	0 0		0	0	1	0052689	
0712401542222	0							0
0712401542232	111MIPRAMINE						0	0
0712501542211	420	0 0		0	0	1	4052689	
0712501542221	0							0
0712501542231	10						0	0
0712601542212	420	0 0		0	0	1	4052689	
0712601542222	0							0
0712601542232	10						0	0
0712701542211	420	0 0		0	0	1	4052689	
0712701542221	0							0
0712701542231	10						0	0
0712801542211	420	0 0		0	0	1	4062889	
0712801542221	0							0
0712801542231	10						0	0
0712901521212	2110607891370			0	0	1	0060789	
0712901521222	0							0
0712901521232	111MIPRAMINE						0	0
0713001521212	2110607891410			0	0	1	0060789	
0713001521222	0							0
0713001521232	111MIPRAMINE						0	0
0713101521212	2110607891300			0	0	1	0060189	
0713101521221	0							0
0713101521231	111MIPRAMINE						0	0
0713201521212	2110607891360			0	0	1	0060139	
0713201521222	0							0
0713201521232	111MIPRAMINE						0	0
0714101542212	420	0 0		0	0	1	1050689	
0714101542222	0							0
0714101542232	10						0	0
0714201521212	2110605891410			0	0	1	0050500	
0714201521222	0							0
0714201521232	111MIPRAMINE						0	0
0714301542211	420	0 0					524	

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0714301542221	0			0	1	4052669	
0714301542231	10						
0714401542211	420	0	0		0	0	0
0714401542221	0			0	1	4062889	
0714401542231	10						
0714501542211	420	0	0		0	0	0
0714501542221	0			0	1	4062889	
0714501542231	10						
0714601521212	2110607891380			0	0	0	0
0714601521222	0			0	1	0060789	
0714601521232	11IMIPRAMINE						
0714701521212	2110712891370			0	0	0	0
0714701521222	0			0	1	0071289	
0714701521232	11IMIPRAMINE						
0714801542211	420	0	0		0	0	0
0714801542221	0			0	1	4062889	
0714801542231	0		10				
0714901542211	420	0	0		0	0	0
0714901542221	0			0	1	0062889	
0714901542231	11IMIPRAMINE						
0715001542212	420	0	0		0	0	0
0715001542222	0			0	1	4071289	
0715001542232	10						
0715101521212	2110621891400			0	0	0	0
0715101521222	0			0	1	0062189	
0715101521232	11IMIPRAMINE						
0715301542211	420	0	0		0	0	0
0715301542221	0			0	1	3071289	
0715301542231	10						

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FOLLOW-UP

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	New sign: 0=No 1=Yes
16-35	Specified new sign
36	Patient on antidepressant medication: 0=No 1=Yes
37-51	Specified antidepressant medication
52-59	Dose
60	Efficacy: 0=None 1=Good/Moderate/Regular 2=Very Good/Excellent 3=Fair/Minimum/Mild 4=Poor/Doubtful 5=Very Poor/Bad
61	Tolerability: 0=None 1=Good/Moderate/Regular/Well-tolerated 2=Very Good 3=Fair/Mild 4=Poor 5=Very Poor/Bad
62	Present Condition: 0=Outpatient 1=Inpatient 2=Discharged

0100101749211	1SUICIDE	0	0
0100201705212	0	0	2
0101601705212	0	1Chlhydr/Amitripr	0100.000131
0101701714211	0	1Desipramine	0050.000111
0403101750211	0	1Imip/Chlndiazpx	0060.000110011690
0403201749211			
0403301749212			
0403401749212			
0403501749212	0		1
0404601749211			
0404701742211	0		1
0404801742212	0		1
0708101772211	0		2121889
0708201772212	0	1Imipramine	0300.000110121889
0708301772212	0	1Imipramine	140121889
0708401772211	0		2121309
0708501742212	0	1Imipramine	0200.000110112789
0708601772211	0		0121309
0708701712212	0	1Imipramine	0250.000110112489
0708801742212	0	1Imipramine	0300.000110121389

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0708901772211	0	0	0121889
0709001774211	0	0	2121889
0709101772211	0	0	0012690
0709201772211	0	0	0012690
0709301772212	1DM/LIA/MR/SI	1imipramine	0300.000140012690
0709401752212	0	1imipramine	0250.000110010590
0709501772211	0	0	0012690
0709601752212	0	0	0012690
0709701772211	0	0	0012690
0709801772211	0	0	0012690
0709901752212	0	1imipramine	0200.000441012690
0710001742212	0	1imipramine	0275.000110010590
0712101770211	0	1IMIPRAMINE	0300.000130062389
0712201770211	0	0	0062389
0712301770212	0	0	0062389
0712401770212	0	1IMIPRAMINE	0250.000110072389
0712501770211	0	0	0062389
0712601777212	0	0	0063089
0712701770211	0	0	0063089
0712801770211	0	0	0060289
0712901749212	0	1IMIPRAMINE	0300.000110071289
0713001749212	0	1IMIPRAMINE	0250.000110062389
0713101749211	0	1IMIPRAMINE	0300.000110071989
0713301749212	0	1IMIPRAMINE	0250.000110071989
0714101770212	0	1IMIPRAMINE	0150.000140062389
0714201749212	0	1IMIPRAMINE	0300.000110060289
0714301770211	0	0	0062389
0714401770211	0	0	0080289
0714501770211	0	1IMIPRAMINE	0200.000110080289
0714601749212	0	1IMIPRAMINE	0250.000110070589
0714701749212	0	1IMIPRAMINE	0250.000110080989
0714801770211	0	0	0072689
0714901770211	0	1IMIPRAMINE	0300.000110072689
0715001770212	0	0	0080989
0715101749212	0	1IMIPRAMINE	0300.000110071989
0715301770211	0	0	0080989

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ECG-EEG

Column No.	Contents
RECORD: 1	
1-2	Center Number: 1=Montreal 4=Pointe Claire 7=Rio de Janeiro
3-5	Patient Number
6-8	Form Number
9-11	Assessment Day
12	Record Number
13	Treatment Group: 1=Reboxetine 2=Placebo
15	E.C.G. Day 0 0=Normal 1=Abnormal
16	E.C.G. Day 21 0=Normal 1=Abnormal
17	E.C.G. Day 42 0=Normal 1=Abnormal
18	E.E.G. Day 0 0=Normal 1=Abnormal
19	E.E.G. Day 42 0=Normal 1=Abnormal
20-80	Comments

0100100104211 00000
 0100200104212 11 00ECG: WNL Min.Tachycard./Auric.Hypert. Final:Day 3
 0101600104212 1 0 ECG: WNL Min.Tachycard./Auric.Hypert.
 0101700104211 11 1 ECG: Few Ext.Systol-Vent./ECG Limited Final:Day 7
 0403100104211 00000
 0403200104211 00 0
 0403300104212 00 00Final:Day 15
 0403400104212 0 0
 0403500104212 0 0
 0404600104211 0 0
 0404700104211 00000
 0404800104212 00000
 0708100104211 11100ECG: Lft.Vent.Hypertro.
 0708200104212 00 00Final:Day 21
 0708300104212 00000
 0708400104211 00000
 0708500104212 00 00Final:Day 21
 0708600104211 11100ECG: Lft.Anter.Div.Block
 0708700104212 00 00Final:Day 21
 0708800104212 00000
 0708900104211 11100ECG: Lft.Atrial Enlarg.
 0709000104211 00000
 0709100104211 00000
 0709200104211 11100ECG: Unspec.Repolar.Alteration/QT Prolong.
 0709300104212 11100ECG: Lft.Axis Deviat./1st Degree A-V Block
 0709400104212 11 00ECG: Sinus Bradycard./Lft.Atrial Enlarg. Final:Day 21
 0709500104211 00000
 0709600104212 00000
 0709700104211 00000
 0709800104211 00000
 0709900104212 00 00Final:Day 21
 0710000104212 00 00Final:Day 21

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A P P E N D I X

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APPENDIX 1

**Frequency Distribution of Patients
by Center and Country**

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(6.3) Frequency Distribution of Patients by Center

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Montreal	1	4	7.1	7.1	7.1
Pointe Claire	2	8	14.3	14.3	21.4
Rio de Janeiro	3	44	78.6	78.6	100.0
Total		56	100.0	100.0	

Frequency Distribution of Patients by Country

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
CANADA	1	12	21.4	21.4	21.4
BRAZIL	2	44	78.6	78.6	100.0
Total		56	100.0	100.0	

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APPENDIX 2

Frequency Distribution of Sex and Age in Total Recruited Population by Center and Country

534

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(6.3) Frequency Distribution of Sex by Centers

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Female	0	2	50.0	50.0	50.0
Male	1	2	50.0	50.0	100.0
Total		4	100.0	100.0	

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Female	0	3	37.5	37.5	37.5
Male	1	5	62.5	62.5	100.0
Total		8	100.0	100.0	

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Female	0	22	50.0	50.0	50.0
Male	1	22	50.0	50.0	100.0
Total		44	100.0	100.0	

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(6.3) Frequency Distribution of Sex by Countries

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Female	0	5	41.7	41.7	41.7
Male	1	7	58.3	58.3	100.0
		-----	-----	-----	
Total		12	100.0	100.0	

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Female	0	22	50.0	50.0	50.0
Male	1	22	50.0	50.0	100.0
		-----	-----	-----	
Total		44	100.0	100.0	

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(6.3) Frequency Distribution of Age at Time of Recruitment

TOTAL POPULATION

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	18	1	1.8	1.8	1.8
	20	2	3.6	3.6	5.4
	24	1	1.8	1.8	7.1
	25	2	3.6	3.6	10.7
	26	2	3.6	3.6	14.3
	27	1	1.8	1.8	16.1
	29	1	1.8	1.8	17.9
	30	2	3.6	3.6	21.4
	32	1	1.8	1.8	23.2
	33	2	3.6	3.6	26.8
	34	3	5.4	5.4	32.1
	37	2	3.6	3.6	35.7
	38	3	5.4	5.4	41.1
	39	1	1.8	1.8	42.9
	40	2	3.6	3.6	46.4
	41	2	3.6	3.6	50.0
	42	2	3.6	3.6	53.6
	43	2	3.6	3.6	57.1
	46	2	3.6	3.6	60.7
	47	3	5.4	5.4	66.1
	48	2	3.6	3.6	69.6
	49	1	1.8	1.8	71.4
	50	4	7.1	7.1	78.6
	51	1	1.8	1.8	80.4
	52	2	3.6	3.6	83.9
	53	2	3.6	3.6	87.5
	54	1	1.8	1.8	89.3
	55	1	1.8	1.8	91.1
	57	1	1.8	1.8	92.9
	58	3	5.4	5.4	98.2
	60	1	1.8	1.8	100.0
	Total	56	100.0	100.0	
Mean	41.036	Median	41.500	Std dev	11.117

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(6.3) Frequency Distribution of Age at Time of Recruitment by Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	50	2	50.0	50.0	50.0
	53	1	25.0	25.0	75.0
	60	1	25.0	25.0	100.0
	Total	4	100.0	100.0	
Mean	53.250	Median	51.500	Std dev	4.717

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	20	1	12.5	12.5	12.5
	30	1	12.5	12.5	25.0
	38	1	12.5	12.5	37.5
	42	1	12.5	12.5	50.0
	46	2	25.0	25.0	75.0
	53	1	12.5	12.5	87.5
	54	1	12.5	12.5	100.0
	Total	8	100.0	100.0	
Mean	41.125	Median	44.000	Std dev	11.557

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(6.3) Frequency Distribution of Age at Time of Recruitment by Center

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	18	1	2.3	2.3	2.3
	20	1	2.3	2.3	4.5
	24	1	2.3	2.3	6.8
	25	2	4.5	4.5	11.4
	26	2	4.5	4.5	15.9
	27	1	2.3	2.3	18.2
	29	1	2.3	2.3	20.5
	30	1	2.3	2.3	22.7
	32	1	2.3	2.3	25.0
	33	2	4.5	4.5	29.5
	34	3	6.8	6.8	36.4
	37	2	4.5	4.5	40.9
	38	2	4.5	4.5	45.5
	39	1	2.3	2.3	47.7
	40	2	4.5	4.5	52.3
	41	2	4.5	4.5	56.8
	42	1	2.3	2.3	59.1
	43	2	4.5	4.5	63.6
	47	3	6.8	6.8	70.5
	48	2	4.5	4.5	75.0
	49	1	2.3	2.3	77.3
	50	2	4.5	4.5	81.8
	51	1	2.3	2.3	84.1
	52	2	4.5	4.5	88.6
	55	1	2.3	2.3	90.9
	57	1	2.3	2.3	93.2
	58	3	6.8	6.8	100.0
	Total	44	100.0	100.0	
Mean	39.909	Median	40.000	Std dev	10.937

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(6.3) Frequency Distribution of Age at Time of Recruitment by Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	20	1	8.3	8.3	8.3
	30	1	8.3	8.3	16.7
	38	1	8.3	8.3	25.0
	42	1	8.3	8.3	33.3
	46	2	16.7	16.7	50.0
	50	2	16.7	16.7	66.7
	53	2	16.7	16.7	83.3
	54	1	8.3	8.3	91.7
	60	1	8.3	8.3	100.0
	Total	12	100.0	100.0	
Mean	45.167	Median	48.000	Std dev	11.256

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(6.3) Frequency Distribution of Age at Time of Recruitment by Country

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	18	1	2.3	2.3	2.3
	20	1	2.3	2.3	4.5
	24	1	2.3	2.3	6.8
	25	2	4.5	4.5	11.4
	26	2	4.5	4.5	15.9
	27	1	2.3	2.3	18.2
	29	1	2.3	2.3	20.5
	30	1	2.3	2.3	22.7
	32	1	2.3	2.3	25.0
	33	2	4.5	4.5	29.5
	34	3	6.8	6.8	36.4
	37	2	4.5	4.5	40.9
	38	2	4.5	4.5	45.5
	39	1	2.3	2.3	47.7
	40	2	4.5	4.5	52.3
	41	2	4.5	4.5	56.8
	42	1	2.3	2.3	59.1
	43	2	4.5	4.5	63.6
	47	3	6.8	6.8	70.5
	48	2	4.5	4.5	75.0
	49	1	2.3	2.3	77.3
	50	2	4.5	4.5	81.8
	51	1	2.3	2.3	84.1
	52	2	4.5	4.5	88.6
	55	1	2.3	2.3	90.9
	57	1	2.3	2.3	93.2
	58	3	6.8	6.8	100.0
	Total	44	100.0	100.0	
Mean	39.909	Median	40.000	Std dev	10.937

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APPENDIX 3

Frequency Distribution of Height and Weight in Total Recruited Population by Center and Country

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(6.3) Frequency Distribution of Height at Time of Recruitment
by Total Population

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	150	3	5.4	5.4	5.4
	152	1	1.8	1.8	7.1
	155	1	1.8	1.8	8.9
	156	2	3.6	3.6	12.5
	157	1	1.8	1.8	14.3
	158	3	5.4	5.4	19.6
	159	1	1.8	1.8	21.4
	160	6	10.7	10.7	32.1
	161	1	1.8	1.8	33.9
	162	2	3.6	3.6	37.5
	163	3	5.4	5.4	42.9
	164	2	3.6	3.6	46.4
	165	3	5.4	5.4	51.8
	166	3	5.4	5.4	57.1
	167	1	1.8	1.8	58.9
	168	2	3.6	3.6	62.5
	169	3	5.4	5.4	67.9
	170	2	3.6	3.6	71.4
	172	2	3.6	3.6	75.0
	173	2	3.6	3.6	78.6
	174	2	3.6	3.6	82.1
	176	1	1.8	1.8	83.9
	177	1	1.8	1.8	85.7
	178	3	5.4	5.4	91.1
	180	4	7.1	7.1	98.2
	186	1	1.8	1.8	100.0
	Total	56	100.0	100.0	
Mean	165.982	Median	165.000	Std dev	8.656

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(6.3) Frequency Distribution of Height at Time of Recruitment by Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	152	1	25.0	25.0	25.0
	155	1	25.0	25.0	50.0
	170	1	25.0	25.0	75.0
	177	1	25.0	25.0	100.0
	Total	4	100.0	100.0	

Mean 163.500 Median 162.500 Std dev 11.958

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	158	1	12.5	12.5	12.5
	162	1	12.5	12.5	25.0
	165	1	12.5	12.5	37.5
	166	1	12.5	12.5	50.0
	168	1	12.5	12.5	62.5
	172	1	12.5	12.5	75.0
	178	1	12.5	12.5	87.5
	180	1	12.5	12.5	100.0
	Total	8	100.0	100.0	

Mean 168.625 Median 167.000 Std dev 7.615

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(6.3) Frequency Distribution of Height at Time of Recruitment by Center

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	150	3	6.8	6.8	6.8
	156	2	4.5	4.5	11.4
	157	1	2.3	2.3	13.6
	158	2	4.5	4.5	18.2
	159	1	2.3	2.3	20.5
	160	6	13.6	13.6	34.1
	161	1	2.3	2.3	36.4
	162	1	2.3	2.3	38.6
	163	3	6.8	6.8	45.5
	164	2	4.5	4.5	50.0
	165	2	4.5	4.5	54.5
	166	2	4.5	4.5	59.1
	167	1	2.3	2.3	61.4
	168	1	2.3	2.3	63.6
	169	3	6.8	6.8	70.5
	170	1	2.3	2.3	72.7
	172	1	2.3	2.3	75.0
	173	2	4.5	4.5	79.5
	174	2	4.5	4.5	84.1
	176	1	2.3	2.3	86.4
	178	2	4.5	4.5	90.9
	180	3	6.8	6.8	97.7
	186	1	2.3	2.3	100.0
	Total	44	100.0	100.0	
Mean	165.727	Median	164.500	Std dev	8.630

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(6.3) Frequency Distribution of Height at Time of Recruitment by Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	152	1	8.3	8.3	8.3
	155	1	8.3	8.3	16.7
	158	1	8.3	8.3	25.0
	162	1	8.3	8.3	33.3
	165	1	8.3	8.3	41.7
	166	1	8.3	8.3	50.0
	168	1	8.3	8.3	58.3
	170	1	8.3	8.3	66.7
	172	1	8.3	8.3	75.0
	177	1	8.3	8.3	83.3
	178	1	8.3	8.3	91.7
	180	1	8.3	8.3	100.0
	Total	12	100.0	100.0	
Mean	166.917	Median	167.000	Std dev	9.070

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(6.3) Frequency Distribution of Weight at Time of Recruitment by Total Population

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	38	1	1.8	1.8	1.8
	42	1	1.8	1.8	3.6
	44	2	3.6	3.6	7.1
	45	1	1.8	1.8	8.9
	47	1	1.8	1.8	10.7
	48	1	1.8	1.8	12.5
	49	1	1.8	1.8	14.3
	50	1	1.8	1.8	16.1
	51	2	3.6	3.6	19.6
	52	2	3.6	3.6	23.2
	53	1	1.8	1.8	25.0
	55	3	5.4	5.4	30.4
	56	1	1.8	1.8	32.1
	58	4	7.1	7.1	39.3
	59	2	3.6	3.6	42.9
	60	3	5.4	5.4	48.2
	61	1	1.8	1.8	50.0
	62	2	3.6	3.6	53.6
	63	2	3.6	3.6	57.1
	64	1	1.8	1.8	58.9
	66	1	1.8	1.8	60.7
	68	2	3.6	3.6	64.3
	70	2	3.6	3.6	67.9
	71	1	1.8	1.8	69.6
	72	3	5.4	5.4	75.0
	74	2	3.6	3.6	78.6
	75	2	3.6	3.6	82.1
	77	2	3.6	3.6	85.7
	78	1	1.8	1.8	87.5
	80	3	5.4	5.4	92.9
	82	1	1.8	1.8	94.6
	85	1	1.8	1.8	96.4
	88	1	1.8	1.8	98.2
	111	1	1.8	1.8	100.0
	Total	56	100.0	100.0	
Mean	63.518	Median	61.500	Std dev	13.640

548

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FCE 20124/706 i

(6.3) Frequency Distribution of Weight at Time of Recruitment by Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	38	1	25.0	25.0	25.0
	44	1	25.0	25.0	50.0
	64	1	25.0	25.0	75.0
	88	1	25.0	25.0	100.0
	Total	4	100.0	100.0	
Mean	58.500	Median	54.000	Std dev	22.591

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	49	1	12.5	12.5	12.5
	53	1	12.5	12.5	25.0
	58	1	12.5	12.5	37.5
	74	1	12.5	12.5	50.0
	80	2	25.0	25.0	75.0
	85	1	12.5	12.5	87.5
	111	1	12.5	12.5	100.0
	Total	8	100.0	100.0	
Mean	73.750	Median	77.000	Std dev	20.296

FCE 20124/706 i

(6.3) Frequency Distribution of Weight at Time of Recruitment by Center

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	42	1	2.3	2.3	2.3
	44	1	2.3	2.3	4.5
	45	1	2.3	2.3	6.8
	47	1	2.3	2.3	9.1
	48	1	2.3	2.3	11.4
	50	1	2.3	2.3	13.6
	51	2	4.5	4.5	18.2
	52	2	4.5	4.5	22.7
	55	3	6.8	6.8	29.5
	56	1	2.3	2.3	31.8
	58	3	6.8	6.8	38.6
	59	2	4.5	4.5	43.2
	60	3	6.8	6.8	50.0
	61	1	2.3	2.3	52.3
	62	2	4.5	4.5	56.8
	63	2	4.5	4.5	61.4
	66	1	2.3	2.3	63.6
	68	2	4.5	4.5	68.2
	70	2	4.5	4.5	72.7
	71	1	2.3	2.3	75.0
	72	3	6.8	6.8	81.8
	74	1	2.3	2.3	84.1
	75	2	4.5	4.5	88.6
	77	2	4.5	4.5	93.2
	78	1	2.3	2.3	95.5
	80	1	2.3	2.3	97.7
	82	1	2.3	2.3	100.0
	Total	44	100.0	100.0	
Mean	62.114	Median	60.500	Std dev	10.557

550

FCE 20124/706 i

(6.3) Frequency Distribution of Weight at Time of Recruitment by Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	38	1	8.3	8.3	8.3
	44	1	8.3	8.3	16.7
	49	1	8.3	8.3	25.0
	53	1	8.3	8.3	33.3
	58	1	8.3	8.3	41.7
	64	1	8.3	8.3	50.0
	74	1	8.3	8.3	58.3
	80	2	16.7	16.7	75.0
	85	1	8.3	8.3	83.3
	88	1	8.3	8.3	91.7
	111	1	8.3	8.3	100.0
	Total	12	100.0	100.0	
Mean	68.667	Median	69.000	Std dev	21.394

FCE 20124/706 i

(6.3) Frequency Distribution of Weight at Time of Recruitment by Country

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	42	1	2.3	2.3	2.3
	44	1	2.3	2.3	4.5
	45	1	2.3	2.3	6.8
	47	1	2.3	2.3	9.1
	48	1	2.3	2.3	11.4
	50	1	2.3	2.3	13.6
	51	2	4.5	4.5	18.2
	52	2	4.5	4.5	22.7
	55	3	6.8	6.8	29.5
	56	1	2.3	2.3	31.8
	58	3	6.8	6.8	38.6
	59	2	4.5	4.5	43.2
	60	3	6.8	6.8	50.0
	61	1	2.3	2.3	52.3
	62	2	4.5	4.5	56.8
	63	2	4.5	4.5	61.4
	66	1	2.3	2.3	63.6
	68	2	4.5	4.5	68.2
	70	2	4.5	4.5	72.7
	71	1	2.3	2.3	75.0
	72	3	6.8	6.8	81.8
	74	1	2.3	2.3	84.1
	75	2	4.5	4.5	88.6
	77	2	4.5	4.5	93.2
	78	1	2.3	2.3	95.5
	80	1	2.3	2.3	97.7
	82	1	2.3	2.3	100.0
	Total	44	100.0	100.0	
Mean	62.114	Median	60.500	Std dev	10.557

FCE 20124/706 i

APPENDIX 4

Frequency Distribution of Age at the Time of Onset of First Depressive Episode and Number of Prior Episodes by Center and Country

553

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FCE 20124/706 i

(6.3) Frequency Distribution of Age at Time of First Depressive Episode by Total Population

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	7	1	1.8	1.8	1.8
	11	1	1.8	1.8	3.6
	18	1	1.8	1.8	5.4
	19	1	1.8	1.8	7.1
	20	1	1.8	1.8	8.9
	23	1	1.8	1.8	10.7
	24	2	3.6	3.6	14.3
	25	3	5.4	5.4	19.6
	26	2	3.6	3.6	23.2
	27	2	3.6	3.6	26.8
	28	1	1.8	1.8	28.6
	29	1	1.8	1.8	30.4
	30	5	8.9	8.9	39.3
	31	1	1.8	1.8	41.1
	32	4	7.1	7.1	48.2
	33	1	1.8	1.8	50.0
	34	4	7.1	7.1	57.1
	35	2	3.6	3.6	60.7
	36	1	1.8	1.8	62.5
	37	1	1.8	1.8	64.3
	38	1	1.8	1.8	66.1
	40	4	7.1	7.1	73.2
	42	2	3.6	3.6	76.8
	43	1	1.8	1.8	78.6
	44	1	1.8	1.8	80.4
	46	1	1.8	1.8	82.1
	47	1	1.8	1.8	83.9
	48	2	3.6	3.6	87.5
	49	1	1.8	1.8	89.3
	50	2	3.6	3.6	92.9
	52	1	1.8	1.8	94.6
	57	1	1.8	1.8	96.4
	58	2	3.6	3.6	100.0
	Total	56	100.0	100.0	
Mean	34.589	Median	33.500	Std dev	11.122

FCE 20124/706 i

(6.3) Frequency Distribution of Age at Time of First Depressive Episode by Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	31	1	25.0	25.0	25.0
	42	1	25.0	25.0	50.0
	43	1	25.0	25.0	75.0
	50	1	25.0	25.0	100.0
	Total	4	100.0	100.0	

Mean 41.500 Median 42.500 Std dev 7.853

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	7	1	12.5	12.5	12.5
	11	1	12.5	12.5	25.0
	23	1	12.5	12.5	37.5
	25	2	25.0	25.0	62.5
	32	1	12.5	12.5	75.0
	34	1	12.5	12.5	87.5
	44	1	12.5	12.5	100.0
	Total	8	100.0	100.0	

Mean 25.125 Median 25.000 Std dev 12.041

FCE 20124/706 i

(6.3) Frequency Distribution of Age at Time of First Depressive Episode by Center

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	18	1	2.3	2.3	2.3
	19	1	2.3	2.3	4.5
	20	1	2.3	2.3	6.8
	24	2	4.5	4.5	11.4
	25	1	2.3	2.3	13.6
	26	2	4.5	4.5	18.2
	27	2	4.5	4.5	22.7
	28	1	2.3	2.3	25.0
	29	1	2.3	2.3	27.3
	30	5	11.4	11.4	38.6
	32	3	6.8	6.8	45.5
	33	1	2.3	2.3	47.7
	34	3	6.8	6.8	54.5
	35	2	4.5	4.5	59.1
	36	1	2.3	2.3	61.4
	37	1	2.3	2.3	63.6
	38	1	2.3	2.3	65.9
	40	4	9.1	9.1	75.0
	42	1	2.3	2.3	77.3
	46	1	2.3	2.3	79.5
	47	1	2.3	2.3	81.8
	48	2	4.5	4.5	86.4
	49	1	2.3	2.3	88.6
	50	1	2.3	2.3	90.9
	52	1	2.3	2.3	93.2
	57	1	2.3	2.3	95.5
	58	2	4.5	4.5	100.0
	Total	44	100.0	100.0	
Mean	35.682	Median	34.000	Std dev	10.392

556

FCE 20124/706 i

(6.3) Frequency Distribution of Age at Time of First Depressive Episode by Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	7	1	8.3	8.3	8.3
	11	1	8.3	8.3	16.7
	23	1	8.3	8.3	25.0
	25	2	16.7	16.7	41.7
	31	1	8.3	8.3	50.0
	32	1	8.3	8.3	58.3
	34	1	8.3	8.3	66.7
	42	1	8.3	8.3	75.0
	43	1	8.3	8.3	83.3
	44	1	8.3	8.3	91.7
	50	1	8.3	8.3	100.0
	Total	12	100.0	100.0	

Mean 30.583 Median 31.500 Std dev 13.194

FCE 20124/706 i

(6.3) Frequency Distribution of Age at Time of First Depressive Episode by Country

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	18	1	2.3	2.3	2.3
	19	1	2.3	2.3	4.5
	20	1	2.3	2.3	6.8
	24	2	4.5	4.5	11.4
	25	1	2.3	2.3	13.6
	26	2	4.5	4.5	18.2
	27	2	4.5	4.5	22.7
	28	1	2.3	2.3	25.0
	29	1	2.3	2.3	27.3
	30	5	11.4	11.4	38.6
	32	3	6.8	6.8	45.5
	33	1	2.3	2.3	47.7
	34	3	6.8	6.8	54.5
	35	2	4.5	4.5	59.1
	36	1	2.3	2.3	61.4
	37	1	2.3	2.3	63.6
	38	1	2.3	2.3	65.9
	40	4	9.1	9.1	75.0
	42	1	2.3	2.3	77.3
	46	1	2.3	2.3	79.5
	47	1	2.3	2.3	81.8
	48	2	4.5	4.5	86.4
	49	1	2.3	2.3	88.6
	50	1	2.3	2.3	90.9
	52	1	2.3	2.3	93.2
	57	1	2.3	2.3	95.5
	58	2	4.5	4.5	100.0
	Total	44	100.0	100.0	
Mean	35.682	Median	34.000	Std dev	10.392

558

FCE 20124/706 i

(6.3) Frequency Distribution of Number of Prior Episodes by Total Population

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	26	46.4	47.3	47.3
	1	6	10.7	10.9	58.2
	2	4	7.1	7.3	65.5
	3	1	1.8	1.8	67.3
	4	2	3.6	3.6	70.9
	5	4	7.1	7.3	78.2
	6	3	5.4	5.5	83.6
	7	1	1.8	1.8	85.5
	8	3	5.4	5.5	90.9
	10	4	7.1	7.3	98.2
	20	1	1.8	1.8	100.0
	.	1	1.8	Missing	
	Total	56	100.0	100.0	
Mean	2.800	Median	1.000	Std dev	4.039

FCE 20124/706 i

(6.3) Frequency Distribution of Number of Prior Episodes Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	3	75.0	75.0	75.0
	8	1	25.0	25.0	100.0
	Total	4	100.0	100.0	

Mean 2.750 Median 1.000 Std dev 3.500

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	12.5	14.3	14.3
	4	1	12.5	14.3	28.6
	5	1	12.5	14.3	42.9
	6	1	12.5	14.3	57.1
	10	2	25.0	28.6	85.7
	20	1	12.5	14.3	100.0
	.	1	12.5	Missing	
	Total	8	100.0	100.0	

Mean 8.000 Median 6.000 Std dev 6.191

FCE 20124/706 i

(6.3) Frequency Distribution of Number of Prior Episodes Center

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	26	59.1	59.1	59.1
	1	2	4.5	4.5	63.6
	2	4	9.1	9.1	72.7
	3	1	2.3	2.3	75.0
	4	1	2.3	2.3	77.3
	5	3	6.8	6.8	84.1
	6	2	4.5	4.5	88.6
	7	1	2.3	2.3	90.9
	8	2	4.5	4.5	95.5
	10	2	4.5	4.5	100.0
	Total	44	100.0	100.0	

Mean 1.977 Median .000 Std dev 3.031

Frequency Distribution of Number of Prior Episodes Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	4	33.3	36.4	36.4
	4	1	8.3	9.1	45.5
	5	1	8.3	9.1	54.5
	6	1	8.3	9.1	63.6
	8	1	8.3	9.1	72.7
	10	2	16.7	18.2	90.9
	20	1	8.3	9.1	100.0
	.	1	8.3	Missing	
	Total	12	100.0	100.0	

Mean 6.091 Median 5.000 Std dev 5.804

FCE 20124/706 i

(6.3) Frequency Distribution of Number of Prior Episodes Country

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	0	26	59.1	59.1	59.1
	1	2	4.5	4.5	63.6
	2	4	9.1	9.1	72.7
	3	1	2.3	2.3	75.0
	4	1	2.3	2.3	77.3
	5	3	6.8	6.8	84.1
	6	2	4.5	4.5	88.6
	7	1	2.3	2.3	90.9
	8	2	4.5	4.5	95.5
	10	2	4.5	4.5	100.0
	Total	44	100.0	100.0	
Mean	1.977	Median	.000	Std dev	3.031

FCE 20124/706 i

APPENDIX 5

Frequency Distribution of Characteristics of Present Episode by Center and Country

563

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FCE 20124/706 i

(6.3) Frequency Distribution of Precipitating Factor by Total Population

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Absent	1	41	73.2	73.2	73.2
Prob.Present	2	11	19.6	19.6	92.9
Def.Present	3	4	7.1	7.1	100.0
		-----	-----	-----	
Total		56	100.0	100.0	

Frequency Distribution of Precipitating Factor by Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Absent	1	2	50.0	50.0	50.0
Prob.Present	2	2	50.0	50.0	100.0
		-----	-----	-----	
Total		4	100.0	100.0	

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Absent	1	4	50.0	50.0	50.0
Prob.Present	2	4	50.0	50.0	100.0
		-----	-----	-----	
Total		8	100.0	100.0	

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Absent	1	35	79.5	79.5	79.5
Prob.Present	2	5	11.4	11.4	90.9
Def.Present	3	4	9.1	9.1	100.0
		-----	-----	-----	
Total		44	100.0	100.0	

554

36

FCE 20124/706 i

(6.3) Frequency Distribution of Precipitating Factor by Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Absent	1	6	50.0	50.0	50.0
Prob.Present	2	6	50.0	50.0	100.0
		-----	-----	-----	
Total		12	100.0	100.0	

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Absent	1	35	79.5	79.5	79.5
Prob.Present	2	5	11.4	11.4	90.9
Def.Present	3	4	9.1	9.1	100.0
		-----	-----	-----	
Total		44	100.0	100.0	

FCE 20124/706 i

(6.3) Frequency Distribution of Form of Onset by Total Population

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Acute <2wks	1	24	42.9	42.9	42.9
Subacute >2wks	2	21	37.5	37.5	80.4
Insidious >3mo	3	11	19.6	19.6	100.0
		-----	-----	-----	
Total		56	100.0	100.0	

Frequency Distribution of Form of Onset by Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Subacute >2wks	2	2	50.0	50.0	50.0
Insidious >3mo	3	2	50.0	50.0	100.0
		-----	-----	-----	
Total		4	100.0	100.0	

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Acute <2wks	1	2	25.0	25.0	25.0
Subacute >2wks	2	4	50.0	50.0	75.0
Insidious >3mo	3	2	25.0	25.0	100.0
		-----	-----	-----	
Total		8	100.0	100.0	

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Acute <2wks	1	22	50.0	50.0	50.0
Subacute >2wks	2	15	34.1	34.1	84.1
Insidious >3mo	3	7	15.9	15.9	100.0
		-----	-----	-----	
Total		44	100.0	100.0	

568

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FCE 20124/706 i

(6.3) Frequency Distribution of Form of Onset by Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Acute <2wks	1	2	16.7	16.7	16.7
Subacute >2wks	2	6	50.0	50.0	66.7
Insidious >3mo	3	4	33.3	33.3	100.0
		-----	-----	-----	
Total		12	100.0	100.0	

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Acute <2wks	1	22	50.0	50.0	50.0
Subacute >2wks	2	15	34.1	34.1	84.1
Insidious >3mo	3	7	15.9	15.9	100.0
		-----	-----	-----	
Total		44	100.0	100.0	

FCE 20124/706 i

(6.3) Frequency Distribution of Subform of Illness by Total Population

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Sing.Epi.	29620	27	48.2	48.2	48.2
Recur.	29630	23	41.1	41.1	89.3
Rec.Mo.Sv.	29632	1	1.8	1.8	91.1
Rec.Sv.wo.Pf	29633	4	7.1	7.1	98.2
Rec.Sv.w.Pf	29634	1	1.8	1.8	100.0
		-----	-----	-----	
Total		56	100.0	100.0	

Frequency Distribution of Subform of Illness by Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Rec.Sv.wo.Pf	29633	3	75.0	75.0	75.0
Rec.Sv.w.Pf	29634	1	25.0	25.0	100.0
		-----	-----	-----	
Total		4	100.0	100.0	

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Recur.	29630	6	75.0	75.0	75.0
Rec.Mo.Sv.	29632	1	12.5	12.5	87.5
Rec.Sv.wo.Pf	29633	1	12.5	12.5	100.0
		-----	-----	-----	
Total		8	100.0	100.0	

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Sing.Epi.	29620	27	61.4	61.4	61.4
Recur.	29630	17	38.6	38.6	100.0
		-----	-----	-----	
Total		44	100.0	100.0	

560

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FCE 20124/706 i

(6.3) Frequency Distribution of Subform of illness by Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Recur.	29630	6	50.0	50.0	50.0
Rec.Mo.Sv.	29632	1	8.3	8.3	58.3
Rec.Sv.w.o.Pf	29633	4	33.3	33.3	91.7
Rec.Sv.w.Pf	29634	1	8.3	8.3	100.0
Total		12	100.0	100.0	

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Sing.Epi.	29620	27	61.4	61.4	61.4
Recur.	29630	17	38.6	38.6	100.0
Total		44	100.0	100.0	

FCE 20124/706 i

(6.3) Frequency Distribution of Duration of Present Episode (in months)
by Total Population

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	5	8.9	8.9	8.9
	2	12	21.4	21.4	30.4
	3	9	16.1	16.1	46.4
	4	11	19.6	19.6	66.1
	5	3	5.4	5.4	71.4
	6	3	5.4	5.4	76.8
	8	4	7.1	7.1	83.9
	9	4	7.1	7.1	91.1
	10	3	5.4	5.4	96.4
	12	2	3.6	3.6	100.0
	Total	56	100.0	100.0	
Mean	4.554	Median	4.000	Std dev	3.015

Frequency Distribution of Duration of Present Episode (in months)
by Center

MONTREAL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	25.0	25.0	25.0
	2	2	50.0	50.0	75.0
	3	1	25.0	25.0	100.0
	Total	4	100.0	100.0	
Mean	2.000	Median	2.000	Std dev	.816

570

42

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(6.3) Frequency Distribution of Duration of Present Episode (in months)
by Center

POINTE CLAIRE

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	4	50.0	50.0	50.0
	3	1	12.5	12.5	62.5
	6	1	12.5	12.5	75.0
	8	1	12.5	12.5	87.5
	9	1	12.5	12.5	100.0
	Total	8	100.0	100.0	

Mean 4.250 Median 2.500 Std dev 2.964

RIO DE JANEIRO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	4	9.1	9.1	9.1
	2	6	13.6	13.6	22.7
	3	7	15.9	15.9	38.6
	4	11	25.0	25.0	63.6
	5	3	6.8	6.8	70.5
	6	2	4.5	4.5	75.0
	8	3	6.8	6.8	81.8
	9	3	6.8	6.8	88.6
	10	3	6.8	6.8	95.5
	12	2	4.5	4.5	100.0
	Total	44	100.0	100.0	

Mean 4.841 Median 4.000 Std dev 3.072

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(6.3) Frequency Distribution of Duration of Present Episode (in months)
by Country

CANADA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	8.3	8.3	8.3
	2	6	50.0	50.0	58.3
	3	2	16.7	16.7	75.0
	6	1	8.3	8.3	83.3
	8	1	8.3	8.3	91.7
	9	1	8.3	8.3	100.0
	Total	12	100.0	100.0	

Mean 3.500 Median 2.000 Std dev 2.646

BRAZIL

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	4	9.1	9.1	9.1
	2	6	13.6	13.6	22.7
	3	7	15.9	15.9	38.6
	4	11	25.0	25.0	63.6
	5	3	6.8	6.8	70.5
	6	2	4.5	4.5	75.0
	8	3	6.8	6.8	81.8
	9	3	6.8	6.8	88.6
	10	3	6.8	6.8	95.5
	12	2	4.5	4.5	100.0
	Total	44	100.0	100.0	

Mean 4.841 Median 4.000 Std dev 3.072

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APPENDIX 6

Total Population: Comparison of Two Treatment Groups

573

45

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(6.5) C R O S S T A B U L A T I O N

SEX by DRUGRP

Page 1 of 1

SEX	Row Pct Col Pct	DRUGRP		Row Total
		Reboxeti ne	Placebo	
		1	2	
Female	0	51.9 50.0	48.1 46.4	27 48.2
Male	1	48.3 50.0	51.7 53.6	29 51.8
Column Total		28 50.0	28 50.0	56 100.0

Chi-Square	Value	DF	Significance
Pearson	.07152	1	.78914
Continuity Correction	.00000	1	1.00000
Likelihood Ratio	.07153	1	.78912
Mantel-Haenszel test for linear association	.07024	1	.79098
Minimum Expected Frequency -	13.500		

574

46

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(6.5) ----- O N E W A Y -----

Variable AGE at Admission

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	25.7857	25.7857	.2056	.6520
Within Groups	54	6772.1429	125.4101		
Total	55	6797.9286			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	28	41.7143	9.9363	1.8778	37.8614 To 45.5672
Grp 2	28	40.3571	12.3325	2.3306	35.5751 To 45.1392
Total	56	41.0357	11.1175	1.4856	38.0584 To 44.0130

Group	Minimum	Maximum
Grp 1	24.0000	58.0000
Grp 2	18.0000	60.0000
Total	18.0000	60.0000

573

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(6.5) ----- O N E W A Y -----

Variable HEIGHT at Admission

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	21.8750	21.8750	.2882	.5936
Within Groups	54	4099.1071	75.9094		
Total	55	4120.9821			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	28	165.3571	8.9493	1.6913	161.8870 To 168.8273
Grp 2	28	166.6071	8.4693	1.6005	163.3231 To 169.8912
Total	56	165.9821	8.6560	1.1567	163.6640 To 168.3002

Group	Minimum	Maximum
Grp 1	150.0000	186.0000
Grp 2	150.0000	180.0000
Total	150.0000	186.0000

578

48

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(6.5) ----- O N E W A Y -----

Variable WEIGHT at Admission

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	3.0179	3.0179	.0159	.9000
Within Groups	54	10228.9643	189.4253		
Total	55	10231.9821			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	28	63.7500	15.4623	2.9221	57.7543 To 69.7457
Grp 2	28	63.2857	11.8223	2.2342	58.7015 To 67.8699
Total	56	63.5179	13.6395	1.8227	59.8652 To 67.1705

Group	Minimum	Maximum
Grp 1	42.0000	111.0000
Grp 2	38.0000	85.0000
Total	38.0000	111.0000

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(6.5) ----- O N E W A Y -----

Variable ONAGE Onset Age of Depressive Illness

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	154.4464	154.4464	1.2543	.2677
Within Groups	54	6649.1071	123.1316		
Total	55	6803.5536			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	28	36.2500	11.9896	2.2658	31.6009 To 40.8991
Grp 2	28	32.9286	10.1249	1.9134	29.0026 To 36.8546
Total	56	34.5893	11.1221	1.4863	31.6108 To 37.5678

Group	Minimum	Maximum
Grp 1	7.0000	58.0000
Grp 2	11.0000	58.0000
Total	7.0000	58.0000

578

50

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(6.5) ----- O N E W A Y -----

Variable NPE No. Prior Depressive Episodes

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	8.1743	8.1743	.4965	.4841
Within Groups	53	872.6257	16.4646		
Total	54	880.8000			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	27	2.4074	4.4658	.8594	.6408 To 4.1740
Grp 2	28	3.1786	3.6215	.6844	1.7743 To 4.5828
Total	55	2.8000	4.0387	.5446	1.7082 To 3.8918

Group	Minimum	Maximum
Grp 1	.0000	20.0000
Grp 2	.0000	10.0000
Total	.0000	20.0000

578

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(6.5) C R O S S T A B U L A T I O N

STRESS Precip.Ext.Stress by DRUGRP

Page 1 of 1

		DRUGRP		Row
		Reboxeti	Placebo	
Row Pct	Col Pct	ne		Total
		1	2	
STRESS				
Absent	1	51.2	48.8	41
		75.0	71.4	73.2
Prob.Present	2	63.6	36.4	11
		25.0	14.3	19.6
Def.Present	3		100.0	4
			14.3	7.1
Column Total		28	28	56
		50.0	50.0	100.0

Chi-Square	Value	DF	Significance
Pearson	4.84257	2	.08881
Likelihood Ratio	6.39821	2	.04080
Mantel-Haenszel test for linear association	1.19461	1	.27440
Minimum Expected Frequency -	2.000		
Cells with Expected Frequency < 5 -	2 OF	6 (33.3%)	

580

52

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(6.) C R O S S T A B U L A T I O N

EPIONS Form of Onset by DRUGRP

Page 1 of 1

		DRUGRP		Row
		Reboxeti	Placebo	Pct
		ne		
Col Pct	Row Pct	1	2	Total
EPIONS				
	1	37.5	62.5	24
Acute <2wks		32.1	53.6	42.9
	2	57.1	42.9	21
Subacute >2wks		42.9	32.1	37.5
	3	63.6	36.4	11
Insidious >3mo		25.0	14.3	19.6
Column		28	28	56
Total		50.0	50.0	100.0

Chi-Square	Value	DF	Significance
Pearson	2.74675	2	.25325
Likelihood Ratio	2.77471	2	.24973
Mantel-Haenszel test for linear association	2.48744	1	.11476
Minimum Expected Frequency -	5.500		

581

53

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(6.5) C R O S S T A B U L A T I O N

DSM Subform of illness by DRUGRP

Page 1 of 1

Row Pct	DRUGRP		Row Total
	Reboxetine	Placebo	
Col Pct	1	2	
DSM			
29620	51.9	48.1	27
	50.0	46.4	48.2
29630	43.5	56.5	23
	35.7	46.4	41.1
29632	100.0		1
	3.6		1.8
29633	50.0	50.0	4
	7.1	7.1	7.1
29634	100.0		1
	3.6		1.8
Column Total	28	28	56
	50.0	50.0	100.0

Chi-Square	Value	DF	Significance
Pearson	2.42834	4	.65751
Likelihood Ratio	3.20205	4	.52460
Mantel-Haenszel test for linear association	.00969	1	.92159
Minimum Expected Frequency -	.500		
Cells with Expected Frequency < 5 -	6 OF	10 (60.0%)	

582

54

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(6.5) ----- O N E W A Y -----

Variable PRESMOS Duration of Present Episode

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	4.0179	4.0179	.4376	.5111
Within Groups	54	495.8214	9.1819		
Total	55	499.8393			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	28	4.2857	2.8266	.5342	3.1897 To 5.3817
Grp 2	28	4.8214	3.2209	.6087	3.5725 To 6.0704
Total	56	4.5536	3.0146	.4028	3.7462 To 5.3609

Group	Minimum	Maximum
Grp 1	1.0000	12.0000
Grp 2	1.0000	12.0000
Total	1.0000	12.0000

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APPENDIX 7

**Screening to Day 0: Comparison
of Two Treatment Groups**

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(7.1) Summaries of S21SC · HAM-21 Scr.Tot.Score
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			35.2857	4.5516	56
GROUP	1		36.2143	4.5733	28
GROUP	2		34.3571	4.4156	28

Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			35.2857	3.9987	56
GROUP	1		35.8571	3.9036	28
GROUP	2		34.7143	4.0812	28

Criterion Variable S21SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	48.2857	1	48.2857	2.3896	.1280
Within Groups	1091.1429	54	20.2063		

Eta = .2059 Eta Squared = .0424

Criterion Variable D021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	18.2857	1	18.2857	1.1466	.2890
Within Groups	861.1429	54	15.9471		

Eta = .1442 Eta Squared = .0208

585

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APPENDIX 8

Analytic Cohort: Comparison of Two Treatment Groups

586

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(7.3) RBX - SEX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Female	0	13	48.1	48.1	48.1
Male	1	14	51.9	51.9	100.0
Total		27	100.0	100.0	

PBO - SEX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Female	0	11	44.0	44.0	44.0
Male	1	14	56.0	56.0	100.0
Total		25	100.0	100.0	

C R O S S T A B S

SEX by DRUGRP

Page 1 of 1

SEX	Row Pct	Col Pct	DRUGRP		Row Total
			Reboxeti ne	Placebo	
Female	0	54.2	45.8	24	46.2
Male	1	50.0	50.0	28	53.8
Column Total		27	25	52	100.0

Chi-Square	Value	DF	Significance
Pearson	.08908	1	.76433
Continuity Correction	.00046	1	.98292
Likelihood Ratio	.08992	1	.76428
Mantel-Haenszel test for linear association	.08815	1	.76654

Minimum Expected Frequency = 11.538

587

60

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(7.3) ----- O N E W A Y -----

Variable AGE at Admission

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	30.2838	30.2838	.2640	.6096
Within Groups	50	5735.1585	114.7032		
Total	51	5765.4423			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int	for Mean
Grp 1	27	41.4074	9.9895	1.9225	37.4557 To	45.3591
Grp 2	25	39.8800	11.4394	2.2879	35.1580 To	44.6020
Total	52	40.6731	10.6324	1.4744	37.7130 To	43.6332

Group	Minimum	Maximum
Grp 1	24.0000	58.0000
Grp 2	18.0000	58.0000
Total	18.0000	58.0000

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(7.3) ----- O N E W A Y -----

Variable HEIGHT

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	13.7218	13.7218	.1823	.6713
Within Groups	50	3764.0474	75.2809		
Total	51	3777.7692			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	27	165.8519	8.7209	1.6783	162.4020 To 169.3017
Grp 2	25	166.8800	8.6281	1.7256	163.3185 To 170.4415
Total	52	166.3462	8.6066	1.1935	163.9501 To 168.7423

Group	Minimum	Maximum
Grp 1	150.0000	186.0000
Grp 2	150.0000	180.0000
Total	150.0000	186.0000

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(7.3) ----- O N E W A Y -----

Variable WEIGHT

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	.0000	.0000	.0000	.9997
Within Groups	50	9120.9807	182.4196		
Total	51	9120.9808			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	27	64.4815	15.2552	2.9359	58.4467 To 70.5162
Grp 2	25	64.4800	11.3105	2.2621	59.8113 To 69.1487
Total	52	64.4808	13.3732	1.8545	60.7576 To 68.2039

Group	Minimum	Maximum
Grp 1	42.0000	111.0000
Grp 2	44.0000	85.0000
Total	42.0000	111.0000

590

63

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(7.3) - - - - - O N E W A Y - - - - -

Variable ONAGE Onset Age of First Depressive Episode

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	150.4503	150.4503	1.2631	.2664
Within Groups	50	5955.6267	119.1125		
Total	51	6106.0769			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	27	36.4444	12.1729	2.3427	31.6290 To 41.2599
Grp 2	25	33.0400	9.3607	1.8721	29.1761 To 36.9039
Total	52	34.8077	10.9420	1.5174	31.7614 To 37.8540

Group	Minimum	Maximum
Grp 1	7.0000	58.0000
Grp 2	18.0000	58.0000
Total	7.0000	58.0000

FCE 20124/706 i

(7.3) - - - - - O N E W A Y - - - - -

Variable NPE Number of Prior Episodes

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	1.4600	1.4600	.0903	.7651
Within Groups	49	792.4615	16.1727		
Total	50	793.9216			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	26	2.4615	4.5452	.8914	.6257 To 4.2974
Grp 2	25	2.8000	3.3912	.6782	1.4002 To 4.1998
Total	51	2.6275	3.9848	.5580	1.5067 To 3.7482

Group	Minimum	Maximum
Grp 1	.0000	20.0000
Grp 2	.0000	10.0000
Total	.0000	20.0000

FCE 20124/706 i

(7.3) RBX - STRESS Precipitating Stress

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Absent	1	21	77.8	77.8	77.8
Prob.Present	2	6	22.2	22.2	100.0
Total		27	100.0	100.0	

PBO - STRESS Precipitating Stress

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Absent	1	18	72.0	72.0	72.0
Prob.Present	2	3	12.0	12.0	84.0
Def.Present	3	4	16.0	16.0	100.0
Total		25	100.0	100.0	

C R O S S T A B S

STRESS Precipitating Stress by DRUGRP

Page 1 of 1

STRESS	Row Pct Col Pct	DRUGRP		Row Total
		1	2	
Absent	1	53.8 77.8	46.2 72.0	39 75.0
Prob.Present	2	66.7 22.2	33.3 12.0	9 17.3
Def.Present	3		100.0 16.0	4 7.7
Column Total		27 51.9	25 48.1	52 100.0

Chi-Square	Value	DF	Significance
Pearson	5.16148	2	.07572
Likelihood Ratio	6.71869	2	.03476
Mantel-Haenszel test for linear association	1.61492	1	.20380

Minimum Expected Frequency = 1.923
 Cells with Expected Frequency < 5 = 4 of 6 (66.7%)

593

66

FCE 20124/706 i

(7.3) RBX - EPIONS Form of Onset

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Acute <2wks	1	9	33.3	33.3	33.3
Subacute >2wks	2	12	44.4	44.4	77.8
Insidious >3mo	3	6	22.2	22.2	100.0
Total		27	100.0	100.0	

PBO - EPIONS Form of Onset

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Acute <2wks	1	14	56.0	56.0	56.0
Subacute >2wks	2	7	28.0	28.0	84.0
Insidious >3mo	3	4	16.0	16.0	100.0
Total		25	100.0	100.0	

C R O S S T A B S

EPIONS Form of Onset by DRUGRP Page 1 of 1

EPIONS	Form of Onset	DRUGRP		Row Total
		1	2	
Acute <2wks	1	39.1	60.9	23
Subacute >2wks	2	63.2	36.8	19
Insidious >3mo	3	60.0	40.0	10
Column Total		27	25	52
		51.9	48.1	100.0

Chi-Square	Value	DF	Significance
Pearson	2.72986	2	.25540
Likelihood Ratio	2.75286	2	.25248
Mantel-Haenszel test for linear association	1.85714	1	.17295

Minimum Expected Frequency = 4.808
 Cells with Expected Frequency < 5 = 1 OF 6 (16.7%)

594

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FCE 20124/706 i

(7.3) RBX - DSM		DSM-III-R Subform		Valid	Cum
Value	Label	Value	Frequency	Percent	Percent
29620			14	51.9	51.9
29630			10	37.0	88.9
29632			1	3.7	92.6
29633			2	7.4	100.0
Total			27	100.0	100.0

PBO - DSM		DSM-III-R Subform		Valid	Cum
Value	Label	Value	Frequency	Percent	Percent
29620			13	52.0	52.0
29630			12	48.0	100.0
Total			25	100.0	100.0

C R O S S T A B S

DSM DSM-III-R Subform by DRUGRP

DSM	DRUGRP		Row Total
	1	2	
29620	51.9	48.1	27
29630	45.5	54.5	22
29632	100.0		1
29633	100.0		2
Column Total	27	25	52
	51.9	48.1	100.0

Chi-Square	Value	DF	Significance
Pearson	3.14659	3	.36957
Likelihood Ratio	4.30106	3	.23074
Mantel-Haenszel test for linear association	.04571	1	.83071

Minimum Expected Frequency = .481
 Cells with Expected Frequency < 5 = 4 of 8 (50.0%)

FCE 20124/706 i

(7.3) - - - - - O N E W A Y - - - - -

Variable PRES MOS Duration of Present Episode (in months)

By Variable DRUGRP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	7.3523	7.3523	.8029	.3745
Within Groups	50	457.8785	9.1576		
Total	51	465.2308			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int for Mean
Grp 1	27	4.4074	2.8047	.5398	3.2979 To 5.5169
Grp 2	25	5.1600	3.2491	.6498	3.8188 To 6.5012
Total	52	4.7692	3.0203	.4188	3.9284 To 5.6101

Group	Minimum	Maximum
Grp 1	1.0000	12.0000
Grp 2	1.0000	12.0000
Total	1.0000	12.0000

FCE 20124/706 i

APPENDIX 9

Course of Treatment

597

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FCE 20124/706 i

(8.1) RBX - PDC Premature DC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	23	85.2	85.2	85.2
Yes	1	4	14.8	14.8	100.0
Total		27	100.0	100.0	

PBO - PDC Premature DC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	9	36.0	36.0	36.0
Yes	1	16	64.0	64.0	100.0
Total		25	100.0	100.0	

C R O S S T A B S

PDC Premature DC by DRUGRP

Page 1 of 1

PDC	Row Pct Col Pct	DRUGRP		Row Total
		1 RBX	2 PBO	
No	0	71.9	28.1	32
		85.2	36.0	61.5
Yes	1	20.0	80.0	20
		14.8	64.0	38.5
Column Total		27	25	52
		51.9	48.1	100.0

Chi-Square	Value	DF	Significance
Pearson	13.26770	1	.00027
Continuity Correction	11.27100	1	.00079
Likelihood Ratio	13.96995	1	.00019
Mantel-Haenszel test for linear association	13.01256	1	.00031
Minimum Expected Frequency -	9.615		

598

71

FCE 20124/706 i

(8.1.1) RBX - EVENTS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No Events	1	18	78.3	78.3	78.3
Events	2	5	21.7	21.7	100.0
Total		23	100.0	100.0	

PBO - EVENTS

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No Events	1	9	100.0	100.0	100.0
Total		9	100.0	100.0	

C R O S S T A B S

EVENTS by DRUGRP

Page 1 of 1

EVENT	Row Pct	DRUGRP		Row Total
		RBX	PBO	
No Events	1	66.7	33.3	27
Events	2	100.0		5
Column Total		23	9	32
		71.9	28.1	100.0

Chi-Square	Value	DF	Significance
Pearson	2.31884	1	.12782
Continuity Correction	.96303	1	.32642
Likelihood Ratio	3.65256	1	.05598
Mantel-Haenszel test for linear association	2.24638	1	.13393
Fisher's Exact Test:			
One-Tail			.16710
Two-Tail			.28765

Minimum Expected Frequency = 1.406
 Cells with Expected Frequency < 5 = 2 OF 4 (50.0%)

599

72

FCE 20124/706 i

(8.2.1) RBX - ADVR Adverse Reaction

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	26	96.3	96.3	96.3
Yes	1	1	3.7	3.7	100.0
Total		27	100.0	100.0	

PBO - ADVR Adverse Reaction

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	24	96.0	96.0	96.0
Yes	1	1	4.0	4.0	100.0
Total		25	100.0	100.0	

C R O S S T A B S

ADVR Adverse Reaction by DRUGRP

Page 1 of 1

	Row Pct	Col Pct	DRUGRP		Row Total
			1	2	
ADVR					
No	0	52.0	48.0	50	96.2
Yes	1	50.0	50.0	2	3.8
Column Total		27	25	52	100.0

Chi-Square	Value	DF	Significance
Pearson	.00308	1	.95573
Continuity Correction	.00000	1	1.00000
Likelihood Ratio	.00308	1	.95574
Mantel-Haenszel test for linear association	.00302	1	.95616
Fisher's Exact Test:			
One-Tail			.73529
Two-Tail			1.00000

Minimum Expected Frequency = .962
 Cells with Expected Frequency < 5 = 2 OF 4 (50.0%)

FCE 20124/706 i

(8.2.2) RBX - NONRSP Non-responder

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	24	88.9	88.9	88.9
Yes	1	3	11.1	11.1	100.0
Total		27	100.0	100.0	

PBO - NONRSP Non-responder

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	10	40.0	40.0	40.0
Yes	1	15	60.0	60.0	100.0
Total		25	100.0	100.0	

C R O S S T A B U L A T I O N

NONRSP Non-responder by DRUGRP

Page 1 of 1

		DRUGRP		Row Total
		1	2	
NONRSP	Row Pct Col Pct			
No	0	70.6 88.9	29.4 40.0	34 65.4
Yes	1	16.7 11.1	83.3 60.0	18 34.6
Column Total		27 51.9	25 48.1	52 100.0

Chi-Square	Value	DF	Significance
Pearson	13.70806	1	.00021
Continuity Correction	11.63310	1	.00065
Likelihood Ratio	14.59593	1	.00013
Mantel-Haenszel test for linear association	13.44444	1	.00025
Minimum Expected Frequency -	8.654		

601

74

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APPENDIX 10

Compliance, Non-Pharmacologic Treatment and Significant Life Events

602

75

FCE 20124/706 i

(8.3) TOOK As Prescribed - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	27	100.0	100.0	100.0
	Total	27	100.0	100.0	

TOOK As Prescribed - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	25	100.0	100.0	100.0
	Total	25	100.0	100.0	

TOOK As Prescribed by DRUGRP Treatment Group

Page 1 of 1

		DRUGRP		Row
Row Pct	Col Pct	Reboxetine	Placebo	Total
		1	2	Total
TOOK	1	51.9	48.1	52
Yes		100.0	100.0	100.0
	Column	27	25	52
	Total	51.9	48.1	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

603

76

FCE 20124/706 i

(8.3) NPTX Non-Pharm. Tx. - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	26	96.3	96.3	96.3
Yes	1	1	3.7	3.7	100.0
Total		27	100.0	100.0	

NPTX Non-Pharm. Tx. - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	25	100.0	100.0	100.0
Total		25	100.0	100.0	

NPTX Non-Pharm. Tx. by DRUGRP Treatment Group

Page 1 of 1

NPTX	Row Pct	Col Pct	DRUGRP		Row Total
			Reboxetine	Placebo	
No	0	51.0	49.0	51	98.1
Yes	1	100.0		1	1.9
		Column Total	27	25	52
		Total	51.9	48.1	100.0

Chi-Square	Value	DF	Significance
Pearson	.94408	1	.33123
Continuity Correction	.00000	1	1.00000
Likelihood Ratio	1.32896	1	.24899
Mantel-Haenszel test for linear association	.92593	1	.33592
Fisher's Exact Test:			
One-Tail			.51923
Two-Tail			1.00000

Minimum Expected Frequency = .481
 Cells with Expected Frequency < 5 = 2 OF 4 (50.0%)

604

FCE 20124/706 i

(8.3) SIGEV Signif.Events - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	27	100.0	100.0	100.0
	Total	27	100.0	100.0	

SIGEV Signif.Events - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	25	100.0	100.0	100.0
	Total	25	100.0	100.0	

SIGEV Signif.Events by DRUGRP Treatment Group

Page 1 of 1

Row Pct	Col Pct	DRUGRP		Row Total
		Reboxetine	Placebo	
	0	51.9	48.1	52
		100.0	100.0	100.0
	Column Total	27	25	52
		51.9	48.1	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

605

78

FCE 20124/706 i

(8.3) TOOK As Prescribed - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	28	100.0	100.0	100.0
	Total	28	100.0	100.0	

TOOK As Prescribed - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	24	100.0	100.0	100.0
	Total	24	100.0	100.0	

TOOK As Prescribed by SEX

Page 1 of 1

		SEX		
Row Pct	Col Pct	Female	Male	Row Total
		0	1	
TOOK	1	46.2	53.8	52
Yes		100.0	100.0	100.0
	Column Total	24	28	52
		46.2	53.8	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

FCE 20124/706 i

(8.3) NPTX Non-Pharm. Tx. - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	27	96.4	96.4	96.4
Yes	1	1	3.6	3.6	100.0
Total		28	100.0	100.0	

NPTX Non-Pharm. Tx. - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	24	100.0	100.0	100.0
Total		24	100.0	100.0	

NPTX Non-Pharm. Tx. by SEX

Page 1 of 1

	Row Pct	SEX		Row Total
		Female	Male	
NPTX		0	1	
No	47.1	52.9	51	98.1
Yes	100.0	96.4	1	1.9
Column Total		24	28	52
		46.2	53.8	100.0

Chi-Square	Value	DF	Significance
Pearson	.87395	1	.34986
Continuity Correction	.00000	1	1.00000
Likelihood Ratio	1.25487	1	.26262
Mantel-Haenszel test for linear association	.85714	1	.35454
Fisher's Exact Test:			
One-Tail			.53846
Two-Tail			1.00000

Minimum Expected Frequency = .462
 Cells with Expected Frequency < 5 = 2 OF 4 (50.0%)

807

80

FCE 20124/706 i

(8.3) SIGEV Signif.Events - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	28	100.0	100.0	100.0
	Total	28	100.0	100.0	

SIGEV Signif.Events - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	24	100.0	100.0	100.0
	Total	24	100.0	100.0	

SIGEV Signif.Events by SEX

Page 1 of 1

		SEX		
Row Pct	Col Pct	Female	Male	Row Total
		0	1	52
SIGEV	0	46.2	53.8	100.0
No		100.0	100.0	100.0
	Column Total	24	28	52
	Total	46.2	53.8	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

800

81

FCE 20124/706 i

(8.3) TOOK As Prescribed - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	8	100.0	100.0	100.0
	Total	8	100.0	100.0	

TOOK As Prescribed - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	44	100.0	100.0	100.0
	Total	44	100.0	100.0	

TOOK As Prescribed by COUNTRY

		COUNTRY		Page 1 of 1
Row Pct	Col Pct	Canada	Brazil	Row Total
		1.00	2.00	
TOOK	1	15.4	84.6	52
Yes		100.0	100.0	100.0
	Column Total	8	44	52
		15.4	84.6	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

FCE 20124/706 i

(8.3) NPTX Non-Pharm. Tx. - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	7	87.5	87.5	87.5
Yes	1	1	12.5	12.5	100.0
Total		8	100.0	100.0	

NPTX Non-Pharm. Tx. - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	44	100.0	100.0	100.0
Total		44	100.0	100.0	

NPTX Non-Pharm. Tx. by COUNTRY

Page 1 of 1

	Row Pct	COUNTRY		Row Total
		Canada	Brazil	
	Col Pct	1.00	2.00	
NPTX				
No	0	13.7	86.3	51
		87.5	100.0	98.1
Yes	1	100.0		1
		12.5		1.9
	Column Total	8	44	52
		15.4	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	5.60784	1	.01788
Continuity Correction	.93850	1	.33266
Likelihood Ratio	3.85480	1	.04960
Mantel-Haenszel test for linear association	5.50000	1	.01902
Fisher's Exact Test:			
One-Tail			.15385
Two-Tail			.15385

Minimum Expected Frequency = .154
 Cells with Expected Frequency < 5 = 2 OF 4 (50.0%)

810

83

FCE 20124/706 i

(8.3) SIGEV Signif.Events - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	8	100.0	100.0	100.0
	Total	8	100.0	100.0	

SIGEV Signif.Events - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	44	100.0	100.0	100.0
	Total	44	100.0	100.0	

SIGEV Signif.Events by COUNTRY

Page 1 of 1

		COUNTRY		Row
Row Pct	Col Pct	Canada	Brazil	Total
		1.00	2.00	
SIGEV				
	0	15.4	84.6	52
No		100.0	100.0	100.0
	Column	8	44	52
	Total	15.4	84.6	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

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FCE 20124/706 i

(8.3) TOOK As Prescribed - Age 18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	19	100.0	100.0	100.0
	Total	19	100.0	100.0	

TOOK As Prescribed - Age 38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	20	100.0	100.0	100.0
	Total	20	100.0	100.0	

TOOK As Prescribed - Age ≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	13	100.0	100.0	100.0
	Total	13	100.0	100.0	

TOOK As Prescribed by AGEGRP Age Group

Page 1 of 1

		AGEGRP			
Row Pct	Col Pct	(18-37)	(38-49)	(50+)	Row Total
		1.00	2.00	3.00	
TOOK	1	36.5	38.5	25.0	52
Yes		100.0	100.0	100.0	100.0
	Column Total	19	20	13	52
		36.5	38.5	25.0	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

FCE 20124/706 i

(8.3) NPTX Non-Pharm. Tx. - Age 18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	19	100.0	100.0	100.0
Total		19	100.0	100.0	

NPTX Non-Pharm. Tx. - Age 38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	19	95.0	95.0	95.0
Yes	1	1	5.0	5.0	100.0
Total		20	100.0	100.0	

NPTX Non-Pharm. Tx. - Age ≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	13	100.0	100.0	100.0
Total		13	100.0	100.0	

NPTX Non-Pharm. Tx. by AGEGRP Age Group

Page 1 of 1

	Row Pct	AGEGRP			Row Total
		(18-37)	(38-49)	(50+)	
	Col Pct	1.00	2.00	3.00	
NPTX					
No	0	37.3	37.3	25.5	51
		100.0	95.0	100.0	98.1
Yes	1		100.0		1
			5.0		1.9
	Column Total	19	20	13	52
		36.5	38.5	25.0	100.0

Chi-Square	Value	DF	Significance
Pearson	1.63137	2	.44234
Likelihood Ratio	1.94253	2	.37860
Mantel-Haenszel test for linear association	.02211	1	.88179

Minimum Expected Frequency = .250
 Cells with Expected Frequency < 5 = 3 of 52 (5.0%)

FCE 20124/706 i

(8.3) SIGEV Signif.Events - Age 18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	19	100.0	100.0	100.0
	Total	19	100.0	100.0	

SIGEV Signif.Events - Age 38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	20	100.0	100.0	100.0
	Total	20	100.0	100.0	

SIGEV Signif.Events - Age ≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	13	100.0	100.0	100.0
	Total	13	100.0	100.0	

SIGEV Signif.Events by AGEGRP Age Group

Page 1 of 1

		AGEGRP			
		(18-37)	(38-49)	(50+)	Row Total
Row Pct	Col Pct	1.00	2.00	3.00	
SIGEV	0	36.5	38.5	25.0	52
No		100.0	100.0	100.0	100.0
	Column Total	19	20	13	52
		36.5	38.5	25.0	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

FCE 20124/706 i

(8.3) TOOK As Prescribed - Single Episode

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	27	100.0	100.0	100.0
Total		27	100.0	100.0	

TOOK As Prescribed - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	22	100.0	100.0	100.0
Total		22	100.0	100.0	

TOOK As Prescribed - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	1	100.0	100.0	100.0
Total		1	100.0	100.0	

TOOK As Prescribed - Recurrent-Severe without Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	1	2	100.0	100.0	100.0
Total		2	100.0	100.0	

TOOK As Prescribed by SUBFORM DSM-III-R Subform

Page 1 of 1

		SUBFORM				Row
Row Pct	Col Pct	Sing.Epi	Recurr.	Rec.-Mod .Sv.	Rec.Sv.w o.Pf	Total
TOOK		1.00	2.00	3.00	4.00	
Yes	1	51.9	42.3	1.9	3.8	52
	Yes	100.0	100.0	100.0	100.0	100.0
	Column	27	22	1	2	52
	Total	51.9	42.3	1.9	3.8	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

015

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(8.3) NPTX Non-Pharm. Tx. - Single Episode

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	27	100.0	100.0	100.0
	Total	27	100.0	100.0	

NPTX Non-Pharm. Tx. - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	22	100.0	100.0	100.0
	Total	22	100.0	100.0	

NPTX Non-Pharm. Tx. - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	1	100.0	100.0	100.0
	Total	1	100.0	100.0	

NPTX Non-Pharm. Tx. - Recurrent-Severe without Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	1	50.0	50.0	50.0
Yes	1	1	50.0	50.0	100.0
	Total	2	100.0	100.0	

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(8.3) NPTX Non-Pharm. Tx. by SUBFORM DSM-III-R Subform

Page 1 of 1

		SUBFORM				Row
		Sing.Epi	Recurr.	Rec.-Mod	Rec.Sv.w	Total
Row Pct	Col Pct	1.00	2.00	3.00	4.00	
		Sv.		Sv.	o.Pf	
NPTX	0	52.9	43.1	2.0	2.0	51
	No	100.0	100.0	100.0	50.0	98.1
	1				100.0	1
	Yes				50.0	1.9
Column Total		27	22	1	2	52
		51.9	42.3	1.9	3.8	100.0

Chi-Square	Value	DF	Significance
Pearson	25.49019	3	.00001
Likelihood Ratio	7.11054	3	.06846
Mantel-Haenszel test for linear association	11.43804	1	.00072

Minimum Expected Frequency = .019
 Cells with Expected Frequency < 5 = 6 OF 8 (75.0%)

Number of Missing Observations: 0

(8.3) SIGEV Signif.Events - Single Episode **FCE 20124/706 i**

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	27	100.0	100.0	100.0
		-----	-----	-----	
Total		27	100.0	100.0	

SIGEV Signif.Events - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	22	100.0	100.0	100.0
		-----	-----	-----	
Total		22	100.0	100.0	

SIGEV Signif.Events - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	1	100.0	100.0	100.0
		-----	-----	-----	
Total		1	100.0	100.0	

SIGEV Signif.Events - Recurrent-Severe without Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	2	100.0	100.0	100.0
		-----	-----	-----	
Total		2	100.0	100.0	

PCB 20124/706 i

(8.3) SIGEV Signif.Events by SUBFORM DSM-III-R Subform

Page 1 of 1

		SUBFORM				
Row Pct	Col Pct	Sing.Epi	Recurr.	Rec.-Mod	Rec.Sv.w	Row
				.Sv.	o.Pf	Total
		1.00	2.00	3.00	4.00	
SIGEV	0	51.9	42.3	1.9	3.8	52
No		100.0	100.0	100.0	100.0	100.0
Column Total		27	22	1	2	52
Total		51.9	42.3	1.9	3.8	100.0

Statistics cannot be computed when the number of non-empty rows or columns is one.

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APPENDIX 11

Therapeutic Efficacy: HAM-D

620

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FCE 20124/706 i

(9.1.1.1.1) Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			35.4423	3.6644	52
GROUP	1		35.7407	3.9281	27
GROUP	2		35.1200	3.4073	25

Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			21.2308	14.8504	52
GROUP	1		12.5926	10.8318	27
GROUP	2		30.5600	12.9199	25

*** ANALYSIS OF VARIANCE ***

D4221SC HAM-21 Dy42 Tot.Score
BY GROUP
WITH D021SC HAM-21 Dy0 Tot.Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	102.782	1	102.782	.716	.402
D021SC	102.782	1	102.782	.716	.402
Main Effects	4109.140	1	4109.140	28.620	.000
GROUP	4109.140	1	4109.140	28.620	.000
Explained	4211.922	2	2105.961	14.668	.000
Residual	7035.308	49	143.578		
Total	11247.231	51	220.534		

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(9.1.1.1.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D4221SC HAM-21 Dy42 Tot.Score
 BY SEX
 WITH D021SC HAM-21 Dy0 Tot.Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	102.782	1	102.782	.453	.504
D021SC	102.782	1	102.782	.453	.504
Main Effects	31.585	1	31.585	.139	.711
SEX	31.585	1	31.585	.139	.711
Explained	134.367	2	67.184	.296	.745
Residual	11112.863	49	226.793		
Total	11247.231	51	220.534		

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(9.1.1.1.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D4221SC HAM-21 Dy42 Tot.Score
 BY COUNTRY
 WITH D021SC HAM-21 Dy0 Tot.Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	102.782	1	102.782	.453	.504
D021SC	102.782	1	102.782	.453	.504
Main Effects	21.301	1	21.301	.094	.761
COUNTRY	21.301	1	21.301	.094	.761
Explained	124.083	2	62.042	.273	.762
Residual	11123.148	49	227.003		
Total	11247.231	51	220.534		

623

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FCE 20124/706 i

(9.1.1.1.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D4221SC HAM-21 Dy42 Tot.Score
 BY AGEGP Age Group
 WITH D021SC HAM-21 Dy0 Tot.Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	102.782	1	102.782	.457	.502
D021SC	102.782	1	102.782	.457	.502
Main Effects	338.302	2	169.151	.751	.477
AGEGP	338.302	2	169.151	.751	.477
Explained	441.085	3	147.028	.653	.585
Residual	10806.146	48	225.128		
Total	11247.231	51	220.534		

624

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(9.1.1.1.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D4221SC HAM-21 Dy42 Tot.Score
 BY SUBFORM DSM-III-R Subform
 WITH D021SC HAM-21 Dy0 Tot.Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	102.782	1	102.782	.439	.511
D021SC	102.782	1	102.782	.439	.511
Main Effects	141.253	3	47.084	.201	.895
SUBFORM	141.253	3	47.084	.201	.895
Explained	244.035	4	61.009	.261	.902
Residual	11003.196	47	234.111		
Total	11247.231	51	220.534		

FCE 20124/706 i

(9.1.1.1.2) RBX - PCT50 50% Change in HAMD Total Score: Day 0 to Day 42

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not 50%	.00	7	25.9	25.9	25.9
Is 50%	1.00	20	74.1	74.1	100.0
Total		27	100.0	100.0	

PBO - PCT50 50% Change in HAMD Total Score: Day 0 to Day 42

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not 50%	.00	20	80.0	80.0	80.0
Is 50%	1.00	5	20.0	20.0	100.0
Total		25	100.0	100.0	

PCT50 by GROUP

Page 1 of 1

PCT50	Row Pct Col Pct	GROUP		Row Total
		1	2	
Not 50%	.00	25.9	74.1	27
Is 50%	1.00	80.0	20.0	25
Column Total		27	25	52
		51.9	48.1	100.0

Chi-Square	Value	DF	Significance
Pearson	15.20483	1	.00010
Continuity Correction	13.11581	1	.00029
Likelihood Ratio	16.08709	1	.00006
Mantel-Haenszel test for linear association	14.91243	1	.00011

Minimum Expected Frequency = 12.019

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(9.1.1.1.2) FEMALE - PCT50 50% Change in HAMD Total Score: Day 0 to Day 42

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	10	41.7	41.7	41.7
Is ≥50%	1.00	14	58.3	58.3	100.0
Total		24	100.0	100.0	

MALE - PCT50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	17	60.7	60.7	60.7
Is ≥50%	1.00	11	39.3	39.3	100.0
Total		28	100.0	100.0	

C R O S S T A B U L A T I O N

PCT50 by SEX

Page 1 of 1

PCT50	Row Pct Col Pct	SEX		Row Total
		Female	Male	
Not ≥50%	.00	37.0 41.7	63.0 60.7	27 51.9
Is ≥50%	1.00	56.0 58.3	44.0 39.3	25 48.1
Column Total		24 46.2	28 53.8	52 100.0

Chi-Square	Value	DF	Significance
Pearson	1.87824	1	.17053
Continuity Correction	1.19270	1	.27479
Likelihood Ratio	1.88858	1	.16936
Mantel-Haenszel test for linear association	1.84212	1	.17470
Minimum Expected Frequency -	11.536		

627

100

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(9.1.1.1.2) CANADA - PCT50 50% Change in HAMD Total Score: Day 0 to Day 42

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not \geq 50%	.00	7	87.5	87.5	87.5
Is \geq 50%	1.00	1	12.5	12.5	100.0
Total		8	100.0	100.0	

BRAZIL - PCT50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not \geq 50%	.00	20	45.5	45.5	45.5
Is \geq 50%	1.00	24	54.5	54.5	100.0
Total		44	100.0	100.0	

C R O S S T A B U L A T I O N

PCT50 by COUNTRY

Page 1 of 1

PCT50	Row Pct Col Pct	COUNTRY		Row Total
		Canada	Brazil	
		1.00	2.00	
Not \geq 50%	.00	25.9 87.5	74.1 45.5	27 51.9
Is \geq 50%	1.00	4.0 12.5	96.0 54.5	25 48.1
	Column Total	8 15.4	44 84.6	52 100.0

Chi-Square	Value	DF	Significance
Pearson	4.79380	1	.02856
Continuity Correction	3.25744	1	.07110
Likelihood Ratio	5.34923	1	.02073
Mantel-Haenszel test for linear association	4.70162	1	.03013
Fisher's Exact Test:			
One-Tail			.03245
Two-Tail			.05114

Minimum Expected Frequency = 3.846
 Cells with Expected Frequency < 5 = 2 OF 4 (50.0%)

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(9.1.1.1.2) AGE 18-37 - PCT50 50% Change in HAMD Total Score: Day 0 to Day 42

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	11	57.9	57.9	57.9
Is ≥50%	1.00	8	42.1	42.1	100.0
Total		19	100.0	100.0	

AGE 38-49 - PCT50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	11	55.0	55.0	55.0
Is ≥50%	1.00	9	45.0	45.0	100.0
Total		20	100.0	100.0	

AGE ≥50 - PCT50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	5	38.5	38.5	38.5
Is ≥50%	1.00	8	61.5	61.5	100.0
Total		13	100.0	100.0	

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(9.1.1.1.2) C R O S S T A B U L A T I O N

PCT50 by AGEGP Age Group

Page 1 of 1

		AGEGP			Row
		Low(18-37)	Middle(38-49)	High(≥50)	Total
Row Pct	Col Pct	1.00	2.00	3.00	
PCT50					
	.00	40.7	40.7	18.5	27
Not ≥50%		57.9	55.0	38.5	51.9
	1.00	32.0	36.0	32.0	25
Is ≥50%		42.1	45.0	61.5	48.1
	Column Total	19	20	13	52
		36.5	38.5	25.0	100.0

Chi-Square	Value	DF	Significance
Pearson	1.29098	2	.52441
Likelihood Ratio	1.29765	2	.52266
Mantel-Haenszel test for linear association	1.04423	1	.30684
Minimum Expected Frequency -	6.250		

630

105

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(9.1.1.1.2) SINGLE EPISODE - PCT50 50% Change in HAMD Total Score: Day 0 to Day 42

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	12	44.4	44.4	44.4
Is ≥50%	1.00	15	55.6	55.6	100.0
Total		27	100.0	100.0	

RECURRENT - PCT50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	12	54.5	54.5	54.5
Is ≥50%	1.00	10	45.5	45.5	100.0
Total		22	100.0	100.0	

RECURRENT-MODERATELY SEVERE - PCT50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	1	100.0	100.0	100.0
Total		1	100.0	100.0	

RECURRENT-SEVERE WITHOUT PSYCHOTIC FEATURES - PCT50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Not ≥50%	.00	2	100.0	100.0	100.0
Total		2	100.0	100.0	

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(9.1.1.1.2) C R O S S T A B U L A T I O N

PCT50 by SUBFORM DSM-III-R Subform

Page 1 of 1

		SUBFORM				Row
Row Pct	Col Pct	Sing.Epi	Recurr.	Rec.-Mod	Rec.Sv.w	Total
		1.00	2.00	3.00	4.00	
PCT50	.00	44.4	44.4	3.7	7.4	27
Not ≥50%		44.4	54.5	100.0	100.0	51.9
Is ≥50%	1.00	60.0	40.0			25
		55.6	45.5			48.1
Column Total		27	22	1	2	52
		51.9	42.3	1.9	3.8	100.0

Chi-Square	Value	DF	Significance
Pearson	3.44332	3	.32819
Likelihood Ratio	4.59803	3	.20371
Mantel-Haenszel test for linear association	2.87960	1	.08971
Minimum Expected Frequency -	.481		
Cells with Expected Frequency < 5 -	4 OF	8 (50.0%)	

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APPENDIX 12

Onset of Therapeutic Activity: HAMD

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(9.1.1.2) Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		35.4423	3.6644	52
GROUP	1	35.7407	3.9281	27
GROUP	2	35.1200	3.4073	25

Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	35.7407	3.9281	401.1852	27
2	35.1200	3.4073	278.6400	25

Within Groups Total	35.4423	3.6873	679.8252	52

Criterion Variable D021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	5.0017	1	5.0017	.3679	.5469
Within Groups	679.8252	50	13.5965		
Eta = .0855 Eta Squared = .0073					

FCE 20124/706 i

(9.1.1.2) Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		33.0385	5.8577	52
GROUP	1	32.8148	6.8950	27
GROUP	2	33.2800	4.6145	25

Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	32.8148	6.8950	1236.0741	27
2	33.2800	4.6145	511.0400	25

Within Groups Total	33.0385	5.9112	1747.1141	52

Criterion Variable D421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.8090	1	2.8090	.0804	.7779
Within Groups	1747.1141	50	34.9423		

Eta = .0401 Eta Squared = .0016

FCE 20124/706 i

(9.1.1.2) Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			30.5192	6.4336	52
GROUP	1		29.5926	6.7269	27
GROUP	2		31.5200	6.0767	25

Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		29.5926	6.7269	1176.5185	27
2		31.5200	6.0767	886.2400	25

Within Groups Total		30.5192	6.4230	2062.7585	52

Criterion Variable D721SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	48.2223	1	48.2223	1.1689	.2848
Within Groups	2062.7585	50	41.2552		
Eta = .1511 Eta Squared = .0228					

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(9.1.1.2) Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		28.4808	6.5514	52
GROUP	1	26.1481	6.8708	27
GROUP	2	31.0000	5.2281	25

Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	26.1481	6.8708	1227.4074	27
2	31.0000	5.2281	656.0000	25

Within Groups Total	28.4808	6.1374	1883.4074	52

Criterion Variable D1021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	305.5734	1	305.5734	8.1122	.0064
Within Groups	1883.4074	50	37.6681		
Eta = .3736 Eta Squared = .1396					

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(9.1.1.2) Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		25.3077	7.6094	52
GROUP	1	22.3333	7.1951	27
GROUP	2	28.5200	6.8015	25

Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	22.3333	7.1951	1346.0000	27
2	28.5200	6.8015	1110.2400	25

Within Groups Total	25.3077	7.0089	2456.2400	52

Criterion Variable D1421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	496.8369	1	496.8369	10.1138	.0025
Within Groups	2456.2400	50	49.1248		

Eta = .4102 Eta Squared = .1682

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(9.1.1.2) Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		24.9615	11.3154	52
GROUP	1	18.4074	7.8066	27
GROUP	2	32.0400	10.2733	25

Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	18.4074	7.8066	1584.5185	27
2	32.0400	10.2733	2532.9600	25
<hr/>				
Within Groups Total	24.9615	9.0747	4117.4785	52

Criterion Variable D2121SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2412.4446	1	2412.4446	29.2952	.0000
Within Groups	4117.4785	50	82.3496		
Eta = .6078		Eta Squared = .3694			

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(9.1.1.2) Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		22.7500	13.2189	52
GROUP	1	15.2593	9.4486	27
GROUP	2	30.8400	11.9711	25

Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	15.2593	9.4486	2321.1852	27
2	30.8400	11.9711	3439.3600	25

Within Groups Total	22.7500	10.7336	5760.5452	52

Criterion Variable D2821SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3151.2048	1	3151.2048	27.3516	.0000
Within Groups	5760.5452	50	115.2109		

Eta = .5946 Eta Squared = .3536

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(9.1.1.2) Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		21.6538	14.0460	52
GROUP	1	13.3704	9.6681	27
GROUP	2	30.6000	12.5466	25

Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	13.3704	9.6681	2430.2963	27
2	30.6000	12.5466	3778.0000	25

Within Groups Total	21.6538	11.1430	6208.2963	52

Criterion Variable D3521SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3853.4729	1	3853.4729	31.0349	.0000
Within Groups	6208.2963	50	124.1659		

Eta = .6189 Eta Squared = .3830

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(9.1.1.2) Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		21.2308	14.8504	52
GROUP	1	12.5926	10.8318	27
GROUP	2	30.5600	12.9199	25

Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	12.5926	10.8318	3050.5185	27
2	30.5600	12.9199	4006.1600	25

Within Groups Total	21.2308	11.8800	7056.6785	52

Criterion Variable D4221SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4190.5523	1	4190.5523	29.6921	.0000
Within Groups	7056.6785	50	141.1336		

Eta = .6104 Eta Squared = .3726

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```
( 9.1.1.2 ) manova
d021sc d421sc d721sc d1021sc d1421sc d2121sc d2821sc d3521sc d4221sc
by sex(0,1)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	27716.29	50	554.33		
CONSTANT	339593.68	1	339593.68	612.62	.000
SEX	49.96	1	49.96	.09	.765

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

Mauchly sphericity test, $W = 4.936687E-07$
 Chi-square approx. = 684.32103 with 35 D. F.
 Significance = .000

Greenhouse-Geisser Epsilon = .16259
 Huynh-Feldt Epsilon = .16847
 Lower-bound Epsilon = .12500

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

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(9.1.1.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.22217	1.53527	8.00	43.00	.174
Hotellings	.28563	1.53527	8.00	43.00	.174
Wilks	.77783	1.53527	8.00	43.00	.174
Roys	.22217				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.71112	13.23159	8.00	43.00	.000
Hotellings	2.46169	13.23159	8.00	43.00	.000
Wilks	.28888	13.23159	8.00	43.00	.000
Roys	.71112				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	18430.71	400	46.08		
TIME	11055.77	8	1381.97	29.99	.000
SEX BY TIME	241.49	8	30.19	.66	.731

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(9.1.1.2) Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			35.4423	3.6644	52
SEX	0	Female	36.0417	3.7933	24
SEX	1	Male	34.9286	3.5374	28

Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	36.0417	3.7933	330.9583	24	
1	Male	34.9286	3.5374	337.8571	28	
<hr/>						
Within Groups Total			35.4423	3.6574	668.8155	52

Criterion Variable D021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	16.0114	1	16.0114	1.1970	.2792
Within Groups	668.8155	50	13.3763		
Eta = .1529		Eta Squared = .0234			

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(9.1.1.2) Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			33.0385	5.8577	52
SEX	0	Female	33.6667	6.4718	24
SEX	1	Male	32.5000	5.3368	28

Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	33.6667	6.4718	963.3333	24	
1	Male	32.5000	5.3368	769.0000	28	

Within Groups Total			33.0385	5.8861	1732.3333	52

Criterion Variable D421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	17.5897	1	17.5897	.5077	.4795
Within Groups	1732.3333	50	34.6467		
Eta = .1003		Eta Squared = .0101			

FCE 20124/706 i

(9.1.1.2) Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			30.5192	6.4336	52
SEX	0	Female	31.0833	7.2166	24
SEX	1	Male	30.0357	5.7702	28

Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	31.0833	7.2166	1197.8333	24	
1	Male	30.0357	5.7702	898.9643	28	
<hr/>						
Within Groups Total			30.5192	6.4758	2096.7976	52

Criterion Variable D721SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	14.1832	1	14.1832	.3382	.5635
Within Groups	2096.7976	50	41.9360		

Eta = .0820 Eta Squared = .0067

FCE 20124/706 i

(9.1.1.2) Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			28.4808	6.5514	52
SEX	0	Female	28.5000	7.8242	24
SEX	1	Male	28.4643	5.3782	28

Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	28.5000	7.8242	1408.0000	24
1	Male	28.4643	5.3782	780.9643	28

Within Groups Total		28.4808	6.6166	2188.9643	52

Criterion Variable D1021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0165	1	.0165	.0004	.9846
Within Groups	2188.9643	50	43.7793		
Eta = .0027		Eta Squared = .0000			

FCE 20124/706 i

(9.1.1.2) Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			25.3077	7.6094	52
SEX	0	Female	24.5417	8.8661	24
SEX	1	Male	25.9643	6.4376	28

Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	24.5417	8.8661	1807.9583	24	
1	Male	25.9643	6.4376	1118.9643	28	

Within Groups Total			25.3077	7.6510	2926.9226	52

Criterion Variable D1421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	26.1543	1	26.1543	.4468	.5069
Within Groups	2926.9226	50	58.5385		
Eta = .0941		Eta Squared = .0089			

FCE 20124/706 i

(9.1.1.2) Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			24.9615	11.3154	52
SEX	0	Female	24.4167	12.4723	24
SEX	1	Male	25.4286	10.4330	28

Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	24.4167	12.4723	3577.8333	24	
1	Male	25.4286	10.4330	2938.8571	28	

Within Groups Total			24.9615	11.4164	6516.6905	52

Criterion Variable D2121SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	13.2326	1	13.2326	.1015	.7513
Within Groups	6516.6905	50	130.3338		

Eta = .0450 Eta Squared = .0020

650

123

FCE 20124/706 i

(9.1.1.2) Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			22.7500	13.2189	52
SEX	0	Female	21.5833	14.4280	24
SEX	1	Male	23.7500	12.2675	28

Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	21.5833	14.4280	4787.8333	24
1	Male	23.7500	12.2675	4063.2500	28

Within Groups Total		22.7500	13.3049	8851.0833	52

Criterion Variable D2821SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	60.6667	1	60.6667	.3427	.5609
Within Groups	8851.0833	50	177.0217		

Eta = .0825 Eta Squared = .0068

FCE 20124/706 i

(9.1.1.2) Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			21.6538	14.0460	52
SEX	0	Female	20.2083	15.0852	24
SEX	1	Male	22.8929	13.2423	28

Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	20.2083	15.0852	5233.9583	24	
1	Male	22.8929	13.2423	4734.6786	28	

Within Groups Total			21.6538	14.1199	9968.6369	52

Criterion Variable D3521SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	93.1323	1	93.1323	.4671	.4975
Within Groups	9968.6369	50	199.3727		
Eta = .0962		Eta Squared = .0093			

FCE 20124/706 i

(9.1.1.2) Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			21.2308	14.8504	52
SEX	0	Female	20.1667	15.9174	24
SEX	1	Male	22.1429	14.1020	28

Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	20.1667	15.9174	5827.3333	24
1	Male	22.1429	14.1020	5369.4286	28

Within Groups Total		21.2308	14.9645	11196.7619	52

Criterion Variable D4221SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	50.4689	1	50.4689	.2254	.6370
Within Groups	11196.7619	50	223.9352		

Eta = .0670 Eta Squared = .0045

FCE 20124/706 i

```
( 9.1.1.2 ) manova
d021sc d421sc d721sc d1021sc d1421sc d2121sc d2821sc d3521sc d4221sc
by country(1,2)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	27179.45	50	543.59		
CONSTANT	164336.24	1	164336.24	302.32	.000
COUNTRY	586.81	1	586.81	1.08	.304

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W =4.031122E-07
Chi-square approx. = 693.87090 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .16139
Huynh-Feldt Epsilon = .16717
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

554

127

FCE 20124/706 i

(9.1.1.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.44014	4.22560	8.00	43.00	.001
Hotellings	.78616	4.22560	8.00	43.00	.001
Wilks	.55986	4.22560	8.00	43.00	.001
Roys	.44014				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.51226	5.64518	8.00	43.00	.000
Hotellings	1.05027	5.64518	8.00	43.00	.000
Wilks	.48774	5.64518	8.00	43.00	.000
Roys	.51226				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	18142.32	400	45.36		
TIME	3889.37	8	486.17	10.72	.000
COUNTRY BY TIME	529.88	8	66.24	1.46	.170

655

128

FCE 20124/706 i

(9.1.1.2) Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			35.4423	3.6644	52
COUNTRY	1.00	Canada	31.8750	3.4821	8
COUNTRY	2.00	Brazil	36.0909	3.3398	44

Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	31.8750	3.4821	84.8750	8	
2.00	Brazil	36.0909	3.3398	479.6364	44	

Within Groups Total			35.4423	3.3601	564.5114	52

Criterion Variable D021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	120.3156	1	120.3156	10.6566	.0020
Within Groups	564.5114	50	11.2902		

Eta = .4192 Eta Squared = .1757

FCE 20124/706 i

(9.1.1.2) Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			33.0385	5.8577	52
COUNTRY	1.00	Canada	25.3750	8.4842	8
COUNTRY	2.00	Brazil	34.4318	4.0081	44

Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	25.3750	8.4842	503.8750	8
2.00	Brazil	34.4318	4.0081	690.7955	44

Within Groups Total		33.0385	4.8881	1194.6705	52

Criterion Variable D421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	555.2526	1	555.2526	23.2387	.0000
Within Groups	1194.6705	50	23.8934		

Eta = .5633 Eta Squared = .3173

657

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FCE 20124/706 i

(9.1.1.2) Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			30.5192	6.4336	52
COUNTRY	1.00	Canada	25.8750	11.9814	8
COUNTRY	2.00	Brazil	31.3636	4.5805	44

Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	25.8750	11.9814	1004.8750	8	
2.00	Brazil	31.3636	4.5805	902.1818	44	

Within Groups Total			30.5192	6.1759	1907.0568	52

Criterion Variable D721SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	203.9240	1	203.9240	5.3466	.0249
Within Groups	1907.0568	50	38.1411		

Eta = .3108 Eta Squared = .0966

558

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FCE 20124/706 i

(9.1.1.2) Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			28.4808	6.5514	52
COUNTRY	1.00	Canada	24.0000	10.6904	8
COUNTRY	2.00	Brazil	29.2955	5.2809	44

Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	24.0000	10.6904	800.0000	8	
2.00	Brazil	29.2955	5.2809	1199.1591	44	

Within Groups Total			28.4808	6.3232	1999.1591	52

Criterion Variable D1021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	189.8217	1	189.8217	4.7475	.0341
Within Groups	1999.1591	50	39.9832		

Eta = .2945 Eta Squared = .0867

: 650

FCE 20124/706 i

(9.1.1.2) Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			25.3077	7.6094	52
COUNTRY	1.00	Canada	24.1250	10.0490	8
COUNTRY	2.00	Brazil	25.5227	7.2062	44

Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	24.1250	10.0490	706.8750	8	
2.00	Brazil	25.5227	7.2062	2232.9773	44	

Within Groups Total			25.3077	7.6679	2939.8523	52

Criterion Variable D1421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	13.2247	1	13.2247	.2249	.6374
Within Groups	2939.8523	50	58.7970		

Eta = .0669 Eta Squared = .0045

FCE 20124/706 i

(9.1.1.2) Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			24.9615	11.3154	52
COUNTRY	1.00	Canada	23.2500	7.4210	8
COUNTRY	2.00	Brazil	25.2727	11.9268	44

Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	23.2500	7.4210	385.5000	8
2.00	Brazil	25.2727	11.9268	6116.7273	44

Within Groups Total		24.9615	11.4037	6502.2273	52

Criterion Variable D2121SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	27.6958	1	27.6958	.2130	.6464
Within Groups	6502.2273	50	130.0445		

Eta = .0651 Eta Squared = .0042

661

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FCE 20124/706 i

(9.1.1.2) Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.7500	13.2189	52
COUNTRY	1.00	Canada	22.0000	10.5153	8
COUNTRY	2.00	Brazil	22.8864	13.7523	44

Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	22.0000	10.5153	774.0000	8
2.00	Brazil	22.8864	13.7523	8132.4318	44

Within Groups Total		22.7500	13.3465	8906.4318	52

Criterion Variable D2821SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	5.3182	1	5.3182	.0299	.8635
Within Groups	8906.4318	50	178.1286		
Eta = .0244		Eta Squared = .0006			

FCE 20124/706 i

(9.1.1.2) Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			21.6538	14.0460	52
COUNTRY	1.00	Canada	22.0000	10.7438	8
COUNTRY	2.00	Brazil	21.5909	14.6689	44

Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	22.0000	10.7438	808.0000	8	
2.00	Brazil	21.5909	14.6689	9252.6364	44	
<hr/>						
Within Groups Total			21.6538	14.1849	10060.6364	52

Criterion Variable D3521SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.1329	1	1.1329	.0056	.9405
Within Groups	10060.6364	50	201.2127		
Eta = .0106		Eta Squared = .0001			

§ § §

FCE 20124/706 i

(9.1.1.2) Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			21.2308	14.8504	52
COUNTRY	1.00	Canada	21.2500	11.1066	8
COUNTRY	2.00	Brazil	21.2273	15.5397	44

Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	21.2500	11.1066	863.5000	8
2.00	Brazil	21.2273	15.5397	10383.7273	44
Within Groups Total		21.2308	14.9982	11247.2273	52

Criterion Variable D4221SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0035	1	.0035	.0000	.9969
Within Groups	11247.2273	50	224.9445		
Eta = .0006		Eta Squared = .0000			

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```
( 9.1.1.2 ) manova
d021sc d421sc d721sc d1021sc d1421sc d2121sc d2821sc d3521sc d4221sc
by agegp(1,3)
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/wdesign=time
/design.
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52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
3 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares						
Source of Variation	SS	DF	MS	F	Sig of F	
WITHIN CELLS	26445.71	49	539.71			
CONSTANT	328268.34	1	328268.34	608.23	.000	
AGEGP	1320.54	2	660.27	1.22	.303	

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W =4.800514E-07
Chi-square approx. = 671.08982 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .16174
Huynh-Feldt Epsilon = .17106
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

065

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FCE 20124/706 i

(9.1.1.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. AGEGP BY TIME

Multivariate Tests of Significance (S = 2, M = 2 1/2, N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.30520	.96793	16.00	86.00	.498
Hotellings	.40106	1.02772	16.00	82.00	.437
Wilks	.70585	.99887	16.00	84.00	.466
Roys	.26320				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.68111	11.21354	8.00	42.00	.000
Hotellings	2.13591	11.21354	8.00	42.00	.000
Wilks	.31889	11.21354	8.00	42.00	.000
Roys	.68111				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	18272.14	392	46.61		
TIME	11100.76	8	1387.59	29.77	.000
AGEGP BY TIME	400.06	16	25.00	.54	.927

000

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FCE 20124/706 i

(9.1.1.2) Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			35.4423	3.6644	52
AGEGP	1.00	Low(18-37)	36.8421	3.7898	19
AGEGP	2.00	Middle(38-49)	34.1000	3.6835	20
AGEGP	3.00	High(≥50)	35.4615	2.8171	13

Summaries of D021SC HAM-21 Dy0 Tot.Score
By levels of AGEGP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Low(18-37)	36.8421	3.7898	258.5263	19
2.00	Middle(38-49)	34.1000	3.6835	257.8000	20
3.00	High(≥50)	35.4615	2.8171	95.2308	13

Within Groups Total		35.4423	3.5328	611.5571	52

Criterion Variable D021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	73.2698	2	36.6349	2.9353	.0625
Within Groups	611.5571	49	12.4808		

Eta = .3271 Eta Squared = .1070

FCE 20124/706 i

(9.1.1.2) Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			33.0385	5.8577	52
AGE GP	1.00	Low(18-37)	34.6842	6.7417	19
AGE GP	2.00	Middle(38-49)	31.2500	5.8479	20
AGE GP	3.00	High(≥50)	33.3846	3.7090	13

Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of AGE GP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Low(18-37)	34.6842	6.7417	818.1053	19	
2.00	Middle(38-49)	31.2500	5.8479	649.7500	20	
3.00	High(≥50)	33.3846	3.7090	165.0769	13	

Within Groups Total			33.0385	5.7728	1632.9322	52

Criterion Variable D421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	116.9909	2	58.4954	1.7553	.1836
Within Groups	1632.9322	49	33.3251		

Eta = .2586 Eta Squared = .0669

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(9.1.1.2) Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			30.5192	6.4336	52
AGEGP	1.00	Low(18-37)	32.2105	6.8603	19
AGEGP	2.00	Middle(38-49)	27.9500	7.0223	20
AGEGP	3.00	High(≥50)	32.0000	3.0551	13

Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of AGEGP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Low(18-37)	32.2105	6.8603	847.1579	19
2.00	Middle(38-49)	27.9500	7.0223	936.9500	20
3.00	High(≥50)	32.0000	3.0551	112.0000	13

Within Groups Total		30.5192	6.2206	1896.1079	52

Criterion Variable D721SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	214.8729	2	107.4364	2.7764	.0721
Within Groups	1896.1079	49	38.6961		

Eta = .3190 Eta Squared = .1018

SSQ

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(9.1.1.2) Summaries of D1021SC HAM-21 Dy10 Tot.Score
By Levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			28.4808	6.5514	52
AGEGP	1.00	Low(18-37)	30.2632	7.3321	19
AGEGP	2.00	Middle(38-49)	26.2000	6.2036	20
AGEGP	3.00	High(≥50)	29.3846	5.1241	13

Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of AGE GP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Low(18-37)	30.2632	7.3321	967.6842	19
2.00	Middle(38-49)	26.2000	6.2036	731.2000	20
3.00	High(≥50)	29.3846	5.1241	315.0769	13
Within Groups Total		28.4808	6.4110	2013.9611	52

Criterion Variable D1021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	175.0196	2	87.5098	2.1291	.1298
Within Groups	2013.9611	49	41.1012		

Eta = .2828 Eta Squared = .0800

FCE 20124/706 i

(9.1.1.2) Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			25.3077	7.6094	52
AGEGP	1.00	Low(18-37)	27.4211	8.5135	19
AGEGP	2.00	Middle(38-49)	23.8500	7.5063	20
AGEGP	3.00	High(≥50)	24.4615	6.0638	13

Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of AGEGP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Low(18-37)	27.4211	8.5135	1304.6316	19	
2.00	Middle(38-49)	23.8500	7.5063	1070.5500	20	
3.00	High(≥50)	24.4615	6.0638	441.2308	13	

Within Groups Total			25.3077	7.5814	2816.4123	52

Criterion Variable D1421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	136.6646	2	68.3323	1.1888	.3132
Within Groups	2816.4123	49	57.4778		

Eta = .2151 Eta Squared = .0463

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(9.1.1.2) Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			24.9615	11.3154	52
AGEGP	1.00	Low(18-37)	27.9474	13.2727	19
AGEGP	2.00	Middle(38-49)	23.7000	10.4886	20
AGEGP	3.00	High(≥50)	22.5385	9.0886	13

Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of AGEGP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Low(18-37)	27.9474	13.2727	3170.9474	19	
2.00	Middle(38-49)	23.7000	10.4886	2090.2000	20	
3.00	High(≥50)	22.5385	9.0886	991.2308	13	

Within Groups Total			24.9615	11.2960	6252.3781	52

Criterion Variable D2121SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	277.5449	2	138.7725	1.0876	.3450
Within Groups	6252.3781	49	127.5996		

Eta = .2062 Eta Squared = .0425

672

145

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(9.1.1.2) Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.7500	13.2189	52
AGEGP	1.00	Low(18-37)	25.3684	15.5856	19
AGEGP	2.00	Middle(38-49)	21.5500	12.4667	20
AGEGP	3.00	High(≥50)	20.7692	10.7094	13

Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of AGEGP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Low(18-37)	25.3684	15.5856	4372.4211	19
2.00	Middle(38-49)	21.5500	12.4667	2952.9500	20
3.00	High(≥50)	20.7692	10.7094	1376.3077	13
Within Groups Total		22.7500	13.3261	8701.6787	52

Criterion Variable D2821SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	210.0713	2	105.0356	.5915	.5574
Within Groups	8701.6787	49	177.5853		

Eta = .1535 Eta Squared = .0236

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(9.1.1.2) Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			21.6538	14.0460	52
AGEGP	1.00	Low(18-37)	24.4737	16.4025	19
AGEGP	2.00	Middle(38-49)	21.0500	13.3001	20
AGEGP	3.00	High(≥50)	18.4615	11.4281	13

Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of AGEGP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Low(18-37)	24.4737	16.4025	4842.7368	19	
2.00	Middle(38-49)	21.0500	13.3001	3360.9500	20	
3.00	High(≥50)	18.4615	11.4281	1567.2308	13	

Within Groups Total			21.6538	14.1211	9770.9176	52

Criterion Variable D3521SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	290.8516	2	145.4258	.7293	.4874
Within Groups	9770.9176	49	199.4065		

Eta = .1700 Eta Squared = .0289

674

147

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(9.1.1.2) Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			21.2308	14.8504	52
AGEGP	1.00	Low(18-37)	23.8947	16.9178	19
AGEGP	2.00	Middle(38-49)	20.2000	14.2740	20
AGEGP	3.00	High(≥50)	18.9231	12.9065	13

Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of AGEGP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Low(18-37)	23.8947	16.9178	5151.7895	19
2.00	Middle(38-49)	20.2000	14.2740	3871.2000	20
3.00	High(≥50)	18.9231	12.9065	1998.9231	13

Within Groups Total		21.2308	14.9979	11021.9126	52

Criterion Variable D4221SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	225.3182	2	112.6591	.5008	.6091
Within Groups	11021.9126	49	224.9370		

Eta = .1415 Eta Squared = .0200

675

143

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```
( 9.1.1.2 ) manova
d021sc d421sc d721sc d1021sc d1421sc d2121sc d2821sc d3521sc d4221sc
by subform(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	26275.91	48	547.41		
CONSTANT	56021.08	1	56021.08	102.34	.000
SUBFORM	1490.34	3	496.78	.91	.444

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W =1.861448E-07
Chi-square approx. = 699.29044 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .15597
Huynh-Feldt Epsilon = .16813
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

576

149

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(9.1.1.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	1.01067	2.73074	24.00	129.00	.000
Hotellings	2.12907	3.51888	24.00	119.00	.000
Wilks	.24181	3.14441	24.00	119.51	.000
Roys	.60003				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.42773	3.83052	8.00	41.00	.002
Hotellings	.74742	3.83052	8.00	41.00	.002
Wilks	.57227	3.83052	8.00	41.00	.002
Roys	.42773				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	17991.38	384	46.85		
TIME	1291.11	8	161.39	3.44	.001
SUBFORM BY TIME	680.82	24	28.37	.61	.930

577

150

FCE 20124/706 i

(9.1.1.2) Summaries of D021SC HAM-21 Dy0 Tot.Score
By Levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			35.4423	3.6644	52
SUBFORM	1.00	Sing.Epi.	36.7778	3.2384	27
SUBFORM	2.00	Recurr.	34.5909	3.1268	22
SUBFORM	3.00	Rec.-Mod.Sv.	27.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	31.0000	5.6569	2

Summaries of D021SC HAM-21 Dy0 Tot.Score
By Levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	36.7778	3.2384	272.6667	27	
2.00	Recurr.	34.5909	3.1268	205.3182	22	
3.00	Rec.-Mod.Sv.	27.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	31.0000	5.6569	32.0000	2	
Within Groups Total			35.4423	3.2596	509.9848	52

Criterion Variable D021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	174.8421	3	58.2807	5.4854	.0025
Within Groups	509.9848	48	10.6247		

Eta = .5053 Eta Squared = .2553

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(9.1.1.2) Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			33.0385	5.8577	52
SUBFORM	1.00	Sing.Epi.	34.8889	3.9354	27
SUBFORM	2.00	Recurr.	31.7273	6.0646	22
SUBFORM	3.00	Rec.-Mod.Sv.	12.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	33.0000	1.4142	2

Summaries of D421SC HAM-21 Dy4 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	34.8889	3.9354	402.6667	27	
2.00	Recurr.	31.7273	6.0646	772.3636	22	
3.00	Rec.-Mod.Sv.	12.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	33.0000	1.4142	2.0000	2	
<hr/>						
Within Groups Total			33.0385	4.9519	1177.0303	52

Criterion Variable D421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	572.8928	3	190.9643	7.7876	.0002
Within Groups	1177.0303	48	24.5215		

Eta = .5722 Eta Squared = .3274

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(9.1.1.2) Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			30.5192	6.4336	52
SUBFORM	1.00	Sing.Epi.	32.1111	4.6354	27
SUBFORM	2.00	Recurr.	29.0909	7.2828	22
SUBFORM	3.00	Rec.-Mod.Sv.	13.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	33.5000	.7071	2

Summaries of D721SC HAM-21 Dy7 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	32.1111	4.6354	558.6667	27	
2.00	Recurr.	29.0909	7.2828	1113.8182	22	
3.00	Rec.-Mod.Sv.	13.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	33.5000	.7071	.5000	2	

Within Groups Total			30.5192	5.9037	1672.9848	52

Criterion Variable D721SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	437.9959	3	145.9986	4.1889	.0103
Within Groups	1672.9848	48	34.8539		
Eta = .4555		Eta Squared = .2075			

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(9.1.1.2) Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			28.4808	6.5514	52
SUBFORM	1.00	Sing.Epi.	29.9259	4.9608	27
SUBFORM	2.00	Recurr.	27.4545	7.3855	22
SUBFORM	3.00	Rec.-Mod.Sv.	11.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	29.0000	4.2426	2

Summaries of D1021SC HAM-21 Dy10 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	29.9259	4.9608	639.8519	27	
2.00	Recurr.	27.4545	7.3855	1145.4545	22	
3.00	Rec.-Mod.Sv.	11.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	29.0000	4.2426	18.0000	2	

Within Groups Total			28.4808	6.1293	1803.3064	52

Criterion Variable D1021SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	385.6744	3	128.5581	3.4219	.0244
Within Groups	1803.3064	48	37.5689		
Eta = .4197		Eta Squared = .1762			

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(9.1.1.2) Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			25.3077	7.6094	52
SUBFORM	1.00	Sing.Epi.	26.1852	7.1308	27
SUBFORM	2.00	Recurr.	23.5909	8.0395	22
SUBFORM	3.00	Rec.-Mod.Sv.	21.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	34.5000	.7071	2

Summaries of D1421SC HAM-21 Dy14 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	26.1852	7.1308	1322.0741	27	
2.00	Recurr.	23.5909	8.0395	1357.3182	22	
3.00	Rec.-Mod.Sv.	21.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	34.5000	.7071	.5000	2	
Within Groups Total			25.3077	7.4720	2679.8923	52

Criterion Variable D1421SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	273.1847	3	91.0616	1.6310	.1945
Within Groups	2679.8923	48	55.8311		
Eta = .3042		Eta Squared = .0925			

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(9.1.1.2) Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			24.9615	11.3154	52
SUBFORM	1.00	Sing.Epi.	25.8519	12.3684	27
SUBFORM	2.00	Recurr.	24.1818	10.8875	22
SUBFORM	3.00	Rec.-Mod.Sv.	20.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	24.0000	1.4142	2

Summaries of D2121SC HAM-21 Dy21 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	25.8519	12.3684	3977.4074	27	
2.00	Recurr.	24.1818	10.8875	2489.2727	22	
3.00	Rec.-Mod.Sv.	20.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	24.0000	1.4142	2.0000	2	

Within Groups Total			24.9615	11.6088	6468.6801	52

Criterion Variable D2121SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	61.2429	3	20.4143	.1515	.9282
Within Groups	6468.6801	48	134.7642		
		Eta = .0968		Eta Squared = .0094	

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(9.1.1.2) Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.7500	13.2189	52
SUBFORM	1.00	Sing.Epi.	23.2963	14.4324	27
SUBFORM	2.00	Recurr.	22.2273	12.5468	22
SUBFORM	3.00	Rec.-Mod.Sv.	14.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	25.5000	9.1924	2

Summaries of D2821SC HAM-21 Dy28 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	23.2963	14.4324	5415.6296	27
2.00	Recurr.	22.2273	12.5468	3305.8636	22
3.00	Rec.-Mod.Sv.	14.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	25.5000	9.1924	84.5000	2
Within Groups Total		22.7500	13.5447	8805.9933	52

Criterion Variable D2821SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	105.7567	3	35.2522	.1922	.9012
Within Groups	8805.9933	48	183.4582		
Eta = .1089		Eta Squared = .0119			

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(9.1.1.2) Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			21.6538	14.0460	52
SUBFORM	1.00	Sing.Epi.	21.8889	15.3956	27
SUBFORM	2.00	Recurr.	21.3182	13.3216	22
SUBFORM	3.00	Rec.-Mod.Sv.	14.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	26.0000	8.4853	2

Summaries of D3521SC HAM-21 Dy35 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	21.8889	15.3956	6162.6667	27	
2.00	Recurr.	21.3182	13.3216	3726.7727	22	
3.00	Rec.-Mod.Sv.	14.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	26.0000	8.4853	72.0000	2	
Within Groups Total			21.6538	14.4059	9961.4394	52

Criterion Variable D3521SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	100.3298	3	33.4433	.1611	.9220
Within Groups	9961.4394	48	207.5300		
Eta = .0999		Eta Squared = .0100			

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(9.1.1.2) Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			21.2308	14.8504	52
SUBFORM	1.00	Sing.Epi.	21.2222	15.9309	27
SUBFORM	2.00	Recurr.	21.4091	14.5198	22
SUBFORM	3.00	Rec.-Mod.Sv.	14.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	23.0000	12.7279	2

Summaries of D4221SC HAM-21 Dy42 Tot.Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	21.2222	15.9309	6598.6667	27
2.00	Recurr.	21.4091	14.5198	4427.3182	22
3.00	Rec.-Mod.Sv.	14.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	23.0000	12.7279	162.0000	2
Within Groups Total		21.2308	15.2671	11187.9848	52

Criterion Variable D4221SC

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	59.2459	3	19.7486	.0847	.9681
Within Groups	11187.9848	48	233.0830		
Eta = .0726		Eta Squared = .0053			

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APPENDIX 13

Therapeutic Profile: **HAMD**

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(9.1.1.3) Summaries of DOVAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		3.5769	.4989	52
GROUP	1	3.5926	.5007	27
GROUP	2	3.5600	.5066	25

Summaries of DOVAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	3.5926	.5007	6.5185	27
2	3.5600	.5066	6.1600	25

Within Groups Total	3.5769	.5036	12.6785	52

Criterion Variable DOVAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0138	1	.0138	.0544	.8166
Within Groups	12.6785	50	.2536		

Eta = .0330 Eta Squared = .0011

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(9.1.1.3) Summaries of D4VAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		3.3654	.6271	52
GROUP	1	3.4074	.6360	27
GROUP	2	3.3200	.6272	25

Summaries of D4VAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	3.4074	.6360	10.5185	27
2	3.3200	.6272	9.4400	25

Within Groups Total	3.3654	.6318	19.9585	52

Criterion Variable D4VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0992	1	.0992	.2484	.6204
Within Groups	19.9585	50	.3992		
Eta = .0703 Eta Squared = .0049					

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(9.1.1.3) Summaries of D7VAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		3.1154	.8553	52
GROUP	1	2.9630	.9799	27
GROUP	2	3.2800	.6782	25

Summaries of D7VAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.9630	.9799	24.9630	27
2	3.2800	.6782	11.0400	25

Within Groups Total	3.1154	.8486	36.0030	52

Criterion Variable D7VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.3047	1	1.3047	1.8120	.1843
Within Groups	36.0030	50	.7201		
Eta = .1870		Eta Squared = .0350			

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(9.1.1.3) Summaries of D10VAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.7885	.8708	52
GROUP	1	2.5556	1.0127	27
GROUP	2	3.0400	.6110	25

Summaries of D10VAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.5556	1.0127	26.6667	27
2	3.0400	.6110	8.9600	25

Within Groups Total	2.7885	.8441	35.6267	52

Criterion Variable D10VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.0464	1	3.0464	4.2755	.0439
Within Groups	35.6267	50	.7125		
Eta = .2807		Eta Squared = .0788			

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(9.1.1.3) Summaries of D14VAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.5769	.9149	52
GROUP	1	2.2593	.9443	27
GROUP	2	2.9200	.7594	25

Summaries of D14VAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.2593	.9443	23.1852	27
2	2.9200	.7594	13.8400	25
Within Groups Total	2.5769	.8605	37.0252	52

Criterion Variable D14VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	5.6671	1	5.6671	7.6531	.0079
Within Groups	37.0252	50	.7405		
Eta = .3643		Eta Squared = .1327			

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(9.1.1.3) Summaries of D21VAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.4423	1.2113	52
GROUP	1	1.8519	1.0635	27
GROUP	2	3.0800	1.0376	25

Summaries of D21VAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.8519	1.0635	29.4074	27
2	3.0800	1.0376	25.8400	25

Within Groups Total	2.4423	1.0512	55.2474	52

Criterion Variable D21VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	19.5795	1	19.5795	17.7199	.0001
Within Groups	55.2474	50	1.1049		
Eta = .5115 Eta Squared = .2617					

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(9.1.1.3) Summaries of D28VAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.2500	1.4535	52
GROUP	1	1.5556	1.3397	27
GROUP	2	3.0000	1.1902	25

Summaries of D28VAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.5556	1.3397	46.6667	27
2	3.0000	1.1902	34.0000	25

Within Groups Total	2.2500	1.2702	80.6667	52

Criterion Variable D28VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	27.0833	1	27.0833	16.7872	.0002
Within Groups	80.6667	50	1.6133		
Eta = .5014		Eta Squared = .2514			

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(9.1.1.3) Summaries of D35VAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.0000	1.6088	52
GROUP	1	1.1852	1.3878	27
GROUP	2	2.8800	1.3638	25

Summaries of D35VAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.1852	1.3878	50.0741	27
2	2.8800	1.3638	44.6400	25

Within Groups Total	2.0000	1.3763	94.7141	52

Criterion Variable D35VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	37.2859	1	37.2859	19.6834	.0001
Within Groups	94.7141	50	1.8943		

Eta = .5315 Eta Squared = .2825

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(9.1.1.3) Summaries of D42VAR1 - DEPRESSED MOOD
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.9038	1.7065	52
GROUP	1	1.0000	1.4676	27
GROUP	2	2.8800	1.3940	25

Summaries of D42VAR1 - DEPRESSED MOOD
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.0000	1.4676	56.0000	27
2	2.8800	1.3940	46.6400	25
Within Groups Total	1.9038	1.4328	102.6400	52

Criterion Variable D42VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	45.8792	1	45.8792	22.3496	.0000
Within Groups	102.6400	50	2.0528		
Eta = .5558		Eta Squared = .3089			

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(9.1.1.3) Summaries of DOVAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.6410	.3155	52
GROUP	1	1.6173	.3890	27
GROUP	2	1.6667	.2152	25

Summaries of DOVAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.6173	.3890	3.9342	27
2	1.6667	.2152	1.1111	25

Within Groups Total	1.6410	.3177	5.0453	52

Criterion Variable DOVAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0317	1	.0317	.3137	.5779
Within Groups	5.0453	50	.1009		

Eta = .0790 Eta Squared = .0062

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(9.1.1.3) Summaries of D4VAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.5192	.4497	52
GROUP	1	1.3457	.5349	27
GROUP	2	1.7067	.2219	25

Summaries of D4VAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.3457	.5349	7.4403	27
2	1.7067	.2219	1.1822	25

Within Groups Total	1.5192	.4153	8.6226	52

Criterion Variable D4VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.6916	1	1.6916	9.8089	.0029
Within Groups	8.6226	50	.1725		
Eta = .4050 Eta Squared = .1640					

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(9.1.1.3) Summaries of D7VAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.4038	.4493	52
GROUP	1	1.3210	.4757	27
GROUP	2	1.4933	.4096	25

Summaries of D7VAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.3210	.4757	5.8848	27
2	1.4933	.4096	4.0267	25

Within Groups Total	1.4038	.4452	9.9114	52

Criterion Variable D7VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3856	1	.3856	1.9451	.1693
Within Groups	9.9114	50	.1982		
Eta = .1935 Eta Squared = .0374					

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(9.1.1.3) Summaries of D10VAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.3205	.4475	52
GROUP	1	1.2099	.4727	27
GROUP	2	1.4400	.3935	25

Summaries of D10VAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.2099	.4727	5.8107	27
2	1.4400	.3935	3.7156	25

Within Groups Total	1.3205	.4365	9.5263	52

Criterion Variable D10VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.6874	1	.6874	3.6080	.0633
Within Groups	9.5263	50	.1905		
Eta = .2594 Eta Squared = .0673					

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(9.1.1.3) Summaries of D14VAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.2244	.5228	52
GROUP	1	1.0370	.5175	27
GROUP	2	1.4267	.4566	25

Summaries of D14VAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.0370	.5175	6.9630	27
2	1.4267	.4566	5.0044	25

Within Groups Total	1.2244	.4892	11.9674	52

Criterion Variable D14VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.9706	1	1.9706	8.2333	.0060
Within Groups	11.9674	50	.2393		

Eta = .3760 Eta Squared = .1414

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(9.1.1.3) Summaries of D21VAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.2692	.6194	52
GROUP	1	1.0000	.5624	27
GROUP	2	1.5600	.5504	25

Summaries of D21VAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.0000	.5624	8.2222	27
2	1.5600	.5504	7.2711	25

Within Groups Total	1.2692	.5567	15.4933	52

Criterion Variable D21VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.0708	1	4.0708	13.1372	.0007
Within Groups	15.4933	50	.3099		

Eta = .4562 Eta Squared = .2081

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(9.1.1.3) Summaries of D28VAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.1282	.6737	52
GROUP	1	.7778	.5469	27
GROUP	2	1.5067	.5941	25

Summaries of D28VAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	.7778	.5469	7.7778	27
2	1.5067	.5941	8.4711	25

Within Groups Total	1.1282	.5701	16.2489	52

Criterion Variable D28VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	6.8964	1	6.8964	21.2212	.0000
Within Groups	16.2489	50	.3250		
Eta = .5459 Eta Squared = .2980					

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(9.1.1.3) Summaries of D35VAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.1410	.6965	52
GROUP	1	.7778	.5774	27
GROUP	2	1.5333	.6009	25

Summaries of D35VAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	.7778	.5774	8.6667	27
2	1.5333	.6009	8.6667	25

Within Groups Total	1.1410	.5888	17.3333	52

Criterion Variable D35VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	7.4103	1	7.4103	21.3757	.0000
Within Groups	17.3333	50	.3467		

Eta = .5472 Eta Squared = .2995

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(9.1.1.3) Summaries of D42VAR2 - INSOMNIA
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.1154	.7167	52
GROUP	1	.7654	.6120	27
GROUP	2	1.4933	.6319	25

Summaries of D42VAR2 - INSOMNIA
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	.7654	.6120	9.7366	27
2	1.4933	.6319	9.5822	25

Within Groups Total	1.1154	.6216	19.3188	52

Criterion Variable D42VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	6.8777	1	6.8777	17.8006	.0001
Within Groups	19.3188	50	.3864		
Eta = .5124 Eta Squared = .2625					

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(9.1.1.3) Summaries of DOVAR3 - ACTIVITIES FCE 20124/706 i
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.7885	.6885	52
GROUP	1	2.8333	.6794	27
GROUP	2	2.7400	.7089	25

Summaries of DOVAR3 - ACTIVITIES
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.8333	.6794	12.0000	27
2	2.7400	.7089	12.0600	25
Within Groups Total	2.7885	.6937	24.0600	52

Criterion Variable DOVAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1131	1	.1131	.2350	.6300
Within Groups	24.0600	50	.4812		
Eta = .0684		Eta Squared = .0047			

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(9.1.1.3) Summaries of D4VAR3 - ACTIVITIES FCE 20124/706 i
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.6442	.6812	52
GROUP	1	2.7407	.6985	27
GROUP	2	2.5400	.6602	25

Summaries of D4VAR3 - ACTIVITIES
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.7407	.6985	12.6852	27
2	2.5400	.6602	10.4600	25
Within Groups Total	2.6442	.6804	23.1452	52

Criterion Variable D4VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5231	1	.5231	1.1300	.2929
Within Groups	23.1452	50	.4629		
Eta = .1487		Eta Squared = .0221			

(9.1.1.3) Summaries of D7VAR3 - ACTIVITIES FCB 20124/706 i
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.4904	.6530	52
GROUP	1	2.3704	.6736	27
GROUP	2	2.6200	.6171	25

Summaries of D7VAR3 - ACTIVITIES
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.3704	.6736	11.7963	27
2	2.6200	.6171	9.1400	25

Within Groups Total	2.4904	.6471	20.9363	52

Criterion Variable D7VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.8089	1	.8089	1.9318	.1707
Within Groups	20.9363	50	.4187		
Eta = .1929 Eta Squared = .0372					

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(9.1.1.3) Summaries of D10VAR3 - ACTIVITIES FCE 20124/706 i
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.3269	.6780	52
GROUP	1	2.1667	.7468	27
GROUP	2	2.5000	.5590	25

Summaries of D10VAR3 - ACTIVITIES
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.1667	.7468	14.5000	27
2	2.5000	.5590	7.5000	25

Within Groups Total	2.3269	.6633	22.0000	52

Criterion Variable D10VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.4423	1	1.4423	3.2780	.0762
Within Groups	22.0000	50	.4400		
Eta = .2480		Eta Squared = .0615			

(9.1.1.3) Summaries of D14VAR3 - ACTIVITIES FCE 20124/706 i
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.0769	.7369	52
GROUP	1	1.7963	.7106	27
GROUP	2	2.3800	.6500	25

Summaries of D14VAR3 - ACTIVITIES
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.7963	.7106	13.1296	27
2	2.3800	.6500	10.1400	25
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Within Groups Total	2.0769	.6822	23.2696	52

Criterion Variable D14VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.4227	1	4.4227	9.5031	.0033
Within Groups	23.2696	50	.4654		
Eta = .3996		Eta Squared = .1597			

(9.1.1.3) Summaries of D21VAR3 - ACTIVITIES FCE 20124/706 i
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.9712	.8879	52
GROUP	1	1.5000	.7206	27
GROUP	2	2.4800	.7703	25

Summaries of D21VAR3 - ACTIVITIES
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.5000	.7206	13.5000	27
2	2.4800	.7703	14.2400	25

Within Groups Total	1.9712	.7448	27.7400	52

Criterion Variable D21VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	12.4667	1	12.4667	22.4707	.0000
Within Groups	27.7400	50	.5548		

Eta = .5568 Eta Squared = .3101

(9.1.1.3) Summaries of D28VAR3 - ACTIVITIES FCE 20124/706 i
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.7019	1.0948	52
GROUP	1	1.1296	.8835	27
GROUP	2	2.3200	.9670	25

Summaries of D28VAR3 - ACTIVITIES
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.1296	.8835	20.2963	27
2	2.3200	.9670	22.4400	25

Within Groups Total	1.7019	.9245	42.7363	52

Criterion Variable D28VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	18.3935	1	18.3935	21.5198	.0000
Within Groups	42.7363	50	.8547		

Eta = .5485 Eta Squared = .3009

(9.1.1.3) Summaries of D35VAR3 - ACTIVITIES FCE 20124/706 i
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.5577	1.1701	52
GROUP	1	.8889	.8916	27
GROUP	2	2.2800	1.0008	25

Summaries of D35VAR3 - ACTIVITIES
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	.8889	.8916	20.6667	27
2	2.2800	1.0008	24.0400	25

Within Groups Total	1.5577	.9456	44.7067	52

Criterion Variable D35VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	25.1203	1	25.1203	28.0945	.0000
Within Groups	44.7067	50	.8941		

Eta = .5998 Eta Squared = .3598

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(9.1.1.3) Summaries of D42VAR3 - ACTIVITIES
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.5096	1.2776	52
GROUP	1		.7963	1.0120	27
GROUP	2		2.2800	1.0809	25

Summaries of D42VAR3 - ACTIVITIES
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		.7963	1.0120	26.6296	27
2		2.2800	1.0809	28.0400	25

Within Groups Total		1.5096	1.0457	54.6696	52

Criterion Variable D42VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	28.5756	1	28.5756	26.1348	.0000
Within Groups	54.6696	50	1.0934		

Eta = .5859 Eta Squared = .3433

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(9.1.1.3) Summaries of DOVAR4 - ANXIETY
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.2308	.6528	52
GROUP	1	2.3148	.5743	27
GROUP	2	2.1400	.7292	25

Summaries of DOVAR4 - ANXIETY
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.3148	.5743	8.5741	27
2	2.1400	.7292	12.7600	25

Within Groups Total	2.2308	.6532	21.3341	52

Criterion Variable DOVAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3967	1	.3967	.9297	.3396
Within Groups	21.3341	50	.4267		

Eta = .1351 Eta Squared = .0183

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(9.1.1.3) Summaries of D4VAR4 - ANXIETY
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.1154	.6464	52
GROUP	1	2.1667	.6202	27
GROUP	2	2.0600	.6819	25

Summaries of D4VAR4 - ANXIETY
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	2.1667	.6202	10.0000	27
2	2.0600	.6819	11.1600	25

Within Groups Total	2.1154	.6505	21.1600	52

Criterion Variable D4VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1477	1	.1477	.3490	.5573
Within Groups	21.1600	50	.4232		
Eta = .0833		Eta Squared = .0069			

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(9.1.1.3) Summaries of D7VAR4 - ANXIETY
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.9423	.6977	52
GROUP	1	1.9074	.6799	27
GROUP	2	1.9800	.7286	25

Summaries of D7VAR4 - ANXIETY
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.9074	.6799	12.0185	27
2	1.9800	.7286	12.7400	25

Within Groups Total	1.9423	.7037	24.7585	52

Criterion Variable D7VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0684	1	.0684	.1381	.7117
Within Groups	24.7585	50	.4952		

Eta = .0525 Eta Squared = .0028

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(9.1.1.3) Summaries of D10VAR4 - ANXIETY
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.8750	.6013	52
GROUP	1		1.7593	.5780	27
GROUP	2		2.0000	.6124	25

Summaries of D10VAR4 - ANXIETY
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		1.7593	.5780	8.6852	27
2		2.0000	.6124	9.0000	25
<hr/>					
Within Groups Total		1.8750	.5947	17.6852	52

Criterion Variable D10VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.7523	1	.7523	2.1270	.1510
Within Groups	17.6852	50	.3537		
Eta = .2020		Eta Squared = .0408			

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(9.1.1.3) Summaries of D14VAR4 - ANXIETY
By Levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.6731	.6331	52
GROUP	1	1.5556	.5430	27
GROUP	2	1.8000	.7071	25

Summaries of D14VAR4 - ANXIETY
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.5556	.5430	7.6667	27
2	1.8000	.7071	12.0000	25
Within Groups Total	1.6731	.6272	19.6667	52

Criterion Variable D14VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.7756	1	.7756	1.9720	.1664
Within Groups	19.6667	50	.3933		
Eta = .1948		Eta Squared = .0379			

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(9.1.1.3) Summaries of D21VAR4 - ANXIETY
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.7885	.7881	52
GROUP	1	1.4074	.5553	27
GROUP	2	2.2000	.8036	25

Summaries of D21VAR4 - ANXIETY
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.4074	.5553	8.0185	27
2	2.2000	.8036	15.5000	25
Within Groups Total	1.7885	.6858	23.5185	52

Criterion Variable D21VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	8.1546	1	8.1546	17.3365	.0001
Within Groups	23.5185	50	.4704		
Eta = .5074		Eta Squared = .2575			

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(9.1.1.3) Summaries of D28VAR4 - ANXIETY
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.7212	.8249	52
GROUP	1	1.2963	.5761	27
GROUP	2	2.1800	.8150	25

Summaries of D28VAR4 - ANXIETY
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.2963	.5761	8.6296	27
2	2.1800	.8150	15.9400	25
Within Groups Total	1.7212	.7010	24.5696	52

Criterion Variable D28VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	10.1371	1	10.1371	20.6293	.0000
Within Groups	24.5696	50	.4914		
Eta = .5404		Eta Squared = .2921			

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(9.1.1.3) Summaries of D35VAR4 - ANXIETY
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.6442	.8875	52
GROUP	1	1.1481	.6015	27
GROUP	2	2.1800	.8401	25

Summaries of D35VAR4 - ANXIETY
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.1481	.6015	9.4074	27
2	2.1800	.8401	16.9400	25
Within Groups Total	1.6442	.7259	26.3474	52

Criterion Variable D35VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	13.8209	1	13.8209	26.2281	.0000
Within Groups	26.3474	50	.5269		

Eta = .5866 Eta Squared = .3441

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(9.1.1.3) Summaries of D42VAR4 - ANXIETY
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.6154	.8890	52
GROUP	1	1.1481	.6173	27
GROUP	2	2.1200	.8694	25

Summaries of D42VAR4 - ANXIETY
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.1481	.6173	9.9074	27
2	2.1200	.8694	18.1400	25

Within Groups Total	1.6154	.7490	28.0474	52

Criterion Variable D42VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	12.2603	1	12.2603	21.8564	.0000
Within Groups	28.0474	50	.5609		

Eta = .5515 Eta Squared = .3042

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(9.1.1.3) Summaries of DOVAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.8942	.3513	52
GROUP	1	1.8426	.3807	27
GROUP	2	1.9500	.3146	25

Summaries of DOVAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.8426	.3807	3.7685	27
2	1.9500	.3146	2.3750	25

Within Groups Total	1.8942	.3505	6.1435	52

Criterion Variable DOVAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1498	1	.1498	1.2188	.2749
Within Groups	6.1435	50	.1229		
Eta = .1543		Eta Squared = .0238			

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(9.1.1.3) Summaries of D4VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.7981	.4202	52
GROUP	1	1.7685	.4750	27
GROUP	2	1.8300	.3588	25

Summaries of D4VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.7685	.4750	5.8657	27
2	1.8300	.3588	3.0900	25

Within Groups Total	1.7981	.4232	8.9557	52

Criterion Variable D4VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0491	1	.0491	.2739	.6030
Within Groups	8.9557	50	.1791		
Eta = .0738 Eta Squared = .0054					

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(9.1.1.3) Summaries of D7VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.7019	.3804	52
GROUP	1	1.6574	.3807	27
GROUP	2	1.7500	.3819	25

Summaries of D7VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.6574	.3807	3.7685	27
2	1.7500	.3819	3.5000	25

Within Groups Total	1.7019	.3813	7.2685	52

Criterion Variable D7VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1113	1	.1113	.7656	.3858
Within Groups	7.2685	50	.1454		

Eta = .1228 Eta Squared = .0151

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(9.1.1.3) Summaries of D10VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.6683	.4251	52
GROUP	1	1.5648	.4251	27
GROUP	2	1.7800	.4039	25

Summaries of D10VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.5648	.4251	4.6991	27
2	1.7800	.4039	3.9150	25

Within Groups Total	1.6683	.4151	8.6141	52

Criterion Variable D10VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.6011	1	.6011	3.4889	.0676
Within Groups	8.6141	50	.1723		
Eta = .2554		Eta Squared = .0652			

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(9.1.1.3) Summaries of D14VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.4375	.5283	52
GROUP	1	1.3148	.4682	27
GROUP	2	1.5700	.5661	25

Summaries of D14VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.3148	.4682	5.6991	27
2	1.5700	.5661	7.6900	25

Within Groups Total	1.4375	.5175	13.3891	52

Criterion Variable D14VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.8453	1	.8453	3.1567	.0817
Within Groups	13.3891	50	.2678		

Eta = .2437 Eta Squared = .0594

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(9.1.1.3) Summaries of D21VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.3942	.6111	52
GROUP	1	1.1019	.4767	27
GROUP	2	1.7100	.5893	25

Summaries of D21VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.1019	.4767	5.9074	27
2	1.7100	.5893	8.3350	25

Within Groups Total	1.3942	.5337	14.2424	52

Criterion Variable D21VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.8009	1	4.8009	16.8541	.0001
Within Groups	14.2424	50	.2848		

Eta = .5021 Eta Squared = .2521

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(9.1.1.3) Summaries of D28VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.2644	.7061	52
GROUP	1	.9167	.5633	27
GROUP	2	1.6400	.6578	25

Summaries of D28VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	.9167	.5633	8.2500	27
2	1.6400	.6578	10.3850	25

Within Groups Total	1.2644	.6105	18.6350	52

Criterion Variable D28VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	6.7917	1	6.7917	18.2229	.0001
Within Groups	18.6350	50	.3727		

Eta = .5168 Eta Squared = .2671

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(9.1.1.3) Summaries of D35VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.2308	.7603	52
GROUP	1		.8241	.5957	27
GROUP	2		1.6700	.6759	25

Summaries of D35VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		.8241	.5957	9.2269	27
2		1.6700	.6759	10.9650	25

Within Groups Total		1.2308	.6355	20.1919	52

Criterion Variable D35VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	9.2889	1	9.2889	23.0016	.0000
Within Groups	20.1919	50	.4038		

Eta = .5613 Eta Squared = .3151

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(9.1.1.3) Summaries of D42VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.2115	.7958	52
GROUP	1		.7685	.6314	27
GROUP	2		1.6900	.6742	25

Summaries of D42VAR5 - SOMATIC SYMPTOMS
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		.7685	.6314	10.3657	27
2		1.6900	.6742	10.9100	25

Within Groups Total		1.2115	.6523	21.2757	52

Criterion Variable D42VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	11.0223	1	11.0223	25.9035	.0000
Within Groups	21.2757	50	.4255		

Eta = .5842 Eta Squared = .3413

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(9.1.1.3) Summaries of DOVAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.5769	.4989	52
SEX	0	Female	3.5417	.5090	24
SEX	1	Male	3.6071	.4973	28

Summaries of DOVAR1 - DEPRESSED MOOD
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	3.5417	.5090	5.9583	24
1	Male	3.6071	.4973	6.6786	28

Within Groups Total		3.5769	.5027	12.6369	52

Criterion Variable DOVAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0554	1	.0554	.2192	.6417
Within Groups	12.6369	50	.2527		
Eta = .0661		Eta Squared = .0044			

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(9.1.1.3) Summaries of D4VAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.3654	.6271	52
SEX	0	Female	3.3750	.6469	24
SEX	1	Male	3.3571	.6215	28

Summaries of D4VAR1 - DEPRESSED MOOD
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	3.3750	.6469	9.6250	24
1	Male	3.3571	.6215	10.4286	28

Within Groups Total		3.3654	.6333	20.0536	52

Criterion Variable D4VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0041	1	.0041	.0103	.9197
Within Groups	20.0536	50	.4011		
Eta = .0143		Eta Squared = .0002			

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(9.1.1.3) Summaries of D7VAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1154	.8553	52
SEX	0	Female	3.0417	.8587	24
SEX	1	Male	3.1786	.8630	28

Summaries of D7VAR1 - DEPRESSED MOOD
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	3.0417	.8587	16.9583	24	
1	Male	3.1786	.8630	20.1071	28	

Within Groups Total			3.1154	.8610	37.0655	52

Criterion Variable D7VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2422	1	.2422	.3267	.5701
Within Groups	37.0655	50	.7413		

Eta = .0806 Eta Squared = .0065

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(9.1.1.3) Summaries of D10VAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.7885	.8708	52
SEX	0	Female	2.7083	.8587	24
SEX	1	Male	2.8571	.8909	28

Summaries of D10VAR1 - DEPRESSED MOOD
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	2.7083	.8587	16.9583	24
1	Male	2.8571	.8909	21.4286	28

Within Groups Total		2.7885	.8762	38.3869	52

Criterion Variable D10VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2862	1	.2862	.3727	.5443
Within Groups	38.3869	50	.7677		
Eta = .0860		Eta Squared = .0074			

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(9.1.1.3) Summaries of D14VAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.5769	.9149	52
SEX	0	Female	2.3333	.9168	24
SEX	1	Male	2.7857	.8759	28

Summaries of D14VAR1 - DEPRESSED MOOD
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	2.3333	.9168	19.3333	24	
1	Male	2.7857	.8759	20.7143	28	

Within Groups Total			2.5769	.8950	40.0476	52

Criterion Variable D14VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.6447	1	2.6447	3.3019	.0752
Within Groups	40.0476	50	.8010		
Eta = .2489		Eta Squared = .0619			

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(9.1.1.3) Summaries of D21VAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.2113	52
SEX	0	Female	2.1250	1.1910	24
SEX	1	Male	2.7143	1.1819	28

Summaries of D21VAR1 - DEPRESSED MOOD
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	2.1250	1.1910	32.6250	24	
1	Male	2.7143	1.1819	37.7143	28	
<hr/>						
Within Groups Total			2.4423	1.1861	70.3393	52

Criterion Variable D21VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.4876	1	4.4876	3.1900	.0802
Within Groups	70.3393	50	1.4068		
Eta = .2449		Eta Squared = .0600			

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(9.1.1.3) Summaries of D28VAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.2500	1.4535	52
SEX	0 Female	1.9583	1.4590	24
SEX	1 Male	2.5000	1.4272	28

Summaries of D28VAR1 - DEPRESSED MOOD
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.9583	1.4590	48.9583	24
1 Male	2.5000	1.4272	55.0000	28

Within Groups Total	2.2500	1.4419	103.9583	52

Criterion Variable D28VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.7917	1	3.7917	1.8236	.1830
Within Groups	103.9583	50	2.0792		
Eta = .1876 Eta Squared = .0352					

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(9.1.1.3) Summaries of D35VAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.0000	1.6088	52
SEX	0	Female	1.6250	1.5551	24
SEX	1	Male	2.3214	1.6114	28

Summaries of D35VAR1 - DEPRESSED MOOD
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.6250	1.5551	55.6250	24
1	Male	2.3214	1.6114	70.1071	28

Within Groups Total		2.0000	1.5858	125.7321	52

Criterion Variable D35VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	6.2679	1	6.2679	2.4925	.1207
Within Groups	125.7321	50	2.5146		
Eta = .2179		Eta Squared = .0475			

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(9.1.1.3) Summaries of D42VAR1 - DEPRESSED MOOD
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.9038	1.7065	52
SEX	0 Female	1.5833	1.6659	24
SEX	1 Male	2.1786	1.7225	28

Summaries of D42VAR1 - DEPRESSED MOOD
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.5833	1.6659	63.8333	24
1 Male	2.1786	1.7225	80.1071	28

Within Groups Total	1.9038	1.6967	143.9405	52

Criterion Variable D42VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.5788	1	4.5788	1.5905	.2131
Within Groups	143.9405	50	2.8788		
Eta = .1756 Eta Squared = .0308					

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```
( 9.1.1.3 ) manova
d0var1 d4var1 d7var1 d10var1 d14var1 d21var1 d28var1 d35var1 d42var1
by sex(0,1)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	325.77	50	6.52		
CONSTANT	3279.65	1	3279.65	503.36	.000
SEX	14.78	1	14.78	2.27	.138

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00018
Chi-square approx. = 405.37930 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .22861
Huynh-Feldt Epsilon = .24159
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

742

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(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME
 Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2) FCE 20124/706 i

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.08939	.52766	8.00	43.00	.829
Hotellings	.09817	.52766	8.00	43.00	.829
Wilks	.91061	.52766	8.00	43.00	.829
Roys	.08939				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME
 Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.59918	8.03492	8.00	43.00	.000
Hotellings	1.49487	8.03492	8.00	43.00	.000
Wilks	.40082	8.03492	8.00	43.00	.000
Roys	.59918				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	266.39	400	.67		
TIME	149.09	8	18.64	27.98	.000
SEX BY TIME	7.58	8	.95	1.42	.185

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(9.1.1.3) Summaries of DOVAR2 - INSOMNIA
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.6410	.3155	52
SEX	0	Female	1.6250	.3970	24
SEX	1	Male	1.6548	.2310	28

Summaries of DOVAR2 - INSOMNIA
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.6250	.3970	3.6250	24
1	Male	1.6548	.2310	1.4405	28

Within Groups Total		1.6410	.3183	5.0655	52

Criterion Variable DOVAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0114	1	.0114	.1130	.7382
Within Groups	5.0655	50	.1013		
Eta = .0475		Eta Squared = .0023			

744

217

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(9.1.1.3) Summaries of D4VAR2 - INSOMNIA
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.5192	.4497	52
SEX	0	Female	1.4583	.4695	24
SEX	1	Male	1.5714	.4337	28

Summaries of D4VAR2 - INSOMNIA
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	1.4583	.4695	5.0694	24	
1	Male	1.5714	.4337	5.0794	28	

Within Groups Total			1.5192	.4505	10.1488	52

Criterion Variable D4VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1653	1	.1653	.8143	.3712
Within Groups	10.1488	50	.2030		
Eta = .1266		Eta Squared = .0160			

745

218

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(9.1.1.3) Summaries of D7VAR2 - INSOMNIA
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.4038	.4493	52
SEX	0 Female	1.3472	.4110	24
SEX	1 Male	1.4524	.4819	28

Summaries of D7VAR2 - INSOMNIA
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.3472	.4110	3.8843	24
1 Male	1.4524	.4819	6.2698	28

Within Groups Total	1.4038	.4506	10.1541	52

Criterion Variable D7VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1429	1	.1429	.7037	.4055
Within Groups	10.1541	50	.2031		
Eta = .1178 Eta Squared = .0139					

746

219

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(9.1.1.3) Summaries of D10VAR2 - INSOMNIA
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.3205	.4475	52
SEX	0	Female	1.3056	.4275	24
SEX	1	Male	1.3333	.4714	28

Summaries of D10VAR2 - INSOMNIA
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	1.3056	.4275	4.2037	24	
1	Male	1.3333	.4714	6.0000	28	

Within Groups Total			1.3205	.4517	10.2037	52

Criterion Variable D10VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0100	1	.0100	.0489	.8260
Within Groups	10.2037	50	.2041		
Eta = .0312		Eta Squared = .0010			

747

220

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(9.1.1.3) Summaries of D14VAR2 - INSOMNIA
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.2244	.5228	52
SEX	0	Female	1.1667	.5108	24
SEX	1	Male	1.2738	.5371	28

Summaries of D14VAR2 - INSOMNIA
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	1.1667	.5108	6.0000	24	
1	Male	1.2738	.5371	7.7897	28	
<hr/>						
Within Groups Total			1.2244	.5252	13.7897	52

Criterion Variable D14VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1484	1	.1484	.5379	.4667
Within Groups	13.7897	50	.2758		
Eta = .1032		Eta Squared = .0106			

740

221

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(9.1.1.3) Summaries of D21VAR2 - INSOMNIA
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.2692	.6194	52
SEX	0 Female	1.2778	.6495	24
SEX	1 Male	1.2619	.6042	28

Summaries of D21VAR2 - INSOMNIA
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.2778	.6495	9.7037	24
1 Male	1.2619	.6042	9.8571	28

Within Groups Total	1.2692	.6255	19.5608	52

Criterion Variable D21VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0033	1	.0033	.0083	.9277
Within Groups	19.5608	50	.3912		
Eta = .0129 Eta Squared = .0002					

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(9.1.1.3) Summaries of D28VAR2 - INSOMNIA
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
SEX	0 Female	1.0972	.7053	24
SEX	1 Male	1.1548	.6572	28

Summaries of D28VAR2 - INSOMNIA
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.0972	.7053	11.4398	24
1 Male	1.1548	.6572	11.6627	28

Within Groups Total	1.1282	.6797	23.1025	52

Criterion Variable D28VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0428	1	.0428	.0926	.7622
Within Groups	23.1025	50	.4621		
Eta = .0430 Eta Squared = .0018					

750

223

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(9.1.1.3) Summaries of D35VAR2 - INSOMNIA
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.1410	.6965	52
SEX	0	Female	1.0556	.7268	24
SEX	1	Male	1.2143	.6741	28

Summaries of D35VAR2 - INSOMNIA
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.0556	.7268	12.1481	24
1	Male	1.2143	.6741	12.2698	28

Within Groups Total		1.1410	.6988	24.4180	52

Criterion Variable D35VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3256	1	.3256	.6667	.4181
Within Groups	24.4180	50	.4884		
Eta = .1147		Eta Squared = .0132			

751

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(9.1.1.3) Summaries of D42VAR2 - INSOMNIA
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.1154	.7167	52
SEX	0	Female	1.0694	.7676	24
SEX	1	Male	1.1548	.6818	28

Summaries of D42VAR2 - INSOMNIA
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	1.0694	.7676	13.5509	24	
1	Male	1.1548	.6818	12.5516	28	

Within Groups Total			1.1154	.7225	26.1025	52

Criterion Variable D42VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0941	1	.0941	.1802	.6730
Within Groups	26.1025	50	.5221		
Eta = .0599		Eta Squared = .0036			

752

225

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```
( 9.1.1.3 ) manova
d0var2 d4var2 d7var2 d10var2 d14var2 d21var2 d28var2 d35var2 d42var2
by sex(0,1)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	86.23	50	1.72		
CONSTANT	791.23	1	791.23	458.79	.000
SEX	.64	1	.64	.37	.545

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00233
Chi-square approx. = 285.56639 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .30689
Huynh-Feldt Epsilon = .33038
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

753

226

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(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.09985	.59625	8.00	43.00	.776
Hotellings	.11093	.59625	8.00	43.00	.776
Wilks	.90015	.59625	8.00	43.00	.776
Roys	.09985				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.48015	4.96451	8.00	43.00	.000
Hotellings	.92363	4.96451	8.00	43.00	.000
Wilks	.51985	4.96451	8.00	43.00	.000
Roys	.48015				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	56.32	400	.14		
TIME	14.06	8	1.76	12.48	.000
SEX BY TIME	.30	8	.04	.27	.976

754

227

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(9.1.1.3) Summaries of DOVAR3 - ACTIVITIES
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.7885	.6885	52
SEX	0	Female	2.8542	.6672	24
SEX	1	Male	2.7321	.7134	28

Summaries of DOVAR3 - ACTIVITIES
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	2.8542	.6672	10.2396	24
1	Male	2.7321	.7134	13.7411	28

Within Groups Total		2.7885	.6925	23.9807	52

Criterion Variable DOVAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1924	1	.1924	.4012	.5294
Within Groups	23.9807	50	.4796		
Eta = .0892		Eta Squared = .0080			

755

223

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(9.1.1.3) Summaries of D4VAR3 - ACTIVITIES
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.6442	.6812	52
SEX	0 Female	2.6875	.6886	24
SEX	1 Male	2.6071	.6853	28

Summaries of D4VAR3 - ACTIVITIES
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	2.6875	.6886	10.9063	24
1 Male	2.6071	.6853	12.6786	28

Within Groups Total	2.6442	.6868	23.5848	52

Criterion Variable D4VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0834	1	.0834	.1769	.6758
Within Groups	23.5848	50	.4717		
Eta = .0594 Eta Squared = .0035					

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(9.1.1.3) Summaries of D7VAR3 - ACTIVITIES
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4904	.6530	52
SEX	0	Female	2.5000	.7223	24
SEX	1	Male	2.4821	.6007	28

Summaries of D7VAR3 - ACTIVITIES
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	2.5000	.7223	12.0000	24
1	Male	2.4821	.6007	9.7411	28

Within Groups Total		2.4904	.6594	21.7411	52

Criterion Variable D7VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0041	1	.0041	.0095	.9228
Within Groups	21.7411	50	.4348		
Eta = .0138		Eta Squared = .0002			

757

230

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(9.1.1.3) Summaries of D10VAR3 - ACTIVITIES
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.3269	.6780	52
SEX	0	Female	2.2500	.7223	24
SEX	1	Male	2.3929	.6434	28

Summaries of D10VAR3 - ACTIVITIES
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	2.2500	.7223	12.0000	24	
1	Male	2.3929	.6434	11.1786	28	

Within Groups Total			2.3269	.6809	23.1786	52

Criterion Variable D10VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2637	1	.2637	.5689	.4542
Within Groups	23.1786	50	.4636		
Eta = .1061		Eta Squared = .0113			

758

271

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(9.1.1.3) Summaries of D14VAR3 - ACTIVITIES
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.0769	.7369	52
SEX	0 Female	2.0208	.9146	24
SEX	1 Male	2.1250	.5549	28

Summaries of D14VAR3 - ACTIVITIES
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	2.0208	.9146	19.2396	24
1 Male	2.1250	.5549	8.3125	28

Within Groups Total	2.0769	.7423	27.5521	52

Criterion Variable D14VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1402	1	.1402	.2545	.6162
Within Groups	27.5521	50	.5510		
Eta = .0712		Eta Squared = .0051			

759

250

FCE 20124/706 i

(9.1.1.3) Summaries of D21VAR3 - ACTIVITIES
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.9712	.8879	52
SEX	0	Female	1.9167	1.0495	24
SEX	1	Male	2.0179	.7389	28

Summaries of D21VAR3 - ACTIVITIES
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.9167	1.0495	25.3333	24
1	Male	2.0179	.7389	14.7411	28

Within Groups Total		1.9712	.8953	40.0744	52

Criterion Variable D21VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1323	1	.1323	.1651	.6862
Within Groups	40.0744	50	.8015		
Eta = .0574		Eta Squared = .0033			

760

255

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(9.1.1.3) Summaries of D28VAR3 - ACTIVITIES
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.7019	1.0948	52
SEX	0	Female	1.5833	1.2910	24
SEX	1	Male	1.8036	.9061	28

Summaries of D28VAR3 - ACTIVITIES
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.5833	1.2910	38.3333	24
1	Male	1.8036	.9061	22.1696	28

Within Groups Total		1.7019	1.1000	60.5030	52

Criterion Variable D28VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.6268	1	.6268	.5180	.4750
Within Groups	60.5030	50	1.2101		
Eta = .1013		Eta Squared = .0103			

761

274

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(9.1.1.3) Summaries of D35VAR3 - ACTIVITIES
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.5577	1.1701	52
SEX	0	Female	1.5208	1.3145	24
SEX	1	Male	1.5893	1.0546	28

Summaries of D35VAR3 - ACTIVITIES
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.5208	1.3145	39.7396	24
1	Male	1.5893	1.0546	30.0268	28

Within Groups Total		1.5577	1.1812	69.7664	52

Criterion Variable D35VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0606	1	.0606	.0434	.8358
Within Groups	69.7664	50	1.3953		
Eta = .0294		Eta Squared = .0009			

762

235

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(9.1.1.3) Summaries of D42VAR3 - ACTIVITIES
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.5096	1.2776	52
SEX	0 Female	1.5208	1.3947	24
SEX	1 Male	1.5000	1.1941	28

Summaries of D42VAR3 - ACTIVITIES
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.5208	1.3947	44.7396	24
1 Male	1.5000	1.1941	38.5000	28

Within Groups Total	1.5096	1.2903	83.2396	52

Criterion Variable D42VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0056	1	.0056	.0034	.9539
Within Groups	83.2396	50	1.6648		
Eta = .0082		Eta Squared = .0001			

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```
( 9.1.1.3 ) manova
d0var3 d4var3 d7var3 d10var3 d14var3 d21var3 d28var3 d35var3 d42var3
by sex(0,1)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	221.78	50	4.44		
CONSTANT	2084.82	1	2084.82	470.03	.000
SEX	.22	1	.22	.05	.823

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

Mauchly sphericity test, W = .00002
Chi-square approx. = 514.51152 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .18203
Huynh-Feldt Epsilon = .18984
Lower-bound Epsilon = .12500

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

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(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.18216	1.19722	8.00	43.00	.323
Hotellings	.22274	1.19722	8.00	43.00	.323
Wilks	.81784	1.19722	8.00	43.00	.323
Roys	.18216				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.53860	6.27427	8.00	43.00	.000
Hotellings	1.16731	6.27427	8.00	43.00	.000
Wilks	.46140	6.27427	8.00	43.00	.000
Roys	.53860				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	151.84	400	.38		
TIME	93.44	8	11.68	30.77	.000
SEX BY TIME	1.28	8	.16	.42	.907

FCE 20124/706 i

(9.1.1.3) Summaries of DOVAR4 - ANXIETY
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		2.2308	.6528	52
SEX	0 Female	2.1667	.6539	24
SEX	1 Male	2.2857	.6587	28

Summaries of DOVAR4 - ANXIETY
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	2.1667	.6539	9.8333	24
1 Male	2.2857	.6587	11.7143	28
Within Groups Total	2.2308	.6565	21.5476	52

Criterion Variable DOVAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1832	1	.1832	.4250	.5174
Within Groups	21.5476	50	.4310		
Eta = .0918		Eta Squared = .0084			

766

239

FCE 20124/706 i

(9.1.1.3) Summaries of D4VAR4 - ANXIETY
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.1154	.6464	52
SEX	0	Female	2.1667	.6370	24
SEX	1	Male	2.0714	.6627	28

Summaries of D4VAR4 - ANXIETY
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	2.1667	.6370	9.3333	24
1	Male	2.0714	.6627	11.8571	28

Within Groups Total		2.1154	.6510	21.1905	52

Criterion Variable D4VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1172	1	.1172	.2766	.6013
Within Groups	21.1905	50	.4238		
Eta = .0742		Eta Squared = .0055			

767

240

FCE 20124/706 i

(9.1.1.3) Summaries of D7VAR4 - ANXIETY
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.9423	.6977	52
SEX	0	Female	1.9375	.7418	24
SEX	1	Male	1.9464	.6714	28

Summaries of D7VAR4 - ANXIETY
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.9375	.7418	12.6563	24
1	Male	1.9464	.6714	12.1696	28

Within Groups Total		1.9423	.7046	24.8259	52

Criterion Variable D7VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0010	1	.0010	.0021	.9638
Within Groups	24.8259	50	.4965		
Eta = .0064		Eta Squared = .0000			

768

241

FCE 20124/706 i

(9.1.1.3) Summaries of D10VAR4 - ANXIETY
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.8750	.6013	52
SEX	0 Female	1.8750	.6635	24
SEX	1 Male	1.8750	.5549	28

Summaries of D10VAR4 - ANXIETY
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.8750	.6635	10.1250	24
1 Male	1.8750	.5549	8.3125	28

Within Groups Total	1.8750	.6072	18.4375	52

Criterion Variable D10VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0000	1	.0000	.0000	1.0000
Within Groups	18.4375	50	.3688		
Eta = .0000		Eta Squared = .0000			

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(9.1.1.3) Summaries of D14VAR4 - ANXIETY
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.6731	.6331	52
SEX	0 Female	1.6250	.6635	24
SEX	1 Male	1.7143	.6151	28

Summaries of D14VAR4 - ANXIETY
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.6250	.6635	10.1250	24
1 Male	1.7143	.6151	10.2143	28
Within Groups Total	1.6731	.6378	20.3393	52

Criterion Variable D14VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1030	1	.1030	.2533	.6170
Within Groups	20.3393	50	.4068		
Eta = .0710		Eta Squared = .0050			

770

247

FCE 20124/706 i

(9.1.1.3) Summaries of D21VAR4 - ANXIETY
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.7885	.7881	52
SEX	0	Female	1.7917	.7929	24
SEX	1	Male	1.7857	.7985	28

Summaries of D21VAR4 - ANXIETY
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.7917	.7929	14.4583	24
1	Male	1.7857	.7985	17.2143	28
<hr/>					
Within Groups Total		1.7885	.7959	31.6726	52

Criterion Variable D21VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0005	1	.0005	.0007	.9787
Within Groups	31.6726	50	.6335		
Eta = .0038		Eta Squared = .0000			

771

244

FCE 20124/706 i

(9.1.1.3) Summaries of D28VAR4 - ANXIETY
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.7212	.8249	52
SEX	0 Female	1.7292	.8467	24
SEX	1 Male	1.7143	.8213	28

Summaries of D28VAR4 - ANXIETY
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.7292	.8467	16.4896	24
1 Male	1.7143	.8213	18.2143	28

Within Groups Total	1.7212	.8331	34.7039	52

Criterion Variable D28VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0029	1	.0029	.0041	.9491
Within Groups	34.7039	50	.6941		
Eta = .0091		Eta Squared = .0001			

772

245

FCE 20124/706 i

(9.1.1.3) Summaries of D35VAR4 - ANXIETY
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.6442	.8875	52
SEX	0 Female	1.6250	.8999	24
SEX	1 Male	1.6607	.8929	28

Summaries of D35VAR4 - ANXIETY
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.6250	.8999	18.6250	24
1 Male	1.6607	.8929	21.5268	28

Within Groups Total	1.6442	.8961	40.1518	52

Criterion Variable D35VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0165	1	.0165	.0205	.8867
Within Groups	40.1518	50	.8030		
Eta = .0203 Eta Squared = .0004					

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(9.1.1.3) Summaries of D42VAR4 - ANXIETY
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.6154	.8890	52
SEX	0 Female	1.5417	.9771	24
SEX	1 Male	1.6786	.8189	28

Summaries of D42VAR4 - ANXIETY
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.5417	.9771	21.9583	24
1 Male	1.6786	.8189	18.1071	28

Within Groups Total	1.6154	.8952	40.0655	52

Criterion Variable D42VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2422	1	.2422	.3023	.5849
Within Groups	40.0655	50	.8013		
Eta = .0775		Eta Squared = .0060			

774

247

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var4 d4var4 d7var4 d10var4 d14var4 d21var4 d28var4 d35var4 d42var4
by sex(0,1)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
Source of Variation      SS      DF      MS      F      Sig of F

WITHIN CELLS             147.63     50      2.95
CONSTANT                 1581.80      1    1581.80    535.72    .000
SEX                      .11        1      .11        .04    .849
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00128
Chi-square approx. = 313.86065 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .27086
Huynh-Feldt Epsilon = .29923
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to
univariate or split-plot or mixed-model approach to repeated measures.
Epsilons may be used to adjust d.f. for the AVERAGED results.
```

775

298

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.11062	.66854	8.00	43.00	.716
Hotellings	.12438	.66854	8.00	43.00	.716
Wilks	.89938	.66854	8.00	43.00	.716
Roys	.11062				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.50868	5.56503	8.00	43.00	.000
Hotellings	1.03535	5.56503	8.00	43.00	.000
Wilks	.49132	5.56503	8.00	43.00	.000
Roys	.50868				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	105.30	400	.26		
TIME	19.43	8	2.43	9.23	.000
SEX BY TIME	.56	8	.07	.27	.977

776

249

FCE 20124/706 i

(9.1.1.3) Summaries of DOVAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		1.8942	.3513	52
SEX	0 Female	1.9896	.3495	24
SEX	1 Male	1.8125	.3376	28

Summaries of DOVAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.9896	.3495	2.8099	24
1 Male	1.8125	.3376	3.0781	28

Within Groups Total	1.8942	.3432	5.8880	52

Criterion Variable DOVAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.4052	1	.4052	3.4413	.0695
Within Groups	5.8880	50	.1178		
Eta = .2538		Eta Squared = .0644			

???

???

FCE 20124/706 i

(9.1.1.3) Summaries of D4VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.7981	.4202	52
SEX	0	Female	1.8438	.4652	24
SEX	1	Male	1.7589	.3818	28

Summaries of D4VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.8438	.4652	4.9766	24
1	Male	1.7589	.3818	3.9353	28

Within Groups Total		1.7981	.4222	8.9118	52

Criterion Variable D4VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0930	1	.0930	.5217	.4735
Within Groups	8.9118	50	.1782		
Eta = .1016		Eta Squared = .0103			

778

201

FCE 20124/706 i

(9.1.1.3) Summaries of D7VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.7019	.3804	52
SEX	0	Female	1.7708	.4099	24
SEX	1	Male	1.6429	.3498	28

Summaries of D7VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.7708	.4099	3.8646	24
1	Male	1.6429	.3498	3.3036	28

Within Groups Total		1.7019	.3786	7.1682	52

Criterion Variable D7VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2117	1	.2117	1.4763	.2301
Within Groups	7.1682	50	.1434		
Eta = .1694		Eta Squared = .0287			

779

252

FCE 20124/706 i

(9.1.1.3) Summaries of D10VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.6683	.4251	52
SEX	0 Female	1.7188	.5017	24
SEX	1 Male	1.6250	.3503	28

Summaries of D10VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.7188	.5017	5.7891	24
1 Male	1.6250	.3503	3.3125	28

Within Groups Total	1.6683	.4267	9.1016	52

Criterion Variable D10VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1136	1	.1136	.6240	.4333
Within Groups	9.1016	50	.1820		
Eta = .1110		Eta Squared = .0123			

786

257

FCE 20124/706 i

(9.1.1.3) Summaries of D14VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.4375	.5283	52
SEX	0	Female	1.4375	.5863	24
SEX	1	Male	1.4375	.4841	28

Summaries of D14VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.4375	.5863	7.9063	24
1	Male	1.4375	.4841	6.3281	28

Within Groups Total		1.4375	.5336	14.2344	52

Criterion Variable D14VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0000	1	.0000	.0000	1.0000
Within Groups	14.2344	50	.2847		
Eta = .0000		Eta Squared = .0000			

781

254

FCE 20124/706 i

(9.1.1.3) Summaries of D21VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.3942	.6111	52
SEX	0 Female	1.4063	.5981	24
SEX	1 Male	1.3839	.6328	28

Summaries of D21VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	1.4063	.5981	8.2266	24
1 Male	1.3839	.6328	10.8103	28

Within Groups Total	1.3942	.6170	19.0368	52

Criterion Variable D21VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0064	1	.0064	.0169	.8971
Within Groups	19.0368	50	.3807		
Eta = .0184 Eta Squared = .0003					

782

255

FCE 20124/706 i

(9.1.1.3) Summaries of D28VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.2644	.7061	52
SEX	0	Female	1.2500	.7033	24
SEX	1	Male	1.2768	.7212	28

Summaries of D28VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	1.2500	.7033	11.3750	24	
1	Male	1.2768	.7212	14.0424	28	

Within Groups Total			1.2644	.7130	25.4174	52

Criterion Variable D28VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0093	1	.0093	.0182	.8931
Within Groups	25.4174	50	.5083		
Eta = .0191		Eta Squared = .0004			

763

250

FCE 20124/706 i

(9.1.1.3) Summaries of D35VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.2308	.7603	52
SEX	0	Female	1.1563	.7795	24
SEX	1	Male	1.2946	.7517	28

Summaries of D35VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.1563	.7795	13.9766	24
1	Male	1.2946	.7517	15.2567	28

Within Groups Total		1.2308	.7646	29.2333	52

Criterion Variable D35VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2475	1	.2475	.4233	.5180
Within Groups	29.2333	50	.5847		
Eta = .0916		Eta Squared = .0084			

784

257

FCE 20124/706 i

(9.1.1.3) Summaries of D42VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.2115	.7958	52
SEX	0	Female	1.1771	.8058	24
SEX	1	Male	1.2411	.8007	28

Summaries of D42VAR5 - SOMATIC SYMPTOMS
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	1.1771	.8058	14.9349	24
1	Male	1.2411	.8007	17.3103	28

Within Groups Total		1.2115	.8031	32.2452	52

Criterion Variable D42VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0529	1	.0529	.0820	.7757
Within Groups	32.2452	50	.6449		
Eta = .0405		Eta Squared = .0016			

785

250

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var5 d4var5 d7var5 d10var5 d14var5 d21var5 d28var5 d35var5 d42var5
by sex(0,1)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	90.85	50	1.82		
CONSTANT	1064.15	1	1064.15	585.65	.000
SEX	.11	1	.11	.06	.807

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00007
Chi-square approx. = 448.89658 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .21559
Huynh-Feldt Epsilon = .22704
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

786

258

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.20326	1.37124	8.00	43.00	.236
Hotellings	.25511	1.37124	8.00	43.00	.236
Wilks	.79674	1.37124	8.00	43.00	.236
Roys	.20326				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.52161	5.86060	8.00	43.00	.000
Hotellings	1.09034	5.86060	8.00	43.00	.000
Wilks	.47839	5.86060	8.00	43.00	.000
Roys	.52161				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	60.38	400	.15		
TIME	28.61	9	3.18	23.69	.000
SEX BY TIME	1.03	8	.13	.85	.557

787

260

FCE 20124/706 i

(9.1.1.3) Summaries of DOVAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5769	.4989	52
COUNTRY	1.00	Canada	3.8750	.3536	8
COUNTRY	2.00	Brazil	3.5227	.5053	44

Summaries of DOVAR1 - DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.8750	.3536	.8750	8
2.00	Brazil	3.5227	.5053	10.9773	44
<hr/>					
Within Groups Total		3.5769	.4869	11.8523	52

Criterion Variable DOVAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.8400	1	.8400	3.5438	.0656
Within Groups	11.8523	50	.2370		
Eta = .2573 Eta Squared = .0662					

FCE 20124/706 i

(9.1.1.3) Summaries of D4VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.3654	.6271	52
COUNTRY	1.00	Canada	3.0000	.9258	8
COUNTRY	2.00	Brazil	3.4318	.5455	44

Summaries of D4VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.0000	.9258	6.0000	8
2.00	Brazil	3.4318	.5455	12.7955	44

Within Groups Total		3.3654	.6131	18.7955	52

Criterion Variable D4VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.2622	1	1.2622	3.3578	.0728
Within Groups	12.7955	50	.3759		
Eta = .2509		Eta Squared = .0629			

783

202

FCE 20124/706 i

(9.1.1.3) Summaries of D7VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.1154	.8553	52
COUNTRY	1.00	Canada	3.0000	1.8516	8
COUNTRY	2.00	Brazil	3.1364	.5537	44

Summaries of D7VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.0000	1.8516	24.0000	8
2.00	Brazil	3.1364	.5537	13.1818	44

Within Groups Total		3.1154	.8623	37.1818	52

Criterion Variable D7VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1259	1	.1259	.1693	.6825
Within Groups	37.1818	50	.7436		
Eta = .0581		Eta Squared = .0034			

796

267

FCE 20124/706 i

(9.1.1.3) Summaries of D10VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.7885	.8708	52
COUNTRY	1.00	Canada	2.8750	1.8077	8
COUNTRY	2.00	Brazil	2.7727	.6048	44

Summaries of D10VAR1- DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Cum of Sq	Cases
1.00	Canada	2.8750	1.8077	22.8750	8
2.00	Brazil	2.7727	.6048	15.7273	44

Within Groups Total		2.7885	.8787	38.6023	52

Criterion Variable D10VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0708	1	.0708	.0917	.7633
Within Groups	38.6023	50	.7720		
Eta = .0428		Eta Squared = .0018			

791

264

FCE 20124/706 i

(9.1.1.3) Summaries of D14VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.5769	.9149	52
COUNTRY	1.00	Canada	3.3750	1.4079	8
COUNTRY	2.00	Brazil	2.4318	.7281	44

Summaries of D14VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.3750	1.4079	13.8750	8
2.00	Brazil	2.4318	.7281	22.7955	44

Within Groups Total		2.5769	.8564	36.6705	52

Criterion Variable D14VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	6.0219	1	6.0219	8.2108	.0061
Within Groups	36.6705	50	.7334		
Eta = .3756		Eta Squared = .1411			

792

265

PCE 20124/706 i

(9.1.1.3) Summaries of D21VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.2113	52
COUNTRY	1.00	Canada	3.0000	1.4142	8
COUNTRY	2.00	Brazil	2.3409	1.1603	44

Summaries of D21VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.0000	1.4142	14.0000	8
2.00	Brazil	2.3409	1.1603	57.8864	44

Within Groups Total		2.4423	1.1991	71.8864	52

Criterion Variable D21VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.9406	1	2.9406	2.0453	.1589
Within Groups	71.8864	50	1.4377		
Eta = .1982		Eta Squared = .0393			

793

266

FCE 20124/706 i

(9.1.1.3) Summaries of D28VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.2500	1.4535	52
COUNTRY	1.00	Canada	3.1250	1.3562	8
COUNTRY	2.00	Brazil	2.0909	1.4276	44

Summaries of D28VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.1250	1.3562	12.8750	8
2.00	Brazil	2.0909	1.4276	87.6364	44

Within Groups Total		2.2500	1.4178	100.5114	52

Criterion Variable D28VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	7.2386	1	7.2386	3.6009	.0635
Within Groups	100.5114	50	2.0102		

Eta = .2592 Eta Squared = .0672

794

267

FCE 20124/706 i

(9.1.1.3) Summaries of D35VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.0000	1.6088	52
COUNTRY	1.00	Canada	3.0000	1.6036	8
COUNTRY	2.00	Brazil	1.8182	1.5593	44

Summaries of D35VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.0000	1.6036	18.0000	8
2.00	Brazil	1.8182	1.5593	104.5455	44

Within Groups Total		2.0000	1.5655	122.5455	52

Criterion Variable D35VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	9.4545	1	9.4545	3.8576	.0551
Within Groups	122.5455	50	2.4509		
Eta = .2676		Eta Squared = .0716			

795

263

FCE 20124/706 i

(9.1.1.3) Summaries of D42VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.9038	1.7065	52
COUNTRY	1.00	Canada	2.8750	1.6421	8
COUNTRY	2.00	Brazil	1.7273	1.6756	44

Summaries of D42VAR1 - DEPRESSED MOOD
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	2.8750	1.6421	18.8750	8	
2.00	Brazil	1.7273	1.6756	120.7273	44	

Within Groups Total			1.9038	1.6709	139.6023	52

Criterion Variable D42VAR1 - DEPRESSED MOOD

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	8.9170	1	8.9170	3.1937	.0800
Within Groups	139.6023	50	2.7920		
Eta = .2450		Eta Squared = .0600			

786

209

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var1 d4var1 d7var1 d10var1 d14var1 d21var1 d28var1 d35var1 d42var1
by country(1,2)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	322.84	50	6.46		
CONSTANT	1986.94	1	1986.94	307.72	.000
COUNTRY	17.71	1	17.71	2.74	.104

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00017
Chi-square approx. = 409.61086 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .22830
Huynh-Feldt Epsilon = .24124
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

797

270

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.41674	3.84052	8.00	43.00	.002
Hotellings	.71452	3.84052	8.00	43.00	.002
Wilks	.58326	3.84052	8.00	43.00	.002
Roys	.41674				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.49128	5.19073	8.00	43.00	.000
Hotellings	.96572	5.19073	8.00	43.00	.000
Wilks	.50872	5.19073	8.00	43.00	.000
Roys	.49128				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	254.80	400	.64		
TIME	40.39	8	5.05	7.93	.000
COUNTRY BY TIME	19.16	8	2.40	3.76	.000

706

271

FCE 20124/706 i

(9.1.1.3) Summaries of DOVAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.6410	.3155	52
COUNTRY	1.00	Canada	1.7083	.3753	8
COUNTRY	2.00	Brazil	1.6288	.3068	44

Summaries of DOVAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.7083	.3753	.9861	8
2.00	Brazil	1.6288	.3068	4.0480	44

Within Groups Total		1.6410	.3173	5.0341	52

Criterion Variable DOVAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0428	1	.0428	.4254	.5172
Within Groups	5.0341	50	.1007		
Eta = .0919		Eta Squared = .0084			

799

272

FCE 20124/706 i

(9.1.1.3) Summaries of D4VAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.5192	.4497	52
COUNTRY	1.00	Canada	1.2500	.7507	8
COUNTRY	2.00	Brazil	1.5682	.3636	44

Summaries of D4VAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.2500	.7507	3.9444	8
2.00	Brazil	1.5682	.3636	5.6843	44

Within Groups Total		1.5192	.4388	9.6288	52

Criterion Variable D4VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.6853	1	.6853	3.5587	.0650
Within Groups	9.6288	50	.1926		
Eta = .2578		Eta Squared = .0664			

800

273

FCE 20124/706 i

(9.1.1.3) Summaries of D7VAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.4038	.4493	52
COUNTRY	1.00	Canada	1.2083	.7546	8
COUNTRY	2.00	Brazil	1.4394	.3720	44

Summaries of D7VAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.2083	.7546	3.9861	8
2.00	Brazil	1.4394	.3720	5.9495	44

Within Groups Total		1.4038	.4458	9.9356	52

Criterion Variable D7VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3614	1	.3614	1.8187	.1835
Within Groups	9.9356	50	.1987		
Eta = .1873		Eta Squared = .0351			

801

274

FCE 20124/706 i

(9.1.1.3) Summaries of D10VAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.3205	.4475	52
COUNTRY	1.00	Canada	1.2083	.7546	8
COUNTRY	2.00	Brazil	1.3409	.3769	44

Summaries of D10VAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	1.2083	.7546	3.9861	8	
2.00	Brazil	1.3409	.3769	6.1086	44	

Within Groups Total			1.3205	.4493	10.0947	52

Criterion Variable D10VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1190	1	.1190	.5893	.4463
Within Groups	10.0947	50	.2019		
Eta = .1079		Eta Squared = .0116			

802

275

FCE 20124/706 i

(9.1.1.3) Summaries of D14VAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.2244	.5228	52
COUNTRY	1.00	Canada	1.1250	.7546	8
COUNTRY	2.00	Brazil	1.2424	.4788	44

Summaries of D14VAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.1250	.7546	3.9861	8
2.00	Brazil	1.2424	.4788	9.8586	44

Within Groups Total		1.2244	.5262	13.8447	52

Criterion Variable D14VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0933	1	.0933	.3371	.5641
Within Groups	13.8447	50	.2769		
Eta = .0818		Eta Squared = .0067			

803

276

FCE 20124/706 i

(9.1.1.3) Summaries of D21VAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.2692	.6194	52
COUNTRY	1.00	Canada	1.3333	.7346	8
COUNTRY	2.00	Brazil	1.2576	.6052	44

Summaries of D21VAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.3333	.7346	3.7778	8
2.00	Brazil	1.2576	.6052	15.7475	44

Within Groups Total		1.2692	.6249	19.5253	52

Criterion Variable D21VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0389	1	.0389	.0995	.7538
Within Groups	19.5253	50	.3905		
Eta = .0446		Eta Squared = .0020			

804

277

FCE 20124/706 i

(9.1.1.3) Summaries of D28VAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.1282	.6737	52
COUNTRY	1.00	Canada	1.0000	.7766	8
COUNTRY	2.00	Brazil	1.1515	.6606	44

Summaries of D28VAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.0000	.7766	4.2222	8
2.00	Brazil	1.1515	.6606	18.7677	44

Within Groups Total		1.1282	.6781	22.9899	52

Criterion Variable D28VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1554	1	.1554	.3380	.5636
Within Groups	22.9899	50	.4598		
Eta = .0919		Eta Squared = .0067			

805

270

FCE 20124/706 i

(9.1.1.3) Summaries of D35VAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.1410	.6965	52
COUNTRY	1.00	Canada	1.1250	.7956	8
COUNTRY	2.00	Brazil	1.1439	.6873	44

Summaries of D35VAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.1250	.7956	4.4306	8
2.00	Brazil	1.1439	.6873	20.3106	44

Within Groups Total		1.1410	.7034	24.7412	52

Criterion Variable D35VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0024	1	.0024	.0049	.9444
Within Groups	24.7412	50	.4948		
Eta = .0099		Eta Squared = .0001			

806

279

FCE 20124/706 i

(9.1.1.3) Summaries of D42VAR2 - INSOMNIA
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.1154	.7167	52
COUNTRY	1.00	Canada	1.0833	.7715	8
COUNTRY	2.00	Brazil	1.1212	.7156	44

Summaries of D42VAR2 - INSOMNIA
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.0833	.7715	4.1667	8
2.00	Brazil	1.1212	.7156	22.0202	44

Within Groups Total		1.1154	.7237	26.1869	52

Criterion Variable D42VAR2 - INSOMNIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0097	1	.0097	.0185	.8922
Within Groups	26.1869	50	.5237		
Eta = .0193		Eta Squared = .0004			

807

266

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var2 d4var2 d7var2 d10var2 d14var2 d21var2 d28var2 d35var2 d42var2
by country(1,2)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
Source of Variation      SS      DF      MS      F      Sig of F

WITHIN CELLS             86.33     50      1.73
CONSTANT                 395.66      1     395.66    229.16    .000
COUNTRY                   .55        1      .55        .32    .576
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00213
Chi-square approx. = 289.88432 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .30320
Huynh-Feldt Epsilon = .32615
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

000

001

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.25261	1.81670	8.00	43.00	.100
Hotellings	.33799	1.81670	8.00	43.00	.100
Wilks	.74739	1.81670	8.00	43.00	.100
Roys	.25261				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.50525	5.48905	8.00	43.00	.000
Hotellings	1.02122	5.48905	8.00	43.00	.000
Wilks	.49475	5.48905	8.00	43.00	.000
Roys	.50525				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	55.65	400	.14		
TIME	7.40	8	.92	6.65	.000
COUNTRY BY TIME	.96	8	.12	.86	.547

809

232

FCE 20124/706 i

(9.1.1.3) Summaries of DOVAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.7885	.6885	52
COUNTRY	1.00	Canada	1.9375	.3204	8
COUNTRY	2.00	Brazil	2.9432	.6215	44

Summaries of DOVAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.9375	.3204	.7188	8
2.00	Brazil	2.9432	.6215	16.6080	44

Within Groups Total		2.7885	.5887	17.3267	52

Criterion Variable DOVAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	6.8464	1	6.8464	19.7567	.0000
Within Groups	17.3267	50	.3465		
Eta = .5322		Eta Squared = .2832			

810

265

FCE 20124/706 i

(9.1.1.3) Summaries of D4VAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.6442	.6812	52
COUNTRY	1.00	Canada	1.8750	.2315	8
COUNTRY	2.00	Brazil	2.7841	.6416	44

Summaries of D4VAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.8750	.2315	.3750	8
2.00	Brazil	2.7841	.6416	17.6989	44
Within Groups Total		2.6442	.6012	18.0739	52

Criterion Variable D4VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	5.5944	1	5.5944	15.4765	.0003
Within Groups	18.0739	50	.3615		
Eta = .4862		Eta Squared = .2364			

FCE 20124/706 i

(9.1.1.3) Summaries of D7VAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.4904	.6530	52
COUNTRY	1.00	Canada	1.9375	.8210	8
COUNTRY	2.00	Brazil	2.5909	.5734	44

Summaries of D7VAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.9375	.8210	4.7188	8
2.00	Brazil	2.5909	.5734	14.1364	44

Within Groups Total		2.4904	.6141	18.8551	52

Criterion Variable D7VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.8901	1	2.8901	7.6639	.0079
Within Groups	18.8551	50	.3771		
Eta = .3646		Eta Squared = .1329			

812

285

FCE 20124/706 i

(9.1.1.3) Summaries of D10VAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.3269	.6780	52
COUNTRY	1.00	Canada	1.9375	.8210	8
COUNTRY	2.00	Brazil	2.3977	.6341	44

Summaries of D10VAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.9375	.8210	4.7188	8
2.00	Brazil	2.3977	.6341	17.2898	44

Within Groups Total		2.3269	.6635	22.0085	52

Criterion Variable D10VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.4338	1	1.4338	3.2573	.0771
Within Groups	22.0085	50	.4402		
Eta = .2473		Eta Squared = .0612			

813

200

FCE 20124/706 i

(9.1.1.3) Summaries of D14VAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.0769	.7369	52
COUNTRY	1.00	Canada	1.7500	.8452	8
COUNTRY	2.00	Brazil	2.1364	.7101	44

Summaries of D14VAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	1.7500	.8452	5.0000	8	
2.00	Brazil	2.1364	.7101	21.6818	44	

Within Groups Total			2.0769	.7305	26.6818	52

Criterion Variable D14VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.0105	1	1.0105	1.9936	.1749
Within Groups	26.6818	50	.5336		
Eta = .1910		Eta Squared = .0365			

FCE 20124/706 i

(9.1.1.3) Summaries of D21VAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.9712	.8879	52
COUNTRY	1.00	Canada	1.7500	.8452	8
COUNTRY	2.00	Brazil	2.0114	.8989	44

Summaries of D21VAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.7500	.8452	5.0000	8
2.00	Brazil	2.0114	.8989	34.7443	44
<hr/>					
Within Groups Total		1.9712	.8916	39.7443	52

Criterion Variable D21VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.4624	1	.4624	.5817	.4492
Within Groups	39.7443	50	.7949		
Eta = .1072		Eta Squared = .0115			

815

235

FCE 20124/706 i

(9.1.1.3) Summaries of D28VAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.7019	1.0948	52
COUNTRY	1.00	Canada	1.5625	.9425	8
COUNTRY	2.00	Brazil	1.7273	1.1282	44

Summaries of D28VAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.5625	.9425	6.2188	8
2.00	Brazil	1.7273	1.1282	54.7273	44

Within Groups Total		1.7019	1.1040	60.9460	52

Criterion Variable D28VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1838	1	.1838	.1508	.6994
Within Groups	60.9460	50	1.2189		
Eta = .0548		Eta Squared = .0030			

816

209

FCE 20124/706 i

(9.1.1.3) Summaries of D35VAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.5577	1.1701	52
COUNTRY	1.00	Canada	1.5000	.9258	8
COUNTRY	2.00	Brazil	1.5682	1.2180	44

Summaries of D35VAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.5000	.9258	6.0000	8
2.00	Brazil	1.5682	1.2180	63.7955	44

Within Groups Total		1.5577	1.1815	69.7955	52

Criterion Variable D35VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0015	1	.0015	.0225	.8813
Within Groups	69.7955	50	1.3959		
Eta = .0212		Eta Squared = .0005			

817

290

FCE 20124/706 i

{ 9.1.1.3) Summaries of D42VAR3 - ACTIVITIES
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.5096	1.2776	52
COUNTRY	1.00	Canada	1.5000	.9258	8
COUNTRY	2.00	Brazil	1.5114	1.3403	44

Summaries of D42VAR3 - ACTIVITIES
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.5000	.9258	6.0000	8
2.00	Brazil	1.5114	1.3403	77.2443	44

Within Groups Total		1.5096	1.2903	83.2443	52

Criterion Variable D42VAR3 - ACTIVITIES

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0009	1	.0009	.0005	.9818
Within Groups	83.2443	50	1.6649		
Eta = .0032		Eta Squared = .0000			

818

291

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```
( 9.1.1.3 ) manova
d0var3 d4var3 d7var3 d10var3 d14var3 d21var3 d28var3 d35var3 d42var3
by country(1,2)
/wsactors=time (9)
/wdesign=time
/design.
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52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	210.44	50	4.21		
CONSTANT	943.64	1	943.64	224.20	.000
COUNTRY	11.56	1	11.56	2.75	.104

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00003
Chi-square approx. = 497.05791 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .18640
Huynh-Feldt Epsilon = .19466
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

819

202

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.12352	.75746	8.00	43.00	.641
Hotellings	.14092	.75746	8.00	43.00	.641
Wilks	.87648	.75746	8.00	43.00	.641
Roys	.12352				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.27437	2.03231	8.00	43.00	.065
Hotellings	.37911	2.03231	8.00	43.00	.065
Wilks	.72563	2.03231	8.00	43.00	.065
Roys	.27437				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares					
Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	146.23	400	.37		
TIME	20.97	8	2.62	9.22	.000
CCOUNTRY BY TIME	6.89	8	.86	2.36	.017

820

293

FCE 20124/706 i

(9.1.1.3) Summaries of DOVAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.2308	.6528	52
COUNTRY	1.00	Canada	2.1250	.6944	8
COUNTRY	2.00	Brazil	2.2500	.6515	44

Summaries of DOVAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	2.1250	.6944	3.3750	8
2.00	Brazil	2.2500	.6515	18.2500	44

Within Groups Total		2.2308	.6576	21.6250	52

Criterion Variable DOVAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1058	1	.1058	.2446	.6231
Within Groups	21.6250	50	.4325		
Eta = .0698		Eta Squared = .0049			

821

294

FCE 20124/706 i

(9.1.1.3) Summaries of D4VAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.1154	.6464	52
COUNTRY	1.00	Canada	1.6250	.5825	8
COUNTRY	2.00	Brazil	2.2045	.6224	44

Summaries of D4VAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.6250	.5825	2.3750	8
2.00	Brazil	2.2045	.6224	16.6591	44

Within Groups Total		2.1154	.6170	19.0341	52

Criterion Variable D4VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.2736	1	2.2736	5.9724	.0181
Within Groups	19.0341	50	.3807		
Eta = .3267		Eta Squared = .1067			

822

295

FCE 20124/706 i

(9.1.1.3) Summaries of D7VAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.9423	.6977	52
COUNTRY	1.00	Canada	1.8125	1.1319	8
COUNTRY	2.00	Brazil	1.9659	.6042	44

Summaries of D7VAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.8125	1.1319	8.9688	8
2.00	Brazil	1.9659	.6042	15.6989	44

Within Groups Total		1.9423	.7024	24.6676	52

Criterion Variable D7VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1593	1	.1593	.3229	.5724
Within Groups	24.6676	50	.4934		
Eta = .0801		Eta Squared = .0064			

823

290

FCE 20124/706 i

(9.1.1.3) Summaries of D10VAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.8750	.6013	52
COUNTRY	1.00	Canada	1.6250	.9910	8
COUNTRY	2.00	Brazil	1.9205	.5051	44

Summaries of D10VAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.6250	.9910	6.8750	8
2.00	Brazil	1.9205	.5051	10.9716	44

Within Groups Total		1.8750	.5974	17.8466	52

Criterion Variable D10VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5909	1	.5909	1.6555	.2041
Within Groups	17.8466	50	.3569		
Eta = .1790		Eta Squared = .0320			

924

297

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(9.1.1.3) Summaries of D14VAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.6731	.6331	52
COUNTRY	1.00	Canada	1.5000	.8864	8
COUNTRY	2.00	Brazil	1.7045	.5839	44

Summaries of D14VAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.5000	.8864	5.5000	8
2.00	Brazil	1.7045	.5839	14.6591	44

Within Groups Total		1.6731	.6350	20.1591	52

Criterion Variable D14VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2832	1	.2832	.7025	.4059
Within Groups	20.1591	50	.4032		
Eta = .1177		Eta Squared = .0139			

825

200

FCE 20124/706 i

(9.1.1.3) Summaries of D21VAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.7885	.7881	52
COUNTRY	1.00	Canada	1.5000	.9258	8
COUNTRY	2.00	Brazil	1.8409	.7608	44

Summaries of D21VAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.5000	.9258	6.0000	8
2.00	Brazil	1.8409	.7608	24.8864	44
Within Groups Total		1.7885	.7860	30.8864	52

Criterion Variable D21VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.7867	1	.7867	1.2736	.2645
Within Groups	30.8864	50	.6177		
Eta = .1576		Eta Squared = .0248			

826

238

FCE 20124/706 i

(9.1.1.3) Summaries of D28VAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.7212	.8249	52
COUNTRY	1.00	Canada	1.4375	1.0501	8
COUNTRY	2.00	Brazil	1.7727	.7810	44

Summaries of D28VAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.4375	1.0501	7.7188	8
2.00	Brazil	1.7727	.7810	26.2273	44
<hr/>					
Within Groups Total		1.7212	.8240	33.9460	52

Criterion Variable D28VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.7607	1	.7607	1.1205	.2949
Within Groups	33.9460	50	.6789		
Eta = .1480		Eta Squared = .0219			

827

300

FCE 20124/706 i

(9.1.1.3) Summaries of D35VAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.6442	.8875	52
COUNTRY	1.00	Canada	1.5000	.9636	8
COUNTRY	2.00	Brazil	1.6705	.8823	44

Summaries of D35VAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.5000	.9636	6.5000	8
2.00	Brazil	1.6705	.8823	33.4716	44
<hr/>					
Within Groups Total		1.6442	.8941	39.9716	52

Criterion Variable D35VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1967	1	.1967	.2460	.6221
Within Groups	39.9716	50	.7994		
Eta = .0700		Eta Squared = .0049			

820

301

FCE 20124/706 i

(9.1.1.3) Summaries of D42VAR4 - ANXIETY
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.6154	.8890	52
COUNTRY	1.00	Canada	1.4375	.9797	8
COUNTRY	2.00	Brazil	1.6477	.8799	44

Summaries of D42VAR4 - ANXIETY
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.4375	.9797	6.7188	8
2.00	Brazil	1.6477	.8799	33.2898	44
<hr/>					
Within Groups Total		1.6154	.8945	40.0085	52

Criterion Variable D42VAR4 - ANXIETY

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2992	1	.2992	.3739	.5437
Within Groups	40.0085	50	.8002		
Eta = .0862		Eta Squared = .0074			

829

502

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var4 d4var4 d7var4 d10var4 d14var4 d21var4 d28var4 d35var4 d42var4
by country(1,2)
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/design.
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0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	143.36	50	2.87		
CONSTANT	748.19	1	748.19	260.96	.000
COUNTRY	4.39	1	4.39	1.53	.222

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00119
Chi-square approx. = 317.40258 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .26855
Huynh-Feldt Epsilon = .28661
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

830

303

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.20653	1.39908	8.00	43.00	.224
Hotellings	.26029	1.39908	8.00	43.00	.224
Wilks	.79347	1.39908	8.00	43.00	.224
Roys	.20653				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.29869	2.28921	8.00	43.00	.039
Hotellings	.42590	2.28921	8.00	43.00	.039
Wilks	.70131	2.28921	8.00	43.00	.039
Roys	.29869				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	104.79	400	.26		
TIME	9.69	8	1.21	4.62	.000
COUNTRY BY TIME	1.07	8	.13	.51	.848

831

504

FCE 20124/706 i

(9.1.1.3) Summaries of DOVAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.8942	.3513	52
COUNTRY	1.00	Canada	1.4375	.2912	8
COUNTRY	2.00	Brazil	1.9773	.2944	44

Summaries of DOVAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.4375	.2912	.5938	8
2.00	Brazil	1.9773	.2944	3.7273	44

Within Groups Total		1.8942	.2940	4.3210	52

Criterion Variable DOVAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.9722	1	1.9722	22.8215	.0000
Within Groups	4.3210	50	.0864		
Eta = .5598		Eta Squared = .3134			

832

305

FCE 20124/706 i

(9.1.1.3) Summaries of D4VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.7981	.4202	52
COUNTRY	1.00	Canada	1.1250	.3536	8
COUNTRY	2.00	Brazil	1.9205	.2991	44

Summaries of D4VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	1.1250	.3536	.8750	8	
2.00	Brazil	1.9205	.2991	3.8466	44	

Within Groups Total			1.7981	.3073	4.7216	52

Criterion Variable D4VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.2832	1	4.2832	45.3578	.0000
Within Groups	4.7216	50	.0944		
Eta = .6897		Eta Squared = .4757			

833

506

FCE 20124/706 i

(9.1.1.3) Summaries of D7VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.7019	.3804	52
COUNTRY	1.00	Canada	1.2188	.4899	8
COUNTRY	2.00	Brazil	1.7898	.2850	44

Summaries of D7VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.2188	.4899	1.6797	8
2.00	Brazil	1.7898	.2850	3.4929	44
Within Groups Total		1.7019	.3216	5.1726	52

Criterion Variable D7VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.2072	1	2.2072	21.3358	.0000
Within Groups	5.1726	50	.1035		
Eta = .5469		Eta Squared = .2991			

834

507

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(9.1.1.3) Summaries of D10VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.6683	.4251	52
COUNTRY	1.00	Canada	1.1875	.4955	8
COUNTRY	2.00	Brazil	1.7557	.3514	44

Summaries of D10VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.1875	.4955	1.7188	8
2.00	Brazil	1.7557	.3514	5.3111	44

Within Groups Total		1.6683	.3750	7.0298	52

Criterion Variable D10VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.1853	1	2.1853	15.5432	.0003
Within Groups	7.0298	50	.1406		
Eta = .4870		Eta Squared = .2371			

835

708

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(9.1.1.3) Summaries of D14VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.4375	.5283	52
COUNTRY	1.00	Canada	1.0000	.5000	8
COUNTRY	2.00	Brazil	1.5170	.4982	44

Summaries of D14VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.0000	.5000	1.7500	8
2.00	Brazil	1.5170	.4982	10.6747	44

Within Groups Total		1.4375	.4985	12.4247	52

Criterion Variable D14VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.8097	1	1.8097	7.2825	.0095
Within Groups	12.4247	50	.2485		
Eta = .3566		Eta Squared = .1271			

836

300

FCE 20124/706 i

(9.1.1.3) Summaries of D21VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.3942	.6111	52
COUNTRY	1.00	Canada	1.0000	.4818	8
COUNTRY	2.00	Brazil	1.4659	.6090	44

Summaries of D21VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	1.0000	.4818	1.6250	8
2.00	Brazil	1.4659	.6090	15.9489	44

Within Groups Total		1.3942	.5929	17.5739	52

Criterion Variable D21VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.4694	1	1.4694	4.1807	.0462
Within Groups	17.5739	50	.3515		
Eta = .2778		Eta Squared = .0772			

837

710

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(9.1.1.3) Summaries of D28VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.2644	.7061	52
COUNTRY	1.00	Canada	.9688	.6187	8
COUNTRY	2.00	Brazil	1.3182	.7140	44

Summaries of D28VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	.9688	.6187	2.6797	8
2.00	Brazil	1.3182	.7140	21.9205	44

Within Groups Total		1.2644	.7014	24.6001	52

Criterion Variable D28VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.8265	1	.8265	1.6800	.2009
Within Groups	24.6001	50	.4920		
Eta = .1803		Eta Squared = .0325			

838

311

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(9.1.1.3) Summaries of D35VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.2308	.7603	52
COUNTRY	1.00	Canada	.9688	.6469	8
COUNTRY	2.00	Brazil	1.2784	.7761	44

Summaries of D35VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	.9688	.6469	2.9297	8	
2.00	Brazil	1.2784	.7761	25.9020	44	
<hr/>						
Within Groups Total			1.2308	.7594	28.8317	52

Criterion Variable D35VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.6491	1	.6491	1.1257	.2938
Within Groups	28.8317	50	.5766		
Eta = .1484		Eta Squared = .0220			

839

512

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(9.1.1.3) Summaries of D42VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			1.2115	.7958	52
COUNTRY	1.00	Canada	.9688	.6469	8
COUNTRY	2.00	Brazil	1.2557	.8186	44

Summaries of D42VAR5 - SOMATIC SYMPTOMS
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	.9688	.6469	2.9297	8	
2.00	Brazil	1.2557	.8186	28.8111	44	

Within Groups Total			1.2115	.7968	31.7408	52

Criterion Variable D42VAR5 - SOMATIC SYMPTOMS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5573	1	.5573	.8779	.3533
Within Groups	31.7408	50	.6348		
Eta = .1314		Eta Squared = .0173			

840

313

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```
( 9.1.1.3 ) manova
d0var5 d4var5 d7var5 d10var5 d14var5 d21var5 d28var5 d35var5 d42var5
by country(1,2)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares					
Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	76.38	50	1.53		
CONSTANT	438.79	1	438.79	287.25	.000
COUNTRY	14.58	1	14.58	9.55	.003

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00008
Chi-square approx. = 445.17321 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .21585
Huynh-Feldt Epsilon = .22733
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

841

314

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(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.17655	1.15241	8.00	43.00	.349
Hotellings	.21440	1.15241	8.00	43.00	.349
Wilks	.82345	1.15241	8.00	43.00	.349
Roys	.17655				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.35874	3.00690	8.00	43.00	.009
Hotellings	.55942	3.00690	8.00	43.00	.009
Wilks	.64126	3.00690	8.00	43.00	.009
Roys	.35874				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	60.04	400	.15		
TIME	9.97	8	1.25	8.30	.000
COUNTRY BY TIME	1.38	8	.17	1.15	.331

842

315

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(9.1.1.3) ----- O N E W A Y -----

Variable DOVAR1

By Variable AGEGRP Age Group

Analysis of Variance					
Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.3285	.1643	.6510	.5260
Within Groups	49	12.3638	.2523		
Total	51	12.6923			

----- O N E W A Y -----

Variable D4VAR1

By Variable AGEGRP Age Group

Analysis of Variance					
Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.5217	.2608	.6542	.5243
Within Groups	49	19.5360	.3987		
Total	51	20.0577			

843

516

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR1

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.7385	.3692	.4947	.6127
Within Groups	49	36.5692	.7463		
Total	51	37.3077			

----- O N E W A Y -----

Variable D10VAR1

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.7789	.3895	.5036	.6074
Within Groups	49	37.8941	.7733		
Total	51	38.6731			

844

317

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR1

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.0300	.0150	.0172	.9829
Within Groups	49	42.6623	.8707		
Total	51	42.6923			

----- O N E W A Y -----

Variable D21VAR1

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.7824	.3912	.2589	.7730
Within Groups	49	74.0445	1.5111		
Total	51	74.8269			

845

312

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR1

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.6413	.3206	.1467	.8639
Within Groups	49	107.1087	2.1859		
Total	51	107.7500			

----- O N E W A Y -----

Variable D35VAR1

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.7374	.3687	.1376	.8717
Within Groups	49	131.2626	2.6788		
Total	51	132.0000			

846

310

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR1

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.7352	.3676	.1219	.8855
Within Groups	49	147.7840	3.0160		
Total	51	148.5192			

847

300

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var1 d4var1 d7var1 d10var1 d14var1 d21var1 d28var1 d35var1 d42var1
by agegrp(1,3)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
3 non-empty cells.
```

```
1 design will be processed.
```

```
* * ANALYSIS OF VARIANCE -- DESIGN 1 * *
```

```
Tests of Between-Subjects Effects.
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	339.01	49	6.92		
CONSTANT	3214.38	1	3214.38	464.61	.000
AGEGRP	1.55	2	.77	.11	.894

```
* * ANALYSIS OF VARIANCE -- DESIGN 1 * *
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00014
Chi-square approx. = 410.89321 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .22337
Huynh-Feldt Epsilon = .24073
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

840

321

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. AGEGRP BY TIME

Multivariate Tests of Significance (S = 2, M = 2 1/2, N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.26456	.81940	16.00	86.00	.660
Hotellings	.30879	.79127	16.00	82.00	.691
Wilks	.75167	.80546	16.00	34.00	.676
Roys	.16793				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.58780	7.48662	8.00	42.00	.000
Hotellings	1.42602	7.48662	8.00	42.00	.000
Wilks	.41220	7.48662	8.00	42.00	.000
Roys	.58780				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares					
Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	270.22	392	.69		
TIME	145.08	8	18.13	26.31	.000
AGEGRP BY TIME	3.75	16	.23	.34	.993

849

322

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable DOVAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.0033	.0017	.0160	.9842
Within Groups	49	5.0736	.1035		
Total	51	5.0769			

----- O N E W A Y -----

Variable D4VAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.1362	.0681	.3279	.7220
Within Groups	49	10.1779	.2077		
Total	51	10.3141			

850

323

FCE 20124/706 i

(9.1.1.3) ----- ONEWAY -----

Variable D7VAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.3660	.1830	.9029	.4120
Within Groups	49	9.9310	.2027		
Total	51	10.2970			

----- ONEWAY -----

Variable D10VAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.2325	.1162	.5706	.5689
Within Groups	49	9.9812	.2037		
Total	51	10.2137			

851

324

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.0560	.0280	.0988	.9061
Within Groups	49	13.8821	.2833		
Total	51	13.9380			

----- O N E W A Y -----

Variable D21VAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.3556	.1778	.4535	.6380
Within Groups	49	19.2085	.3920		
Total	51	19.5641			

852

325

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.8661	.4331	.9525	.3928
Within Groups	49	22.2792	.4547		
Total	51	23.1453			

----- O N E W A Y -----

Variable D35VAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.6462	.8231	1.7461	.1851
Within Groups	49	23.0974	.4714		
Total	51	24.7436			

853

326

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR2

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.8633	.4317	.8349	.4400
Within Groups	49	25.3333	.5170		
Total	51	26.1966			

854

327

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var2 d4var2 d7var2 d10var2 d14var2 d21var2 d28var2 d35var2 d42var2
by agegrp(1,3)
/wsdesign=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
3 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

Tests of Significance for T1 using UNIQUE sums of squares					
Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	84.37	49	1.72		
CONSTANT	759.97	1	759.97	441.35	.000
AGEGRP	2.50	2	1.25	.73	.489

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00189
Chi-square approx. = 289.32302 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .30540
Huynh-Feldt Epsilon = .33573
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to
univariate or split-plot or mixed-model approach to repeated measures.
Epsilons may be used to adjust d.f. for the AVERAGED results.
```

855

328

FCE 20124/706 i

(9.1.1.3) ** ANALYSIS OF VARIANCE -- DESIGN 1 **

EFFECT .. AGEGRP BY TIME
Multivariate Tests of Significance (S = 2, M = 2 1/2, N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.48153	1.70450	16.00	86.00	.061
Hotellings	.67686	1.73447	16.00	82.00	.056
Wilks	.56726	1.72059	16.00	84.00	.058
Roys	.33658				

** ANALYSIS OF VARIANCE -- DESIGN 1 **

EFFECT .. TIME
Multivariate Tests of Significance (S = 1, M = 3 , N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.47738	4.79545	8.00	42.00	.000
Hotellings	.91342	4.79545	8.00	42.00	.000
Wilks	.52262	4.79545	8.00	42.00	.000
Roys	.47738				

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares					
Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	54.59	392	.14		
TIME	14.38	8	1.80	12.91	.000
AGEGRP BY TIME	2.03	16	.13	.91	.558

856

329

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(9.1.1.3) ----- O N E W A Y -----

Variable DOVAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.1611	.0805	.1644	.8489
Within Groups	49	24.0120	.4900		
Total	51	24.1731			

----- O N E W A Y -----

Variable D4VAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.1019	.0509	.1059	.8997
Within Groups	49	23.5664	.4809		
Total	51	23.6683			

857

330

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.0077	.0038	.0087	.9914
Within Groups	49	21.7375	.4436		
Total	51	21.7452			

----- O N E W A Y -----

Variable D10VAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.0914	.0457	.0959	.9087
Within Groups	49	23.3509	.4765		
Total	51	23.4423			

858

331

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.4107	.2053	.3688	.6935
Within Groups	49	27.2816	.5568		
Total	51	27.6923			

----- O N E W A Y -----

Variable D21VAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.0990	.5495	.6885	.5071
Within Groups	49	39.1077	.7981		
Total	51	40.2067			

859

332

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.6300	.8150	.6712	.5158
Within Groups	49	59.4998	1.2143		
Total	51	61.1298			

----- O N E W A Y -----

Variable D35VAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.9113	.4556	.3240	.7248
Within Groups	49	68.9156	1.4064		
Total	51	69.8269			

860

.333

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR3

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.8992	.4496	.2675	.7664
Within Groups	49	82.3460	1.6805		
Total	51	83.2452			

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var3 d4var3 d7var3 d10var3 d14var3 d21var3 d28var3 d35var3 d42var3
by agegrp(1,3)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
3 non-empty cells.

1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	219.54	49	4.48		
CONSTANT	2002.48	1	2002.48	446.95	.000
AGEGRP	2.47	2	1.23	.28	.761

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00002
Chi-square approx. = 505.63139 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .18130
Huynh-Feldt Epsilon = .19301
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

002

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. AGEGRP BY TIME

Multivariate Tests of Significance (S = 2, M = 2 1/2, N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.30210	.95634	16.00	86.00	.510
Hotellings	.35710	.91506	16.00	82.00	.555
Wilks	.72034	.93574	16.00	84.00	.533
Roys	.17057				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.52271	5.74951	8.00	42.00	.000
Hotellings	1.09514	5.74951	8.00	42.00	.000
Wilks	.47729	5.74951	8.00	42.00	.000
Roys	.52271				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	150.28	392	.38		
TIME	91.97	8	11.50	29.99	.000
AGEGRP BY TIME	2.85	16	.18	.46	.963

053

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D0VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.4536	.7268	1.7563	.1834
Within Groups	49	20.2772	.4138		
Total	51	21.7308			

- - - - - O N E W A Y - - - - -

Variable D4VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	2.6443	1.3222	3.4713	.0389
Within Groups	49	18.6634	.3809		
Total	51	21.3077			

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(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	4.1119	2.0560	4.8633	.0118
Within Groups	49	20.7150	.4228		
Total	51	24.8269			

----- O N E W A Y -----

Variable D10VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	3.5664	1.7832	5.8757	.0052
Within Groups	49	14.8711	.3035		
Total	51	18.4375			

865

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	2.9910	1.4955	4.1992	.0207
Within Groups	49	17.4513	.3561		
Total	51	20.4423			

----- O N E W A Y -----

Variable D21VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	4.2170	2.1085	3.7629	.0302
Within Groups	49	27.4561	.5603		
Total	51	31.6731			

866

770

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.7526	.8763	1.3030	.2810

----- O N E W A Y -----

Variable D35VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	2.3559	1.1780	1.5265	.2275
Within Groups	49	37.8123	.7717		
Total	51	40.1683			

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(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR4

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.6006	.8003	1.0131	.3706
Within Groups	49	38.7071	.7899		
Total	51	40.3077			

888

221

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var4 d4var4 d7var4 d10var4 d14var4 d21var4 d28var4 d35var4 d42var4
by agegrp(1,3)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
3 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	124.97	49	2.55		
CONSTANT	1538.44	1	1538.44	603.20	.000
AGEGRP	22.77	2	11.38	4.46	.017

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00111
Chi-square approx. = 313.72232 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .26712
Huynh-Feldt Epsilon = .29106
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

889

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. AGEGRP BY TIME

Multivariate Tests of Significance (S = 2, M = 2 1/2, N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.33010	1.06250	16.00	86.00	.403
Hotellings	.40119	1.02806	16.00	82.00	.437
Wilks	.69545	1.04546	16.00	84.00	.420
Roys	.20624				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.50299	5.31309	8.00	42.00	.000
Hotellings	1.01202	5.31309	8.00	42.00	.000
Wilks	.49701	5.31309	8.00	42.00	.000
Roys	.50299				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	103.93	392	.27		
TIME	19.36	8	2.42	9.13	.000
AGEGRP BY TIME	1.93	16	.12	.45	.966

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(9.1.1.3) ----- O N E W A Y -----

Variable D0VAR5

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.4235	.2117	1.7676	.1815
Within Groups	49	5.8698	.1198		
Total	51	6.2933			

----- O N E W A Y -----

Variable D4VAR5

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.4535	.7268	4.7160	.0134
Within Groups	49	7.5513	.1541		
Total	51	9.0048			

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(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR5

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.7633	.3817	2.8266	.0689
Within Groups	49	6.6165	.1350		
Total	51	7.3798			

----- O N E W A Y -----

Variable D10VAR5

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	.7582	.3791	2.1965	.1220
Within Groups	49	8.4569	.1726		
Total	51	9.2151			

872

ZNF

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(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR5

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.9733	.9867	3.9431	.0258
Within Groups	49	12.2610	.2502		
Total	51	14.2344			

----- O N E W A Y -----

Variable D21VAR5

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.4137	.7068	1.9646	.1511
Within Groups	49	17.6296	.3598		
Total	51	19.0433			

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(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR5

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.4074	.7037	1.4356	.2478
Within Groups	49	24.0193	.4902		
Total	51	25.4267			

----- O N E W A Y -----

Variable D35VAR5

By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	2.1228	1.0614	1.9011	.1603
Within Groups	49	27.3579	.5583		
Total	51	29.4808			

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(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D42VAR5
 By Variable AGEGRP Age Group

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	2	1.3415	.6708	1.0617	.3537
Within Groups	49	30.9565	.6318		
Total	51	32.2981			

875

760

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var5 d4var5 d7var5 d10var5 d14var5 d21var5 d28var5 d35var5 d42var5
by agegrp(1,3)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
3 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	81.26	49	1.66		
CONSTANT	1012.08	1	1012.08	610.28	.000
AGEGRP	9.70	2	4.85	2.93	.063

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00007
Chi-square approx. = 444.15466 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .21318
Huynh-Feldt Epsilon = .22911
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

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(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. AGEGRP BY TIME

Multivariate Tests of Significance (S = 2, M = 2 1/2, N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.39686	1.33060	16.00	86.00	.198
Hotellings	.52579	1.34733	16.00	82.00	.190
Wilks	.63471	1.33980	16.00	84.00	.193
Roys	.28678				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.52314	5.75949	8.00	42.00	.000
Hotellings	1.09705	5.75949	8.00	42.00	.000
Wilks	.47686	5.75949	8.00	42.00	.000
Roys	.52314				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	59.46	392	.15		
TIME	29.24	8	3.65	24.09	.000
AGEGRP BY TIME	1.96	16	.12	.81	.679

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(9.1.1.3) ----- O N E W A Y -----

Variable D0VAR1
By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.3607	.1202	.4679	.7060
Within Groups	48	12.3316	.2569		
Total	51	12.6923			

----- O N E W A Y -----

Variable D4VAR1
By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.4533	.8178	2.2297	.0968
Within Groups	48	17.6044	.3668		
Total	51	20.0577			

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR1

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	11.3094	3.7698	6.9601	.0006
Within Groups	48	25.9983	.5416		
Total	51	37.3077			

----- O N E W A Y -----

Variable D10VAR1

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	8.8263	2.9421	4.7315	.0057
Within Groups	48	29.8468	.6218		
Total	51	38.6731			

879

750

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR1

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	4.2075	1.4025	1.7492	.1695
Within Groups	48	38.4848	.8018		
Total	51	42.6923			

----- O N E W A Y -----

Variable D21VAR1

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.8724	.2908	.1887	.9036
Within Groups	48	73.9545	1.5407		
Total	51	74.8269			

880

880

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(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR1
By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	6.8325	2.2775	1.0833	.3652
Within Groups	48	100.9175	2.1024		
Total	51	107.7500			

----- O N E W A Y -----

Variable D35VAR1
By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	9.5067	3.1689	1.2418	.3050
Within Groups	48	122.4933	2.5519		
Total	51	132.0000			

0 0 1

0 0 0

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(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D42VAR1

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	6.9502	2.3167	.7855	.5079
Within Groups	48	141.5690	2.9494		
Total	51	148.5192			

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var1 d4var1 d7var1 d10var1 d14var1 d21var1 d28var1 d35var1 d42var1
by subform(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	319.66	48	6.66		
CONSTANT	627.29	1	627.29	94.19	.000
SUBFORM	20.89	3	6.96	1.05	.381

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00005
Chi-square approx. = 450.33178 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .19851
Huynh-Feldt Epsilon = .21702
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

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FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	1.26954	3.94334	24.00	129.00	.000
Hotellings	4.81792	7.96296	24.00	119.00	.000
Wilks	.11207	5.61110	24.00	119.51	.000
Roys	.80625				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.68710	11.25412	8.00	41.00	.000
Hotellings	2.19593	11.25412	8.00	41.00	.000
Wilks	.31290	11.25412	8.00	41.00	.000
Roys	.68710				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	243.54	384	.63		
TIME	25.28	8	3.16	4.98	.000
SUBFORM BY TIME	30.43	24	1.27	2.00	.004

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D0VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.5028	.1676	1.7590	.1676
Within Groups	48	4.5741	.0953		
Total	51	5.0769			

----- O N E W A Y -----

Variable D4VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.6723	.8908	5.5952	.0023
Within Groups	48	7.6418	.1592		
Total	51	10.3141			

005

500

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3432	.4477	2.4003	.0793
Within Groups	48	8.9538	.1865		
Total	51	10.2970			

----- O N E W A Y -----

Variable D10VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.6673	.2224	1.1184	.3509
Within Groups	48	9.5464	.1989		
Total	51	10.2137			

880

550

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.7126	.5709	2.2414	.0955
Within Groups	48	12.2254	.2547		
Total	51	13.9380			

----- O N E W A Y -----

Variable D21VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.0132	.3377	.8739	.4612
Within Groups	48	18.5509	.3865		
Total	51	19.5641			

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(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.1893	.0631	.1319	.9406
Within Groups	48	22.9560	.4783		
Total	51	23.1453			

----- O N E W A Y -----

Variable D35VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.0736	.3579	.7257	.5417
Within Groups	48	23.6700	.4931		
Total	51	24.7436			

880

201

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR2

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.6418	.2139	.4018	.7523
Within Groups	48	25.5548	.5324		
Total	51	26.1966			

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FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var2 d4var2 d7var2 d10var2 d14var2 d21var2 d28var2 d35var2 d42var2
by subform(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	80.86	48	1.68		
CONSTANT	141.77	1	141.77	84.16	.000
SUBFORM	6.01	3	2.00	1.19	.324

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00175
Chi-square approx. = 286.55684 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .29876
Huynh-Feldt Epsilon = .33513
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

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FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.74311	1.76980	24.00	129.00	.023
Hotellings	1.14221	1.88782	24.00	119.00	.014
Wilks	.40284	1.83347	24.00	119.51	.018
Roys	.43312				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.41136	3.58148	8.00	41.00	.003
Hotellings	.69883	3.58148	8.00	41.00	.003
Wilks	.58864	3.58148	8.00	41.00	.003
Roys	.41136				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	52.81	384	.14		
TIME	1.49	8	.19	1.35	.216
SUBFORM BY TIME	3.80	24	.16	1.15	.284

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable DOVAR3

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.4222	.8074	1.7818	.1632
Within Groups	48	21.7508	.4531		
Total	51	24.1731			

----- O N E W A Y -----

Variable D4VAR3

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3387	.4462	.9592	.4196
Within Groups	48	22.3295	.4652		
Total	51	23.6683			

892

200

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR3

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.2317	.7439	1.8299	.1543
Within Groups	48	19.5135	.4065		
Total	51	21.7452			

----- O N E W A Y -----

Variable D10VAR3

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.7331	.5777	1.2773	.2928
Within Groups	48	21.7092	.4523		
Total	51	23.4423			

003

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FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR3

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.2495	.0832	.1455	.9321
Within Groups	48	27.4428	.5717		
Total	51	27.6923			

----- O N E W A Y -----

Variable D21VAR3

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.4117	.4706	.5822	.6296
Within Groups	48	38.7950	.8082		
Total	51	40.2067			

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(9.1.1.3) ----- ONEWAY -----

Variable D28VAR3

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.4972	.8324	.6815	.5677
Within Groups	48	58.6326	1.2215		
Total	51	61.1298			

----- ONEWAY -----

Variable D35VAR3

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	3.0003	1.0001	.7184	.5459
Within Groups	48	66.8266	1.3922		
Total	51	69.8269			

895

500

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(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR3
 By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.8630	.9543	.5699	.6376
Within Groups	48	80.3822	1.6746		
Total	51	83.2452			

996

762

090177e1803f22f8\Approved\Approved On: 11-Nov-2002 20:34

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var3 d4var3 d7var3 d10var3 d14var3 d21var3 d28var3 d35var3 d42var3
by subform(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	208.79	48	4.35		
CONSTANT	303.04	1	303.04	69.67	.000
SUBFORM	13.21	3	4.40	1.01	.395

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00001
Chi-square approx. = 509.64514 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .17940
Huynh-Feldt Epsilon = .19497
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.63953	1.45628	24.00	129.00	.094
Hotellings	.89167	1.47374	24.00	119.00	.090
Wilks	.47226	1.47004	24.00	119.51	.091
Roys	.34083				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.31186	2.32265	8.00	41.00	.037
Hotellings	.45320	2.32265	8.00	41.00	.037
Wilks	.68814	2.32265	8.00	41.00	.037
Roys	.31186				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	148.59	384	.39		
TIME	18.98	8	2.37	6.13	.000
SUBFORM BY TIME	4.53	24	.19	.49	.981

838

771

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D0VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.7160	.5720	1.3718	.2627
Within Groups	48	20.0147	.4170		
Total	51	21.7308			

- - - - - O N E W A Y - - - - -

Variable D4VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.9053	.9684	2.5261	.0685
Within Groups	48	18.4024	.3834		
Total	51	21.3077			

899

570

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D7VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.2844	.7615	1.6214	.1967
Within Groups	48	22.5425	.4696		
Total	51	24.8269			

- - - - - O N E W A Y - - - - -

Variable D10VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.7081	.9027	2.7547	.0526
Within Groups	48	15.7294	.3277		
Total	51	18.4375			

900

373

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(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.1776	.3925	.9780	.4110
Within Groups	48	19.2647	.4013		
Total	51	20.4423			

----- O N E W A Y -----

Variable D21VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.1192	.7064	1.1473	.3396
Within Groups	48	29.5539	.6157		
Total	51	31.6731			

901

374

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D28VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.8145	.6048	.8826	.4568
Within Groups	48	32.8923	.6853		
Total	51	34.7067			

- - - - - O N E W A Y - - - - -

Variable D35VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.5584	.5195	.6458	.5894
Within Groups	48	38.6098	.8044		
Total	51	40.1683			

902

375

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(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D42VAR4

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.4154	.4718	.5823	.6295
Within Groups	48	38.8923	.8103		
Total	51	40.3077			

903

376

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var4 d4var4 d7var4 d10var4 d14var4 d21var4 d28var4 d35var4 d42var4
by subform(1,4)
/ws=factors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	135.27	48	2.82		
CONSTANT	231.71	1	231.71	82.22	.000
SUBFORM	12.47	3	4.16	1.47	.233

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00085
Chi-square approx. = 319.16784 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .25203
Huynh-Feldt Epsilon = .27957
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

904

377

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.75269	1.80025	24.00	129.00	.020
Hotellings	1.07803	1.78174	24.00	119.00	.023
Wilks	.40935	1.79596	24.00	119.51	.021
Roys	.38268				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.12539	.73476	8.00	41.00	.660
Hotellings	.14337	.73476	8.00	41.00	.660
Wilks	.87461	.73476	8.00	41.00	.660
Roys	.12539				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	100.63	384	.26		
TIME	2.98	8	.37	1.42	.186
SUBFORM BY TIME	5.23	24	.22	.83	.696

905

378

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable DOVAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.4751	.4917	4.8984	.0047
Within Groups	48	4.8182	.1004		
Total	51	6.2933			

----- O N E W A Y -----

Variable D4VAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.2275	.7425	5.2586	.0032
Within Groups	48	6.7774	.1412		
Total	51	9.0048			

906

379

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(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D7VAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.2170	.7390	6.8708	.0006
Within Groups	48	5.1628	.1076		
Total	51	7.3798			

- - - - - O N E W A Y - - - - -

Variable D10VAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.8115	.6038	3.9149	.0140
Within Groups	48	7.4036	.1542		
Total	51	9.2151			

907

330

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.2145	.4048	1.4925	.2285
Within Groups	48	13.0199	.2712		
Total	51	14.2344			

----- O N E W A Y -----

Variable D21VAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.8723	.2908	.7681	.5176
Within Groups	48	18.1710	.3786		
Total	51	19.0433			

908

581

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(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D28VAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.2077	.0692	.1318	.9407
Within Groups	48	25.2190	.5254		
Total	51	25.4267			

- - - - - O N E W A Y - - - - -

Variable D35VAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.0688	.0229	.0374	.9902
Within Groups	48	29.4119	.6127		
Total	51	29.4808			

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(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR5

By Variable SUBFORM DSM-III-R Subform

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.0548	.0183	.0272	.9939
Within Groups	48	32.2433	.6717		
Total	51	32.2981			

910

383

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var5 d4var5 d7var5 d10var5 d14var5 d21var5 d28var5 d35var5 d42var5
by subform(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares						
Source of Variation	SS	DF	MS	F	Sig of F	
WITHIN CELLS	83.83	48	1.75			
CONSTANT	161.69	1	161.69	92.58	.000	
SUBFORM	7.13	3	2.38	1.36	.266	

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00008
Chi-square approx. = 423.72151 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .21379
Huynh-Feldt Epsilon = .23476
Lower-bound Epsilon = .12500
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.33726	.68079	24.00	129.00	.863
Hotellings	.38431	.63518	24.00	119.00	.901
Wilks	.69788	.65754	24.00	119.51	.883
Roys	.14104				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.12543	.73504	8.00	41.00	.660
Hotellings	.14342	.73504	8.00	41.00	.660
Wilks	.87457	.73504	8.00	41.00	.660
Roys	.12543				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	58.39	384	.15		
TIME	1.86	8	.23	1.53	.144
SUBFORM BY TIME	3.02	24	.13	.83	.702

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D0VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.0484	.3495	1.4406	.2426
Within Groups	48	11.6439	.2426		
Total	51	12.6923			

- - - - - O N E W A Y - - - - -

Variable D4VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.8456	.6152	1.6214	.1967
Within Groups	48	18.2121	.3794		
Total	51	20.0577			

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(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.4592	.4864	.6513	.5860
Within Groups	48	35.8485	.7468		
Total	51	37.3077			

----- O N E W A Y -----

Variable D10VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.2791	.0930	.1163	.9501
Within Groups	48	38.3939	.7999		
Total	51	38.6731			

914

387

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	7.8969	2.6323	3.6312	.0193
Within Groups	48	34.7955	.7249		
Total	51	42.6923			

----- O N E W A Y -----

Variable D21VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	4.2739	1.4246	.9692	.4150
Within Groups	48	70.5530	1.4699		
Total	51	74.8269			

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D28VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	8.6970	2.8990	1.4048	.2528
Within Groups	48	99.0530	2.0636		
Total	51	107.7500			

- - - - - O N E W A Y - - - - -

Variable D35VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	10.7879	3.5960	1.4240	.2473
Within Groups	48	121.2121	2.5253		
Total	51	132.0000			

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR1

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	11.1253	3.7084	1.2956	.2867
Within Groups	48	137.3939	2.8624		
Total	51	148.5192			

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var1 d4var1 d7var1 d10var1 d14var1 d21var1 d28var1 d35var1 d42var1
by rater(1,4)
/wsdesign=time (9)
/wsfactors=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
Source of Variation      SS      DF      MS      F      Sig of F
WITHIN CELLS             321.71    48      6.70
CONSTANT                 831.12     1     831.12    124.01    .000
RATER                    18.84     3      6.28      .94     .430
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00009
Chi-square approx. = 421.01257 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .21556
Huynh-Feldt Epsilon = .23683
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

91g

391

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. RATER BY TIME
Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	1.12508	3.22536	24.00	129.00	.000
Hotellings	2.02723	3.35057	24.00	119.00	.000
Wilks	.22809	3.30966	24.00	119.51	.000
Roys	.53970				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME
Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.48078	4.74549	8.00	41.00	.000
Hotellings	.92595	4.74549	8.00	41.00	.000
Wilks	.51922	4.74549	8.00	41.00	.000
Roys	.48078				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares					
Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	245.40	384	.64		
TIME	8.84	8	1.11	1.73	.090
RATER BY TIME	28.57	24	1.19	1.86	.009

919

592

FCE 20124/706 i

(9.1.1.3) ----- ONEWAY -----

Variable DOVAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.2049	.0683	.6728	.5729
Within Groups	48	4.8721	.1015		
Total	51	5.0769			

----- ONEWAY -----

Variable D4VAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.9909	.3303	1.7005	.1794
Within Groups	48	9.3232	.1942		
Total	51	10.3141			

920

393

FCE 20124/706 i

(9.1.1.1.3) ----- O N E W A Y -----

Variable D7VAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.1901	.7300	4.3225	.0089
Within Groups	48	8.1069	.1689		
Total	51	10.2970			

----- O N E W A Y -----

Variable D10VAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.8366	.2789	1.4274	.2463
Within Groups	48	9.3771	.1954		
Total	51	10.2137			

921

394

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.9683	.3228	1.1946	.3218
Within Groups	48	12.9697	.2702		
Total	51	13.9380			

----- O N E W A Y -----

Variable D21VAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.1870	.0623	.1544	.9263
Within Groups	48	19.3771	.4037		
Total	51	19.5641			

922

395

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D28VAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3035	.4345	.9549	.4217
Within Groups	48	21.8418	.4550		
Total	51	23.1453			

- - - - - O N E W A Y - - - - -

Variable D35VAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.1367	.3789	.7704	.5163
Within Groups	48	23.6069	.4918		
Total	51	24.7436			

923

396

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR2

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.1023	.3674	.7028	.5550
Within Groups	48	25.0943	.5228		
Total	51	26.1966			

924

597

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var2 d4var2 d7var2 d10var2 d14var2 d21var2 d28var2 d35var2 d42var2
by rater(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	82.37	48	1.72		
CONSTANT	166.14	1	166.14	96.81	.000
RATER	4.50	3	1.50	.87	.461

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00113
Chi-square approx. = 306.16330 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .27985
Huynh-Feldt Epsilon = .31254
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

925

398

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. RATER BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	1.09074	3.07067	24.00	129.00	.000
Hotellings	1.99168	3.29180	24.00	119.00	.000
Wilks	.23743	3.19576	24.00	119.51	.000
Roys	.55520				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.34811	2.73678	8.00	41.00	.016
Hotellings	.53401	2.73678	8.00	41.00	.016
Wilks	.65189	2.73678	8.00	41.00	.016
Roys	.34811				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	52.20	384	.14		
TIME	1.86	8	.23	1.71	.094
RATER BY TIME	4.42	24	.18	1.36	.124

926

399

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable DOVAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	7.2110	2.4037	6.8019	.0007
Within Groups	48	16.9621	.3534		
Total	51	24.1731			

- - - - - O N E W A Y - - - - -

Variable D4VAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	5.7194	1.9065	5.0984	.0038
Within Groups	48	17.9489	.3739		
Total	51	23.6683			

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D7VAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	3.2547	1.0849	2.8163	.0490
Within Groups	48	18.4905	.3852		
Total	51	21.7452			

- - - - - O N E W A Y - - - - -

Variable D10VAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.7984	.5995	1.3294	.2758
Within Groups	48	21.6439	.4509		
Total	51	23.4423			

929

401

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3230	.4410	.8027	.4985
Within Groups	48	26.3693	.5494		
Total	51	27.6923			

----- O N E W A Y -----

Variable D21VAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.2749	.7583	.9596	.4195
Within Groups	48	37.9318	.7902		
Total	51	40.2067			

929

402

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.4859	.1620	.1282	.9429
Within Groups	48	60.6439	1.2634		
Total	51	61.1298			

----- O N E W A Y -----

Variable D35VAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3440	.4480	.3140	.8152
Within Groups	48	68.4830	1.4267		
Total	51	69.8269			

930

407

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D42VAR3

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3134	.4378	.2565	.8563
Within Groups	48	81.9318	1.7069		
Total	51	83.2452			

931

404

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var3 d4var3 d7var3 d10var3 d14var3 d21var3 d28var3 d35var3 d42var3
by rater(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
Source of Variation      SS      DF      MS      F      Sig of F
WITHIN CELLS             209.43    48      4.36
CONSTANT                 291.21     1     291.21    66.74    .000
RATER                    12.58     3      4.19      .96     .419
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00002
Chi-square approx. = 498.22650 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .18157
Huynh-Feldt Epsilon = .19747
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

932

405

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. RATER BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.74263	1.76827	24.00	129.00	.023
Hotellings	1.17172	1.93660	24.00	119.00	.011
Wilks	.39933	1.85410	24.00	119.51	.016
Roys	.45460				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.09583	.54319	8.00	41.00	.817
Hotellings	.10599	.54319	8.00	41.00	.817
Wilks	.90417	.54319	8.00	41.00	.817
Roys	.09583				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	140.98	384	.37		
TIME	5.98	8	.75	2.04	.041
RATER BY TIME	12.15	24	.51	1.38	.112

933

406

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D0VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.2933	.7644	1.8877	.1442
Within Groups	48	19.4375	.4049		
Total	51	21.7308			

----- O N E W A Y -----

Variable D4VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.4819	.8273	2.1094	.1114
Within Groups	48	18.8258	.3922		
Total	51	21.3077			

934

407

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.2739	.0913	.1785	.9105
Within Groups	48	24.5530	.5115		
Total	51	24.8269			

----- O N E W A Y -----

Variable D10VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.7992	.2664	.7250	.5420
Within Groups	48	17.6383	.3675		
Total	51	18.4375			

935

408

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D14VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.4291	.4764	1.2026	.3189
Within Groups	48	19.0133	.3961		
Total	51	20.4423			

- - - - - O N E W A Y - - - - -

Variable D21VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.4325	.4775	.7579	.5232
Within Groups	48	30.2405	.6300		
Total	51	31.6731			

938

409

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3128	.4376	.6290	.5998
Within Groups	48	33.3939	.6957		
Total	51	34.7067			

----- O N E W A Y -----

Variable D35VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	.8425	.2808	.3428	.7945
Within Groups	48	39.3258	.8193		
Total	51	40.1683			

937

410

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D42VAR4

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3304	.4435	.5461	.6531
Within Groups	48	38.9773	.8120		
Total	51	40.3077			

938

411

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var4 d4var4 d7var4 d10var4 d14var4 d21var4 d28var4 d35var4 d42var4
by rater(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	140.96	48	2.94		
CONSTANT	272.94	1	272.94	92.94	.000
RATER	6.78	3	2.26	.77	.517

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00091
Chi-square approx. = 316.02039 with 35 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .25251
Huynh-Feldt Epsilon = .28014
Lower-bound Epsilon = .12500
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

939

412

FCE 20124/706 i

(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. RATER BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.66522	1.53144	24.00	129.00	.068
Hotellings	1.08716	1.79684	24.00	119.00	.021
Wilks	.43257	1.66826	24.00	119.51	.038
Roys	.44931				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.11372	.65763	8.00	41.00	.725
Hotellings	.12832	.65763	8.00	41.00	.725
Wilks	.88628	.65763	8.00	41.00	.725
Roys	.11372				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	100.44	384	.26		
TIME	2.29	8	.29	1.09	.368
RATER BY TIME	5.42	24	.23	.86	.654

940

413

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable DOVAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.3525	.7842	9.5511	.0000
Within Groups	48	3.9408	.0821		
Total	51	6.2933			

----- O N E W A Y -----

Variable D4VAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	4.4916	1.4972	15.9230	.0000
Within Groups	48	4.5133	.0940		
Total	51	9.0048			

941

414

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D7VAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.2984	.7661	7.2369	.0004
Within Groups	48	5.0814	.1059		
Total	51	7.3798			

----- O N E W A Y -----

Variable D10VAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.2999	.7666	5.3213	.0030
Within Groups	48	6.9152	.1441		
Total	51	9.2151			

942

415

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D14VAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	2.1222	.7074	2.8033	.0497
Within Groups	48	12.1122	.2523		
Total	51	14.2344			

----- O N E W A Y -----

Variable D21VAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.6309	.5436	1.4986	.2269
Within Groups	48	17.4124	.3628		
Total	51	19.0433			

943

410

FCE 20124/706 i

(9.1.1.3) ----- O N E W A Y -----

Variable D28VAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.7146	.5715	1.1569	.3359
Within Groups	48	23.7121	.4940		
Total	51	25.4267			

----- O N E W A Y -----

Variable D35VAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.4069	.4690	.8018	.4990
Within Groups	48	28.0739	.5849		
Total	51	29.4808			

944

417

FCE 20124/706 i

(9.1.1.3) - - - - - O N E W A Y - - - - -

Variable D42VAR5

By Variable RATER

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	3	1.3151	.4384	.6791	.5691
Within Groups	48	30.9830	.6455		
Total	51	32.2981			

945

418

FCE 20124/706 i

```
( 9.1.1.3 ) manova
d0var5 d4var5 d7var5 d10var5 d14var5 d21var5 d28var5 d35var5 d42var5
by rater(1,4)
/wsfactors=time (9)
/wsdesign=time
/design.
```

52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	73.75	48	1.54		
CONSTANT	152.06	1	152.06	98.97	.000
RATER	17.21	3	5.74	3.73	.017

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

Mauchly sphericity test, W = .00007
Chi-square approx. = 434.84493 with 35 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .21277
Huynh-Feldt Epsilon = .23358
Lower-bound Epsilon = .12500

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

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(9.1.1.3) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. RATER BY TIME

Multivariate Tests of Significance (S = 3, M = 2 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.46102	.97597	24.00	129.00	.502
Hotellings	.60263	.99601	24.00	119.00	.477
Wilks	.59201	.98657	24.00	119.51	.489
Roys	.29665				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 3 , N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.19815	1.26647	8.00	41.00	.287
Hotellings	.24712	1.26647	8.00	41.00	.287
Wilks	.80185	1.26647	8.00	41.00	.287
Roys	.19815				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	59.00	384	.15		
TIME	1.99	8	.25	1.62	.118
RATER BY TIME	2.42	24	.10	.66	.893

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APPENDIX 14

Therapeutic Efficacy: ZUNG

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(9.1.2.1) Summaries of D0SCR Dy0 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			65.7843	5.9609	51
DRUGRP	1	Reboxetine	66.2963	4.9210	27
DRUGRP	2	Placebo	65.2083	7.0154	24
Total Cases =		52			
Missing Cases =		1 OR	1.9 PCT.		

Summaries of D42SCR Dy42 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			50.3846	16.6335	52
DRUGRP	1	Reboxetine	42.8148	13.9919	27
DRUGRP	2	Placebo	58.5600	15.5485	25
Total Cases =		52			

Summaries of INDX0 D0 INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.8223	.0745	51
DRUGRP	1	Reboxetine	.8287	.0615	27
DRUGRP	2	Placebo	.8151	.0877	24
Total Cases =		52			
Missing Cases =		1 OR	1.9 PCT.		

Summaries of INDX42 D42 INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.6298	.2079	52
DRUGRP	1	Reboxetine	.5352	.1749	27
DRUGRP	2	Placebo	.7320	.1944	25
Total Cases =		52			

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(9.1.2.1) Summaries of CHANGE TOT.SCR. %CHANGE
 By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			22.0620	26.4201	51
DRUGRP	1	Reboxetine	33.5750	23.3725	27
DRUGRP	2	Placebo	9.1099	23.8591	24
Total Cases = 52					
Missing Cases = 1 OR 1.9 PCT.					

Summaries of INDCHG INDEX %CHANGE
 By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			22.0620	26.4201	51
DRUGRP	1	Reboxetine	33.5750	23.3725	27
DRUGRP	2	Placebo	9.1099	23.8591	24
Total Cases = 52					
Missing Cases = 1 OR 1.9 PCT.					

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(9.1.2.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D42SCR Dy42 Total Score
 BY DRUGRP Treatment Group
 WITH D0SCR Dy0 Total Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.198	1	2.198	.010	.922
D0SCR	2.198	1	2.198	.010	.922
Main Effects	3087.362	1	3087.362	13.648	.001
DRUGRP	3087.362	1	3087.362	13.648	.001
Explained	3089.560	2	1544.780	6.829	.002
Residual	10858.479	48	226.218		
Total	13948.039	50	278.961		

52 Cases were processed.
 1 Cases (1.9 PCT) were missing.

FCE 20124/706 i

(9.1.2.1) Summaries of D0SCR Dy0 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			65.7843	5.9609	51
SEX	0	Female	67.5417	4.6060	24
SEX	1	Male	64.2222	6.6468	27
Total Cases = 52					
Missing Cases = 1 OR 1.9 PCT.					

Summaries of D42SCR Dy42 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			50.3846	16.6335	52
SEX	0	Female	51.2083	17.4878	24
SEX	1	Male	49.6786	16.1545	28
Total Cases = 52					

Summaries of INDX0 D0 INDEX SCR
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.8223	.0745	51
SEX	0	Female	.8443	.0576	24
SEX	1	Male	.8028	.0831	27
Total Cases = 52					
Missing Cases = 1 OR 1.9 PCT.					

Summaries of INDX42 D42 INDEX SCR
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6298	.2079	52
SEX	0	Female	.6401	.2186	24
SEX	1	Male	.6210	.2019	28
Total Cases = 52					

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(9.1.2.1) Summaries of CHANGE TOT.SCR. %CHANGE
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
SEX	0	Female	22.5077	27.1756	24
SEX	1	Male	21.6658	26.2432	27
Total Cases = 52					
Missing Cases = 1 OR 1.9 PCT.					

Summaries of INDCHG INDEX %CHANGE
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
SEX	0	Female	22.5077	27.1756	24
SEX	1	Male	21.6658	26.2432	27
Total Cases = 52					
Missing Cases = 1 OR 1.9 PCT.					

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(9.1.2.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D42SCR Dy42 Total Score
 BY SEX
 WITH D0SCR Dy0 Total Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.198	1	2.198	.008	.931
D0SCR	2.198	1	2.198	.008	.931
Main Effects	63.160	1	63.160	.218	.642
SEX	63.160	1	63.160	.218	.642
Explained	65.358	2	32.679	.113	.893
Residual	13882.681	48	289.223		
Total	13948.039	50	278.961		

52 Cases were processed.
 1 Cases (1.9 PCT) were missing.

FCE 20124/706 i

(9.1.2.1) Summaries of D0SCR Dy0 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			65.7843	5.9609	51
COUNTRY	1.00	Canada	55.8571	8.8962	7
COUNTRY	2.00	Brazil	67.3636	3.4174	44
Total Cases =		52			
Missing Cases =		1 OR	1.9 PCT.		

Summaries of D42SCR Dy42 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			50.3846	16.6335	52
COUNTRY	1.00	Canada	50.8750	12.2526	8
COUNTRY	2.00	Brazil	50.2955	17.4257	44
Total Cases =		52			

Summaries of INDX0 D0 INDEX SCR
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.8223	.0745	51
COUNTRY	1.00	Canada	.6982	.1112	7
COUNTRY	2.00	Brazil	.8420	.0427	44
Total Cases =		52			
Missing Cases =		1 OR	1.9 PCT.		

Summaries of :INDX42 D42 INDEX SCR
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.6298	.2079	52
COUNTRY	1.00	Canada	.6359	.1532	8
COUNTRY	2.00	Brazil	.6287	.2178	44
Total Cases =		52			

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(9.1.2.1) Summaries of CHANGE TOT.SCR. %CHANGE
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.0620	26.4201	51
COUNTRY	1.00	Canada	11.1313	16.2605	7
COUNTRY	2.00	Brazil	23.8010	27.4265	44
Total Cases =	52				
Missing Cases =	1 OR	1.9 PCT.			

Summaries of INDCHG INDEX %CHANGE
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.0620	26.4201	51
COUNTRY	1.00	Canada	11.1313	16.2605	7
COUNTRY	2.00	Brazil	23.8010	27.4265	44
Total Cases =	52				
Missing Cases =	1 OR	1.9 PCT.			

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(9.1.2.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D42SCR Dy42 Total Score
 BY COUNTRY
 WITH D0SCR Dy0 Total Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.198	1	2.198	.008	.931
D0SCR	2.198	1	2.198	.008	.931
Main Effects	26.633	1	26.633	.092	.763
COUNTRY	26.633	1	26.633	.092	.763
Explained	28.831	2	14.416	.050	.952
Residual	13919.208	48	289.984		
Total	13948.039	50	278.961		

52 Cases were processed.
 1 Cases (1.9 PCT) were missing.

957

450

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(9.1.2.1) Summaries of D0SCR Dy0 Total Score
By levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			65.7843	5.9609	51
AGEGP	1.00	Low(18-37)	68.1053	3.4944	19
AGEGP	2.00	Middle(38-49)	63.3000	6.0966	20
AGEGP	3.00	High(≥50)	48.6154	15.0196	13
Total Cases =		52			

Summaries of D42SCR Dy42 Total Score
By levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			50.3846	16.6335	52
AGEGP	1.00	Low(18-37)	51.1579	19.0621	19
AGEGP	2.00	Middle(38-49)	50.8000	15.9063	20
AGEGP	3.00	High(≥50)	48.6154	15.0196	13
Total Cases =		52			

Summaries of CHANGE TOT.SCR. %CHANGE
By levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.0620	26.4201	51
AGEGP	1.00	Low(18-37)	23.7220	27.9351	19
AGEGP	2.00	Middle(38-49)	17.8719	26.9588	20
AGEGP	3.00	High(≥50)	26.4173	24.1482	12
Total Cases =		52			
Missing Cases =		1 OR 1.9 PCT.			

Summaries of INDCHG INDEX %CHANGE
By levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.0620	26.4201	51
AGEGP	1.00	Low(18-37)	23.7220	27.9351	19
AGEGP	2.00	Middle(38-49)	17.8719	26.9588	20
AGEGP	3.00	High(≥50)	26.4173	24.1482	12
Total Cases =		52			
Missing Cases =		1 OR 1.9 PCT.	958		

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(9.1.2.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D42SCR Dy42 Total Score
 BY AGE GP Age Group
 WITH D0SCR Dy0 Total Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.198	1	2.198	.007	.931
D0SCR	2.198	1	2.198	.007	.931
Main Effects	117.475	2	58.737	.200	.820
AGE GP	117.475	2	58.737	.200	.820
Explained	119.673	3	39.891	.136	.938
Residual	13828.367	47	294.221		
Total	13948.039	50	278.961		

52 Cases were processed.
 1 Cases (1.9 PCT) were missing.

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(9.1.2.1) Summaries of D0SCR Dy0 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			65.7843	5.9609	51
SUBFORM	1.00	Sing.Epi.	67.7778	2.9786	27
SUBFORM	2.00	Recurr.	63.7143	7.7404	21
SUBFORM	3.00	Rec.-Mod.Sv.	57.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	65.0000	8.4853	2
Total Cases =		52			
Missing Cases =		1 OR	1.9 PCT.		

Summaries of D42SCR Dy42 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			50.3846	16.6335	52
SUBFORM	1.00	Sing.Epi.	49.8519	18.0697	27
SUBFORM	2.00	Recurr.	51.0455	15.8609	22
SUBFORM	3.00	Rec.-Mod.Sv.	39.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	56.0000	11.3137	2
Total Cases =		52			

Summaries of INDX0 D0 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.8223	.0745	51
SUBFORM	1.00	Sing.Epi.	.8472	.0372	27
SUBFORM	2.00	Recurr.	.7964	.0968	21
SUBFORM	3.00	Rec.-Mod.Sv.	.7125	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	.8125	.1061	2
Total Cases =		52			
Missing Cases =		1 OR	1.9 PCT.		

FCE 20124/706 i

(9.1.2.1) Summaries of INDX42 D42 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.6298	.2079	52
SUBFORM	1.00	Sing.Epi.	.6231	.2259	27
SUBFORM	2.00	Recurr.	.6381	.1983	22
SUBFORM	3.00	Rec.-Mod.Sv.	.4875	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	.7000	.1414	2

Total Cases = 52

Summaries of CHANGE TOT.SCR. %CHANGE
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.0620	26.4201	51
SUBFORM	1.00	Sing.Epi.	25.2521	27.0311	27
SUBFORM	2.00	Recurr.	18.3940	27.4588	21
SUBFORM	3.00	Rec.-Mod.Sv.	30.5789	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	13.2516	6.2119	2

Total Cases = 52

Missing Cases = 1 OR 1.9 PCT.

Summaries of INDCHG INDEX %CHANGE
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			22.0620	26.4201	51
SUBFORM	1.00	Sing.Epi.	25.2521	27.0311	27
SUBFORM	2.00	Recurr.	18.3940	27.4588	21
SUBFORM	3.00	Rec.-Mod.Sv.	30.5789	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	13.2516	6.2119	2

Total Cases = 52

Missing Cases = 1 OR 1.9 PCT.

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(9.1.2.1) * * * A N A L Y S I S O F V A R I A N C E * * *

D42SCR Dy42 Total Score
 BY SUBFORM DSM-III-R Subform
 WITH D0SCR Dy0 Total Score

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.198	1	2.198	.007	.932
D0SCR	2.198	1	2.198	.007	.932
Main Effects	204.955	3	68.318	.229	.876
SUBFORM	204.955	3	68.318	.229	.876
Explained	207.153	4	51.788	.173	.951
Residual	13740.886	46	298.715		
Total	13948.039	50	278.961		

52 Cases were processed.
 1 Cases (1.9 PCT) were missing.

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APPENDIX 15

Onset of Therapeutic Activity: ZUNG

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```
( 9.1.2.2 ) manova d0scr d7scr d14scr d21scr d28scr d35scr d42scr by drugrp(1,2)
/wsactors=time(7)
/wsdesign=time
/design.
```

```
50 cases accepted.
0 cases rejected because of out-of-range factor values.
2 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
Source of Variation      SS      DF      MS      F      Sig of F
WITHIN CELLS             31274.03    48     651.54
CONSTANT                 1123856.51    1 1123856.5  1724.92    .000
DRUGRP                   8921.47     1   8921.47   13.69     .001
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00327
Chi-square approx. = 261.94560 with 20 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .29982
Huynh-Feldt Epsilon = .31726
Lower-bound Epsilon = .16667
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

964

437

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(9.1.2.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. DRUGRP BY TIME
Multivariate Tests of Significance (S = 1, M = 2 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.33171	3.55724	6.00	43.00	.006
Hotellings	.49636	3.55724	6.00	43.00	.006
Wilks	.66829	3.55724	6.00	43.00	.006
Roys	.33171				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME
Multivariate Tests of Significance (S = 1, M = 2 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.52493	7.91878	6.00	43.00	.000
Hotellings	1.10495	7.91878	6.00	43.00	.000
Wilks	.47507	7.91878	6.00	43.00	.000
Roys	.52493				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares					
Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	15785.21	288	54.81		
TIME	11005.19	6	1834.20	33.46	.000
DRUGRP BY TIME	3741.91	6	623.65	11.38	.000

965

438

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(9.1.2.2) Summaries of D0SCR Dy0 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			65.7843	5.9609	51
DRUGRP	1	Reboxetine	66.2963	4.9210	27
DRUGRP	2	Placebo	65.2083	7.0154	24

Summaries of D0SCR Dy0 Total Score
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	66.2963	4.9210	629.6296	27	
2	Placebo	65.2083	7.0154	1131.9583	24	

Within Groups Total			65.7843	5.9959	1761.5880	51

Criterion Variable D0SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15.0395	1	15.0395	.4183	.5208
Within Groups	1761.5880	49	35.9508		

Eta = .0920 Eta Squared = .0085

966

439

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(9.1.2.2) Summaries of INDX0 DO INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
DRUGRP	1	Reboxetine	.8287	.0615	27
DRUGRP	2	Placebo	.8151	.0877	24

Summaries of INDX0 DO INDEX SCR
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	.8287	.0615	.0984	27	
2	Placebo	.8151	.0877	.1769	24	
<hr/>						
Within Groups Total			.8223	.0749	.2752	51

Criterion Variable INDX0

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0023	1	.0023	.4183	.5208
Within Groups	.2752	49	.0056		

Eta = .0920 Eta Squared = .0085

967

440

FCE 20124/706 i

(9.1.2.2) Summaries of D7SCR Dy7 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			63.4902	8.4531	51
DRUGRP	1	Reboxetine	62.5185	9.8854	27
DRUGRP	2	Placebo	64.5833	6.5203	24

Summaries of D7SCR Dy7 Total Score
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	62.5185	9.8854	2540.7407	27
2	Placebo	64.5833	6.5203	977.8333	24
Within Groups Total		63.4902	8.4739	3518.5741	51

Criterion Variable D7SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	54.1710	1	54.1710	.7544	.3893
Within Groups	3518.5741	49	71.8076		
Eta = .1231		Eta Squared = .0152			

968

441

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(9.1.2.2) Summaries of INDX7 D7 INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		.7936	.1057	51
DRUGRP	1 Reboxetine	.7815	.1236	27
DRUGRP	2 Placebo	.8073	.0815	24

Summaries of INDX7 D7 INDEX SCR
By levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	.7815	.1236	.3970	27
2 Placebo	.8073	.0815	.1528	24

Within Groups Total	.7936	.1059	.5498	51

Criterion Variable INDX7

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0085	1	.0085	.7544	.3893
Within Groups	.5498	49	.0112		
Eta = .1231 Eta Squared = .0152					

969

442

FCE 20124/706 i

(9.1.2.2) Summaries of DOT7CG %Change 0-7
By levels of DRUGGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.8657	11.5097	50
DRUGGRP	1	Reboxetine	5.1186	11.7994	27
DRUGGRP	2	Placebo	.2210	10.8154	23
Total Cases = 52					
Missing Cases = 2 OR 3.8 PCT.					

Summaries of DOT7CG %Change 0-7
By levels of DRUGGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	5.1186	11.7994	3619.8421	27	
2	Placebo	.2210	10.8154	2573.3899	23	

Within Groups Total			2.8657	11.3589	6193.2320	50

Criterion Variable DOT7CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	297.9081	1	297.9081	2.3089	.1352
Within Groups	6193.2320	48	129.0257		
Eta = .2142 Eta Squared = .0459					

970

443

FCE 20124/706 i

(9.1.2.2) Summaries of D14SCR Dy14 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			57.6731	10.4745	52
DRUGRP	1	Reboxetine	54.7407	9.6261	27
DRUGRP	2	Placebo	60.8400	10.6132	25

Summaries of D14SCR Dy14 Total Score
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	54.7407	9.6261	2409.1852	27
2	Placebo	60.8400	10.6132	2703.3600	25
Within Groups Total		57.6731	10.1119	5112.5452	52

Criterion Variable D14SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	482.8971	1	482.8971	4.7227	.0345
Within Groups	5112.5452	50	102.2509		
Eta = .2938		Eta Squared = .0863			

FCE 20124/706 i

(9.1.2.2) Summaries of INDX14 D14 INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.7209	.1309	52
DRUGRP	1	Reboxetine	.6843	.1203	27
DRUGRP	2	Placebo	.7605	.1327	25

Summaries of INDX14 D14 INDEX SCR
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	.6843	.1203	.3764	27	
2	Placebo	.7605	.1327	.4224	25	

Within Groups Total			.7209	.1264	.7988	52

Criterion Variable INDX14

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0755	1	.0755	4.7227	.0345
Within Groups	.7988	50	.0160		
Eta = .2938		Eta Squared = .0863			

972

445

FCE 20124/706 i

(9.1.2.2) Summaries of DOT14CG %Change 0-14
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			11.2417	15.7313	51
DRUGRP	1	Reboxetine	16.2491	15.2229	27
DRUGRP	2	Placebo	5.6083	14.6108	24

Summaries of DOT14CG %Change 0-14
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	16.2491	15.2229	6025.1488	27	
2	Placebo	5.6083	14.6108	4909.9541	24	

Within Groups Total			11.2417	14.9387	10935.1028	51

Criterion Variable DOT14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1438.6553	1	1438.6553	6.4466	.0143
Within Groups	10935.1028	49	223.1654		

Eta = .3410 Eta Squared = .1163

FCE 20124/706 i

(9.1.2.2) Summaries of D21SCR Dy21 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			54.0962	14.2075	52
DRUGRP	1	Reboxetine	48.3704	11.9169	27
DRUGRP	2	Placebo	60.2800	14.0846	25

Summaries of D21SCR Dy21 Total Score
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	48.3704	11.9169	3692.2963	27
2	Placebo	60.2800	14.0846	4761.0400	25
Within Groups Total		54.0962	13.0026	8453.3363	52

Criterion Variable D21SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1841.1829	1	1841.1829	10.8903	.0018
Within Groups	8453.3363	50	169.0667		
Eta = .4229		Eta Squared = .1789			

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(9.1.2.2) Summaries of INDX21 D21 INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6762	.1776	52
DRUGRP	1	Reboxetine	.6046	.1490	27
DRUGRP	2	Placebo	.7535	.1761	25

Summaries of INDX21 D21 INDEX SCR
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	.6046	.1490	.5769	27
2	Placebo	.7535	.1761	.7439	25

Within Groups Total		.6762	.1625	1.3208	52

Criterion Variable INDX21

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2877	1	.2877	10.8903	.0018
Within Groups	1.3208	50	.0264		
Eta = .4229		Eta Squared = .1789			

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(9.1.2.2) Summaries of DOT21OG %Change 0-21
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			16.6485	22.0807	51
DRUGRP	1	Reboxetine	25.6689	19.0621	27
DRUGRP	2	Placebo	6.5007	21.1228	24

Summaries of DOT21OG %Change 0-21
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	25.6689	19.0621	9447.4354	27
2	Placebo	6.5007	21.1228	10262.0149	24
Within Groups Total		16.6485	20.0558	19709.4503	51

Criterion Variable DOT21OG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4668.3961	1	4668.3961	11.6062	.0013
Within Groups	19709.4503	49	402.2337		
Eta = .4376		Eta Squared = .1915			

976

449

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(9.1.2.2) Summaries of D28SCR Dy28 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			51.8846	15.8196	52
DRUGRP	1	Reboxetine	44.2593	12.9929	27
DRUGRP	2	Placebo	60.1200	14.5897	25

Summaries of D28SCR Dy28 Total Score
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	44.2593	12.9929	4389.1852	27	
2	Placebo	60.1200	14.5897	5108.6400	25	

Within Groups Total			51.8846	13.7825	9497.8252	52

Criterion Variable D28SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3265.4825	1	3265.4825	17.1907	.0001
Within Groups	9497.8252	50	189.9565		

Eta = .5058 Eta Squared = .2558

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(9.1.2.2) Summaries of INDX28 D28 INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6486	.1977	52
DRUGRP	1	Reboxetine	.5532	.1624	27
DRUGRP	2	Placebo	.7515	.1824	25

Summaries of INDX28 D28 INDEX SCR
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	.5532	.1624	.6858	27	
2	Placebo	.7515	.1824	.7982	25	
<hr/>						
Within Groups Total			.6486	.1723	1.4840	52

Criterion Variable INDX28

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5102	1	.5102	17.1907	.0001
Within Groups	1.4840	50	.0297		
Eta = .5058		Eta Squared = .2558			

978

451

FCE 20124/706 i

(9.1.2.2) Summaries of DOT28CG %Change 0-28
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			20.0641	24.3251	51
DRUGRP	1	Reboxetine	31.9242	20.0049	27
DRUGRP	2	Placebo	6.7214	21.9780	24

Summaries of DOT28CG %Change 0-28
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	31.9242	20.0049	10405.1459	27	
2	Placebo	6.7214	21.9780	11109.7975	24	

Within Groups Total			20.0641	20.9542	21514.9434	51

Criterion Variable DOT28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	8070.5002	1	8070.5002	18.3805	.0001
Within Groups	21514.9434	49	439.0805		
Eta = .5223 Eta Squared = .2728					

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(9.1.2.2) Summaries of D35SCR Dy35 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			51.1923	16.0527	52
DRUGRP	1	Reboxetine	43.4815	13.2066	27
DRUGRP	2	Placebo	59.5200	14.8159	25

Summaries of D35SCR Dy35 Total Score
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	43.4815	13.2066	4534.7407	27	
2	Placebo	59.5200	14.8159	5268.2400	25	

Within Groups Total			51.1923	14.0021	9802.9807	52

Criterion Variable D35SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3339.0962	1	3339.0962	17.0310	.0001
Within Groups	9802.9807	50	196.0596		

Eta = .5041 Eta Squared = .2541

980

453

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(9.1.2.2) Summaries of INDX35 D35 INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
DRUGRP	1 Reboxetine	.5435	.1651	27
DRUGRP	2 Placebo	.7440	.1852	25

Summaries of INDX35 D35 INDEX SCR
By Levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	.5435	.1651	.7086	27
2 Placebo	.7440	.1852	.8232	25

Within Groups Total	.6399	.1750	1.5317	52

Criterion Variable INDX35

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5217	1	.5217	17.0310	.0001
Within Groups	1.5317	50	.0306		
Eta = .5041 Eta Squared = .2541					

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(9.1.2.2) Summaries of DOT35CG %Change 0-35
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			21.1261	24.7492	51
DRUGRP	1	Reboxetine	33.1201	20.2842	27
DRUGRP	2	Placebo	7.6329	22.5299	24

Summaries of DOT35CG %Change 0-35
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	33.1201	20.2842	10697.7145	27	
2	Placebo	7.6329	22.5299	11674.7524	24	
<hr/>						
Within Groups Total			21.1261	21.3678	22372.4669	51

Criterion Variable DOT35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	8253.7422	1	8253.7422	18.0773	.0001
Within Groups	22372.4669	49	456.5810		

Eta = .5191 Eta Squared = .2695

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(9.1.2.2) Summaries of D42SCR Dy42 Total Score
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			50.3846	16.6335	52
DRUGRP	1	Reboxetine	42.8148	13.9919	27
DRUGRP	2	Placebo	58.5600	15.5485	25

Summaries of D42SCR Dy42 Total Score
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	42.8148	13.9919	5090.0741	27	
2	Placebo	58.5600	15.5485	5802.1600	25	

Within Groups Total			50.3846	14.7596	10892.2341	52

Criterion Variable D42SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3218.0736	1	3218.0736	14.7723	.0003
Within Groups	10892.2341	50	217.8447		

Eta = .4776 Eta Squared = .2281

983

456

FCE 20124/706 i

(9.1.2.2) Summaries of INDX42 D42 INDEX SCR
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
DRUGRP	1	Reboxetine	.5352	.1749	27
DRUGRP	2	Placebo	.7320	.1944	25

Summaries of INDX42 D42 INDEX SCR
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	.5352	.1749	.7953	27
2	Placebo	.7320	.1944	.9066	25

Within Groups Total		.6298	.1845	1.7019	52

Criterion Variable INDX42

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5028	1	.5028	14.7723	.0003
Within Groups	1.7019	50	.0340		
Eta = .4776		Eta Squared = .2281			

984

457

FCE 20124/706 i

(9.1.2.2) Summaries of DOT42CG %Change 0-42
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			22.0620	26.4201	51
DRUGRP	1	Reboxetine	33.5750	23.3725	27
DRUGRP	2	Placebo	9.1099	23.8591	24

Summaries of DOT42CG %Change 0-42
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	33.5750	23.3725	14203.1628	27	
2	Placebo	9.1099	23.8591	13092.9147	24	

Within Groups Total			22.0620	23.6022	27296.0775	51

Criterion Variable DOT42CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	7605.0077	1	7605.0077	13.6520	.0006
Within Groups	27296.0775	49	557.0628		

Eta = .4668 Eta Squared = .2179

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```
( 9.1.2.2 ) manova d0scr d7scr d14scr d21scr d28scr d35scr d42scr by sex(0,1)
/wsufactors=time(7)
/wsdesign=time
/design.
```

```
50 cases accepted.
0 cases rejected because of out-of-range factor values.
2 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	40149.20	48	836.44		
CONSTANT	1113819.03	1	1113819.0	1331.62	.000
SEX	46.30	1	46.30	.06	.815

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00126
Chi-square approx. = 305.56181 with 20 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .26622
Huynh-Feldt Epsilon = .27968
Lower-bound Epsilon = .16667
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

986

459

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(9.1.2.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.11858	.96418	6.00	43.00	.461
Hotellings	.13454	.96418	6.00	43.00	.461
Wilks	.88142	.96418	6.00	43.00	.461
Roys	.11858				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.48039	6.62570	6.00	43.00	.000
Hotellings	.92452	6.62570	6.00	43.00	.000
Wilks	.51961	6.62570	6.00	43.00	.000
Roys	.48039				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	19375.42	288	67.28		
TIME	12159.68	6	2026.61	30.12	.000
SEX BY TIME	151.70	6	25.28	.38	.894

987

460

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(9.1.2.2) Summaries of D0SCR Dy0 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			65.7843	5.9609	51
SEX	0	Female	67.5417	4.6060	24
SEX	1	Male	64.2222	6.6468	27

Summaries of D0SCR Dy0 Total Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	67.5417	4.6060	487.9583	24
1	Male	64.2222	6.6468	1148.6667	27

Within Groups Total		65.7843	5.7793	1636.6250	51

Criterion Variable D0SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	140.0025	1	140.0025	4.1916	.0460
Within Groups	1636.6250	49	33.4005		

Eta = .2807 Eta Squared = .0788

988

461

FCE 20124/706 i

(9.1.2.2) Summaries of INDx0 DO INDEX SCR
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.8223	.0745	51
SEX	0	Female	.8443	.0576	24
SEX	1	Male	.8028	.0831	27

Summaries of INDx0 DO INDEX SCR
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	.8443	.0576	.0762	24	
1	Male	.8028	.0831	.1795	27	
<hr/>						
Within Groups Total			.8223	.0722	.2557	51

Criterion Variable INDx0

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0219	1	.0219	4.1916	.0460
Within Groups	.2557	49	.0052		

Eta = .2807 Eta Squared = .0788

989

462

FCE 20124/706 i

(9.1.2.2) Summaries of D7SCR Dy7 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			63.4902	8.4531	51
SEX	0	Female	64.6250	9.3195	24
SEX	1	Male	62.4815	7.6378	27

Summaries of D7SCR Dy7 Total Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	64.6250	9.3195	1997.6250	24	
1	Male	62.4815	7.6378	1516.7407	27	
<hr/>						
Within Groups Total			63.4902	8.4689	3514.3657	51

Criterion Variable D7SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	58.3794	1	58.3794	.8140	.3714
Within Groups	3514.3657	49	71.7217		

Eta = .1278 Eta Squared = .0163

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(9.1.2.2) Summaries of INDX7 D7 INDEX SCR
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.7936	.1057	51
SEX	0	Female	.8078	.1165	24
SEX	1	Male	.7810	.0955	27

Summaries of INDX7 D7 INDEX SCR
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	.8078	.1165	.3121	24	
1	Male	.7810	.0955	.2370	27	

Within Groups Total			.7936	.1059	.5491	51

Criterion Variable INDX7

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0091	1	.0091	.8140	.3714
Within Groups	.5491	49	.0112		

Eta = .1278 Eta Squared = .0163

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(9.1.2.2) Summaries of D14SCR Dy14 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			57.6731	10.4745	52
SEX	0	Female	57.7500	11.0778	24
SEX	1	Male	57.6071	10.1337	28

Summaries of D14SCR Dy14 Total Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	57.7500	11.0778	2822.5000	24	
1	Male	57.6071	10.1337	2772.6786	28	
<hr/>						
Within Groups Total			57.6731	10.5784	5595.1786	52

Criterion Variable D14SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2637	1	.2637	.0024	.9615
Within Groups	5595.1786	50	111.9036		

Eta = .0069 Eta Squared = .0000

FCE 20124/706 i

(9.1.2.2) Summaries of INDX14 D14 INDEX SCR
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.7209	.1309	52
SEX	0	Female	.7219	.1385	24
SEX	1	Male	.7201	.1267	28

Summaries of INDX14 D14 INDEX SCR
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	.7219	.1385	.4410	24	
1	Male	.7201	.1267	.4332	28	

Within Groups Total			.7209	.1322	.8742	52

Criterion Variable INDX14

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0000	1	.0000	.0024	.9615
Within Groups	.8742	50	.0175		
Eta = .0069		Eta Squared = .0000			

FCE 20124/706 i

(9.1.2.2) Summaries of D21SCR Dy21 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			54.0962	14.2075	52
SEX	0	Female	53.7083	14.6539	24
SEX	1	Male	54.4286	14.0750	28

Summaries of D21SCR Dy21 Total Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	53.7083	14.6539	4938.9583	24	
1	Male	54.4286	14.0750	5348.8571	28	

Within Groups Total			54.0962	14.3442	10287.8155	52

Criterion Variable D21SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	6.7038	1	6.7038	.0326	.8575
Within Groups	10287.8155	50	205.7563		

Eta = .0255 Eta Squared = .0007

FCE 20124/706 i

(9.1.2.2) Summaries of INDX21 D21 INDEX SCR
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6762	.1776	52
SEX	0	Female	.6714	.1832	24
SEX	1	Male	.6804	.1759	28

Summaries of INDX21 D21 INDEX SCR
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	.6714	.1832	.7717	24	
1	Male	.6804	.1759	.8358	28	

Within Groups Total			.6762	.1793	1.6075	52

Criterion Variable INDX21

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0010	1	.0010	.0326	.8575
Within Groups	1.6075	50	.0321		

Eta = .0255 Eta Squared = .0007

FCE 20124/706 i

(9.1.2.2) Summaries of D28SCR Dy28 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
SEX	0	Female	51.2917	16.7422	24
SEX	1	Male	52.3929	15.2761	28

Summaries of D28SCR Dy28 Total Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	51.2917	16.7422	6446.9583	24
1	Male	52.3929	15.2761	6300.6786	28

Within Groups Total		51.8846	15.9672	12747.6369	52

Criterion Variable D28SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15.6708	1	15.6708	.0615	.8052
Within Groups	12747.6369	50	254.9527		

Eta = .0350 Eta Squared = .0012

FCE 20124/706 i

(9.1.2.2) Summaries of INDX28 D28 INDEX SCR
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6486	.1977	52
SEX	0	Female	.6411	.2093	24
SEX	1	Male	.6549	.1910	28

Summaries of INDX28 D28 INDEX SCR
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	.6411	.2093	1.0073	24	
1	Male	.6549	.1910	.9845	28	

Within Groups Total			.6486	.1996	1.9918	52

Criterion Variable INDX28

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0024	1	.0024	.0615	.8052
Within Groups	1.9918	50	.0398		

Eta = .0350 Eta Squared = .0012

FCE 20124/706 i

(9.1.2.2) Summaries of D35SCR Dy35 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			51.1923	16.0527	52
SEX	0	Female	51.6250	16.7768	24
SEX	1	Male	50.8214	15.7058	28

Summaries of D35SCR Dy35 Total Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	51.6250	16.7768	6473.6250	24	
1	Male	50.8214	15.7058	6660.1071	28	

Within Groups Total			51.1923	16.2072	13133.7321	52

Criterion Variable D35SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	8.3448	1	8.3448	.0318	.8593
Within Groups	13133.7321	50	262.6746		
		Eta = .0252		Eta Squared = .0006	

998

471

FCE 20124/706 i

(9.1.2.2) Summaries of INDX35 D35 INDEX SCR
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
SEX	0	Female	.6453	.2097	24
SEX	1	Male	.6353	.1963	28

Summaries of INDX35 D35 INDEX SCR
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	.6453	.2097	1.0115	24	
1	Male	.6353	.1963	1.0406	28	

Within Groups Total			.6399	.2026	2.0521	52

Criterion Variable INDX35

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0013	1	.0013	.0318	.8593
Within Groups	2.0521	50	.0410		

Eta = .0252 Eta Squared = .0006

999

472

FCE 20124/706 i

(9.1.2.2) Summaries of D42SCR Dy42 Total Score
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			50.3846	16.6335	52
SEX	0	Female	51.2083	17.4878	24
SEX	1	Male	49.6786	16.1545	28

Summaries of D42SCR Dy42 Total Score
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	51.2083	17.4878	7033.9583	24	
1	Male	49.6786	16.1545	7046.1071	28	

Within Groups Total			50.3846	16.7810	14080.0655	52

Criterion Variable D42SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	30.2422	1	30.2422	.1074	.7445
Within Groups	14080.0655	50	281.6013		

Eta = .0463 Eta Squared = .0021

1000

473

FCE 20124/706 i

```
( 9.1.2.2 ) manova d0scr d7scr d14scr d21scr d28scr d35scr d42scr by country(1,2)
/wsactors=time(7)
/wsdesign=time
/design.
```

```
50 cases accepted.
0 cases rejected because of out-of-range factor values.
2 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
* * ANALYSIS OF VARIANCE -- DESIGN 1 * *
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	38441.68	48	800.87		
CONSTANT	428315.24	1	428315.24	534.81	.000
COUNTRY	1753.82	1	1753.82	2.19	.145

```
* * ANALYSIS OF VARIANCE -- DESIGN 1 * *
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00120
Chi-square approx. = 307.99688 with 20 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .26657
Huynh-Feldt Epsilon = .28006
Lower-bound Epsilon = .16667
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to
univariate or split-plot or mixed-mode} approach to repeated measures.
Epsilons may be used to adjust d.f. for the AVERAGED results.
```

1001

474

FCE 20124/706 i

(9.1.2.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.25933	2.50928	6.00	43.00	.036
Hotellings	.35013	2.50928	6.00	43.00	.036
Wilks	.74067	2.50928	6.00	43.00	.036
Roys	.25933				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.32185	3.40132	6.00	43.00	.008
Hotellings	.47460	3.40132	6.00	43.00	.008
Wilks	.67815	3.40132	6.00	43.00	.008
Roys	.32185				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	18989.28	288	65.94		
TIME	3423.46	6	570.58	8.65	.000
COUNTRY BY TIME	537.84	6	89.64	1.36	.231

1002

475

FCE 20124/706 i

(9.1.2.2) Summaries of D0SCR Dy0 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			65.7843	5.9609	51
COUNTRY	1.00	Canada	55.8571	8.8962	7
COUNTRY	2.00	Brazil	67.3636	3.4174	44

Summaries of D0SCR Dy0 Total Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	55.8571	8.8962	474.8571	7
2.00	Brazil	67.3636	3.4174	502.1818	44
<hr/>					
Within Groups Total		65.7843	4.4654	977.0390	51

Criterion Variable D0SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	799.5885	1	799.5885	40.1006	.0000
Within Groups	977.0390	49	19.9396		

Eta = .6709 Eta Squared = .4501

1003

476

FCE 20124/706 i

(9.1.2.2) Summaries of INDX0 DO INDEX SCR
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.8223	.0745	51
COUNTRY	1.00	Canada	.6982	.1112	7
COUNTRY	2.00	Brazil	.8420	.0427	44

Summaries of INDX0 DO INDEX SCR
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	.6982	.1112	.0742	7
2.00	Brazil	.8420	.0427	.0785	44

Within Groups Total		.8223	.0558	.1527	51

Criterion Variable INDX0

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1249	1	.1249	40.1006	.0000
Within Groups	.1527	49	.0031		
Eta = .6709		Eta Squared = .4501			

1004

477

FCE 20124/706 i

(9.1.2.2) Summaries of D7SCR Dy7 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			63.4902	8.4531	51
COUNTRY	1.00	Canada	52.2857	15.3483	7
COUNTRY	2.00	Brazil	65.2727	5.1506	44

Summaries of D7SCR Dy7 Total Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	52.2857	15.3483	1413.4286	7
2.00	Brazil	65.2727	5.1506	1140.7273	44

Within Groups Total		63.4902	7.2198	2554.1558	51

Criterion Variable D7SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1018.5893	1	1018.5893	19.5410	.0001
Within Groups	2554.1558	49	52.1256		

Eta = .5339 Eta Squared = .2851

1005

478

FCE 20124/706 i

(9.1.2.2) Summaries of IND7 D7 INDEX SCR
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.7936	.1057	51
COUNTRY	1.00	Canada	.6536	.1919	7
COUNTRY	2.00	Brazil	.8159	.0644	44

Summaries of IND7 D7 INDEX SCR
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	.6536	.1919	.2208	7
2.00	Brazil	.8159	.0644	.1782	44

Within Groups Total		.7936	.0902	.3991	51

Criterion Variable IND7

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1592	1	.1592	19.5410	.0001
Within Groups	.3991	49	.0081		

Eta = .5339 Eta Squared = .2851

1006

479

FCE 20124/706 i

(9.1.2.2) Summaries of D14SCR Dy14 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			57.6731	10.4745	52
COUNTRY	1.00	Canada	51.7500	15.2198	8
COUNTRY	2.00	Brazil	58.7500	9.2034	44

Summaries of D14SCR Dy14 Total Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	51.7500	15.2198	1621.5000	8	
2.00	Brazil	58.7500	9.2034	3642.2500	44	

Within Groups Total			57.6731	10.2604	5263.7500	52

Criterion Variable D14SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	331.6923	1	331.6923	3.1507	.0820
Within Groups	5263.7500	50	105.2750		

Eta = .2435 Eta Squared = .0593

1007

480

FCE 20124/706 i

(9.1.2.2) Summaries of INDX14 D14 INDEX SCR
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.7209	.1309	52
COUNTRY	1.00	Canada	.6469	.1902	8
COUNTRY	2.00	Brazil	.7344	.1150	44

Summaries of INDX14 D14 INDEX SCR
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	.6469	.1902	.2534	8
2.00	Brazil	.7344	.1150	.5691	44

Within Groups Total		.7209	.1283	.8225	52

Criterion Variable INDX14

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0518	1	.0518	3.1507	.0820
Within Groups	.8225	50	.0164		

Eta = .2435 Eta Squared = .0593

1000

481

FCE 20124/706 i

(9.1.2.2) Summaries of D21SCR Dy21 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			54.0962	14.2075	52
COUNTRY	1.00	Canada	50.7500	14.0687	8
COUNTRY	2.00	Brazil	54.7045	14.3082	44

Summaries of D21SCR Dy21 Total Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	50.7500	14.0687	1385.5000	8
2.00	Brazil	54.7045	14.3082	8803.1591	44
<hr/>					
Within Groups Total		54.0962	14.2749	10188.6591	52

Criterion Variable D21SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	105.8601	1	105.8601	.5195	.4744
Within Groups	10188.6591	50	203.7732		

Eta = .1014 Eta Squared = .0103

1009

482

FCE 20124/706 i

(9.1.2.2) Summaries of INDX21 D21 INDEX SCR
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6762	.1776	52
COUNTRY	1.00	Canada	.6344	.1759	8
COUNTRY	2.00	Brazil	.6838	.1789	44

Summaries of INDX21 D21 INDEX SCR
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	.6344	.1759	.2165	8	
2.00	Brazil	.6838	.1789	1.3755	44	

Within Groups Total			.6762	.1784	1.5920	52

Criterion Variable INDX21

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0165	1	.0165	.5195	.4744
Within Groups	1.5920	50	.0318		

Eta = .1014 Eta Squared = .0103

1010

483

FCE 20124/706 i

(9.1.2.2) Summaries of D28SCR Dy28 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			51.8846	15.8196	52
COUNTRY	1.00	Canada	48.2500	13.7607	8
COUNTRY	2.00	Brazil	52.5455	16.2201	44

Summaries of D28SCR Dy28 Total Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	48.2500	13.7607	1325.5000	8	
2.00	Brazil	52.5455	16.2201	11312.9091	44	

Within Groups Total			51.8846	15.8987	12638.4091	52

Criterion Variable D28SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	124.8986	1	124.8986	.4941	.4854
Within Groups	12638.4091	50	252.7682		

Eta = .0989 Eta Squared = .0098

1011

484

FCE 20124/706 i

(9.1.2.2) Summaries of INDX28 D28 INDEX SCR
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6486	.1977	52
COUNTRY	1.00	Canada	.6031	.1720	8
COUNTRY	2.00	Brazil	.6568	.2028	44

Summaries of INDX28 D28 INDEX SCR
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	.6031	.1720	.2071	8	
2.00	Brazil	.6568	.2028	1.7676	44	

Within Groups Total			.6486	.1987	1.9748	52

Criterion Variable INDX28

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0195	1	.0195	.4941	.4854
Within Groups	1.9748	50	.0395		

Eta = .0989 Eta Squared = .0098

FCE 20124/706 i

(9.1.2.2) Summaries of D35SCR Dy35 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			51.1923	16.0527	52
COUNTRY	1.00	Canada	47.0000	14.3726	8
COUNTRY	2.00	Brazil	51.9545	16.3749	44

Summaries of D35SCR Dy35 Total Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	47.0000	14.3726	1446.0000	8
2.00	Brazil	51.9545	16.3749	11529.9091	44

Within Groups Total		51.1923	16.1096	12975.9091	52

Criterion Variable D35SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	166.1678	1	166.1678	.6403	.4274
Within Groups	12975.9091	50	259.5182		

Eta = .1124 Eta Squared = .0126

FCE 20124/706 i

(9.1.2.2) Summaries of INDX35 D35 INDEX SCR
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6399	.2007	52
COUNTRY	1.00	Canada	.5875	.1797	8
COUNTRY	2.00	Brazil	.6494	.2047	44

Summaries of INDX35 D35 INDEX SCR
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	.5875	.1797	.2259	8	
2.00	Brazil	.6494	.2047	1.8015	44	
<hr/>						
Within Groups Total			.6399	.2014	2.0275	52

Criterion Variable INDX35

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0260	1	.0260	.6403	.4274
Within Groups	2.0275	50	.0405		

Eta = .1124 Eta Squared = .0126

FCE 20124/706 i

(9.1.2.2) Summaries of D42SCR Dy42 Total Score
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			50.3846	16.6335	52
COUNTRY	1.00	Canada	50.8750	12.2526	8
COUNTRY	2.00	Brazil	50.2955	17.4257	44

Summaries of D42SCR Dy42 Total Score
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	50.8750	12.2526	1050.8750	8	
2.00	Brazil	50.2955	17.4257	13057.1591	44	

Within Groups Total			50.3846	16.7976	14108.0341	52

Criterion Variable D42SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.2736	1	2.2736	.0081	.9288
Within Groups	14108.0341	50	282.1607		

Eta = .0127 Eta Squared = .0002

FCE 20124/706 i

```
( 9.1.2.2 ) manova d0scr d7scr d14scr d21scr d28scr d35scr d42scr by agegp(1,3)
/wsactors=time(7)
/wsdesign=time
/design.
```

```
50 cases accepted.
0 cases rejected because of out-of-range factor values.
2 cases rejected because of missing data.
3 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	39525.85	47	840.98		
CONSTANT	1035413.23	1	1035413.2	1231.21	.000
AGEGP	669.65	2	334.83	.40	.674

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00140
Chi-square approx. = 294.09191 with 20 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .26811
Huynh-Feldt Epsilon = .28799
Lower-bound Epsilon = .16667
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1016

489

FCE 20124/706 i

(9.1.2.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. AGEGP BY TIME

Multivariate Tests of Significance (S = 2, M = 1 1/2, N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.20126	.80187	12.00	86.00	.648
Hotellings	.22953	.78422	12.00	82.00	.665
Wilks	.80678	.79328	12.00	84.00	.656
Roys	.14630				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 20)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.48254	6.52771	6.00	42.00	.000
Hotellings	.93253	6.52771	6.00	42.00	.000
Wilks	.51746	6.52771	6.00	42.00	.000
Roys	.48254				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	18754.09	282	66.50		
TIME	12549.52	6	2091.59	31.45	.000
AGEGP BY TIME	773.03	12	64.42	.97	.479

1017

490

FCE 20124/706 i

(9.1.2.2) Summaries of D0SCR
By levels of AGEGP Age Group Dy0 Total Score

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			65.7843	5.9609	51
AGEGP	1.00	Low(18-37)	68.1053	3.4944	19
AGEGP	2.00	Middle(38-49)	63.3000	6.0966	20
AGEGP	3.00	High(≥50)	66.2500	7.5212	12
Within Groups Total			65.7843	5.6793	51

Criterion Variable D0SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	228.3880	2	114.1940	3.5404	.0368
Within Groups	1548.2395	48	32.2550		

Eta = .3585 Eta Squared = .1286

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FCE 20124/706 i

(9.1.2.2) Summaries of INDX0 DO INDEX SCR
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.8223	.0745	51
AGEGP	1.00	Low(18-37)	.8513	.0437	19
AGEGP	2.00	Middle(38-49)	.7913	.0762	20
AGEGP	3.00	High(≥50)	.8281	.0940	12

Within Groups Total			.8223	.0710	51

Criterion Variable INDX0

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0357	2	.0178	3.5404	.0368
Within Groups	.2419	48	.0050		
Eta = .3585		Eta Squared = .1286			

1019

492

FCE 20124/706 i

(9.1.2.2) Summaries of D7SCR Dy7 Total Score
By Levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			63.4902	8.4531	51
AGEGP	1.00	Low(18-37)	64.5789	8.5720	19
AGEGP	2.00	Middle(38-49)	60.8000	9.2087	20
AGEGP	3.00	High(≥50)	66.2500	5.8795	12
Within Groups Total			63.4902	8.3092	51

Criterion Variable D7SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	258.6635	2	129.3318	1.8732	.1647
Within Groups	3314.0816	48	69.0434		

Eta = .2691 Eta Squared = .0724

1020

495

FCE 20124/706 i

(9.1.2.2) Summaries of IND7 D7 INDEX SCR
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.7936	.1057	51
AGEGP	1.00	Low(18-37)	.8072	.1072	19
AGEGP	2.00	Middle(38-49)	.7600	.1151	20
AGEGP	3.00	High(≥50)	.8281	.0735	12

Within Groups Total			.7936	.1039	51

Criterion Variable IND7

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0404	2	.0202	1.8732	.1647
Within Groups	.5178	48	.0108		

Eta = .2691 Eta Squared = .0724

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FCE 20124/706 i

(9.1.2.2) Summaries of D14SCR Dy14 Total Score
By levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			57.6731	10.4745	52
AGEGP	1.00	Low(18-37)	60.0000	10.5830	19
AGEGP	2.00	Middle(38-49)	55.5500	11.9626	20
AGEGP	3.00	High(≥50)	57.5385	7.4567	13
Within Groups Total			57.6731	10.4999	52

Criterion Variable D14SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	193.2615	2	96.6308	.8765	.4227
Within Groups	5402.1808	49	110.2486		

Eta = .1858 Eta Squared = .0345

FCE 20124/706 i

(9.1.2.2) Summaries of INDX14 D14 INDEX SCR
By levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.7209	.1309	52
AGEGP	1.00	Low(18-37)	.7500	.1323	19
AGEGP	2.00	Middle(38-49)	.6944	.1495	20
AGEGP	3.00	High(≥50)	.7192	.0932	13

Within Groups Total			.7209	.1312	52

Criterion Variable INDX14

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0302	2	.0151	.8765	.4227
Within Groups	.8441	49	.0172		
Eta = .1858		Eta Squared = .0345			

FCE 20124/706 i

(9.1.2.2) Summaries of D21SCR Dy21 Total Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			54.0962	14.2075	52
AGEGP	1.00	Low(18-37)	57.5789	14.2529	19
AGEGP	2.00	Middle(38-49)	52.5000	15.2367	20
AGEGP	3.00	High(≥50)	51.4615	12.4339	13
Within Groups Total			54.0962	14.2305	52

Criterion Variable D21SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	371.6569	2	185.8284	.9176	.4062
Within Groups	9922.8623	49	202.5074		

Eta = .1900 Eta Squared = .0361

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FCE 20124/706 i

(9.1.2.2) Summaries of INDX21 D21 INDEX SCR
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.6762	.1776	52
AGEGP	1.00	Low(18-37)	.7197	.1782	19
AGEGP	2.00	Middle(38-49)	.6563	.1905	20
AGEGP	3.00	High(≥50)	.6433	.1554	13
Within Groups Total			.6762	.1779	52

Criterion Variable INDX21

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0581	2	.0290	.9176	.4062
Within Groups	1.5504	49	.0316		

Eta = .1900 Eta Squared = .0361

FCE 20124/706 i

(9.1.2.2) Summaries of D28SCR Dy28 Total Score
By Levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			51.8846	15.8196	52
AGE GP	1.00	Low(18-37)	53.6316	17.2634	19
AGE GP	2.00	Middle(38-49)	51.6000	15.7994	20
AGE GP	3.00	High(≥50)	49.7692	14.5439	13
Within Groups Total			51.8846	16.0646	52

Criterion Variable D28SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	117.7789	2	58.8895	.2282	.7968
Within Groups	12645.5287	49	258.0720		

Eta = .0961 Eta Squared = .0092

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FCE 20124/706 i

(9.1.2.2) Summaries of INDX28 D28 INDEX SCR
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6486	.1977	52
AGEGP	1.00	Low(18-37)	.6704	.2158	19
AGEGP	2.00	Middle(38-49)	.6450	.1975	20
AGEGP	3.00	High(≥50)	.6221	.1818	13

Within Groups Total			.6486	.2008	52

Criterion Variable INDX28

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0184	2	.0092	.2282	.7968
Within Groups	1.9759	49	.0403		

Eta = .0961 Eta Squared = .0092

FCE 20124/706 i

(9.1.2.2) Summaries of D35SCR Dy35 Total Score
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			51.1923	16.0527	52
AGEGP	1.00	Low(18-37)	52.0526	18.3953	19
AGEGP	2.00	Middle(38-49)	51.0000	15.7447	20
AGEGP	3.00	High(≥50)	50.2308	13.8874	13
Within Groups Total			51.1923	16.3603	52

Criterion Variable D35SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	26.8219	2	13.4109	.0501	.9512
Within Groups	13115.2551	49	267.6583		

Eta = .0452 Eta Squared = .0020

FCE 20124/706 i

(9.1.2.2) Summaries of INDX35 D35 INDEX SCR
By levels of AGEGP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6399	.2007	52
AGEGP	1.00	Low(18-37)	.6507	.2299	19
AGEGP	2.00	Middle(38-49)	.6375	.1968	20
AGEGP	3.00	High(≥50)	.6279	.1736	13
Within Groups Total			.6399	.2045	52

Criterion Variable INDX35

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0042	2	.0021	.0501	.9512
Within Groups	2.0493	49	.0418		

Eta = .0452 Eta Squared = .0020

1029

502

PCE 20124/706 i

(9.1.2.2) Summaries of D42SCR Dy42 Total Score
By Levels of AGE GP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			50.3846	16.6335	52
AGE GP	1.00	Low(18-37)	51.1579	19.0621	19
AGE GP	2.00	Middle(38-49)	50.8000	15.9063	20
AGE GP	3.00	High(≥50)	48.6154	15.0196	13
Within Groups Total			50.3846	16.9361	52

Criterion Variable D42SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	55.5045	2	27.7522	.0968	.9080
Within Groups	14054.8032	49	286.8327		

Eta = .0627 Eta Squared = .0039

1030

503

FCE 22891/726 i

```
( 9.1.2.2 ) manova d0scr d7scr d14scr d21scr d28scr d35scr d42scr by subform(1 -)
/wsfactors=time(7)
/wsdesign=time
/design.
```

```
50 cases accepted.
0 cases rejected because of out-of-range factor values.
2 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
Source of Variation      SS      DF      MS      F      Sig of F

WITHIN CELLS             39053.07    46    848.98
CONSTANT                 213800.07     1 213800.07    251.83    .000
SUBFORM                  1142.43      3    380.81      .45    .720
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00066
Chi-square approx. = 320.27234 with 20 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .24748
Huynh-Feldt Epsilon = .27048
Lower-bound Epsilon = .16667
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to
univariate or split-plot or mixed-model approach to repeated measures.
Epsilons may be used to adjust d.f. for the AVERAGED results.
```

1031

504

FCE 22891/726 i

(9.1.2.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 1, N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.80356	2.62189	18.00	129.00	.001
Hotellings	1.59476	3.51439	18.00	119.00	.000
Wilks	.33486	3.05528	18.00	116.45	.000
Roys	.57062				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2, N = 19 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.41995	4.94733	6.00	41.00	.001
Hotellings	.72400	4.94733	6.00	41.00	.001
Wilks	.58005	4.94733	6.00	41.00	.001
Roys	.41995				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	18348.23	276	66.48		
TIME	2044.35	6	340.73	5.13	.000
SUBFORM BY TIME	1178.89	18	65.49	.99	.477

1032

505

FCE 22891/726 i

(9.1.2.2) Summaries of D0SCR Dy0 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			65.7843	5.9609	51
SUBFORM	1.00	Sing.Epi.	67.7778	2.9786	27
SUBFORM	2.00	Recurr.	63.7143	7.7404	21
SUBFORM	3.00	Rec.-Mod.Sv.	57.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	65.0000	8.4853	2

Summaries of D0SCR Dy0 Total Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	67.7778	2.9786	230.6667	27
2.00	Recurr.	63.7143	7.7404	1198.2857	21
3.00	Rec.-Mod.Sv.	57.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	65.0000	8.4853	72.0000	2

Within Groups Total		65.7843	5.6511	1500.9524	51

Criterion Variable D0SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	275.6751	3	91.8917	2.8774	.0459
Within Groups	1500.9524	47	31.9352		
Eta = .3939		Eta Squared = .1552			

1033

506

FCE 22891/726 i

(9.1.2.2) Summaries of INDX0 DO INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.8223	.0745	51
SUBFORM	1.00	Sing.Epi.	.8472	.0372	27
SUBFORM	2.00	Recurr.	.7964	.0968	21
SUBFORM	3.00	Rec.-Mod.Sv.	.7125	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	.8125	.1061	2

Summaries of INDX0 DO INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	.8472	.0372	.0360	27	
2.00	Recurr.	.7964	.0968	.1872	21	
3.00	Rec.-Mod.Sv.	.7125	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	.8125	.1061	.0112	2	

Within Groups Total			.8223	.0706	.2345	51

Criterion Variable INDX0

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0431	3	.0144	2.8774	.0459
Within Groups	.2345	47	.0050		
Eta = .3939		Eta Squared = .1552			

1034

507

FCE 22891/726 i

(9.1.2.2) Summaries of D7SCR Dy7 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			63.4902	8.4531	51
SUBFORM	1.00	Sing.Epi.	66.2222	4.8859	27
SUBFORM	2.00	Recurr.	61.0000	9.5289	21
SUBFORM	3.00	Rec.-Mod.Sv.	39.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	65.0000	14.1421	2

Summaries of D7SCR Dy7 Total Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	66.2222	4.8859	620.6667	27
2.00	Recurr.	61.0000	9.5289	1816.0000	21
3.00	Rec.-Mod.Sv.	39.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	65.0000	14.1421	200.0000	2
Within Groups Total		63.4902	7.4899	2636.6667	51

Criterion Variable D7SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	936.0784	3	312.0261	5.5620	.0024
Within Groups	2636.6667	47	56.0993		
Eta = .5119		Eta Squared = .2620			

1035

508

FCE 22891/726 i

(9.1.2.2) Summaries of INDX7 D7 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.7936	.1057	51
SUBFORM	1.00	Sing.Epi.	.8278	.0611	27
SUBFORM	2.00	Recurr.	.7625	.1191	21
SUBFORM	3.00	Rec.-Mod.Sv.	.4875	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	.8125	.1768	2

Summaries of INDX7 D7 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	.8278	.0611	.0970	27
2.00	Recurr.	.7625	.1191	.2837	21
3.00	Rec.-Mod.Sv.	.4875	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	.8125	.1768	.0313	2
Within Groups Total		.7936	.0936	.4120	51

Criterion Variable INDX7

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1463	3	.0488	5.5620	.0024
Within Groups	.4120	47	.0088		
Eta = .5119		Eta Squared = .2620			

1036

509

FCE 22891/726 i

(9.1.2.2) Summaries of D14SCR Dy14 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			57.6731	10.4745	52
SUBFORM	1.00	Sing.Epi.	59.8148	9.0937	27
SUBFORM	2.00	Recurr.	54.4545	12.0108	22
SUBFORM	3.00	Rec.-Mod.Sv.	60.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	63.0000	1.4142	2

Summaries of D14SCR Dy14 Total Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	59.8148	9.0937	2150.0741	27	
2.00	Recurr.	54.4545	12.0108	3029.4545	22	
3.00	Rec.-Mod.Sv.	60.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	63.0000	1.4142	2.0000	2	
Within Groups Total			57.6731	10.3898	5181.5286	52

Criterion Variable D14SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	413.9137	3	137.9712	1.2781	.2925
Within Groups	5181.5286	48	107.9485		
Eta = .2720		Eta Squared = .0740			

1037

510

FCE 22891/726 i

(9.1.2.2) Summaries of INDX14 D14 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.7209	.1309	52
SUBFORM	1.00	Sing.Epi.	.7477	.1137	27
SUBFORM	2.00	Recurr.	.6807	.1501	22
SUBFORM	3.00	Rec.-Mod.Sv.	.7500	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	.7875	.0177	2

Summaries of INDX14 D14 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	.7477	.1137	.3359	27
2.00	Recurr.	.6807	.1501	.4734	22
3.00	Rec.-Mod.Sv.	.7500	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	.7875	.0177	.0003	2

Within Groups Total		.7209	.1299	.8096	52

Criterion Variable INDX14

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0647	3	.0216	1.2781	.2925
Within Groups	.8096	48	.0169		
Eta = .2720		Eta Squared = .0740			

1038

511

FCE 22891/726 i

(9.1.2.2) Summaries of D21SCR Dy21 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			54.0962	14.2075	52
SUBFORM	1.00	Sing.Epi.	55.5185	13.9735	27
SUBFORM	2.00	Recurr.	51.8182	15.2398	22
SUBFORM	3.00	Rec.-Mod.Sv.	64.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	55.0000	8.4853	2

Summaries of D21SCR Dy21 Total Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	55.5185	13.9735	5076.7407	27	
2.00	Recurr.	51.8182	15.2398	4877.2727	22	
3.00	Rec.-Mod.Sv.	64.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	55.0000	8.4853	72.0000	2	
Within Groups Total			54.0962	14.4525	10026.0135	52

Criterion Variable D21SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	268.5058	3	89.5019	.4285	.7335
Within Groups	10026.0135	48	208.8753		
Eta = .1615		Eta Squared = .0261			

1039

512

FCE 22891/726 i

(9.1.2.2) Summaries of INDX21 D21 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6762	.1776	52
SUBFORM	1.00	Sing.Epi.	.6940	.1747	27
SUBFORM	2.00	Recurr.	.6477	.1905	22
SUBFORM	3.00	Rec.-Mod.Sv.	.8000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	.6875	.1061	2

Summaries of INDX21 D21 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	.6940	.1747	.7932	27
2.00	Recurr.	.6477	.1905	.7621	22
3.00	Rec.-Mod.Sv.	.8000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	.6875	.1061	.0112	2

Within Groups Total		.6762	.1807	1.5666	52

Criterion Variable INDX21

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0420	3	.0140	.4285	.7335
Within Groups	1.5666	48	.0326		
Eta = .1615		Eta Squared = .0261			

1040

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(9.1.2.2) Summaries of D28SCR Dy28 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			51.8846	15.8196	52
SUBFORM	1.00	Sing.Epi.	52.5556	16.4465	27
SUBFORM	2.00	Recurr.	51.1364	16.0840	22
SUBFORM	3.00	Rec.-Mod.Sv.	41.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	56.5000	10.6066	2

Summaries of D28SCR Dy28 Total Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	52.5556	16.4465	7032.6667	27	
2.00	Recurr.	51.1364	16.0840	5432.5909	22	
3.00	Rec.-Mod.Sv.	41.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	56.5000	10.6066	112.5000	2	
Within Groups Total			51.8846	16.1875	12577.7576	52

Criterion Variable D28SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	185.5501	3	61.8500	.2360	.8708
Within Groups	12577.7576	48	262.0366		
Eta = .1206		Eta Squared = .0145			

1041

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FCE 22891/726 i

(9.1.2.2) Summaries of INDX28 D28 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6486	.1977	52
SUBFORM	1.00	Sing.Epi.	.6569	.2056	27
SUBFORM	2.00	Recurr.	.6392	.2010	22
SUBFORM	3.00	Rec.-Mod.Sv.	.5125	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	.7063	.1326	2

Summaries of INDX28 D28 INDEX SCR
By Levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	.6569	.2056	1.0989	27	
2.00	Recurr.	.6392	.2010	.8488	22	
3.00	Rec.-Mod.Sv.	.5125	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	.7063	.1326	.0176	2	

Within Groups Total			.6486	.2023	1.9653	52

Criterion Variable INDX28

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0290	3	.0097	.2360	.8708
Within Groups	1.9653	48	.0409		
Eta = .1206		Eta Squared = .0145			

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FCE 22891/726 i

(9.1.2.2) Summaries of D35SCR Dy35 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			51.1923	16.0527	52
SUBFORM	1.00	Sing.Epi.	51.8148	16.8592	27
SUBFORM	2.00	Recurr.	50.7727	15.9730	22
SUBFORM	3.00	Rec.-Mod.Sv.	39.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	53.5000	14.8492	2

Summaries of D35SCR Dy35 Total Score
By Levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	51.8148	16.8592	7390.0741	27	
2.00	Recurr.	50.7727	15.9730	5357.8636	22	
3.00	Rec.-Mod.Sv.	39.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	53.5000	14.8492	220.5000	2	
Within Groups Total			51.1923	16.4370	12968.4377	52

Criterion Variable D35SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	173.6392	3	57.8797	.2142	.8861
Within Groups	12968.4377	48	270.1758		
Eta = .1149		Eta Squared = .0132			

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FCE 22891/726 i

(9.1.2.2) Summaries of INDX35 D35 INDEX SCR
By Levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			.6399	.2007	52
SUBFORM	1.00	Sing.Epi.	.6477	.2107	27
SUBFORM	2.00	Recurr.	.6347	.1997	22
SUBFORM	3.00	Rec.-Mod.Sv.	.4875	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	.6688	.1856	2

Summaries of INDX35 D35 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	.6477	.2107	1.1547	27	
2.00	Recurr.	.6347	.1997	.8372	22	
3.00	Rec.-Mod.Sv.	.4875	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	.6688	.1856	.0345	2	
Within Groups Total			.6399	.2055	2.0263	52

Criterion Variable INDX35

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0271	3	.0090	.2142	.8861
Within Groups	2.0263	48	.0422		
Eta = .1149		Eta Squared = .0132			

1044

517

FCE 22891/726 i

(9.1.2.2) Summaries of D42SCR Dy42 Total Score
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			50.3846	16.6335	52
SUBFORM	1.00	Sing.Epi.	49.8519	18.0697	27
SUBFORM	2.00	Recurr.	51.0455	15.8609	22
SUBFORM	3.00	Rec.-Mod.Sv.	39.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	56.0000	11.3137	2

Summaries of D42SCR Dy42 Total Score
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	49.8519	18.0697	8489.4074	27
2.00	Recurr.	51.0455	15.8609	5282.9545	22
3.00	Rec.-Mod.Sv.	39.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	56.0000	11.3137	128.0000	2
Within Groups Total		50.3846	17.0174	13900.3620	52

Criterion Variable D42SCR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	209.9457	3	69.9819	.2417	.8668
Within Groups	13900.3620	48	289.5909		
Eta = .1220		Eta Squared = .0149			

1045

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(9.1.2.2) Summaries of INDX42 D42 INDEX SCR
By Levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			.6298	.2079	52
SUBFORM	1.00	Sing.Epi.	.6231	.2259	27
SUBFORM	2.00	Recurr.	.6381	.1983	22
SUBFORM	3.00	Rec.-Mod.Sv.	.4875	.0000	1
SUBFORM	4.00	Rec.Sv.w.o.Pf	.7000	.1414	2

Summaries of INDX42 D42 INDEX SCR
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	.6231	.2259	1.3265	27	
2.00	Recurr.	.6381	.1983	.8255	22	
3.00	Rec.-Mod.Sv.	.4875	.0000	.0000	1	
4.00	Rec.Sv.w.o.Pf	.7000	.1414	.0200	2	

Within Groups Total			.6298	.2127	2.1719	52

Criterion Variable INDX42

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0328	3	.0109	.2417	.8668
Within Groups	2.1719	48	.0452		
Eta = .1220		Eta Squared = .0149			

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APPENDIX 16

Therapeutic Efficacy: CGI-SI

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(9.1.3.1) Summaries of DOSEV Severity - Day 0
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
DRUGRP	1	Reboxetine	5.7407	.4466	27
DRUGRP	2	Placebo	5.4000	.5774	25

Summaries of D42SEV Severity - Day 42
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
DRUGRP	1	Reboxetine	2.0741	1.6624	27
DRUGRP	2	Placebo	4.2400	1.8991	25

*** ANALYSIS OF VARIANCE ***

D42SEV
BY DRUGRP Treatment Group
WITH DOSEV Severity

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.030	1	2.030	.633	.430
DOSEV	2.030	1	2.030	.633	.430
Main Effects	60.152	1	60.152	18.759	.000
DRUGRP	60.152	1	60.152	18.759	.000
Explained	62.182	2	31.091	9.696	.000
Residual	157.125	49	3.207		
Total	219.308	51	4.300		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

1048

521

FCE 22891/726 i

(9.1.3.1) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			42.2051	37.9368	52
DRUGRP	1	Reboxetine	62.3333	29.6706	27
DRUGRP	2	Placebo	20.4667	34.0082	25

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	62.3333	29.6706	22888.8889	27
2	Placebo	20.4667	34.0082	27757.3333	25

Within Groups Total		42.2051	31.8265	50646.2222	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	22752.9231	1	22752.9231	22.4626	.0000
Within Groups	50646.2222	50	1012.9244		
Eta = .5568		Eta Squared = .3100			

1049

522

FCE 22891/726 i

(9.1.3.1) Summaries of DOSEV Severity - Day 0
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			5.5769	.5367	52
SEX	0	Female	5.7083	.5500	24
SEX	1	Male	5.4643	.5079	28

Summaries of D42SEV Severity - Day 42
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1154	2.0737	52
SEX	0	Female	2.9167	2.2051	24
SEX	1	Male	3.2857	1.9787	28

*** ANALYSIS OF VARIANCE ***

D42SEV
BY SEX
WITH DOSEV Severity

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.030	1	2.030	.460	.501
DOSEV	2.030	1	2.030	.460	.501
Main Effects	1.056	1	1.056	.239	.627
SEX	1.056	1	1.056	.239	.627
Explained	3.087	2	1.543	.350	.707
Residual	216.221	49	4.413		
Total	219.308	51	4.300		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

1050

523

FCE 20124/706 i

(9.1.3.1) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			42.2051	37.9368	52
SEX	0	Female	46.0833	41.2874	24
SEX	1	Male	38.8810	35.2356	28

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	46.0833	41.2874	39206.9444	24	
1	Male	38.8810	35.2356	33521.8254	28	
<hr/>						
Within Groups Total			42.2051	38.1389	72728.7698	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	670.3755	1	670.3755	.4609	.5003
Within Groups	72728.7698	50	1454.5754		

Eta = .0956 Eta Squared = .0091

1051

524

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(9.1.3.1) Summaries of DOSEV Severity - Day 0
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
COUNTRY	1.00	Canada	5.5000	.5345	8
COUNTRY	2.00	Brazil	5.5909	.5421	44

Summaries of D42SEV Severity - Day 42
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
COUNTRY	1.00	Canada	3.5000	1.5119	8
COUNTRY	2.00	Brazil	3.0455	2.1669	44

*** ANALYSIS OF VARIANCE ***

D42SEV
BY COUNTRY
WITH DOSEV Severity

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.030	1	2.030	.460	.501
DOSEV	2.030	1	2.030	.460	.501
Main Effects	1.203	1	1.203	.273	.604
COUNTRY	1.203	1	1.203	.273	.604
Explained	3.233	2	1.617	.367	.695
Residual	216.075	49	4.410		
Total	219.308	51	4.300		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

1052

525

FCE 20124/706 i

(9.1.3.1) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			42.2051	37.9368	52
COUNTRY	1.00	Canada	35.2500	26.4538	8
COUNTRY	2.00	Brazil	43.4697	39.7794	44

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	35.2500	26.4538	4898.6111	8
2.00	Brazil	43.4697	39.7794	68043.1818	44

Within Groups Total		42.2051	38.1947	72941.7929	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	457.3524	1	457.3524	.3135	.5780
Within Groups	72941.7929	50	1458.8359		

Eta = .0789 Eta Squared = .0062

FCE 20124/706 i

(9.1.3.1) Summaries of DOSEV Severity - Day 0
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
AGEGRP	1.00	(18-37)	5.5263	.5130	19
AGEGRP	2.00	(38-49)	5.6000	.5026	20
AGEGRP	3.00	(50+)	5.6154	.6504	13

Summaries of D42SEV Severity - Day 42
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
AGEGRP	1.00	(18-37)	3.2632	2.2814	19
AGEGRP	2.00	(38-49)	3.3000	2.0545	20
AGEGRP	3.00	(50+)	2.6154	1.8502	13

*** ANALYSIS OF VARIANCE ***

D42SEV
BY AGEGRP Age Group
WITH DOSEV Severity

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.030	1	2.030	.457	.502
DOSEV	2.030	1	2.030	.457	.502
Main Effects	4.135	2	2.067	.466	.631
AGEGRP	4.135	2	2.067	.466	.631
Explained	6.165	3	2.055	.463	.710
Residual	213.143	48	4.440		
Total	219.308	51	4.300		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

1054

527

FCE 20124/706 i

(9.1.3.1) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			42.2051	37.9368	52
AGEGRP	1.00	(18-37)	39.8772	40.3968	19
AGEGRP	2.00	(38-49)	39.0000	37.9751	20
AGEGRP	3.00	(50+)	50.5385	35.8395	13

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	(18-37)	39.8772	40.3968	29374.2690	19	
2.00	(38-49)	39.0000	37.9751	27400.0000	20	
3.00	(50+)	50.5385	35.8395	15413.6752	13	

Within Groups Total			42.2051	38.3826	72187.9442	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1211.2011	2	605.6005	.4111	.6652
Within Groups	72187.9442	49	1473.2234		

Eta = .1285 Eta Squared = .0165

FCE 20124/706 i

(9.1.3.1) Summaries of DOSEV Severity - Day 0
 By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
SUBFORM	1.00	Sing.Epi.	5.5926	.5724	27
SUBFORM	2.00	Recurr.	5.6364	.4924	22
SUBFORM	3.00	Rec.-Mod.Sv.	5.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	5.0000	.0000	2

Summaries of D42SEV Severity - Day 42
 By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
SUBFORM	1.00	Sing.Epi.	3.0370	2.1390	27
SUBFORM	2.00	Recurr.	3.1818	2.1300	22
SUBFORM	3.00	Rec.-Mod.Sv.	2.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	4.0000	1.4142	2

*** ANALYSIS OF VARIANCE ***

D42SEV
 BY SUBFORM DSM-III-R Subform
 WITH DOSEV Severity

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.030	1	2.030	.445	.508
DOSEV	2.030	1	2.030	.445	.508
Main Effects	2.982	3	.994	.218	.883
SUBFORM	2.982	3	.994	.218	.883
Explained	5.012	4	1.253	.275	.893
Residual	214.296	47	4.559		
Total	219.308	51	4.300		

52 Cases were processed.
 0 Cases (.0 PCT) were missing.

1056

529

FCE 20124/706 i

(9.1.3.1) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			42.2051	37.9368	52
SUBFORM	1.00	Sing.Epi.	43.3210	39.9766	27
SUBFORM	2.00	Recurr.	42.1818	37.5785	22
SUBFORM	3.00	Rec.-Mod.Sv.	59.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	19.0000	28.2843	2

Summaries of CHANGE Dy0 to Dy42 %Change
By Levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	43.3210	39.9766	41551.4403	27
2.00	Recurr.	42.1818	37.5785	29655.0505	22
3.00	Rec.-Mod.Sv.	59.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	19.0000	28.2843	800.0000	2
Within Groups Total		42.2051	38.7316	72006.4908	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1392.6545	3	464.2182	.3095	.8184
Within Groups	72006.4908	48	1500.1352		
Eta = .1377		Eta Squared = .0190			

FCE 20124/706 i

(9.1.3.1) Summaries of DOSEV Severity - Day 0
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			5.5769	.5367	52
RATER	1.00	Beauclair	5.0000	.0000	1
RATER	2.00	Mirmiran	5.3333	.5774	3
RATER	3.00	Song	5.7500	.5000	4
RATER	4.00	Nardi	5.5909	.5421	44

Summaries of D42SEV Severity - Day 42
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1154	2.0737	52
RATER	1.00	Beauclair	5.0000	.0000	1
RATER	2.00	Mirmiran	3.3333	1.5275	3
RATER	3.00	Song	3.2500	1.7078	4
RATER	4.00	Nardi	3.0455	2.1669	44

*** ANALYSIS OF VARIANCE ***

D42SEV
BY RATER
WITH DOSEV Severity

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.030	1	2.030	.446	.508
DOSEV	2.030	1	2.030	.446	.508
Main Effects	3.246	3	1.082	.238	.870
RATER	3.246	3	1.082	.238	.870
Explained	5.276	4	1.319	.290	.883
Residual	214.031	47	4.554		
Total	219.308	51	4.300		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

1058

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FCE 20124/706 i

(9.1.3.1) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			42.2051	37.9368	52
RATER	1.00	Beauclair	-1.0000	.0000	1
RATER	2.00	Mirimiran	37.8889	21.6880	3
RATER	3.00	Song	42.3333	28.4149	4
RATER	4.00	Nardi	43.4697	39.7794	44

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	-1.0000	.0000	.0000	1
2.00	Mirimiran	37.8889	21.6880	940.7407	3
3.00	Song	42.3333	28.4149	2422.2222	4
4.00	Nardi	43.4697	39.7794	68043.1818	44

Within Groups Total		42.2051	38.5698	71406.1448	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1993.0005	3	664.3335	.4466	.7208
Within Groups	71406.1448	48	1487.6280		
Eta = .1648		Eta Squared = .0272			

1059

532

FCE 20124/706 i

APPENDIX 17

Onset of Therapeutic Activity: CGI-SI

1060

533

FCE 20124/706 i

```
( 9.1.3.2 ) manova
d0sev d7sev d14sev d21sev d28sev d35sev d42sev by drugrp(1,2)
/wsfactors=time (7)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	470.48	50	9.41		
CONSTANT	5986.78	1	5986.78	636.24	.000
DRUGRP	127.77	1	127.77	13.58	.001

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00271
Chi-square approx. = 282.40560 with 20 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .29093
Huynh-Feldt Epsilon = .30660
Lower-bound Epsilon = .16667
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1061

534

FCE 20124/706 i

(9.1.3.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. DRUGRP BY TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 21 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.52483	8.28386	6.00	45.00	.000
Hotellings	1.10451	8.28386	6.00	45.00	.000
Wilks	.47517	8.28386	6.00	45.00	.000
Roys	.52483				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 21 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.67594	15.64370	6.00	45.00	.000
Hotellings	2.08583	15.64370	6.00	45.00	.000
Wilks	.32406	15.64370	6.00	45.00	.000
Roys	.67594				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	211.69	300	.71		
TIME	260.42	6	43.40	61.51	.000
DRUGRP BY TIME	76.97	6	12.83	18.18	.000

1062

535

FCE 20124/706 i

(9.1.3.2) Summaries of DOSEV Severity - Day 0
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			5.5769	.5367	52
DRUGRP	1	Reboxetine	5.7407	.4466	27
DRUGRP	2	Placebo	5.4000	.5774	25

Summaries of DOSEV Severity
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	5.7407	.4466	5.1852	27	
2	Placebo	5.4000	.5774	8.0000	25	

Within Groups Total			5.5769	.5135	13.1852	52

Criterion Variable DOSEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.5071	1	1.5071	5.7152	.0206
Within Groups	13.1852	50	.2637		

Eta = .3203 Eta Squared = .1026

1063

536

FCE 20124/706 i

(9.1.3.2) Summaries of D7SEV Severity - Day 7
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.9615	.9280	52
DRUGRP	1	Reboxetine	4.8889	1.0860	27
DRUGRP	2	Placebo	5.0400	.7348	25

Summaries of D7SEV
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	4.8889	1.0860	30.6667	27	
2	Placebo	5.0400	.7348	12.9600	25	

Within Groups Total			4.9615	.9341	43.6267	52

Criterion Variable D7SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2964	1	.2964	.3397	.5626
Within Groups	43.6267	50	.8725		
Eta = .0821		Eta Squared = .0067			

FCE 20124/706 i

(9.1.3.2) Summaries of D14SEV Severity - Day 14
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.1538	1.2739	52
DRUGRP	1	Reboxetine	3.7778	1.1875	27
DRUGRP	2	Placebo	4.5600	1.2610	25

Summaries of D14SEV
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	3.7778	1.1875	36.6667	27	
2	Placebo	4.5600	1.2610	38.1600	25	

Within Groups Total			4.1538	1.2233	74.8267	52

Criterion Variable D14SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	7.9426	1	7.9426	5.3073	.0254
Within Groups	74.8267	50	1.4965		

Eta = .3098 Eta Squared = .0960

1065

538

FCE 20124/706 i

(9.1.3.2) Summaries of D21SEV Severity - Day 21
 By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.8269	1.6296	52
DRUGRP	1	Reboxetine	3.0000	1.3868	27
DRUGRP	2	Placebo	4.7200	1.4000	25

Summaries of D21SEV
 By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	3.0000	1.3868	50.0000	27	
2	Placebo	4.7200	1.4000	47.0400	25	

Within Groups Total			3.8269	1.3931	97.0400	52

Criterion Variable D21SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	38.4023	1	38.4023	19.7868	.0000
Within Groups	97.0400	50	1.9408		

Eta = .5325 Eta Squared = .2835

FCE 20124/706 i

(9.1.3.2) Summaries of D28SEV Severity - Day 28
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.4231	1.9133	52
DRUGRP	1	Reboxetine	2.5926	1.6701	27
DRUGRP	2	Placebo	4.3200	1.7729	25

Summaries of D28SEV
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	2.5926	1.6701	72.5185	27	
2	Placebo	4.3200	1.7729	75.4400	25	

Within Groups Total			3.4231	1.7202	147.9585	52

Criterion Variable D28SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	38.7338	1	38.7338	13.0894	.0007
Within Groups	147.9585	50	2.9592		
Eta = .4555		Eta Squared = .2075			

1067

540

FCE 20124/706 i

(9.1.3.2) Summaries of D35SEV Severity - Day 35
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1923	2.0004	52
DRUGRP	1	Reboxetine	2.1852	1.6181	27
DRUGRP	2	Placebo	4.2800	1.8148	25

Summaries of D35SEV
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	2.1852	1.6181	68.0741	27	
2	Placebo	4.2800	1.8148	79.0400	25	

Within Groups Total			3.1923	1.7153	147.1141	52

Criterion Variable D35SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	56.9628	1	56.9628	19.3601	.0001
Within Groups	147.1141	50	2.9423		
Eta = .5283		Eta Squared = .2791			

FCE 20124/706 i

(9.1.3.2) Summaries of D42SEV Severity - Day 42
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
DRUGRP	1 Reboxetine	2.0741	1.6624	27
DRUGRP	2 Placebo	4.2400	1.8991	25

Summaries of D42SEV
By levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	2.0741	1.6624	71.8519	27
2 Placebo	4.2400	1.8991	86.5600	25

Within Groups Total	3.1154	1.7800	158.4119	52

Criterion Variable D42SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	60.8958	1	60.8958	19.2207	.0001
Within Groups	158.4119	50	3.1682		

Eta = .5269 Eta Squared = .2777

1069

542

FCE 20124/706 i

(9.1.3.2) Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			9.7051	15.5696	52
DRUGRP	1	Reboxetine	13.5679	18.6545	27
DRUGRP	2	Placebo	5.5333	10.1598	25

Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	13.5679	18.6545	9047.7366	27
2	Placebo	5.5333	10.1598	2477.3333	25
Within Groups Total		9.7051	15.1823	11525.0700	52

Criterion Variable DOT7CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	837.9642	1	837.9642	3.6354	.0623
Within Groups	11525.0700	50	230.5014		
Eta = .2603		Eta Squared = .0678			

1070

543

FCE 20124/706 i

(9.1.3.2) Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			23.9359	23.5007	52
DRUGRP	1	Reboxetine	32.5802	22.1673	27
DRUGRP	2	Placebo	14.6000	21.5965	25

Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	32.5802	22.1673	12776.1317	27	
2	Placebo	14.6000	21.5965	11193.7778	25	

Within Groups Total			23.9359	21.8952	23969.9095	52

Criterion Variable DOT14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4196.5435	1	4196.5435	8.7538	.0047
Within Groups	23969.9095	50	479.3982		
Eta = .3860		Eta Squared = .1490			

FCE 20124/706 i

(9.1.3.2) Summaries of DOT21CG Dy0 to Dy21 %Change
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			29.6410	30.1921	52
DRUGRP	1	Reboxetine	46.4074	24.5181	27
DRUGRP	2	Placebo	11.5333	25.0607	25

Summaries of DOT21CG Dy0 to Dy21 %Change
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	46.4074	24.5181	15629.6296	27
2	Placebo	11.5333	25.0607	15072.8889	25

Within Groups Total		29.6410	24.7800	30702.5185	52

Criterion Variable DOT21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15787.2251	1	15787.2251	25.7100	.0000
Within Groups	30702.5185	50	614.0504		
Eta = .5827		Eta Squared = .3396			

FCE 20124/706 i

(9.1.3.2) Summaries of DOT28CG Dy0 to Dy28 %Change
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			37.0128	34.9183	52
DRUGRP	1	Reboxetine	53.4444	29.7137	27
DRUGRP	2	Placebo	19.2667	31.6655	25

Summaries of DOT28CG Dy0 to Dy28 %Change
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	53.4444	29.7137	22955.5556	27
2	Placebo	19.2667	31.6655	24064.8889	25

Within Groups Total		37.0128	30.6661	47020.4444	52

Criterion Variable DOT28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15163.1026	1	15163.1026	16.1239	.0002
Within Groups	47020.4444	50	940.4089		
Eta = .4938 Eta Squared = .2438					

FCE 20124/706 i

(9.1.3.2) Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			40.9872	36.5939	52
DRUGRP	1	Reboxetine	60.4815	28.8428	27
DRUGRP	2	Placebo	19.9333	32.4825	25

Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	60.4815	28.8428	21629.6296	27	
2	Placebo	19.9333	32.4825	25322.6667	25	

Within Groups Total			40.9872	30.6439	46952.2963	52

Criterion Variable DOT35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	21342.3618	1	21342.3618	22.7277	.0000
Within Groups	46952.2963	50	939.0459		
Eta = .5590		Eta Squared = .3125			

FCE 20124/706 i

(9.1.3.2) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			42.2051	37.9368	52
DRUGRP	1	Reboxetine	62.3333	29.6706	27
DRUGRP	2	Placebo	20.4667	34.0082	25

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	62.3333	29.6706	22888.8889	27	
2	Placebo	20.4667	34.0082	27757.3333	25	
<hr/>						
Within Groups Total			42.2051	31.8265	50646.2222	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	22752.9231	1	22752.9231	22.4626	.0000
Within Groups	50646.2222	50	1012.9244		
Eta = .5568 Eta Squared = .3100					

1075

548

FCE 20124/706 i

```
( 9.1.3.2 ) manova
d0sev d7sev d14sev d21sev d28sev d35sev d42sev by sex(0,1)
/wsactors=time (7)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	595.06	50	11.90		
CONSTANT	5872.29	1	5872.29	493.42	.000
SEX	3.19	1	3.19	.27	.607

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00093
Chi-square approx. = 333.48743 with 20 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .25517
Huynh-Feldt Epsilon = .26688
Lower-bound Epsilon = .16667
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1076

549

FCE 20124/706 i

(9.1.3.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 21 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.04736	.37286	6.00	45.00	.892
Hotellings	.04972	.37286	6.00	45.00	.892
Wilks	.95264	.37286	6.00	45.00	.892
Roys	.04736				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 21 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.59579	11.05478	6.00	45.00	.000
Hotellings	1.47397	11.05478	6.00	45.00	.000
Wilks	.40421	11.05478	6.00	45.00	.000
Roys	.59579				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	284.07	300	.95		
TIME	275.25	6	45.88	48.45	.000
SEX BY TIME	4.58	6	.76	.81	.565

1077

550

FCE 20124/706 i

(9.1.3.2) Summaries of DOSEV Severity - Day 0
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			5.5769	.5367	52
SEX	0	Female	5.7083	.5500	24
SEX	1	Male	5.4643	.5079	28

Summaries of DOSEV Severity
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	5.7083	.5500	6.9583	24	
1	Male	5.4643	.5079	6.9643	28	

Within Groups Total			5.5769	.5277	13.9226	52

Criterion Variable DOSEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.7697	1	.7697	2.7642	.1027
Within Groups	13.9226	50	.2785		
Eta = .2289 Eta Squared = .0524					

FCE 20124/706 i

(9.1.3.2) Summaries of D7SEV Severity - Day 7
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.9615	.9280	52
SEX	0	Female	5.0000	1.0632	24
SEX	1	Male	4.9286	.8133	28

Summaries of D7SEV
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	5.0000	1.0632	26.0000	24	
1	Male	4.9286	.8133	17.8571	28	

Within Groups Total			4.9615	.9366	43.8571	52

Criterion Variable D7SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0659	1	.0659	.0752	.7851
Within Groups	43.8571	50	.8771		
Eta = .0387		Eta Squared = .0015			

FCE 20124/706 i

(9.1.3.2) Summaries of D14SEV Severity - Day 14
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.1538	1.2739	52
SEX	0	Female	4.0000	1.4446	24
SEX	1	Male	4.2857	1.1174	28

Summaries of D14SEV
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	4.0000	1.4446	48.0000	24
1	Male	4.2857	1.1174	33.7143	28

Within Groups Total		4.1538	1.2784	81.7143	52

Criterion Variable D14SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.0549	1	1.0549	.6455	.4255
Within Groups	81.7143	50	1.6343		

Eta = .1129 Eta Squared = .0127

1080

553

FCE 20124/706 i

(9.1.3.2) Summaries of D21SEV Severity - Day 21
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.8269	1.6296	52
SEX	0	Female	3.6667	1.7611	24
SEX	1	Male	3.9643	1.5271	28

Summaries of D21SEV
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	3.6667	1.7611	71.3333	24
1	Male	3.9643	1.5271	62.9643	28

Within Groups Total		3.8269	1.6389	134.2976	52

Criterion Variable D21SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.1447	1	1.1447	.4262	.5169
Within Groups	134.2976	50	2.6860		

Eta = .0919 Eta Squared = .0085

1081

554

FCE 20124/706 i

(9.1.3.2) Summaries of D28SEV Severity - Day 28
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.4231	1.9133	52
SEX	0	Female	3.2500	2.0694	24
SEX	1	Male	3.5714	1.7936	28

Summaries of D28SEV
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	3.2500	2.0694	98.5000	24
1	Male	3.5714	1.7936	86.8571	28

Within Groups Total		3.4231	1.9254	185.3571	52

Criterion Variable D28SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.3352	1	1.3352	.3602	.5511
Within Groups	185.3571	50	3.7071		
Eta = .0846		Eta Squared = .0072			

1082

555

FCE 20124/706 i

(9.1.3.2) Summaries of D35SEV Severity - Day 35
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1923	2.0004	52
SEX	0	Female	3.0000	2.1264	24
SEX	1	Male	3.3571	1.9093	28

Summaries of D35SEV
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	3.0000	2.1264	104.0000	24	
1	Male	3.3571	1.9093	98.4286	28	

Within Groups Total			3.1923	2.0121	202.4286	52

Criterion Variable D35SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.6484	1	1.6484	.4071	.5263
Within Groups	202.4286	50	4.0486		

Eta = .0899 Eta Squared = .0081

1083

556

FCE 20124/706 i F...

(9.1.3.2) Summaries of D42SEV Severity - Day 42
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		3.1154	2.0737	52
SEX	0 Female	2.9167	2.2051	24
SEX	1 Male	3.2857	1.9787	28

Summaries of D42SEV
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	2.9167	2.2051	111.8333	24
1 Male	3.2857	1.9787	105.7143	28

Within Groups Total	3.1154	2.0859	217.5476	52

Criterion Variable D42SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.7601	1	1.7601	.4045	.5277
Within Groups	217.5476	50	4.3510		

Eta = .0896 Eta Squared = .0080

1084

557

FCE 20124/706 i

(9.1.3.2) Summaries of D0T7OG Dy0 to Dy7 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
SEX	0	Female	10.9444	18.0957	24
SEX	1	Male	8.6429	13.2820	28

Summaries of D0T7OG Dy0 to Dy7 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	10.9444	18.0957	7531.4815	24
1	Male	8.6429	13.2820	4763.0952	28

Within Groups Total		9.7051	15.6809	12294.5767	52

Criterion Variable D0T7OG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	68.4575	1	68.4575	.2784	.6001
Within Groups	12294.5767	50	245.8915		

Eta = .0744 Eta Squared = .0055

1085

558

FCE 20124/706 i

(9.1.3.2) Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			23.9359	23.5007	52
SEX	0	Female	28.0278	26.9994	24
SEX	1	Male	20.4286	19.8643	28

Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	28.0278	26.9994	16766.2037	24
1	Male	20.4286	19.8643	10653.9683	28

Within Groups Total		23.9359	23.4180	27420.1720	52

Criterion Variable DOT14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	746.2810	1	746.2810	1.3608	.2489
Within Groups	27420.1720	50	548.4034		
Eta = .1628		Eta Squared = .0265			

1086

559

FCE 20124/706 i

(9.1.3.2) Summaries of D0T210G Dy0 to Dy21 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			29.6410	30.1921	52
SEX	0	Female	33.4444	33.1687	24
SEX	1	Male	26.3810	27.5824	28

Summaries of D0T210G Dy0 to Dy21 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	33.4444	33.1687	25303.7037	24	
1	Male	26.3810	27.5824	20541.2698	28	

Within Groups Total			29.6410	30.2803	45844.9735	52

Criterion Variable D0T210G

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	644.7700	1	644.7700	.7032	.4057
Within Groups	45844.9735	50	916.8995		
Eta = .1178		Eta Squared = .0139			

FCE 20124/706 i

(9.1.3.2) Summaries of DOT28CG Dy0 to Dy28 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			37.0128	34.9183	52
SEX	0	Female	40.6667	38.5235	24
SEX	1	Male	33.8810	31.8882	28

Summaries of DOT28CG Dy0 to Dy28 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	40.6667	38.5235	34133.3333	24	
1	Male	33.8810	31.8882	27455.1587	28	

Within Groups Total			37.0128	35.0966	61588.4921	52

Criterion Variable DOT28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	595.0549	1	595.0549	.4831	.4902
Within Groups	61588.4921	50	1231.7698		
Eta = .0978		Eta Squared = .0096			

1088

561

FCE 20124/706 i

(9.1.3.2) Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			40.9872	36.5939	52
SEX	0	Female	44.8333	39.8336	24
SEX	1	Male	37.6905	33.9612	28

Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	44.8333	39.8336	36494.4444	24	
1	Male	37.6905	33.9612	31140.8730	28	

Within Groups Total			40.9872	36.7792	67635.3175	52

Criterion Variable DOT35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	659.3407	1	659.3407	.4874	.4883
Within Groups	67635.3175	50	1352.7063		
Eta = .0983		Eta Squared = .0097			

1089

562

FCE 20124/706 i

(9.1.3.2) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			42.2051	37.9368	52
SEX	0	Female	46.0833	41.2874	24
SEX	1	Male	38.8810	35.2356	28

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	46.0833	41.2874	39206.9444	24	
1	Male	38.8810	35.2356	33521.8254	28	

Within Groups Total			42.2051	38.1389	72728.7698	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	670.3755	1	670.3755	.4609	.5003
Within Groups	72728.7698	50	1454.5754		

Eta = .0956 Eta Squared = .0091

1090

563

FCE 20124/706 i

```
( 9.1.3.2 ) manova
d0sev d7sev d14sev d21sev d28sev d35sev d42sev by country(1,2)
/wsfactors=time (7)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	597.49	50	11.95		
CONSTANT	3154.43	1	3154.43	263.97	.000
COUNTRY	.76	1	.76	.06	.802

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00087
Chi-square approx. = 336.81325 with 20 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .25192
Huynh-Feldt Epsilon = .26329
Lower-bound Epsilon = .16667
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1091

564

FCE 20124/706 i

(9.1.3.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 21 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.19521	1.81923	6.00	45.00	.117
Hotellings	.24256	1.81923	6.00	45.00	.117
Wilks	.80479	1.81923	6.00	45.00	.117
Roys	.19521				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 21 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.45834	6.34641	6.00	45.00	.000
Hotellings	.84619	6.34641	6.00	45.00	.000
Wilks	.54166	6.34641	6.00	45.00	.000
Roys	.45834				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	279.42	300	.93		
TIME	107.80	6	17.97	19.29	.000
COUNTRY BY TIME	9.24	6	1.54	1.65	.132

1092

565

FCE 20124/706 i

(9.1.3.2) Summaries of DOSEV Severity - Day 0
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			5.5769	.5367	52
COUNTRY	1.00	Canada	5.5000	.5345	8
COUNTRY	2.00	Brazil	5.5909	.5421	44

Summaries of DOSEV Severity
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	5.5000	.5345	2.0000	8
2.00	Brazil	5.5909	.5421	12.6364	44
<hr/>					
Within Groups Total		5.5769	.5410	14.6364	52

Criterion Variable DOSEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0559	1	.0559	.1911	.6639
Within Groups	14.6364	50	.2927		

Eta = .0617 Eta Squared = .0038

FCE 20124/706 i

(9.1.3.2) Summaries of D7SEV Severity - Day 7
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			4.9615	.9280	52
COUNTRY	1.00	Canada	4.2500	1.5811	8
COUNTRY	2.00	Brazil	5.0909	.7093	44

Summaries of D7SEV
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	4.2500	1.5811	17.5000	8
2.00	Brazil	5.0909	.7093	21.6364	44
<hr/>					
Within Groups Total		4.9615	.8847	39.1364	52

Criterion Variable D7SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.7867	1	4.7867	6.1154	.0168
Within Groups	39.1364	50	.7827		

Eta = .3301 Eta Squared = .1090

1094

567

FCE 20124/706 i

(9.1.3.2) Summaries of D14SEV Severity - Day 14
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.1538	1.2739	52
COUNTRY	1.00	Canada	4.2500	1.3887	8
COUNTRY	2.00	Brazil	4.1364	1.2684	44

Summaries of D14SEV
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	4.2500	1.3887	13.5000	8
2.00	Brazil	4.1364	1.2684	69.1818	44

Within Groups Total		4.1538	1.2659	82.6818	52

Criterion Variable D14SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0874	1	.0874	.0529	.8191
Within Groups	82.6818	50	1.6536		
Eta = .0325		Eta Squared = .0011			

1095

563

FCE 20124/706 i

(9.1.3.2) Summaries of D21SEV Severity - Day 21
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.8269	1.6296	52
COUNTRY	1.00	Canada	4.1250	1.4577	8
COUNTRY	2.00	Brazil	3.7727	1.6686	44

Summaries of D21SEV
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	4.1250	1.4577	14.8750	8
2.00	Brazil	3.7727	1.6686	119.7273	44
<hr/>					
Within Groups Total		3.8269	1.6407	134.6023	52

Criterion Variable D21SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.8400	1	.8400	.3120	.5789
Within Groups	134.6023	50	2.6920		

Eta = .0788 Eta Squared = .0062

1096

569

FCE 20124/706 i

(9.1.3.2) Summaries of D28SEV Severity - Day 28
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.4231	1.9133	52
COUNTRY	1.00	Canada	3.8750	1.1260	8
COUNTRY	2.00	Brazil	3.3409	2.0225	44

Summaries of D28SEV
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.8750	1.1260	8.8750	8
2.00	Brazil	3.3409	2.0225	175.8864	44
<hr/>					
Within Groups Total		3.4231	1.9223	184.7614	52

Criterion Variable D28SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.9309	1	1.9309	.5226	.4731
Within Groups	184.7614	50	3.6952		

Eta = .1017 Eta Squared = .0103

1097

570

FCE 20124/706 i

(9.1.3.2) Summaries of D35SEV Severity - Day 35
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1923	2.0004	52
COUNTRY	1.00	Canada	3.5000	1.5119	8
COUNTRY	2.00	Brazil	3.1364	2.0864	44

Summaries of D35SEV
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	3.5000	1.5119	16.0000	8	
2.00	Brazil	3.1364	2.0864	187.1818	44	
<hr/>						
Within Groups Total			3.1923	2.0158	203.1818	52

Criterion Variable D35SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.8951	1	.8951	.2203	.6409
Within Groups	203.1818	50	4.0636		

Eta = .0662 Eta Squared = .0044

1098

571

FCE 20124/706 i

(9.1.3.2) Summaries of D42SEV Severity - Day 42
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
COUNTRY	1.00	Canada	3.5000	1.5119	8
COUNTRY	2.00	Brazil	3.0455	2.1669	44

Summaries of D42SEV
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.5000	1.5119	16.0000	8
2.00	Brazil	3.0455	2.1669	201.9091	44

Within Groups Total		3.1154	2.0876	217.9091	52

Criterion Variable D42SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.3986	1	1.3986	.3209	.5736
Within Groups	217.9091	50	4.3582		

Eta = .0799 Eta Squared = .0064

FCE 20124/706 i .

(9.1.3.2) Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			9.7051	15.5696	52
COUNTRY	1.00	Canada	20.6667	29.7076	8
COUNTRY	2.00	Brazil	7.7121	10.8362	44

Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	20.6667	29.7076	6177.7778	8	
2.00	Brazil	7.7121	10.8362	5049.2424	44	

Within Groups Total			9.7051	14.9847	11227.0202	52

Criterion Variable DOT7CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1136.0140	1	1136.0140	5.0593	.0289
Within Groups	11227.0202	50	224.5404		
Eta = .3031 Eta Squared = .0919					

1100

573

FCE 20124/706 i

(9.1.3.2) Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			23.9359	23.5007	52
COUNTRY	1.00	Canada	20.2500	27.7710	8
COUNTRY	2.00	Brazil	24.6061	22.9455	44

Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Canada	20.2500	27.7710	5398.6111	8	
2.00	Brazil	24.6061	22.9455	22639.3939	44	
<hr/>						
Within Groups Total			23.9359	23.6804	28038.0051	52

Criterion Variable DOT14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	128.4479	1	128.4479	.2291	.6343
Within Groups	28038.0051	50	560.7601		

Eta = .0675 Eta Squared = .0046

FCE 20124/706 i

(9.1.3.2) Summaries of DOT21CG Dy0 to Dy21 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			29.6410	30.1921	52
COUNTRY	1.00	Canada	22.7500	28.5322	8
COUNTRY	2.00	Brazil	30.8939	30.6299	44

Summaries of DOT21CG Dy0 to Dy21 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	22.7500	28.5322	5698.6111	8
2.00	Brazil	30.8939	30.6299	40342.1717	44

Within Groups Total		29.6410	30.3449	46040.7828	52

Criterion Variable DOT21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	448.9608	1	448.9608	.4876	.4882
Within Groups	46040.7828	50	920.8157		

Eta = .0983 Eta Squared = .0097

FCE 20124/706 i

(9.1.3.2) Summaries of D0T28CG Dy0 to Dy28 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
COUNTRY	1.00	Canada	28.1667	20.3735	8
COUNTRY	2.00	Brazil	38.6212	36.8965	44

Summaries of D0T28CG Dy0 to Dy28 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	28.1667	20.3735	2905.5556	8
2.00	Brazil	38.6212	36.8965	58538.1313	44

Within Groups Total		37.0128	35.0553	61443.6869	52

Criterion Variable D0T28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	739.8601	1	739.8601	.6021	.4414
Within Groups	61443.6869	50	1228.8737		
Eta = .1091		Eta Squared = .0119			

1103

576

FCE 20124/706 i . .

(9.1.3.2) Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			40.9872	36.5939	52
COUNTRY	1.00	Canada	35.2500	26.4538	8
COUNTRY	2.00	Brazil	42.0303	38.3026	44

Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	35.2500	26.4538	4898.6111	8
2.00	Brazil	42.0303	38.3026	63084.8485	44
<hr/>					
Within Groups Total		40.9872	36.8737	67983.4596	52

Criterion Variable DOT35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	311.1985	1	311.1985	.2289	.6344
Within Groups	67983.4596	50	1359.6692		
Eta = .0675		Eta Squared = .0046			

FCE 20124/706 i . . .

(9.1.3.2) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			42.2051	37.9368	52
COUNTRY	1.00	Canada	35.2500	26.4538	8
COUNTRY	2.00	Brazil	43.4697	39.7794	44

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	35.2500	26.4538	4898.6111	8
2.00	Brazil	43.4697	39.7794	68043.1818	44
Within Groups Total		42.2051	38.1947	72941.7929	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	457.3524	1	457.3524	.3135	.5780
Within Groups	72941.7929	50	1458.8359		

Eta = .0789 Eta Squared = .0062

1105

578

FCE 20124/706 i

```
( 9.1.3.2 ) manova
d0sev d7sev d14sev d21sev d28sev d35sev d42sev by agegrp(1,3)
/wsdesign=time (7)
/wsfactors=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
3 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	595.89	49	12.16		
CONSTANT	5673.47	1	5673.47	466.53	.000
AGEGRP	2.36	2	1.18	.10	.908

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

Mauchly sphericity test, W = .00073
Chi-square approx. = 337.74950 with 20 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .25072
Huynh-Feldt Epsilon = .26748
Lower-bound Epsilon = .16667

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1106

579

FCE 20124/706 i

(9.1.3.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. AGEGRP BY TIME

Multivariate Tests of Significance (S = 2, M = 1 1/2, N = 21)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.33028	1.48356	12.00	90.00	.145
Hotellings	.39988	1.43289	12.00	86.00	.167
Wilks	.69575	1.45840	12.00	88.00	.156
Roys	.20031				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 21)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.59424	10.73963	6.00	44.00	.000
Hotellings	1.46450	10.73963	6.00	44.00	.000
Wilks	.40576	10.73963	6.00	44.00	.000
Roys	.59424				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	280.59	294	.95		
TIME	275.15	6	45.86	48.05	.000
AGEGRP BY TIME	8.06	12	.67	.70	.747

1107

580

FCE 20124/706 i

(9.1.3.2) Summaries of DOSEV Severity - Day 0
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			5.5769	.5367	52
AGEGRP	1.00	(18-37)	5.5263	.5130	19
AGEGRP	2.00	(38-49)	5.6000	.5026	20
AGEGRP	3.00	(50+)	5.6154	.6504	13

Summaries of DOSEV Severity
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	5.5263	.5130	4.7368	19
2.00	(38-49)	5.6000	.5026	4.8000	20
3.00	(50+)	5.6154	.6504	5.0769	13
Within Groups Total		5.5769	.5461	14.6138	52

Criterion Variable DOSEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0785	2	.0393	.1317	.8769
Within Groups	14.6138	49	.2982		

Eta = .0731 Eta Squared = .0053

FCE 20124/706 i

(9.1.3.2) Summaries of D7SEV Severity - Day 7
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.9615	.9280	52
AGEGRP	1.00	(18-37)	4.8947	.8753	19
AGEGRP	2.00	(38-49)	4.8500	1.1367	20
AGEGRP	3.00	(50+)	5.2308	.5991	13

Summaries of D7SEV
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	4.8947	.8753	13.7895	19
2.00	(38-49)	4.8500	1.1367	24.5500	20
3.00	(50+)	5.2308	.5991	4.3077	13

Within Groups Total		4.9615	.9329	42.6472	52

Criterion Variable D7SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.2759	2	.6380	.7330	.4857
Within Groups	42.6472	49	.8704		
Eta = .1704		Eta Squared = .0290			

1109

582

FCE 20124/706 i

(9.1.3.2) Summaries of D14SEV Severity - Day 14
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
AGEGRP	1.00	(18-37)	4.3684	1.3421	19
AGEGRP	2.00	(38-49)	4.0500	1.3563	20
AGEGRP	3.00	(50+)	4.0000	1.0801	13

Summaries of D14SEV
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	4.3684	1.3421	32.4211	19
2.00	(38-49)	4.0500	1.3563	34.9500	20
3.00	(50+)	4.0000	1.0801	14.0000	13

Within Groups Total		4.1538	1.2887	81.3711	52

Criterion Variable D14SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.3982	2	.6991	.4210	.6588
Within Groups	81.3711	49	1.6606		

Eta = .1300 Eta Squared = .0169

1110

583

FCE 20124/706 i

(9.1.3.2) Summaries of D21SEV Severity - Day 21
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.8269	1.6296	52
AGEGRP	1.00	(18-37)	3.9474	1.7472	19
AGEGRP	2.00	(38-49)	3.7500	1.7130	20
AGEGRP	3.00	(50+)	3.7692	1.4233	13

Summaries of D21SEV
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	(18-37)	3.9474	1.7472	54.9474	19	
2.00	(38-49)	3.7500	1.7130	55.7500	20	
3.00	(50+)	3.7692	1.4233	24.3077	13	

Within Groups Total			3.8269	1.6599	135.0051	52

Criterion Variable D21SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.4372	2	.2186	.0793	.9238
Within Groups	135.0051	49	2.7552		

Eta = .0568 Eta Squared = .0032

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584

FCE 20124/706 i

(9.1.3.2) Summaries of D28SEV Severity - Day 28
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.4231	1.9133	52
AGEGRP	1.00	(18-37)	3.4211	2.1684	19
AGEGRP	2.00	(38-49)	3.5500	1.9050	20
AGEGRP	3.00	(50+)	3.2308	1.6408	13

Summaries of D28SEV
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	3.4211	2.1684	84.6316	19
2.00	(38-49)	3.5500	1.9050	68.9500	20
3.00	(50+)	3.2308	1.6408	32.3077	13

Within Groups Total		3.4231	1.9477	185.8893	52

Criterion Variable D28SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.8030	2	.4015	.1058	.8998
Within Groups	185.8893	49	3.7937		

Eta = .0656 Eta Squared = .0043

FCE 20124/706 i

(9.1.3.2) Summaries of D35SEV Severity - Day 35
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1923	2.0004	52
AGEGRP	1.00	(18-37)	3.3158	2.2374	19
AGEGRP	2.00	(38-49)	3.3000	2.0287	20
AGEGRP	3.00	(50+)	2.8462	1.6756	13

Summaries of D35SEV
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	3.3158	2.2374	90.1053	19
2.00	(38-49)	3.3000	2.0287	78.2000	20
3.00	(50+)	2.8462	1.6756	33.6923	13

Within Groups Total		3.1923	2.0304	201.9976	52

Criterion Variable D35SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.0794	2	1.0397	.2522	.7781
Within Groups	201.9976	49	4.1224		

Eta = .1009 Eta Squared = .0102

FCE 20124/706 i

(9.1.3.2) Summaries of D42SEV Severity - Day 42
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
AGEGRP	1.00	(18-37)	3.2632	2.2814	19
AGEGRP	2.00	(38-49)	3.3000	2.0545	20
AGEGRP	3.00	(50+)	2.6154	1.8502	13

Summaries of D42SEV
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	3.2632	2.2814	93.6842	19
2.00	(38-49)	3.3000	2.0545	80.2000	20
3.00	(50+)	2.6154	1.8502	41.0769	13

Within Groups Total		3.1154	2.0945	214.9611	52

Criterion Variable D42SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.3466	2	2.1733	.4954	.6123
Within Groups	214.9611	49	4.3870		

Eta = .1408 Eta Squared = .0198

1114

587

FCE 20124/706 i

(9.1.3.2) Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			9.7051	15.5696	52
AGEGRP	1.00	(18-37)	10.2281	14.7075	19
AGEGRP	2.00	(38-49)	12.0000	19.5535	20
AGEGRP	3.00	(50+)	5.4103	8.4395	13

Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	10.2281	14.7075	3893.5673	19
2.00	(38-49)	12.0000	19.5535	7264.4444	20
3.00	(50+)	5.4103	8.4395	854.7009	13
Within Groups Total		9.7051	15.6575	12012.7126	52

Criterion Variable DOT7CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	350.3216	2	175.1608	.7145	.4945
Within Groups	12012.7126	49	245.1574		

Eta = .1683 Eta Squared = .0283

1115

588

FCE 20124/706 i

(9.1.3.2) Summaries of DOT14CG
By levels of AGEGRP Age Group Dy0 to Dy14 %Change

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			23.9359	23.5007	52
AGEGRP	1.00	(18-37)	19.7018	23.4805	19
AGEGRP	2.00	(38-49)	26.0000	25.6130	20
AGEGRP	3.00	(50+)	26.9487	20.8850	13

Summaries of DOT14CG
By levels of AGEGRP Age Group Dy0 to Dy14 %Change

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	19.7018	23.4805	9923.9766	19
2.00	(38-49)	26.0000	25.6130	12464.4444	20
3.00	(50+)	26.9487	20.8850	5234.1880	13

Within Groups Total		23.9359	23.7429	27622.6091	52

Criterion Variable DOT14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	543.8439	2	271.9220	.4824	.6202
Within Groups	27622.6091	49	563.7267		

Eta = .1390 Eta Squared = .0193

1116

589

FCE 20124/706 i

(9.1.3.2) Summaries of DOT21OG Dy0 to Dy21 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			29.6410	30.1921	52
AGEGRP	1.00	(18-37)	27.4211	30.8595	19
AGEGRP	2.00	(38-49)	31.1667	32.1778	20
AGEGRP	3.00	(50+)	30.5385	28.1733	13

Summaries of DOT21OG Dy0 to Dy21 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	(18-37)	27.4211	30.8595	17141.5205	19	
2.00	(38-49)	31.1667	32.1778	19672.7778	20	
3.00	(50+)	30.5385	28.1733	9524.7863	13	

Within Groups Total			29.6410	30.7522	46339.0846	52

Criterion Variable DOT21OG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	150.6590	2	75.3295	.0797	.9236
Within Groups	46339.0846	49	945.6956		

Eta = .0569 Eta Squared = .0032

FCE 20124/706 i

(9.1.3.2) Summaries of DOT28CG Dy0 to Dy28 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			37.0128	34.9183	52
AGEGRP	1.00	(18-37)	37.0702	38.4309	19
AGEGRP	2.00	(38-49)	34.8333	35.3078	20
AGEGRP	3.00	(50+)	40.2821	31.1965	13

Summaries of DOT28CG Dy0 to Dy28 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	(18-37)	37.0702	38.4309	26584.7953	19	
2.00	(38-49)	34.8333	35.3078	23686.1111	20	
3.00	(50+)	40.2821	31.1965	11678.6325	13	

Within Groups Total			37.0128	35.5567	61949.5389	52

Criterion Variable DOT28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	234.0081	2	117.0040	.0925	.9118
Within Groups	61949.5389	49	1264.2763		

Eta = .0613 Eta Squared = .0038

FCE 20124/706 i

(9.1.3.2) Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			40.9872	36.5939	52
AGEGRP	1.00	(18-37)	39.0000	39.5967	19
AGEGRP	2.00	(38-49)	39.1667	37.4396	20
AGEGRP	3.00	(50+)	46.6923	32.7557	13

Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	(18-37)	39.0000	39.5967	28222.2222	19	
2.00	(38-49)	39.1667	37.4396	26632.7778	20	
3.00	(50+)	46.6923	32.7557	12875.2137	13	

Within Groups Total			40.9872	37.1786	67730.2137	52

Criterion Variable DOT35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	564.4444	2	282.2222	.2042	.8160
Within Groups	67730.2137	49	1382.2493		

Eta = .0909 Eta Squared = .0083

FCE 20124/706 i

(9.1.3.2) Summaries of CHANGE
By levels of AGEGRP Age Group Dy0 to Dy42 %Change

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			42.2051	37.9368	52
AGEGRP	1.00	(18-37)	39.8772	40.3968	19
AGEGRP	2.00	(38-49)	39.0000	37.9751	20
AGEGRP	3.00	(50+)	50.5385	35.8395	13

Summaries of CHANGE
By levels of AGEGRP Age Group Dy0 to Dy42 %Change

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	39.8772	40.3968	29374.2690	19
2.00	(38-49)	39.0000	37.9751	27400.0000	20
3.00	(50+)	50.5385	35.8395	15413.6752	13

Within Groups Total		42.2051	38.3826	72187.9442	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1211.2011	2	605.6005	.4111	.6652
Within Groups	72187.9442	49	1473.2234		

Eta = .1285 Eta Squared = .0165

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```
( 9.1.3.2 ) manova
d0sev d7sev d14sev d21sev d28sev d35sev d42sev by subform(1,4)
/wsfactors=time (7)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares					
Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	592.61	48	12.35		
CONSTANT	1130.28	1	1130.28	91.55	.000
SUBFORM	5.64	3	1.88	.15	.928

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00045
Chi-square approx. = 352.84476 with 20 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .24014
Huynh-Feldt Epsilon = .26104
Lower-bound Epsilon = .16667
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1121

594

FCE 20124/706 i

(9.1.3.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 1 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.75468	2.52084	18.00	135.00	.001
Hotellings	1.32023	3.05609	18.00	125.00	.000
Wilks	.37630	2.80013	18.00	122.11	.000
Roys	.50168				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.41965	5.18220	6.00	43.00	.000
Hotellings	.72310	5.18220	6.00	43.00	.000
Wilks	.58035	5.18220	6.00	43.00	.000
Roys	.41965				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	274.71	288	.95		
TIME	41.90	6	6.98	7.32	.000
SUBFORM BY TIME	13.94	18	.77	.81	.686

1122

595

FCE 20124/706 i

(9.1.3.2) Summaries of DOSEV Severity - Day 0
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			5.5769	.5367	52
SUBFORM	1.00	Sing.Epi.	5.5926	.5724	27
SUBFORM	2.00	Recurr.	5.6364	.4924	22
SUBFORM	3.00	Rec.-Mod.Sv.	5.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	5.0000	.0000	2

Summaries of DOSEV Severity
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	5.5926	.5724	8.5185	27	
2.00	Recurr.	5.6364	.4924	5.0909	22	
3.00	Rec.-Mod.Sv.	5.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	5.0000	.0000	.0000	2	
Within Groups Total			5.5769	.5325	13.6094	52

Criterion Variable DOSEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.0829	3	.3610	1.2731	.2942
Within Groups	13.6094	48	.2835		
Eta = .2715		Eta Squared = .0737			

FCE 20124/706 i

(9.1.3.2) Summaries of D7SEV Severity - Day 7
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			4.9615	.9280	52
SUBFORM	1.00	Sing.Epi.	5.1111	.6980	27
SUBFORM	2.00	Recurr.	4.8636	1.1253	22
SUBFORM	3.00	Rec.-Mod.Sv.	3.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	5.0000	.0000	2

Summaries of D7SEV
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	5.1111	.6980	12.6667	27	
2.00	Recurr.	4.8636	1.1253	26.5909	22	
3.00	Rec.-Mod.Sv.	3.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	5.0000	.0000	.0000	2	
Within Groups Total			4.9615	.9044	39.2576	52

Criterion Variable D7SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.6655	3	1.5552	1.9015	.1419
Within Groups	39.2576	48	.8179		
Eta = .3259		Eta Squared = .1062			

FCE 20124/706 i

(9.1.3.2) Summaries of D14SEV Severity - Day 14
 By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.1538	1.2739	52
SUBFORM	1.00	Sing.Epi.	4.2963	1.2030	27
SUBFORM	2.00	Recurr.	3.8636	1.3903	22
SUBFORM	3.00	Rec.-Mod.Sv.	5.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	5.0000	.0000	2

Summaries of D14SEV
 By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	4.2963	1.2030	37.6296	27	
2.00	Recurr.	3.8636	1.3903	40.5909	22	
3.00	Rec.-Mod.Sv.	5.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	5.0000	.0000	.0000	2	

Within Groups Total			4.1538	1.2766	78.2205	52

Criterion Variable D14SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.5487	3	1.5162	.9304	.4333
Within Groups	78.2205	48	1.6296		
Eta = .2344		Eta Squared = .0550			

FCE 20124/706 i FCE 22891/726 i

(9.1.3.2) Summaries of D21SEV Severity - Day 21
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.8269	1.6296	52
SUBFORM	1.00	Sing.Epi.	3.7778	1.6486	27
SUBFORM	2.00	Recurr.	3.8636	1.7538	22
SUBFORM	3.00	Rec.-Mod.Sv.	4.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	4.0000	.0000	2

Summaries of D21SEV
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	3.7778	1.6486	70.6667	27
2.00	Recurr.	3.8636	1.7538	64.5909	22
3.00	Rec.-Mod.Sv.	4.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	4.0000	.0000	.0000	2
Within Groups Total		3.8269	1.6787	135.2576	52

Criterion Variable D21SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1847	3	.0616	.0219	.9956
Within Groups	135.2576	48	2.8179		
Eta = .0369		Eta Squared = .0014			

FCE 20124/706 i

(9.1.3.2) Summaries of D28SEV Severity - Day 28
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.4231	1.9133	52
SUBFORM	1.00	Sing.Epi.	3.3704	2.0220	27
SUBFORM	2.00	Recurr.	3.4091	1.9188	22
SUBFORM	3.00	Rec.-Mod.Sv.	3.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	4.5000	.7071	2

Summaries of D28SEV
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	3.3704	2.0220	106.2963	27
2.00	Recurr.	3.4091	1.9188	77.3182	22
3.00	Rec.-Mod.Sv.	3.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	4.5000	.7071	.5000	2

Within Groups Total		3.4231	1.9585	184.1145	52

Criterion Variable D28SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.5778	3	.8593	.2240	.8792
Within Groups	184.1145	48	3.8357		
Eta = .1175		Eta Squared = .0138			

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(9.1.3.2) Summaries of D35SEV Severity - Day 35
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1923	2.0004	52
SUBFORM	1.00	Sing.Epi.	3.0741	2.1109	27
SUBFORM	2.00	Recurr.	3.3182	1.9853	22
SUBFORM	3.00	Rec.-Mod.Sv.	2.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	4.0000	1.4142	2

Summaries of D35SEV
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	3.0741	2.1109	115.8519	27
2.00	Recurr.	3.3182	1.9853	82.7727	22
3.00	Rec.-Mod.Sv.	2.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	4.0000	1.4142	2.0000	2

Within Groups Total		3.1923	2.0444	200.6246	52

Criterion Variable D35SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.4523	3	1.1508	.2753	.8429
Within Groups	200.6246	48	4.1797		
Eta = .1301		Eta Squared = .0169			

1128

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(9.1.3.2) Summaries of D42SEV Severity - Day 42
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1154	2.0737	52
SUBFORM	1.00	Sing.Epi.	3.0370	2.1390	27
SUBFORM	2.00	Recurr.	3.1818	2.1300	22
SUBFORM	3.00	Rec.-Mod.Sv.	2.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	4.0000	1.4142	2

Summaries of D42SEV
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	3.0370	2.1390	118.9630	27	
2.00	Recurr.	3.1818	2.1300	95.2727	22	
3.00	Rec.-Mod.Sv.	2.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	4.0000	1.4142	2.0000	2	

Within Groups Total			3.1154	2.1225	216.2357	52

Criterion Variable D42SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.0720	3	1.0240	.2273	.8769
Within Groups	216.2357	48	4.5049		
Eta = .1184		Eta Squared = .0140			

1129

602

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(9.1.3.2) Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			9.7051	15.5696	52
SUBFORM	1.00	Sing.Epi.	7.2716	10.9533	27
SUBFORM	2.00	Recurr.	12.3333	19.3273	22
SUBFORM	3.00	Rec.-Mod.Sv.	39.0000	.0000	1
SUBFORM	4.00	Rec.Sv.w.o.Pf	-1.0000	.0000	2

Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	7.2716	10.9533	3119.3416	27
2.00	Recurr.	12.3333	19.3273	7844.4444	22
3.00	Rec.-Mod.Sv.	39.0000	.0000	.0000	1
4.00	Rec.Sv.w.o.Pf	-1.0000	.0000	.0000	2

Within Groups Total		9.7051	15.1133	10963.7860	52

Criterion Variable DOT7CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1399.2482	3	466.4161	2.0420	.1205
Within Groups	10963.7860	48	228.4122		
Eta = .3364		Eta Squared = .1132			

1130

603

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(9.1.3.2) Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			23.9359	23.5007	52
SUBFORM	1.00	Sing.Epi.	21.4691	22.5053	27
SUBFORM	2.00	Recurr.	30.3636	23.9634	22
SUBFORM	3.00	Rec.-Mod.Sv.	-1.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	-1.0000	.0000	2

Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	21.4691	22.5053	13168.7243	27
2.00	Recurr.	30.3636	23.9634	12059.0909	22
3.00	Rec.-Mod.Sv.	-1.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	-1.0000	.0000	.0000	2

Within Groups Total		23.9359	22.9255	25227.8152	52

Criterion Variable DOT14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2938.6378	3	979.5459	1.8637	.1483
Within Groups	25227.8152	48	525.5795		
Eta = .3230		Eta Squared = .1043			

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(9.1.3.2) Summaries of DOT21OG Dy0 to Dy21 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			29.6410	30.1921	52
SUBFORM	1.00	Sing.Epi.	30.4815	30.9443	27
SUBFORM	2.00	Recurr.	30.0606	31.7961	22
SUBFORM	3.00	Rec.-Mod.Sv.	19.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	19.0000	.0000	2

Summaries of DOT21OG Dy0 to Dy21 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	30.4815	30.9443	24896.2963	27	
2.00	Recurr.	30.0606	31.7961	21230.8081	22	
3.00	Rec.-Mod.Sv.	19.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	19.0000	.0000	.0000	2	
Within Groups Total			29.6410	30.9997	46127.1044	52

Criterion Variable DOT21OG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	362.6392	3	120.8797	.1258	.9444
Within Groups	46127.1044	48	960.9813		
Eta = .0883		Eta Squared = .0078			

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(9.1.3.2) Summaries of DOT28CG Dy0 to Dy28 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			37.0128	34.9183	52
SUBFORM	1.00	Sing.Epi.	37.7654	37.4753	27
SUBFORM	2.00	Recurr.	38.5455	33.6854	22
SUBFORM	3.00	Rec.-Mod.Sv.	39.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	9.0000	14.1421	2

Summaries of DOT28CG Dy0 to Dy28 %Change
By Levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	37.7654	37.4753	36514.4033	27	
2.00	Recurr.	38.5455	33.6854	23828.7879	22	
3.00	Rec.-Mod.Sv.	39.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	9.0000	14.1421	200.0000	2	

Within Groups Total			37.0128	35.5150	60543.1912	52

Criterion Variable DOT28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1640.3558	3	546.7853	.4335	.7300
Within Groups	60543.1912	48	1261.3165		
Eta = .1624		Eta Squared = .0264			

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(9.1.3.2) Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			40.9872	36.5939	52
SUBFORM	1.00	Sing.Epi.	42.7037	39.4766	27
SUBFORM	2.00	Recurr.	40.0606	34.9056	22
SUBFORM	3.00	Rec.-Mod.Sv.	59.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	19.0000	28.2843	2

Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	42.7037	39.4766	40518.5185	27	
2.00	Recurr.	40.0606	34.9056	25586.3636	22	
3.00	Rec.-Mod.Sv.	59.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	19.0000	28.2843	800.0000	2	

Within Groups Total			40.9872	37.3343	66904.8822	52

Criterion Variable DOT35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1389.7760	3	463.2587	.3324	.8020
Within Groups	66904.8822	48	1393.8517		
Eta = .1427		Eta Squared = .0203			

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(9.1.3.2) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			42.2051	37.9368	52
SUBFORM	1.00	Sing.Epi.	43.3210	39.9766	27
SUBFORM	2.00	Recurr.	42.1818	37.5785	22
SUBFORM	3.00	Rec.-Mod.Sv.	59.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	19.0000	28.2843	2

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	43.3210	39.9766	41551.4403	27
2.00	Recurr.	42.1818	37.5785	29655.0505	22
3.00	Rec.-Mod.Sv.	59.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	19.0000	28.2843	800.0000	2
Within Groups Total		42.2051	38.7316	72006.4908	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1392.6545	3	464.2182	.3095	.8184
Within Groups	72006.4908	48	1500.1352		
		Eta = .1377	Eta Squared = .0190		

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```
( 9.1.3.2 ) manova
d0sev d7sev d14sev d21sev d28sev d35sev d42sev by rater(1,4)
/wsfactors=time (7)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	591.20	48	12.32		
CONSTANT	1262.01	1	1262.01	102.46	.000
RATER	7.05	3	2.35	.19	.902

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00062
Chi-square approx. = 338.35198 with 20 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .24257
Huynh-Feldt Epsilon = .26384
Lower-bound Epsilon = .16667
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

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(9.1.3.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. RATER BY TIME

Multivariate Tests of Significance (S = 3, M = 1 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.62385	1.96910	18.00	135.00	.015
Hotellings	.88375	2.04573	18.00	125.00	.012
Wilks	.47904	2.01610	18.00	122.11	.013
Roys	.37022				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 20 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.19491	1.73501	6.00	43.00	.136
Hotellings	.24209	1.73501	6.00	43.00	.136
Wilks	.80509	1.73501	6.00	43.00	.136
Roys	.19491				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	271.29	288	.94		
TIME	23.34	6	3.89	4.13	.001
RATER BY TIME	17.37	18	.96	1.02	.432

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(9.1.3.2) Summaries of DOSEV Severity - Day 0
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			5.5769	.5367	52
RATER	1.00	Beauclair	5.0000	.0000	1
RATER	2.00	Mirmiran	5.3333	.5774	3
RATER	3.00	Song	5.7500	.5000	4
RATER	4.00	Nardi	5.5909	.5421	44

Summaries of DOSEV Severity
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	5.0000	.0000	.0000	1
2.00	Mirmiran	5.3333	.5774	.6667	3
3.00	Song	5.7500	.5000	.7500	4
4.00	Nardi	5.5909	.5421	12.6364	44
Within Groups Total		5.5769	.5411	14.0530	52

Criterion Variable DOSEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.6393	3	.2131	.7278	.5404
Within Groups	14.0530	48	.2928		
Eta = .2086		Eta Squared = .0435			

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(9.1.3.2) Summaries of D7SEV Severity - Day 7
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.9615	.9280	52
RATER	1.00	Beauclair	5.0000	.0000	1
RATER	2.00	Mirmiran	4.6667	1.5275	3
RATER	3.00	Song	3.7500	1.8930	4
RATER	4.00	Nardi	5.0909	.7093	44

Summaries of D0SEV Severity
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Beauclair	5.0000	.0000	.0000	1	
2.00	Mirmiran	5.3333	.5774	.6667	3	
3.00	Song	5.7500	.5000	.7500	4	
4.00	Nardi	5.5909	.5421	12.6364	44	

Within Groups Total			5.5769	.5411	14.0530	52

Summaries of D7SEV
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Beauclair	5.0000	.0000	.0000	1	
2.00	Mirmiran	4.6667	1.5275	4.6667	3	
3.00	Song	3.7500	1.8930	10.7500	4	
4.00	Nardi	5.0909	.7093	21.6364	44	

Within Groups Total			4.9615	.8786	37.0530	52

Criterion Variable D7SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	6.8700	3	2.2900	2.9666	.0412
Within Groups	37.0530	48	.7719		
Eta = .3955		Eta Squared = .1564			

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(9.1.3.2) Summaries of D14SEV Severity - Day 14
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			4.1538	1.2739	52
RATER	1.00	Beauclair	5.0000	.0000	1
RATER	2.00	Mirmiran	5.0000	.0000	3
RATER	3.00	Song	3.5000	1.7321	4
RATER	4.00	Nardi	4.1364	1.2684	44

Summaries of D14SEV
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	5.0000	.0000	.0000	1
2.00	Mirmiran	5.0000	.0000	.0000	3
3.00	Song	3.5000	1.7321	9.0000	4
4.00	Nardi	4.1364	1.2684	69.1818	44

Within Groups Total		4.1538	1.2762	78.1818	52

Criterion Variable D14SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.5874	3	1.5291	.9388	.4293
Within Groups	78.1818	48	1.6288		
Eta = .2354		Eta Squared = .0554			

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(9.1.3.2) Summaries of D21SEV Severity - Day 21
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.8269	1.6296	52
RATER	1.00	Beauclair	4.0000	.0000	1
RATER	2.00	Mirmiran	4.3333	.5774	3
RATER	3.00	Song	4.0000	2.1602	4
RATER	4.00	Nardi	3.7727	1.6686	44

Summaries of D21SEV
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Beauclair	4.0000	.0000	.0000	1	
2.00	Mirmiran	4.3333	.5774	.6667	3	
3.00	Song	4.0000	2.1602	14.0000	4	
4.00	Nardi	3.7727	1.6686	119.7273	44	

Within Groups Total			3.8269	1.6733	134.3939	52

Criterion Variable D21SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.0484	3	.3495	.1248	.9450
Within Groups	134.3939	48	2.7999		

Eta = .0880 Eta Squared = .0077

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(9.1.3.2) Summaries of D28SEV Severity - Day 28
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.4231	1.9133	52
RATER	1.00	Beauclair	5.0000	.0000	1
RATER	2.00	Mirmiran	4.0000	1.0000	3
RATER	3.00	Song	3.5000	1.2910	4
RATER	4.00	Nardi	3.3409	2.0225	44

Summaries of D28SEV
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	5.0000	.0000	.0000	1
2.00	Mirmiran	4.0000	1.0000	2.0000	3
3.00	Song	3.5000	1.2910	5.0000	4
4.00	Nardi	3.3409	2.0225	175.8864	44

Within Groups Total		3.4231	1.9520	182.8864	52

Criterion Variable D28SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.8059	3	1.2686	.3330	.8015
Within Groups	182.8864	48	3.8101		
Eta = .1428		Eta Squared = .0204			

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(9.1.3.2) Summaries of D35SEV Severity - Day 35
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1923	2.0004	52
RATER	1.00	Beauclair	5.0000	.0000	1
RATER	2.00	Mirmiran	3.3333	1.5275	3
RATER	3.00	Song	3.2500	1.7078	4
RATER	4.00	Nardi	3.1364	2.0864	44

Summaries of D35SEV
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	5.0000	.0000	.0000	1
2.00	Mirmiran	3.3333	1.5275	4.6667	3
3.00	Song	3.2500	1.7078	8.7500	4
4.00	Nardi	3.1364	2.0864	187.1818	44

Within Groups Total		3.1923	2.0443	200.5985	52

Criterion Variable D35SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.4784	3	1.1595	.2774	.8414
Within Groups	200.5985	48	4.1791		
Eta = .1306		Eta Squared = .0170			

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(9.1.3.2) Summaries of D42SEV Severity - Day 42
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.1154	2.0737	52
RATER	1.00	Beauclair	5.0000	.0000	1
RATER	2.00	Mirmiran	3.3333	1.5275	3
RATER	3.00	Song	3.2500	1.7078	4
RATER	4.00	Nardi	3.0455	2.1669	44

Summaries of D42SEV
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Beauclair	5.0000	.0000	.0000	1	
2.00	Mirmiran	3.3333	1.5275	4.6667	3	
3.00	Song	3.2500	1.7078	8.7500	4	
4.00	Nardi	3.0455	2.1669	201.9091	44	

Within Groups Total			3.1154	2.1180	215.3258	52

Criterion Variable D42SEV

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.9819	3	1.3273	.2959	.8282
Within Groups	215.3258	48	4.4860		
Eta = .1347		Eta Squared = .0182			

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(9.1.3.2) Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			9.7051	15.5696	52
RATER	1.00	Beauclair	-1.0000	.0000	1
RATER	2.00	Mimiran	12.3333	23.0940	3
RATER	3.00	Song	32.3333	36.0041	4
RATER	4.00	Nardi	7.7121	10.8362	44

Summaries of DOT7CG Dy0 to Dy7 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	-1.0000	.0000	.0000	1
2.00	Mimiran	12.3333	23.0940	1066.6667	3
3.00	Song	32.3333	36.0041	3888.8889	4
4.00	Nardi	7.7121	10.8362	5049.2424	44
Within Groups Total		9.7051	14.4372	10004.7980	52

Criterion Variable DOT7CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2358.2362	3	786.0787	3.7714	.0165
Within Groups	10004.7980	48	208.4333		
Eta = .4367		Eta Squared = .1907			

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618

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(9.1.3.2) Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			23.9359	23.5007	52
RATER	1.00	Beauclair	-1.0000	.0000	1
RATER	2.00	Mirmiran	4.5556	9.6225	3
RATER	3.00	Song	37.3333	30.8521	4
RATER	4.00	Nardi	24.6061	22.9455	44

Summaries of DOT14CG Dy0 to Dy14 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Beauclair	-1.0000	.0000	.0000	1	
2.00	Mirmiran	4.5556	9.6225	185.1852	3	
3.00	Song	37.3333	30.8521	2855.5556	4	
4.00	Nardi	24.6061	22.9455	22639.3939	44	

Within Groups Total			23.9359	23.1301	25680.1347	52

Criterion Variable DOT14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2486.3183	3	828.7728	1.5491	.2140
Within Groups	25680.1347	48	535.0028		
Eta = .2971		Eta Squared = .0883			

FCE 20124/706 i

(9.1.3.2) Summaries of DOT21CG Dy0 to Dy21 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			29.6410	30.1921	52
RATER	1.00	Beauclair	19.0000	.0000	1
RATER	2.00	Mirmiran	17.8889	1.9245	3
RATER	3.00	Song	27.3333	42.9039	4
RATER	4.00	Nardi	30.8939	30.6299	44

Summaries of DOT21CG Dy0 to Dy21 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	19.0000	.0000	.0000	1
2.00	Mirmiran	17.8889	1.9245	7.4074	3
3.00	Song	27.3333	42.9039	5522.2222	4
4.00	Nardi	30.8939	30.6299	40342.1717	44

Within Groups Total		29.6410	30.9138	45871.8013	52

Criterion Variable DOT21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	617.9422	3	205.9807	.2155	.8851
Within Groups	45871.8013	48	955.6625		
Eta = .1153		Eta Squared = .0133			

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620

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(9.1.3.2) Summaries of DOT280G Dy0 to Dy28 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			37.0128	34.9183	52
RATER	1.00	Beauclair	-1.0000	.0000	1
RATER	2.00	Mirmiran	24.5556	12.6198	3
RATER	3.00	Song	38.1667	20.7944	4
RATER	4.00	Nardi	38.6212	36.8965	44

Summaries of DOT280G Dy0 to Dy28 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Beauclair	-1.0000	.0000	.0000	1	
2.00	Mirmiran	24.5556	12.6198	318.5185	3	
3.00	Song	38.1667	20.7944	1297.2222	4	
4.00	Nardi	38.6212	36.8965	58538.1313	44	

Within Groups Total			37.0128	35.4006	60153.8721	52

Criterion Variable DOT280G

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2029.6750	3	676.5583	.5399	.6573
Within Groups	60153.8721	48	1253.2057		
Eta = .1807		Eta Squared = .0326			

1148

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FCE 20124/706 i

(9.1.3.2) Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			40.9872	36.5939	52
RATER	1.00	Beauclair	-1.0000	.0000	1
RATER	2.00	Mirmiran	37.8889	21.6880	3
RATER	3.00	Song	42.3333	28.4149	4
RATER	4.00	Nardi	42.0303	38.3026	44

Summaries of DOT35CG Dy0 to Dy35 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	-1.0000	.0000	.0000	1
2.00	Mirmiran	37.8889	21.6880	940.7407	3
3.00	Song	42.3333	28.4149	2422.2222	4
4.00	Nardi	42.0303	38.3026	63084.8485	44
Within Groups Total		40.9872	37.2066	66447.8114	52

Criterion Variable DOT35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1846.8467	3	615.6156	.4447	.7221
Within Groups	66447.8114	48	1384.3294		
Eta = .1644		Eta Squared = .0270			

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(9.1.3.2) Summaries of CHANGE Dy0 to Dy42 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			42.2051	37.9368	52
RATER	1.00	Beauclair	-1.0000	.0000	1
RATER	2.00	Mirmiran	37.8889	21.6880	3
RATER	3.00	Song	42.3333	28.4149	4
RATER	4.00	Nardi	43.4697	39.7794	44

Summaries of CHANGE Dy0 to Dy42 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	-1.0000	.0000	.0000	1
2.00	Mirmiran	37.8889	21.6880	940.7407	3
3.00	Song	42.3333	28.4149	2422.2222	4
4.00	Nardi	43.4697	39.7794	68043.1818	44

Within Groups Total		42.2051	38.5698	71406.1448	52

Criterion Variable CHANGE

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1993.0005	3	664.3335	.4466	.7208
Within Groups	71406.1448	48	1487.6280		

Eta = .1648 Eta Squared = .0272

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APPENDIX 18

Therapeutic Efficacy: CGI-GI

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624

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(9.1.4.1) Summaries of D7IMP Improvement
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5000	.6417	52
DRUGRP	1	Reboxetine	3.3333	.7338	27
DRUGRP	2	Placebo	3.6800	.4761	25

Summaries of D42IMP Improvement
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.4423	1.5893	52
DRUGRP	1	Reboxetine	1.5556	1.0500	27
DRUGRP	2	Placebo	3.4000	1.5275	25

*** ANALYSIS OF VARIANCE ***

D42IMP Improvement
BY DRUGRP Treatment Group
WITH D7IMP improvement

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	26.298	1	26.298	17.705	.000
D7IMP	26.298	1	26.298	17.705	.000
Main Effects	29.747	1	29.747	20.027	.000
DRUGRP	29.747	1	29.747	20.027	.000
Explained	56.045	2	28.023	18.866	.000
Residual	72.782	49	1.485		
Total	128.827	51	2.526		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

1152

625

FCE 20124/706 i

(9.1.4.1) D7IMP Improvement - Day 7 - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	3.7	3.7	3.7
Much Imp.	2	1	3.7	3.7	7.4
Min. Imp	3	13	48.1	48.1	55.6
No Change	4	12	44.4	44.4	100.0
Total		27	100.0	100.0	

D14IMP Improvement - Day 14 - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	3	11.1	11.1	11.1
Much Imp.	2	12	44.4	44.4	55.6
Min. Imp	3	10	37.0	37.0	92.6
No Change	4	2	7.4	7.4	100.0
Total		27	100.0	100.0	

D21IMP Improvement - Day 21 - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	10	37.0	37.0	37.0
Much Imp.	2	9	33.3	33.3	70.4
Min. Imp	3	6	22.2	22.2	92.6
No Change	4	2	7.4	7.4	100.0
Total		27	100.0	100.0	

D28IMP Improvement - Day 28 - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	15	55.6	55.6	55.6
Much Imp.	2	6	22.2	22.2	77.8
Min. Imp	3	3	11.1	11.1	88.9
No Change	4	3	11.1	11.1	100.0
Total		27	100.0	100.0	

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626

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(9.1.4.1) D35IMP Improvement - Day 35 - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	20	74.1	74.1	74.1
Much Imp.	2	1	3.7	3.7	77.8
Min. Imp	3	3	11.1	11.1	88.9
No Change	4	3	11.1	11.1	100.0
Total		27	100.0	100.0	

D42IMP Improvement - Day 42 - Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	20	74.1	74.1	74.1
Much Imp.	2	2	7.4	7.4	81.5
Min. Imp	3	2	7.4	7.4	88.9
No Change	4	3	11.1	11.1	100.0
Total		27	100.0	100.0	

D7IMP Improvement - Day 7 - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	8	32.0	32.0	32.0
No Change	4	17	68.0	68.0	100.0
Total		25	100.0	100.0	

D14IMP Improvement - Day 14 - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	4.0	4.0	4.0
Much Imp.	2	4	16.0	16.0	20.0
Min. Imp	3	6	24.0	24.0	44.0
No Change	4	14	56.0	56.0	100.0
Total		25	100.0	100.0	

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627

FCE 20124/706 i

(9.1.4.1) D21IMP Improvement - Day 21 - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	4.0	4.0	4.0
Much Imp.	2	4	16.0	16.0	20.0
Min. Imp	3	5	20.0	20.0	40.0
No Change	4	9	36.0	36.0	76.0
Min.Worse	5	6	24.0	24.0	100.0
Total		25	100.0	100.0	

D28IMP Improvement - Day 28 - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	4	16.0	16.0	16.0
Much Imp.	2	3	12.0	12.0	28.0
Min. Imp	3	3	12.0	12.0	40.0
No Change	4	9	36.0	36.0	76.0
Min.Worse	5	5	20.0	20.0	96.0
Much Worse	6	1	4.0	4.0	100.0
Total		25	100.0	100.0	

D35IMP Improvement - Day 35 - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	5	20.0	20.0	20.0
Much Imp.	2	3	12.0	12.0	32.0
Min. Imp	3	2	8.0	8.0	40.0
No Change	4	9	36.0	36.0	76.0
Min.Worse	5	5	20.0	20.0	96.0
Much Worse	6	1	4.0	4.0	100.0
Total		25	100.0	100.0	

D42IMP Improvement - Day 42 - Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	5	20.0	20.0	20.0
Much Imp.	2	2	8.0	8.0	28.0
Min. Imp	3	3	12.0	12.0	40.0
No Change	4	9	36.0	36.0	76.0
Min.Worse	5	5	20.0	20.0	96.0
Much Worse	6	1	4.0	4.0	100.0
Total		25	100.0	100.0	

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628

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(9.1.4.1) Summaries of D7IMP Improvement
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.5000	.6417	52
SEX	0	Female	3.4167	.7173	24
SEX	1	Male	3.5714	.5727	28

Summaries of D42IMP Improvement
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.5893	52
SEX	0	Female	2.2917	1.5458	24
SEX	1	Male	2.5714	1.6427	28

*** ANALYSIS OF VARIANCE ***

D42IMP Improvement
BY SEX
WITH D7IMP Improvement

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	26.298	1	26.298	12.586	.001
D7IMP	26.298	1	26.298	12.586	.001
Main Effects	.149	1	.149	.071	.791
SEX	.149	1	.149	.071	.791
Explained	26.447	2	13.223	6.329	.004
Residual	102.380	49	2.089		
Total	128.827	51	2.526		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

1156

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FCE 20124/706 i

(9.1.4.1) D7IMP Improvement - Day 7 - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	4.2	4.2	4.2
Min. Imp	3	11	45.8	45.8	50.0
No Change	4	12	50.0	50.0	100.0
Total		24	100.0	100.0	

D14IMP Improvement - Day 14 - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	3	12.5	12.5	12.5
Much Imp.	2	8	33.3	33.3	45.8
Min. Imp	3	5	20.8	20.8	66.7
No Change	4	8	33.3	33.3	100.0
Total		24	100.0	100.0	

D21IMP Improvement - Day 21 - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	8	33.3	33.3	33.3
Much Imp.	2	5	20.8	20.8	54.2
Min. Imp	3	3	12.5	12.5	66.7
No Change	4	6	25.0	25.0	91.7
Min. Worse	5	2	8.3	8.3	100.0
Total		24	100.0	100.0	

D28IMP Improvement - Day 28 - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	11	45.8	45.8	45.8
Much Imp.	2	3	12.5	12.5	58.3
Min. Imp	3	2	8.3	8.3	66.7
No Change	4	6	25.0	25.0	91.7
Min. Worse	5	2	8.3	8.3	100.0
Total		24	100.0	100.0	

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(9.1.4.1) D35IMP Improvement - Day 35 - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	13	54.2	54.2	54.2
Much Imp.	2	1	4.2	4.2	58.3
Min. Imp	3	2	8.3	8.3	66.7
No Change	4	6	25.0	25.0	91.7
Min.Worse	5	2	8.3	8.3	100.0
		-----	-----	-----	
Total		24	100.0	100.0	

D42IMP Improvement - Day 42 - Female

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	13	54.2	54.2	54.2
Much Imp.	2	1	4.2	4.2	58.3
Min. Imp	3	2	8.3	8.3	66.7
No Change	4	6	25.0	25.0	91.7
Min.Worse	5	2	8.3	8.3	100.0
		-----	-----	-----	
Total		24	100.0	100.0	

D7IMP Improvement - Day 7 - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Much Imp.	2	1	3.6	3.6	3.6
Min. Imp	3	10	35.7	35.7	39.3
No Change	4	17	60.7	60.7	100.0
		-----	-----	-----	
Total		28	100.0	100.0	

D14IMP Improvement - Day 14 - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	3.6	3.6	3.6
Much Imp.	2	8	28.6	28.6	32.1
Min. Imp	3	11	39.3	39.3	71.4
No Change	4	8	28.6	28.6	100.0
		-----	-----	-----	
Total		28	100.0	100.0	

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FCE 20124/706 i

(9.1.4.1) D21IMP Improvement - Day 21 - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	3	10.7	10.7	10.7
Much Imp.	2	8	28.6	28.6	39.3
Min. Imp	3	8	28.6	28.6	67.9
No Change	4	5	17.9	17.9	85.7
Min.Worse	5	4	14.3	14.3	100.0
Total		28	100.0	100.0	

D28IMP Improvement - Day 28 - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	8	28.6	28.6	28.6
Much Imp.	2	6	21.4	21.4	50.0
Min. Imp	3	4	14.3	14.3	64.3
No Change	4	6	21.4	21.4	85.7
Min.Worse	5	3	10.7	10.7	96.4
Much Worse	6	1	3.6	3.6	100.0
Total		28	100.0	100.0	

D35IMP Improvement - Day 35 - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	12	42.9	42.9	42.9
Much Imp.	2	3	10.7	10.7	53.6
Min. Imp	3	3	10.7	10.7	64.3
No Change	4	6	21.4	21.4	85.7
Min.Worse	5	3	10.7	10.7	96.4
Much Worse	6	1	3.6	3.6	100.0
Total		28	100.0	100.0	

D42IMP Improvement - Day 42 - Male

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	12	42.9	42.9	42.9
Much Imp.	2	3	10.7	10.7	53.6
Min. Imp	3	3	10.7	10.7	64.3
No Change	4	6	21.4	21.4	85.7
Min.Worse	5	3	10.7	10.7	96.4
Much Worse	6	1	3.6	3.6	100.0
Total		28	100.0	100.0	

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(9.1.4.1) Summaries of D7IMP Improvement - Day 7
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5000	.6417	52
COUNTRY	1.00	Canada	3.1250	1.1260	8
COUNTRY	2.00	Brazil	3.5682	.5011	44

Summaries of D42IMP Improvement - Day 14
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.4423	1.5893	52
COUNTRY	1.00	Canada	2.8750	1.6421	8
COUNTRY	2.00	Brazil	2.3636	1.5861	44

Total Cases = 52

*** ANALYSIS OF VARIANCE ***

D42IMP Improvement
BY COUNTRY
WITH D7IMP Improvement

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	26.298	1	26.298	13.536	.001
D7IMP	26.298	1	26.298	13.536	.001
Main Effects	7.333	1	7.333	3.774	.058
COUNTRY	7.333	1	7.333	3.774	.058
Explained	33.630	2	16.815	8.655	.001
Residual	95.197	49	1.943		
Total	128.827	51	2.526		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

1160

633

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(9.1.4.1) D7IMP Improvement - Day 7 - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	12.5	12.5	12.5
Much Imp.	2	1	12.5	12.5	25.0
Min. Imp	3	2	25.0	25.0	50.0
No Change	4	4	50.0	50.0	100.0
		-----	-----	-----	
Total		8	100.0	100.0	

D14IMP Improvement - Day 14 - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	12.5	12.5	12.5
Min. Imp	3	6	75.0	75.0	87.5
No Change	4	1	12.5	12.5	100.0
		-----	-----	-----	
Total		8	100.0	100.0	

D21IMP Improvement - Day 21 - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	12.5	12.5	12.5
Min. Imp	3	6	75.0	75.0	87.5
Min. Worse	5	1	12.5	12.5	100.0
		-----	-----	-----	
Total		8	100.0	100.0	

D28IMP Improvement - Day 28 - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	2	25.0	25.0	25.0
Much Imp.	2	1	12.5	12.5	37.5
Min. Imp	3	3	37.5	37.5	75.0
No Change	4	1	12.5	12.5	87.5
Much Worse	6	1	12.5	12.5	100.0
		-----	-----	-----	
Total		8	100.0	100.0	

FCE 20124/706

(9.1.4.1) D35IMP Improvement - Day 35 - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	2	25.0	25.0	25.0
Much Imp.	2	1	12.5	12.5	37.5
Min. Imp	3	3	37.5	37.5	75.0
No Change	4	1	12.5	12.5	87.5
Much Worse	6	1	12.5	12.5	100.0
Total		8	100.0	100.0	

D42IMP Improvement - Day 42 - Canada

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	2	25.0	25.0	25.0
Much Imp.	2	1	12.5	12.5	37.5
Min. Imp	3	3	37.5	37.5	75.0
No Change	4	1	12.5	12.5	87.5
Much Worse	6	1	12.5	12.5	100.0
Total		8	100.0	100.0	

D7IMP Improvement - Day 7 - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	19	43.2	43.2	43.2
No Change	4	25	56.8	56.8	100.0
Total		44	100.0	100.0	

D14IMP Improvement - Day 14 - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	3	6.8	6.8	6.8
Much Imp.	2	16	36.4	36.4	43.2
Min. Imp	3	10	22.7	22.7	65.9
No Change	4	15	34.1	34.1	100.0
Total		44	100.0	100.0	

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FCE 20124/706 i

(9.1.4.1) D21IMP Improvement - Day 21 - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	10	22.7	22.7	22.7
Much Imp.	2	13	29.5	29.5	52.3
Min. Imp	3	5	11.4	11.4	63.6
No Change	4	11	25.0	25.0	88.6
Min.Worse	5	5	11.4	11.4	100.0
Total		44	100.0	100.0	

D28IMP Improvement - Day 28 - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	17	38.6	38.6	38.6
Much Imp.	2	8	18.2	18.2	56.8
Min. Imp	3	3	6.8	6.8	63.6
No Change	4	11	25.0	25.0	88.6
Min.Worse	5	5	11.4	11.4	100.0
Total		44	100.0	100.0	

D35IMP Improvement - Day 35 - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	23	52.3	52.3	52.3
Much Imp.	2	3	6.8	6.8	59.1
Min. Imp	3	2	4.5	4.5	63.6
No Change	4	11	25.0	25.0	88.6
Min.Worse	5	5	11.4	11.4	100.0
Total		44	100.0	100.0	

D42IMP Improvement - Day 42 - Brazil

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	23	52.3	52.3	52.3
Much Imp.	2	3	6.8	6.8	59.1
Min. Imp	3	2	4.5	4.5	63.6
No Change	4	11	25.0	25.0	88.6
Min.Worse	5	5	11.4	11.4	100.0
Total		44	100.0	100.0	

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636

FCE 20124/706 i

(9.1.4.1) Summaries of D7IMP Improvement
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5000	.6417	52
AGEGRP	1.00	(18-37)	3.5263	.6118	19
AGEGRP	2.00	(38-49)	3.4000	.7539	20
AGEGRP	3.00	(50+)	3.6154	.5064	13

Summaries of D42IMP Improvement
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.4423	1.5893	52
AGEGRP	1.00	(18-37)	2.4737	1.6114	19
AGEGRP	2.00	(38-49)	2.5000	1.5728	20
AGEGRP	3.00	(50+)	2.3077	1.7022	13

*** ANALYSIS OF VARIANCE ***

D42IMP Improvement
BY AGEGRP Age Group
WITH D7IMP Improvement

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	26.298	1	26.298	12.495	.001
D7IMP	26.298	1	26.298	12.495	.001
Main Effects	1.506	2	.753	.358	.701
AGEGRP	1.506	2	.753	.358	.701
Explained	27.803	3	9.268	4.403	.008
Residual	101.024	48	2.105		
Total	128.827	51	2.526		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

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FCE 20124/706 i

(9.1.4.1) D7IMP Improvement - Day 7 - Age:18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Much Imp.	2	1	5.3	5.3	5.3
Min. Imp	3	7	36.8	36.8	42.1
No Change	4	11	57.9	57.9	100.0
Total		19	100.0	100.0	

D14IMP Improvement - Day 14 - Age:18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	5.3	5.3	5.3
Much Imp.	2	7	36.8	36.8	42.1
Min. Imp	3	3	15.8	15.8	57.9
No Change	4	8	42.1	42.1	100.0
Total		19	100.0	100.0	

D21IMP Improvement - Day 21 - Age:18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	3	15.8	15.8	15.8
Much Imp.	2	5	26.3	26.3	42.1
Min. Imp	3	3	15.8	15.8	57.9
No Change	4	6	31.6	31.6	89.5
Min. Worse	5	2	10.5	10.5	100.0
Total		19	100.0	100.0	

D28IMP Improvement - Day 21 - Age:18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	8	42.1	42.1	42.1
Much Imp.	2	2	10.5	10.5	52.6
Min. Imp	3	1	5.3	5.3	57.9
No Change	4	6	31.6	31.6	89.5
Min. Worse	5	2	10.5	10.5	100.0
Total		19	100.0	100.0	

FCE 20124/706 i

(9.1.4.1) D35IMP Improvement - Day 35 - Age:18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	9	47.4	47.4	47.4
Much Imp.	2	2	10.5	10.5	57.9
No Change	4	6	31.6	31.6	89.5
Min.Worse	5	2	10.5	10.5	100.0
Total		19	100.0	100.0	

D42IMP Improvement - Day 42 - Age:18-37

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	9	47.4	47.4	47.4
Much Imp.	2	2	10.5	10.5	57.9
No Change	4	6	31.6	31.6	89.5
Min.Worse	5	2	10.5	10.5	100.0
Total		19	100.0	100.0	

D7IMP Improvement - Day 7 - Age:38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	5.0	5.0	5.0
Min.Imp	3	9	45.0	45.0	50.0
No Change	4	10	50.0	50.0	100.0
Total		20	100.0	100.0	

D14IMP Improvement - Day 14 - Age:38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	2	10.0	10.0	10.0
Much Imp.	2	5	25.0	25.0	35.0
Min.Imp	3	8	40.0	40.0	75.0
No Change	4	5	25.0	25.0	100.0
Total		20	100.0	100.0	

FCE 20124/706 i

(9.1.4.1) D21IMP Improvement - Day 21 - Age:38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	5	25.0	25.0	25.0
Much Imp.	2	4	20.0	20.0	45.0
Min.Imp	3	5	25.0	25.0	70.0
No Change	4	3	15.0	15.0	85.0
Min.Worse	5	3	15.0	15.0	100.0
		-----	-----	-----	
Total		20	100.0	100.0	

D28IMP Improvement - Day 21 - Age:38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	6	30.0	30.0	30.0
Much Imp.	2	5	25.0	25.0	55.0
Min.Imp	3	3	15.0	15.0	70.0
No Change	4	3	15.0	15.0	85.0
Min.Worse	5	3	15.0	15.0	100.0
		-----	-----	-----	
Total		20	100.0	100.0	

D35IMP Improvement - Day 35 - Age:38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	9	45.0	45.0	45.0
Much Imp.	2	2	10.0	10.0	55.0
Min.Imp	3	3	15.0	15.0	70.0
No Change	4	3	15.0	15.0	85.0
Min.Worse	5	3	15.0	15.0	100.0
		-----	-----	-----	
Total		20	100.0	100.0	

D42IMP Improvement - Day 42 - Age:38-49

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	9	45.0	45.0	45.0
Much Imp.	2	1	5.0	5.0	50.0
Min.Imp	3	4	20.0	20.0	70.0
No Change	4	3	15.0	15.0	85.0
Min.Worse	5	3	15.0	15.0	100.0
		-----	-----	-----	
Total		20	100.0	100.0	

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FCE 20124/706 i.

(9.1.4.1) D7IMP Improvement - Day 7 - Age:≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	5	38.5	38.5	38.5
No Change	4	8	61.5	61.5	100.0
Total		13	100.0	100.0	

D14IMP Improvement - Day 14 - Age:≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	7.7	7.7	7.7
Much Imp.	2	4	30.8	30.8	38.5
Min. Imp	3	5	38.5	38.5	76.9
No Change	4	3	23.1	23.1	100.0
Total		13	100.0	100.0	

D21IMP Improvement - Day 21 - Age:≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	3	23.1	23.1	23.1
Much Imp.	2	4	30.8	30.8	53.8
Min. Imp	3	3	23.1	23.1	76.9
No Change	4	2	15.4	15.4	92.3
Min. Worse	5	1	7.7	7.7	100.0
Total		13	100.0	100.0	

D28IMP Improvement - Day 28 - Age:≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	5	38.5	38.5	38.5
Much Imp.	2	2	15.4	15.4	53.8
Min. Imp	3	2	15.4	15.4	69.2
No Change	4	3	23.1	23.1	92.3
Much Worse	6	1	7.7	7.7	100.0
Total		13	100.0	100.0	

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(9.1.4.1) D35IMP Improvement - Day 35 - Age:≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	7	53.8	53.8	53.8
Min. Imp	3	2	15.4	15.4	69.2
No Change	4	3	23.1	23.1	92.3
Much Worse	6	1	7.7	7.7	100.0
		-----	-----	-----	
Total		13	100.0	100.0	

D42IMP Improvement - Day 42 - Age:≥50

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	7	53.8	53.8	53.8
Much Imp.	2	1	7.7	7.7	61.5
Min. Imp	3	1	7.7	7.7	69.2
No Change	4	3	23.1	23.1	92.3
Much Worse	6	1	7.7	7.7	100.0
		-----	-----	-----	
Total		13	100.0	100.0	

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FCE 20124/706 i

(9.1.4.1) Summaries of D7IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.5000	.6417	52
SUBFORM	1.00	Sing.Epi.	3.5926	.5007	27
SUBFORM	2.00	Recurr.	3.4091	.7341	22
SUBFORM	3.00	Rec.-Mod.Sv.	2.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	4.0000	.0000	2

Summaries of D42IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.5893	52
SUBFORM	1.00	Sing.Epi.	2.3333	1.5933	27
SUBFORM	2.00	Recurr.	2.5909	1.6521	22
SUBFORM	3.00	Rec.-Mod.Sv.	1.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	3.0000	1.4142	2

*** ANALYSIS OF VARIANCE ***

D42IMP Improvement
BY SUBFORM DSM-III-R Subform
WITH D7IMP Improvement

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	26.298	1	26.298	12.389	.001
D7IMP	26.298	1	26.298	12.389	.001
Main Effects	2.763	3	.921	.434	.730
SUBFORM	2.763	3	.921	.434	.730
Explained	29.060	4	7.265	3.423	.016
Residual	99.766	47	2.123		
Total	128.827	51	2.526		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

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FCE 20124/706 i

(9.1.4.1) D7IMP Improvement - Day 7 - Single Episode

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	11	40.7	40.7	40.7
No Change	4	16	59.3	59.3	100.0
Total		27	100.0	100.0	

D14IMP Improvement - Day 14 - Single Episode

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	3.7	3.7	3.7
Much Imp.	2	9	33.3	33.3	37.0
Min. Imp	3	7	25.9	25.9	63.0
No Change	4	10	37.0	37.0	100.0
Total		27	100.0	100.0	

D21IMP Improvement - Day 21 - Single Episode

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	5	18.5	18.5	18.5
Much Imp.	2	9	33.3	33.3	51.9
Min. Imp	3	3	11.1	11.1	63.0
No Change	4	7	25.9	25.9	88.9
Min. Worse	5	3	11.1	11.1	100.0
Total		27	100.0	100.0	

D28IMP Improvement - Day 28 - Single Episode

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	10	37.0	37.0	37.0
Much Imp.	2	5	18.5	18.5	55.6
Min. Imp	3	2	7.4	7.4	63.0
No Change	4	7	25.9	25.9	88.9
Min. Worse	5	3	11.1	11.1	100.0
Total		27	100.0	100.0	

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FCE 20124/706 i.

(9.1.4.1) D35IMP Improvement - Day 35 - Single Episode

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	14	51.9	51.9	51.9
Much Imp.	2	2	7.4	7.4	59.3
Min. Imp	3	1	3.7	3.7	63.0
No Change	4	7	25.9	25.9	88.9
Min.Worse	5	3	11.1	11.1	100.0
Total		27	100.0	100.0	

D42IMP Improvement - Day 42 - Single Episode

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	14	51.9	51.9	51.9
Much Imp.	2	3	11.1	11.1	63.0
No Change	4	7	25.9	25.9	88.9
Min.Worse	5	3	11.1	11.1	100.0
Total		27	100.0	100.0	

D7IMP Improvement - Day 7 - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	4.5	4.5	4.5
Min. Imp	3	10	45.5	45.5	50.0
No Change	4	11	50.0	50.0	100.0
Total		22	100.0	100.0	

D14IMP Improvement - Day 14 - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	3	13.6	13.6	13.6
Much Imp.	2	7	31.8	31.8	45.5
Min. Imp	3	6	27.3	27.3	72.7
No Change	4	6	27.3	27.3	100.0
Total		22	100.0	100.0	

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FCE 20124/706 i

(9.1.4.1) D21IMP Improvement - Day 21 - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	6	27.3	27.3	27.3
Much Imp.	2	4	18.2	18.2	45.5
Min. Imp	3	5	22.7	22.7	68.2
No Change	4	4	18.2	18.2	86.4
Min.Worse	5	3	13.6	13.6	100.0
Total		22	100.0	100.0	

D28IMP Improvement - Day 28 - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	8	36.4	36.4	36.4
Much Imp.	2	3	13.6	13.6	50.0
Min. Imp	3	4	18.2	18.2	68.2
No Change	4	4	18.2	18.2	86.4
Min.Worse	5	2	9.1	9.1	95.5
Much Worse	6	1	4.5	4.5	100.0
Total		22	100.0	100.0	

D35IMP Improvement - Day 35 - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	10	45.5	45.5	45.5
Much Imp.	2	1	4.5	4.5	50.0
Min. Imp	3	4	18.2	18.2	68.2
No Change	4	4	18.2	18.2	86.4
Min.Worse	5	2	9.1	9.1	95.5
Much Worse	6	1	4.5	4.5	100.0
Total		22	100.0	100.0	

D42IMP Improvement - Day 42 - Recurrent

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	10	45.5	45.5	45.5
Min. Imp	3	5	22.7	22.7	68.2
No Change	4	4	18.2	18.2	86.4
Min.Worse	5	2	9.1	9.1	95.5
Much Worse	6	1	4.5	4.5	100.0
Total		22	100.0	100.0	

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FCE 20124/706 i

(9.1.4.1) D7IMP Improvement - Day 7 - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Much Imp.	2	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D14IMP Improvement - Day 14 - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D21IMP Improvement - Day 21 - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D28IMP Improvement - Day 28 - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D35IMP Improvement - Day 35 - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

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647

(9.1.4.1) D42IMP Improvement - Day 42 - Recurrent-Moderately Severe

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	100.0	100.0	100.0
Total		1	100.0	100.0	

D7IMP Improvement - Day 7 - Recurrent-Severe w/o Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No Change	4	2	100.0	100.0	100.0
Total		2	100.0	100.0	

D14IMP Improvement - Day 14 - Recurrent-Severe w/o Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	2	100.0	100.0	100.0
Total		2	100.0	100.0	

D21IMP Improvement - Day 21 - Recurrent-Severe w/o Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	2	100.0	100.0	100.0
Total		2	100.0	100.0	

D28IMP Improvement - Day 28 - Recurrent-Severe w/o Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Much Imp.	2	1	50.0	50.0	50.0
No Change	4	1	50.0	50.0	100.0
Total		2	100.0	100.0	

FCE 20124/706 i

(9.1.4.1) D35IMP Improvement - Day 35 - Recurrent-Severe w/o Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Much Imp.	2	1	50.0	50.0	50.0
No Change	4	1	50.0	50.0	100.0
		-----	-----	-----	
Total		2	100.0	100.0	

D42IMP Improvement - Day 42 - Recurrent-Severe w/o Psychotic Features

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Much Imp.	2	1	50.0	50.0	50.0
No Change	4	1	50.0	50.0	100.0
		-----	-----	-----	
Total		2	100.0	100.0	

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FCE 20124/706 i

(9.1.4.1) Summaries of D7IMP Improvement - Day 7

By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5000	.6417	52
RATER	1.00	Beauclair	4.0000	.0000	1
RATER	2.00	Mirmiran	3.3333	1.1547	3
RATER	3.00	Song	2.7500	1.2583	4
RATER	4.00	Nardi	3.5682	.5011	44

Summaries of D42IMP Improvement - Day 42
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.4423	1.5893	52
RATER	1.00	Beauclair	4.0000	.0000	1
RATER	2.00	Mirmiran	2.0000	1.0000	3
RATER	3.00	Song	3.2500	2.0616	4
RATER	4.00	Nardi	2.3636	1.5861	44

*** ANALYSIS OF VARIANCE ***

D42IMP Improvement
BY RATER
WITH D7IMP Improvement

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	26.298	1	26.298	14.017	.000
D7IMP	26.298	1	26.298	14.017	.000
Main Effects	14.353	3	4.784	2.550	.067
RATER	14.353	3	4.784	2.550	.067
Explained	40.651	4	10.163	5.417	.001
Residual	88.176	47	1.876		
Total	128.827	51	2.526		

52 Cases were processed.
0 Cases (.0 PCT) were missing.

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FCE 20124/706 i

(9.1.4.1) D7IMP Improvement - Day 7 - Beauclair

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No Change	4	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D14IMP Improvement - Day 14 - Beauclair

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D21IMP Improvement - Day 21 - Beauclair

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D28IMP Improvement - Day 28 - Beauclair

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No Change	4	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D35IMP Improvement - Day 35 - Beauclair

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No Change	4	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

D42IMP Improvement - Day 42 - Beauclair

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No Change	4	1	100.0	100.0	100.0
		-----	-----	-----	-----
Total		1	100.0	100.0	

FCE 20124/706 i

(9.1.4.1) D7IMP Improvement - Day 7 - Mirmiran

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Much Imp.	2	1	33.3	33.3	33.3
No Change	4	2	66.7	66.7	100.0
Total		3	100.0	100.0	

D14IMP Improvement - Day 14 - Mirmiran

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	3	100.0	100.0	100.0
Total		3	100.0	100.0	

D21IMP Improvement - Day 21 - Mirmiran

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	3	100.0	100.0	100.0
Total		3	100.0	100.0	

D28IMP Improvement - Day 28 - Mirmiran

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	33.3	33.3	33.3
Much Imp.	2	1	33.3	33.3	66.7
Min. Imp	3	1	33.3	33.3	100.0
Total		3	100.0	100.0	

D35IMP Improvement - Day 35 - Mirmiran

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	33.3	33.3	33.3
Much Imp.	2	1	33.3	33.3	66.7
Min. Imp	3	1	33.3	33.3	100.0
Total		3	100.0	100.0	

117g

652

FCE 20124/706 i

(9.1.4.1) D42IMP Improvement - Day 42 - Mirmiran

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	33.3	33.3	33.3
Much Imp.	2	1	33.3	33.3	66.7
Min. Imp	3	1	33.3	33.3	100.0
		-----	-----	-----	
Total		3	100.0	100.0	

D7IMP Improvement - Day 7 - Song

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	25.0	25.0	25.0
Min. Imp	3	2	50.0	50.0	75.0
No Change	4	1	25.0	25.0	100.0
		-----	-----	-----	
Total		4	100.0	100.0	

D14IMP Improvement - Day 14 - Song

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	25.0	25.0	25.0
Min. Imp	3	2	50.0	50.0	75.0
No Change	4	1	25.0	25.0	100.0
		-----	-----	-----	
Total		4	100.0	100.0	

D21IMP Improvement - Day 21 - Song

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	25.0	25.0	25.0
Min. Imp	3	2	50.0	50.0	75.0
Min. Worse	5	1	25.0	25.0	100.0
		-----	-----	-----	
Total		4	100.0	100.0	

1180

653

FCE 20124/706 i

(9.1.4.1) D28IMP Improvement - Day 28 - Song

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	25.0	25.0	25.0
Min. Imp	3	2	50.0	50.0	75.0
Much Worse	6	1	25.0	25.0	100.0
Total		4	100.0	100.0	

D35IMP Improvement - Day 35 - Song

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	25.0	25.0	25.0
Min. Imp	3	2	50.0	50.0	75.0
Much Worse	6	1	25.0	25.0	100.0
Total		4	100.0	100.0	

D42IMP Improvement - Day 42 - Song

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	25.0	25.0	25.0
Min. Imp	3	2	50.0	50.0	75.0
Much Worse	6	1	25.0	25.0	100.0
Total		4	100.0	100.0	

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FCE 20124/706 i

(9.1.4.1) D7IMP Improvement - Day 7 - Nardi

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Min. Imp	3	19	43.2	43.2	43.2
No Change	4	25	56.8	56.8	100.0
	Total	44	100.0	100.0	

D14IMP Improvement - Day 14 - Nardi

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	3	6.8	6.8	6.8
Much Imp.	2	16	36.4	36.4	43.2
Min. Imp	3	10	22.7	22.7	65.9
No Change	4	15	34.1	34.1	100.0
	Total	44	100.0	100.0	

D21IMP Improvement - Day 21 - Nardi

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	10	22.7	22.7	22.7
Much Imp.	2	13	29.5	29.5	52.3
Min. Imp	3	5	11.4	11.4	63.6
No Change	4	11	25.0	25.0	88.6
Min. Worse	5	5	11.4	11.4	100.0
	Total	44	100.0	100.0	

D28IMP Improvement - Day 28 - Nardi

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	17	38.6	38.6	38.6
Much Imp.	2	8	18.2	18.2	56.8
Min. Imp	3	3	6.8	6.8	63.6
No Change	4	11	25.0	25.0	88.6
Min. Worse	5	5	11.4	11.4	100.0
	Total	44	100.0	100.0	

FCE 20124/706 i

(9.1.4.1) D35IMP Improvement - Day 35 - Nardi

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	1	25.0	25.0	25.0
Min. Imp	3	2	50.0	50.0	75.0
Much Worse	6	1	25.0	25.0	100.0
		-----	-----	-----	
Total		4	100.0	100.0	

D42IMP Improvement - Day 42 - Nardi

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Very Much Imp.	1	23	52.3	52.3	52.3
Much Imp.	2	3	6.8	6.8	59.1
Min. Imp	3	2	4.5	4.5	63.6
No Change	4	11	25.0	25.0	88.6
Min. Worse	5	5	11.4	11.4	100.0
		-----	-----	-----	
Total		44	100.0	100.0	

Valid cases 44 Missing cases 0

FCE 20124/706 i

APPENDIX 19

Onset of Therapeutic Activity: CGI-GI

1184

657

FCE 20124/706 i .

```
( 9.1.4.2 ) manova
d7imp d14imp d21imp d28imp d35imp d42imp by drugrp(1,2)
/wsactors=time (6)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	285.33	50	5.71		
CONSTANT	2423.12	1	2423.12	424.61	.000
DRUGRP	143.12	1	143.12	25.08	.000

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .01159
Chi-square approx. = 214.41238 with 14 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .37260
Huynh-Feldt Epsilon = .39420
Lower-bound Epsilon = .20000
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1185

658

FCE 20124/706 i

(9.1.4.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. DRUGRP BY TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 22)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.36270	5.23594	5.00	46.00	.001
Hotellings	.56912	5.23594	5.00	46.00	.001
Wilks	.63730	5.23594	5.00	46.00	.001
Roys	.36270				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 22)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.48376	8.62118	5.00	46.00	.000
Hotellings	.93709	8.62118	5.00	46.00	.000
Wilks	.51624	8.62118	5.00	46.00	.000
Roys	.48376				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	79.84	250	.32		
TIME	38.83	5	7.77	24.32	.000
DRUGRP BY TIME	23.06	5	4.61	14.44	.000

1186

659

FCE 20124/706 i

(9.1.4.2) Summaries of D7IMP Improvement
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		3.5000	.6417	52
DRUGRP	1 Reboxetine	3.3333	.7338	27
DRUGRP	2 Placebo	3.6800	.4761	25

Summaries of D7IMP Improvement
By levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	3.3333	.7338	14.0000	27
2 Placebo	3.6800	.4761	5.4400	25

Within Groups Total	3.5000	.6235	19.4400	52

Criterion Variable D7IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.5600	1	1.5600	4.0123	.0506
Within Groups	19.4400	50	.3888		
Eta = .2726 Eta Squared = .0743					

1187

660

FCE 20124/706 i

(9.1.4.2) Summaries of D14IMP Improvement
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.8462	.9576	52
DRUGRP	1	Reboxetine	2.4074	.7971	27
DRUGRP	2	Placebo	3.3200	.9000	25

Summaries of D14IMP Improvement
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	2.4074	.7971	16.5185	27	
2	Placebo	3.3200	.9000	19.4400	25	

Within Groups Total			2.8462	.8480	35.9585	52

Criterion Variable D14IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	10.8107	1	10.8107	15.0322	.0003
Within Groups	35.9585	50	.7192		
Eta = .4808		Eta Squared = .2312			

1188

661

FCE 20124/706 i

(9.1.4.2) Summaries of D21IMP Improvement
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.7692	1.3227	52
DRUGRP	1	Reboxetine	2.0000	.9608	27
DRUGRP	2	Placebo	3.6000	1.1547	25

Summaries of D21IMP Improvement
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	2.0000	.9608	24.0000	27
2	Placebo	3.6000	1.1547	32.0000	25

Within Groups Total			2.7692	1.0583	56.0000
					52

Criterion Variable D21IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	33.2308	1	33.2308	29.6703	.0000
Within Groups	56.0000	50	1.1200		
Eta = .6103		Eta Squared = .3724			

1189

662

FCE 20124/706 i

(9.1.4.2) Summaries of D28IMP Improvement
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.5769	1.5126	52
DRUGRP	1 Reboxetine	1.7778	1.0500	27
DRUGRP	2 Placebo	3.4400	1.4742	25

Summaries of D28IMP Improvement
By levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	1.7778	1.0500	28.6667	27
2 Placebo	3.4400	1.4742	52.1600	25

Within Groups Total	2.5769	1.2714	80.8267	52

Criterion Variable D28IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	35.8656	1	35.8656	22.1868	.0000
Within Groups	80.8267	50	1.6165		
Eta = .5544 Eta Squared = .3074					

1190

663

FCE 20124/706 i

(9.1.4.2) Summaries of D35IMP Improvement
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.5893	52
DRUGRP	1	Reboxetine	1.5926	1.0834	27
DRUGRP	2	Placebo	3.3600	1.5513	25

Summaries of D35IMP Improvement
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1	Reboxetine	1.5926	1.0834	30.5185	27	
2	Placebo	3.3600	1.5513	57.7600	25	

Within Groups Total			2.4423	1.3287	88.2785	52

Criterion Variable D35IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	40.5484	1	40.5484	22.9662	.0000
Within Groups	88.2785	50	1.7656		
Eta = .5610 Eta Squared = .3148					

1191

664

FCE 20124/706 i

(9.1.4.2) Summaries of D42IMP Improvement
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.4423	1.5893	52
DRUGRP	1 Reboxetine	1.5556	1.0500	27
DRUGRP	2 Placebo	3.4000	1.5275	25

Summaries of D42IMP Improvement
By levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	1.5556	1.0500	28.6667	27
2 Placebo	3.4000	1.5275	56.0000	25

Within Groups Total	2.4423	1.3013	84.6667	52

Criterion Variable D42IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	44.1603	1	44.1603	26.0789	.0000
Within Groups	84.6667	50	1.6933		
Eta = .5855 Eta Squared = .3428					

1192

665

FCE 20124/706 i

(9.1.4.2) Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		16.9487	24.9937	52
DRUGRP	1 Reboxetine	24.6173	25.6253	27
DRUGRP	2 Placebo	8.6667	21.8740	25

Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	24.6173	25.6253	17073.0453	27
2 Placebo	8.6667	21.8740	11483.3333	25

Within Groups Total	16.9487	23.8983	28556.3786	52

Criterion Variable D7T14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3302.5958	1	3302.5958	5.7826	.0199
Within Groups	28556.3786	50	571.1276		
Eta = .3220 Eta Squared = .1037					

1193

666

FCE 20124/706 i

(9.1.4.2) Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		19.6731	34.8312	52
DRUGRP	1 Reboxetine	36.9630	30.2530	27
DRUGRP	2 Placebo	1.0000	29.7832	25

Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	36.9630	30.2530	23796.2963	27
2 Placebo	1.0000	29.7832	21288.8889	25

Within Groups Total	19.6731	30.0284	45085.1852	52

Criterion Variable D7T21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	16788.4793	1	16788.4793	18.6186	.0001
Within Groups	45085.1852	50	901.7037		
Eta = .5209 Eta Squared = .2713					

1194

667

FCE 20124/706 i

(9.1.4.2) Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of DRUGRP Treatment Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			26.7244	37.7297	52
DRUGRP	1	Reboxetine	45.2963	27.1838	27
DRUGRP	2	Placebo	6.6667	37.6479	25

Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of DRUGRP Treatment Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1	Reboxetine	45.2963	27.1838	19212.9630	27
2	Placebo	6.6667	37.6479	34016.6667	25

Within Groups Total		26.7244	32.6281	53229.6296	52

Criterion Variable D7T28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	19370.5306	1	19370.5306	18.1953	.0001
Within Groups	53229.6296	50	1064.5926		
		Eta = .5165		Eta Squared = .2668	

1195

668

FCE 20124/706 i

(9.1.4.2) Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of DRUGRP Treatment Group

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		30.5705	40.0958	52
DRUGRP	1 Reboxetine	50.8519	28.2440	27
DRUGRP	2 Placebo	8.6667	39.8696	25

Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of DRUGRP Treatment Group

Value Label	Mean	Std Dev	Sum of Sq	Cases
1 Reboxetine	50.8519	28.2440	20740.7407	27
2 Placebo	8.6667	39.8696	38150.0000	25

Within Groups Total	30.5705	34.3193	58890.7407	52

Criterion Variable D7T35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	23100.4452	1	23100.4452	19.6130	.0001
Within Groups	58890.7407	50	1177.8148		

Eta = .5308 Eta Squared = .2817

1196

669

FCE 20124/706 i - .

```
( 9.1.4.2 ) manova
d7imp d14imp d21imp d28imp d35imp d42imp by sex(0,1)
/ws=factors=time (6)
/wsdesign=time
/design.
```

52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	422.29	50	8.45		
CONSTANT	2348.92	1	2348.92	278.12	.000
SEX	6.16	1	6.16	.73	.397

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

Mauchly sphericity test, W = .00492
Chi-square approx. = 255.59300 with 14 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .32405
Huynh-Feldt Epsilon = .34003
Lower-bound Epsilon = .20000

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1197

670

FCE 20124/706 i -

(9.1.4.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SEX BY TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 22)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.07021	.69471	5.00	46.00	.630
Hotellings	.07551	.69471	5.00	46.00	.630
Wilks	.92979	.69471	5.00	46.00	.630
Roys	.07021				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 22)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.46192	7.89793	5.00	46.00	.000
Hotellings	.85847	7.89793	5.00	46.00	.000
Wilks	.53808	7.89793	5.00	46.00	.000
Roys	.46192				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	102.18	250	.41		
TIME	41.33	5	8.27	20.22	.000
SEX BY TIME	.71	5	.14	.35	.882

1198

671

FCE 20124/706 i .

(9.1.4.2) Summaries of D7IMP Improvement
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.5000	.6417	52
SEX	0	Female	3.4167	.7173	24
SEX	1	Male	3.5714	.5727	28

Summaries of D7IMP Improvement
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	3.4167	.7173	11.8333	24	
1	Male	3.5714	.5727	8.8571	28	

Within Groups Total			3.5000	.6433	20.6905	52

Criterion Variable D7IMP

.Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3095	1	.3095	.7480	.3912
Within Groups	20.6905	50	.4138		

Eta = .1214 Eta Squared = .0147

1199

672

FCE 20124/706 i

(9.1.4.2) Summaries of D14IMP Improvement
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.8462	.9576	52
SEX	0	Female	2.7500	1.0734	24
SEX	1	Male	2.9286	.8576	28

Summaries of D14IMP Improvement
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	2.7500	1.0734	26.5000	24
1	Male	2.9286	.8576	19.8571	28
Within Groups Total		2.8462	.9629	46.3571	52

Criterion Variable D14IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.4121	1	.4121	.4445	.5080
Within Groups	46.3571	50	.9271		
Eta = .0939		Eta Squared = .0088			

1200

673

FCE 20124/706 i

(9.1.4.2) Summaries of D21IMP Improvement
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		2.7692	1.3227	52
SEX	0 Female	2.5417	1.4136	24
SEX	1 Male	2.9643	1.2317	28

Summaries of D21IMP Improvement
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	2.5417	1.4136	45.9583	24
1 Male	2.9643	1.2317	40.9643	28

Within Groups Total	2.7692	1.3185	86.9226	52

Criterion Variable D21IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.3082	1	2.3082	1.3277	.2547
Within Groups	86.9226	50	1.7385		
Eta = .1608 Eta Squared = .0259					

FCE 20124/706 i

(9.1.4.2) Summaries of D28IMP Improvement
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.5769	1.5126	52
SEX	0	Female	2.3750	1.4982	24
SEX	1	Male	2.7500	1.5306	28

Summaries of D28IMP Improvement
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	2.3750	1.4982	51.6250	24	
1	Male	2.7500	1.5306	63.2500	28	

Within Groups Total			2.5769	1.5158	114.8750	52

Criterion Variable D28IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.8173	1	1.8173	.7910	.3781
Within Groups	114.8750	50	2.2975		
Eta = .1248		Eta Squared = .0156			

1202

675

FCE 20124/706 i

(9.1.4.2) Summaries of D35IMP Improvement
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
SEX	0	Female	2.2917	1.5458	24
SEX	1	Male	2.5714	1.6427	28

Summaries of D35IMP Improvement
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	2.2917	1.5458	54.9583	24
1	Male	2.5714	1.6427	72.8571	28

Within Groups Total		2.4423	1.5988	127.8155	52

Criterion Variable D35IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.0114	1	1.0114	.3957	.5322
Within Groups	127.8155	50	2.5563		
Eta = .0886 Eta Squared = .0079					

FCE 20124/706 i -

(9.1.4.2) Summaries of D42IMP Improvement
By levels of SEX

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
SEX	0 Female	2.2917	1.5458	24
SEX	1 Male	2.5714	1.6427	28

Summaries of D42IMP Improvement
By levels of SEX

Value Label	Mean	Std Dev	Sum of Sq	Cases
0 Female	2.2917	1.5458	54.9583	24
1 Male	2.5714	1.6427	72.8571	28

Within Groups Total	2.4423	1.5988	127.8155	52

Criterion Variable D42IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.0114	1	1.0114	.3957	.5322
Within Groups	127.8155	50	2.5563		

Eta = .0886 Eta Squared = .0079

1204

677

FCE 20124/706 i

(9.1.4.2) Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			16.9487	24.9937	52
SEX	0	Female	18.4444	24.0353	24
SEX	1	Male	15.6667	26.1564	28

Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	18.4444	24.0353	13287.0370	24	
1	Male	15.6667	26.1564	18472.2222	28	

Within Groups Total			16.9487	25.2029	31759.2593	52

Criterion Variable D7T14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	99.7151	1	99.7151	.1570	.6936
Within Groups	31759.2593	50	635.1852		
Eta = .0559 Eta Squared = .0031					

1205

678

FCE 20124/706 i

(9.1.4.2) Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			19.6731	34.8312	52
SEX	0	Female	25.7361	33.0586	24
SEX	1	Male	14.4762	36.0551	28

Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
0	Female	25.7361	33.0586	25135.9954	24	
1	Male	14.4762	36.0551	35099.2063	28	

Within Groups Total			19.6731	34.7088	60235.2017	52

Criterion Variable D7T21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1638.4628	1	1638.4628	1.3601	.2491
Within Groups	60235.2017	50	1204.7040		
Eta = .1627 Eta Squared = .0265					

1206

679

PCE 20124/706 i

(9.1.4.2) Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			26.7244	37.7297	52
SEX	0	Female	31.2917	35.1251	24
SEX	1	Male	22.8095	40.0433	28

Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	31.2917	35.1251	28376.7361	24
1	Male	22.8095	40.0433	43293.6508	28

Within Groups Total		26.7244	37.8604	71670.3869	52

Criterion Variable D7T28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	929.7734	1	929.7734	.6486	.4244
Within Groups	71670.3869	50	1433.4077		
Eta = .1132		Eta Squared = .0128			

FCE 20124/706 i

(9.1.4.2) Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of SEX

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			30.5705	40.0958	52
SEX	0	Female	33.7222	36.6689	24
SEX	1	Male	27.8690	43.3002	28

Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of SEX

Value	Label	Mean	Std Dev	Sum of Sq	Cases
0	Female	33.7222	36.6689	30925.9259	24
1	Male	27.8690	43.3002	50622.5198	28

Within Groups Total		30.5705	40.3853	81548.4458	52

Criterion Variable D7T35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	442.7401	1	442.7401	.2715	.6047
Within Groups	81548.4458	50	1630.9689		
Eta = .0735		Eta Squared = .0054			

1208

681

FCB 20124/706 i

```
( 9.1.4.2 ) manova
d7imp d14imp d21imp d28imp d35imp d42imp by country(1,2)
/wsfactors=time (6)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
2 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	426.72	50	8.53		
CONSTANT	1305.08	1	1305.08	152.92	.000
COUNTRY	1.73	1	1.73	.20	.654

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00595
Chi-square approx. = 246.45277 with 14 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .33269
Huynh-Feidt Epsilon = .34962
Lower-bound Epsilon = .20000
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1209

682

FCE 20124/706 i

(9.1.4.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. COUNTRY BY TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 22)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.06854	.67700	5.00	46.00	.643
Hotellings	.07359	.67700	5.00	46.00	.643
Wilks	.93146	.67700	5.00	46.00	.643
Roys	.06854				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 22)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.22160	2.61909	5.00	46.00	.036
Hotellings	.28468	2.61909	5.00	46.00	.036
Wilks	.77840	2.61909	5.00	46.00	.036
Roys	.22160				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	98.41	250	.39		
TIME	10.14	5	2.03	5.15	.000
COUNTRY BY TIME	4.49	5	.90	2.28	.047

1210

683

FCE 20124/706 i

(9.1.4.2) Summaries of D7IMP Improvement
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5000	.6417	52
COUNTRY	1.00	Canada	3.1250	1.1260	8
COUNTRY	2.00	Brazil	3.5682	.5011	44

Summaries of D7IMP Improvement
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.1250	1.1260	8.8750	8
2.00	Brazil	3.5682	.5011	10.7955	44

Within Groups Total		3.5000	.6272	19.6705	52

Criterion Variable D7IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.3295	1	1.3295	3.3795	.0720
Within Groups	19.6705	50	.3934		

Eta = .2516 Eta Squared = .0633

1211

684

FCE 20124/706 i

(9.1.4.2) Summaries of D14IMP Improvement
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.8462	.9576	52
COUNTRY	1.00	Canada	2.8750	.8345	8
COUNTRY	2.00	Brazil	2.8409	.9870	44

Summaries of D14IMP Improvement
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	2.8750	.8345	4.8750	8
2.00	Brazil	2.8409	.9870	41.8864	44

Within Groups Total		2.8462	.9671	46.7614	52

Criterion Variable D14IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0079	1	.0079	.0084	.9273
Within Groups	46.7614	50	.9352		

Eta = .0130 Eta Squared = .0002

FCE 20124/706 i

(9.1.4.2) Summaries of D21IMP Improvement
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.7692	1.3227	52
COUNTRY	1.00	Canada	3.0000	1.0690	8
COUNTRY	2.00	Brazil	2.7273	1.3702	44

Summaries of D21IMP Improvement
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	3.0000	1.0690	8.0000	8
2.00	Brazil	2.7273	1.3702	80.7273	44

Within Groups Total		2.7692	1.3321	88.7273	52

Criterion Variable D21IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5035	1	.5035	.2837	.5966
Within Groups	88.7273	50	1.7745		

Eta = .0751 Eta Squared = .0056

1213

636

FCE 20124/706 i

(9.1.4.2) Summaries of D28IMP Improvement
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.5769	1.5126	52
COUNTRY	1.00	Canada	2.8750	1.6421	8
COUNTRY	2.00	Brazil	2.5227	1.5018	44

Summaries of D28IMP Improvement
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	2.8750	1.6421	18.8750	8
2.00	Brazil	2.5227	1.5018	96.9773	44

Within Groups Total		2.5769	1.5222	115.8523	52

Criterion Variable D28IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.8400	1	.8400	.3625	.5498
Within Groups	115.8523	50	2.3170		

Eta = .0848 Eta Squared = .0072

FCE 20124/706 i

(9.1.4.2) Summaries of D35IMP Improvement
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.4423	1.5893	52
COUNTRY	1.00	Canada	2.8750	1.6421	8
COUNTRY	2.00	Brazil	2.3636	1.5861	44

Summaries of D35IMP Improvement
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	2.8750	1.6421	18.8750	8
2.00	Brazil	2.3636	1.5861	108.1818	44

Within Groups Total		2.4423	1.5941	127.0568	52

Criterion Variable D35IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.7701	1	1.7701	.6966	.4079
Within Groups	127.0568	50	2.5411		
Eta = .1172		Eta Squared = .0137			

FCE 20124/706 i

(9.1.4.2) Summaries of D42IMP Improvement
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.4423	1.5893	52
COUNTRY	1.00	Canada	2.8750	1.6421	8
COUNTRY	2.00	Brazil	2.3636	1.5861	44

Summaries of D42IMP Improvement
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	2.8750	1.6421	18.8750	8
2.00	Brazil	2.3636	1.5861	108.1818	44

Within Groups Total		2.4423	1.5941	127.0568	52

Criterion Variable D42IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.7701	1	1.7701	.6966	.4079
Within Groups	127.0568	50	2.5411		
Eta = .1172		Eta Squared = .0137			

1216

689

FCE 20124/706 i

(9.1.4.2) Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			16.9487	24.9937	52
COUNTRY	1.00	Canada	2.1250	24.7758	8
COUNTRY	2.00	Brazil	19.6439	24.3447	44

Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	2.1250	24.7758	4296.8750	8
2.00	Brazil	19.6439	24.3447	25484.5328	44
Within Groups Total		16.9487	24.4055	29781.4078	52

Criterion Variable D7T14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2077.5665	1	2077.5665	3.4880	.0677
Within Groups	29781.4078	50	595.6282		
Eta = .2554		Eta Squared = .0652			

1217

690

FCE 20124/706 i ..

(9.1.4.2) Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			19.6731	34.8312	52
COUNTRY	1.00	Canada	-1.0000	26.7261	8
COUNTRY	2.00	Brazil	23.4318	35.0525	44

Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	-1.0000	26.7261	5000.0000	8
2.00	Brazil	23.4318	35.0525	52833.0177	44

Within Groups Total		19.6731	34.0097	57833.0177	52

Criterion Variable D7T21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4040.6469	1	4040.6469	3.4934	.0675
Within Groups	57833.0177	50	1156.6604		
Eta = .2555		Eta Squared = .0653			

FCE 20124/706 i

(9.1.4.2) Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			26.7244	37.7297	52
COUNTRY	1.00	Canada	8.3750	32.5618	8
COUNTRY	2.00	Brazil	30.0606	37.9703	44

Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	8.3750	32.5618	7421.8750	8
2.00	Brazil	30.0606	37.9703	61994.9495	44

Within Groups Total		26.7244	37.2604	69416.8245	52

Criterion Variable D7T28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3183.3358	1	3183.3358	2.2929	.1363
Within Groups	69416.8245	50	1388.3365		
Eta = .2094		Eta Squared = .0438			

1219

692

FCE 20124/706 i

(9.1.4.2) Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of COUNTRY

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			30.5705	40.0958	52
COUNTRY	1.00	Canada	8.3750	32.5618	8
COUNTRY	2.00	Brazil	34.6061	40.3218	44

Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of COUNTRY

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Canada	8.3750	32.5618	7421.8750	8
2.00	Brazil	34.6061	40.3218	69911.6162	44
Within Groups Total		30.5705	39.3277	77333.4912	52

Criterion Variable D7T35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4657.6947	1	4657.6947	3.0114	.0888
Within Groups	77333.4912	50	1546.6698		
Eta = .2383		Eta Squared = .0568			

1220

693

FCE 20124/706 i

```
( 9.1.4.2 ) manova
d7imp d14imp d21imp d28imp d35imp d42imp by agegrp(1,3)
/wsfactors=time (6)
/wsdesign=time
/design.
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52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
3 non-empty cells.

1 design will be processed.
```

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	427.61	49	8.73		
CONSTANT	2283.69	1	2283.69	261.69	.000
AGEGRP	.84	2	.42	.05	.953

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

Mauchly sphericity test, W = .00464
Chi-square approx. = 253.06550 with 14 D. F.
Significance = .000

Greenhouse-Geisser Epsilon = .32166
Huynh-Feldt Epsilon = .34450
Lower-bound Epsilon = .20000

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1221

694

FCE 20124/706 i

(9.1.4.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. AGEGRP BY TIME

Multivariate Tests of Significance (S = 2, M = 1, N = 21 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.16579	.83159	10.00	92.00	.599
Hotellings	.18327	.80640	10.00	88.00	.623
Wilks	.84012	.81912	10.00	90.00	.611
Roys	.11389				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 21 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.45773	7.59691	5.00	45.00	.000
Hotellings	.84410	7.59691	5.00	45.00	.000
Wilks	.54227	7.59691	5.00	45.00	.000
Roys	.45773				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	101.32	245	.41		
TIME	41.38	5	8.28	20.01	.000
AGEGRP BY TIME	1.57	10	.16	.38	.954

1222

695

FCE 20124/706 i

(9.1.4.2) Summaries of D7IMP Improvement
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5000	.6417	52
AGEGRP	1.00	(18-37)	3.5263	.6118	19
AGEGRP	2.00	(38-49)	3.4000	.7539	20
AGEGRP	3.00	(50+)	3.6154	.5064	13

Summaries of D7IMP Improvement
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	3.5263	.6118	6.7368	19
2.00	(38-49)	3.4000	.7539	10.8000	20
3.00	(50+)	3.6154	.5064	3.0769	13

Within Groups Total		3.5000	.6486	20.6138	52

Criterion Variable D7IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3862	2	.1931	.4591	.6346
Within Groups	20.6138	49	.4207		

Eta = .1356 Eta Squared = .0184

FCE 20124/706 i

(9.1.4.2) Summaries of D14IMP Improvement
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.8462	.9576	52
AGEGRP	1.00	(18-37)	2.9474	1.0260	19
AGEGRP	2.00	(38-49)	2.8000	.9515	20
AGEGRP	3.00	(50+)	2.7692	.9268	13

Summaries of D14IMP Improvement
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	2.9474	1.0260	18.9474	19
2.00	(38-49)	2.8000	.9515	17.2000	20
3.00	(50+)	2.7692	.9268	10.3077	13
Within Groups Total		2.8462	.9737	46.4551	52

Criterion Variable D14IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3142	2	.1571	.1657	.8478
Within Groups	46.4551	49	.9481		
Eta = .0820		Eta Squared = .0067			

FCE 20124/706 i

(9.1.4.2) Summaries of D211MP Improvement
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.7692	1.3227	52
AGEGRP	1.00	(18-37)	2.9474	1.3112	19
AGEGRP	2.00	(38-49)	2.7500	1.4096	20
AGEGRP	3.00	(50+)	2.5385	1.2659	13

Summaries of D211MP Improvement
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	2.9474	1.3112	30.9474	19
2.00	(38-49)	2.7500	1.4096	37.7500	20
3.00	(50+)	2.5385	1.2659	19.2308	13

Within Groups Total		2.7692	1.3396	87.9281	52

Criterion Variable D211MP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.3026	2	.6513	.3630	.6975
Within Groups	87.9281	49	1.7945		
Eta = .1208		Eta Squared = .0146			

1225

698

FCE 20124/706 i

(9.1.4.2) Summaries of D28IMP Improvement
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.5769	1.5126	52
AGEGRP	1.00	(18-37)	2.5789	1.5747	19
AGEGRP	2.00	(38-49)	2.6000	1.4654	20
AGEGRP	3.00	(50+)	2.5385	1.6132	13

Summaries of D28IMP Improvement
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	2.5789	1.5747	44.6316	19
2.00	(38-49)	2.6000	1.4654	40.8000	20
3.00	(50+)	2.5385	1.6132	31.2308	13
Within Groups Total		2.5769	1.5430	116.6623	52

Criterion Variable D28IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0300	2	.0150	.0063	.9937
Within Groups	116.6623	49	2.3809		

Eta = .0160 Eta Squared = .0003

1226

699

FCE 20124/706 i .

(9.1.4.2) Summaries of D35IMP Improvement
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.5893	52
AGEGRP	1.00	(18-37)	2.4737	1.6114	19
AGEGRP	2.00	(38-49)	2.4500	1.5720	20
AGEGRP	3.00	(50+)	2.3846	1.7097	13

Summaries of D35IMP Improvement
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	2.4737	1.6114	46.7368	19
2.00	(38-49)	2.4500	1.5720	46.9500	20
3.00	(50+)	2.3846	1.7097	35.0769	13

Within Groups Total		2.4423	1.6211	128.7638	52

Criterion Variable D35IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0632	2	.0316	.0120	.9881
Within Groups	128.7638	49	2.6278		

Eta = .0221 Eta Squared = .0005

1227

700

FCE 20124/706 i

(9.1.4.2) Summaries of D42IMP Improvement
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.5893	52
AGEGRP	1.00	(18-37)	2.4737	1.6114	19
AGEGRP	2.00	(38-49)	2.5000	1.5728	20
AGEGRP	3.00	(50+)	2.3077	1.7022	13

Summaries of D42IMP Improvement
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	2.4737	1.6114	46.7368	19
2.00	(38-49)	2.5000	1.5728	47.0000	20
3.00	(50+)	2.3077	1.7022	34.7692	13

Within Groups Total		2.4423	1.6194	128.5061	52

Criterion Variable D42IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3209	2	.1604	.0612	.9407
Within Groups	128.5061	49	2.6226		

Eta = .0499 Eta Squared = .0025

1228

.701

FCE 20124/706 i

(9.1.4.2) Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			16.9487	24.9937	52
AGEGRP	1.00	(18-37)	15.2281	26.9993	19
AGEGRP	2.00	(38-49)	15.2500	24.9963	20
AGEGRP	3.00	(50+)	22.0769	23.1125	13

Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	15.2281	26.9993	13121.3450	19
2.00	(38-49)	15.2500	24.9963	11871.5278	20
3.00	(50+)	22.0769	23.1125	6410.2564	13

Within Groups Total		16.9487	25.3156	31403.1292	52

Criterion Variable D7T14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	455.8451	2	227.9226	.3556	.7025
Within Groups	31403.1292	49	640.8802		

Eta = .1196 Eta Squared = .0143

1229

702

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(9.1.4.2) Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			19.6731	34.8312	52
AGEGRP	1.00	(18-37)	15.6667	33.7931	19
AGEGRP	2.00	(38-49)	16.5000	39.2641	20
AGEGRP	3.00	(50+)	30.4103	28.8983	13

Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	15.6667	33.7931	20555.5556	19
2.00	(38-49)	16.5000	39.2641	29291.6667	20
3.00	(50+)	30.4103	28.8983	10021.3675	13

Within Groups Total		19.6731	34.9544	59868.5897	52

Criterion Variable D7T21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2005.0748	2	1002.5374	.8205	.4462
Within Groups	59868.5897	49	1221.8080		
Eta = .1800		Eta Squared = .0324			

1230

703

FCE 20124/706 i

(9.1.4.2) Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			26.7244	37.7297	52
AGEGRP	1.00	(18-37)	29.2632	35.4872	19
AGEGRP	2.00	(38-49)	21.0833	41.0280	20
AGEGRP	3.00	(50+)	31.6923	37.4941	13

Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	29.2632	35.4872	22668.1287	19
2.00	(38-49)	21.0833	41.0280	31982.6389	20
3.00	(50+)	31.6923	37.4941	16869.6581	13

Within Groups Total		26.7244	38.2047	71520.4257	52

Criterion Variable D7T28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1079.7346	2	539.8673	.3699	.6927
Within Groups	71520.4257	49	1459.6005		

Eta = .1220 Eta Squared = .0149

1231

704

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(9.1.4.2) Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of AGEGRP Age Group

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			30.5705	40.0958	52
AGEGRP	1.00	(18-37)	32.3333	36.6414	19
AGEGRP	2.00	(38-49)	25.2500	44.4488	20
AGEGRP	3.00	(50+)	36.1795	40.0543	13

Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of AGEGRP Age Group

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	(18-37)	32.3333	36.6414	24166.6667	19
2.00	(38-49)	25.2500	44.4488	37538.1944	20
3.00	(50+)	36.1795	40.0543	19252.1368	13

Within Groups Total		30.5705	40.6471	80956.9979	52

Criterion Variable D7T35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1034.1880	2	517.0940	.3130	.7327
Within Groups	80956.9979	49	1652.1836		

Eta = .1123 Eta Squared = .0126

1232

705

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```
( 9.1.4.2 ) manova
d7imp d14imp d21imp d28imp d35imp d42imp by subform(1,4)
/wsfactors=time (6)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	421.31	48	8.78		
CONSTANT	420.45	1	420.45	47.90	.000
SUBFORM	7.14	3	2.38	.27	.846

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00405
Chi-square approx. = 253.98908 with 14 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .30288
Huynh-Feldt Epsilon = .33020
Lower-bound Epsilon = .20000
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

1233

706

FCE 20124/706 i

(9.1.4.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. SUBFORM BY TIME

Multivariate Tests of Significance (S = 3, M = 1/2, N = 21)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.47097	1.71327	15.00	138.00	.055
Hotellings	.71547	2.03512	15.00	128.00	.017
Wilks	.56316	1.87844	15.00	121.87	.032
Roys	.38270				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 21)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.27938	3.41176	5.00	44.00	.011
Hotellings	.38770	3.41176	5.00	44.00	.011
Wilks	.72062	3.41176	5.00	44.00	.011
Roys	.27938				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	96.12	240	.40		
TIME	9.65	5	1.93	4.82	.000
SUBFORM BY TIME	6.77	15	.45	1.13	.332

1234

707

FCE 20124/706 i

(9.1.4.2) Summaries of D7IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5000	.6417	52
SUBFORM	1.00	Sing.Epi.	3.5926	.5007	27
SUBFORM	2.00	Recurr.	3.4091	.7341	22
SUBFORM	3.00	Rec.-Mod.Sv.	2.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	4.0000	.0000	2

Summaries of D7IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	3.5926	.5007	6.5185	27	
2.00	Recurr.	3.4091	.7341	11.3182	22	
3.00	Rec.-Mod.Sv.	2.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	4.0000	.0000	.0000	2	
Within Groups Total			3.5000	.6096	17.8367	52

Criterion Variable D7IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.1633	3	1.0544	2.8376	.0478
Within Groups	17.8367	48	.3716		
Eta = .3881		Eta Squared = .1506			

1235

708

FCE 20124/706 i

(9.1.4.2) Summaries of D14IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.8462	.9576	52
SUBFORM	1.00	Sing.Epi.	2.9630	.9398	27
SUBFORM	2.00	Recurr.	2.6818	1.0414	22
SUBFORM	3.00	Rec.-Mod.Sv.	3.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	3.0000	.0000	2

Summaries of D14IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	2.9630	.9398	22.9630	27
2.00	Recurr.	2.6818	1.0414	22.7727	22
3.00	Rec.-Mod.Sv.	3.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	3.0000	.0000	.0000	2
Within Groups Total		2.8462	.9761	45.7357	52

Criterion Variable D14IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.0335	3	.3445	.3616	.7810
Within Groups	45.7357	48	.9528		

Eta = .1487 Eta Squared = .0221

1236

709

FCE 20124/706 i

(9.1.4.2) Summaries of D21IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.7692	1.3227	52
SUBFORM	1.00	Sing.Epi.	2.7778	1.3397	27
SUBFORM	2.00	Recurr.	2.7273	1.4203	22
SUBFORM	3.00	Rec.-Mod.Sv.	3.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	3.0000	.0000	2

Summaries of D21IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	2.7778	1.3397	46.6667	27	
2.00	Recurr.	2.7273	1.4203	42.3636	22	
3.00	Rec.-Mod.Sv.	3.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	3.0000	.0000	.0000	2	

Within Groups Total			2.7692	1.3619	89.0303	52

Criterion Variable D21IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2005	3	.0668	.0360	.9907
Within Groups	89.0303	48	1.8548		
Eta = .0474		Eta Squared = .0022			

1237

710

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(9.1.4.2) Summaries of D28IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.5769	1.5126	52
SUBFORM	1.00	Sing.Epi.	2.5556	1.5021	27
SUBFORM	2.00	Recurr.	2.6364	1.5900	22
SUBFORM	3.00	Rec.-Mod.Sv.	1.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	3.0000	1.4142	2

Summaries of D28IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	2.5556	1.5021	58.6667	27
2.00	Recurr.	2.6364	1.5900	53.0909	22
3.00	Rec.-Mod.Sv.	1.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	3.0000	1.4142	2.0000	2

Within Groups Total		2.5769	1.5395	113.7576	52

Criterion Variable D28IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.9347	3	.9782	.4128	.7446
Within Groups	113.7576	48	2.3699		
Eta = .1586		Eta Squared = .0251			

1238

711

FCE 20124/706 i

(9.1.4.2) Summaries of D35IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.5893	52
SUBFORM	1.00	Sing.Epi.	2.3704	1.5968	27
SUBFORM	2.00	Recurr.	2.5455	1.6541	22
SUBFORM	3.00	Rec.-Mod.Sv.	1.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	3.0000	1.4142	2

Summaries of D35IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	2.3704	1.5968	66.2963	27	
2.00	Recurr.	2.5455	1.6541	57.4545	22	
3.00	Rec.-Mod.Sv.	1.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	3.0000	1.4142	2.0000	2	

Within Groups Total			2.4423	1.6186	125.7508	52

Criterion Variable D35IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.0761	3	1.0254	.3914	.7597
Within Groups	125.7508	48	2.6198		
Eta = .1545		Eta Squared = .0239			

1239

.712

FCE 20124/706 i

(9.1.4.2) Summaries of D42IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.5893	52
SUBFORM	1.00	Sing.Epi.	2.3333	1.5933	27
SUBFORM	2.00	Recurr.	2.5909	1.6521	22
SUBFORM	3.00	Rec.-Mod.Sv.	1.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	3.0000	1.4142	2

Summaries of D42IMP Improvement
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	2.3333	1.5933	66.0000	27
2.00	Recurr.	2.5909	1.6521	57.3182	22
3.00	Rec.-Mod.Sv.	1.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	3.0000	1.4142	2.0000	2

Within Groups Total		2.4423	1.6158	125.3182	52

Criterion Variable D42IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.5087	3	1.1696	.4480	.7199
Within Groups	125.3182	48	2.6108		
Eta = .1650		Eta Squared = .0272			

1240

713

FCE 20124/706 i

(9.1.4.2) Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			16.9487	24.9937	52
SUBFORM	1.00	Sing.Epi.	16.5926	23.7208	27
SUBFORM	2.00	Recurr.	19.8333	24.2275	22
SUBFORM	3.00	Rec.-Mod.Sv.	-51.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	24.0000	.0000	2

Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Sing.Epi.	16.5926	23.7208	14629.6296	27
2.00	Recurr.	19.8333	24.2275	12326.3889	22
3.00	Rec.-Mod.Sv.	-51.0000	.0000	.0000	1
4.00	Rec.Sv.wo.Pf	24.0000	.0000	.0000	2

Within Groups Total		16.9487	23.6978	26956.0185	52

Criterion Variable D7T14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4902.9558	3	1634.3186	2.9102	.0439
Within Groups	26956.0185	48	561.5837		
Eta = .3923		Eta Squared = .1539			

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(9.1.4.2) Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			19.6731	34.8312	52
SUBFORM	1.00	Sing.Epi.	22.7654	32.6618	27
SUBFORM	2.00	Recurr.	18.6970	37.0494	22
SUBFORM	3.00	Rec.-Mod.Sv.	-51.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	24.0000	.0000	2

Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	22.7654	32.6618	27736.6255	27	
2.00	Recurr.	18.6970	37.0494	28825.7576	22	
3.00	Rec.-Mod.Sv.	-51.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	24.0000	.0000	.0000	2	

Within Groups Total			19.6731	34.3276	56562.3831	52

Criterion Variable D7T21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	5311.2814	3	1770.4271	1.5024	.2259
Within Groups	56562.3831	48	1178.3830		
Eta = .2930		Eta Squared = .0858			

1242

715

FCE 20124/706 i

(9.1.4.2) Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			26.7244	37.7297	52
SUBFORM	1.00	Sing.Epi.	29.8642	36.6036	27
SUBFORM	2.00	Recurr.	22.1061	40.9810	22
SUBFORM	3.00	Rec.-Mod.Sv.	49.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	24.0000	35.3553	2

Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	29.8642	36.6036	34835.3909	27	
2.00	Recurr.	22.1061	40.9810	35268.3081	22	
3.00	Rec.-Mod.Sv.	49.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	24.0000	35.3553	1250.0000	2	
Within Groups Total			26.7244	38.5556	71353.6990	52

Criterion Variable D7T28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1246.4612	3	415.4871	.2795	.8399
Within Groups	71353.6990	48	1486.5354		
Eta = .1310		Eta Squared = .0172			

1243

716

FCE 20124/706 i

(9.1.4.2) Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of SUBFORM DSM-III-R Subform

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			30.5705	40.0958	52
SUBFORM	1.00	Sing.Epi.	35.1111	39.2913	27
SUBFORM	2.00	Recurr.	24.7576	43.0262	22
SUBFORM	3.00	Rec.-Mod.Sv.	49.0000	.0000	1
SUBFORM	4.00	Rec.Sv.wo.Pf	24.0000	35.3553	2

Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of SUBFORM DSM-III-R Subform

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Sing.Epi.	35.1111	39.2913	40138.8889	27	
2.00	Recurr.	24.7576	43.0262	38876.2626	22	
3.00	Rec.-Mod.Sv.	49.0000	.0000	.0000	1	
4.00	Rec.Sv.wo.Pf	24.0000	35.3553	1250.0000	2	

Within Groups Total			30.5705	40.8924	80265.1515	52

Criterion Variable D7T35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1726.0344	3	575.3448	.3441	.7936
Within Groups	80265.1515	48	1672.1907		
Eta = .1451		Eta Squared = .0211			

1244

717

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```
( 9.1.4.2 ) manova
d7imp d14imp d21imp d28imp d35imp d42imp by rater(1,4)
/wsfactors=time (6)
/wsdesign=time
/design.
```

```
52 cases accepted.
0 cases rejected because of out-of-range factor values.
0 cases rejected because of missing data.
4 non-empty cells.

1 design will be processed.
```

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests of Between-Subjects Effects.

Tests of Significance for T1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	420.64	48	8.76		
CONSTANT	537.51	1	537.51	61.34	.000
RATER	7.81	3	2.60	.30	.827

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

```
Mauchly sphericity test, W = .00606
Chi-square approx. = 235.42358 with 14 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .32613
Huynh-Feldt Epsilon = .35710
Lower-bound Epsilon = .20000
```

AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.

1245

718

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(9.1.4.2) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. RATER BY TIME

Multivariate Tests of Significance (S = 3, M = 1/2, N = 21)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.40351	1.42975	15.00	138.00	.142
Hotellings	.55849	1.58860	15.00	128.00	.086
Wilks	.62408	1.51310	15.00	121.87	.111
Roys	.31830				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 1 1/2, N = 21)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.07753	.73957	5.00	44.00	.598
Hotellings	.08404	.73957	5.00	44.00	.598
Wilks	.92247	.73957	5.00	44.00	.598
Roys	.07753				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	90.53	240	.38		
TIME	2.07	5	.41	1.10	.363
RATER BY TIME	12.37	15	.82	2.19	.007

1246

719

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(9.1.4.2) Summaries of D7IMP Improvement
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.5000	.6417	52
RATER	1.00	Beauclair	4.0000	.0000	1
RATER	2.00	Mirmiran	3.3333	1.1547	3
RATER	3.00	Song	2.7500	1.2583	4
RATER	4.00	Nardi	3.5682	.5011	44

Summaries of D7IMP Improvement
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	4.0000	.0000	.0000	1
2.00	Mirmiran	3.3333	1.1547	2.6667	3
3.00	Song	2.7500	1.2583	4.7500	4
4.00	Nardi	3.5682	.5011	10.7955	44
Within Groups Total		3.5000	.6160	18.2121	52

Criterion Variable D7IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.7879	3	.9293	2.4493	.0749
Within Groups	18.2121	48	.3794		
Eta = .3644		Eta Squared = .1328			

1247

720

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(9.1.4.2) Summaries of D14IMP Improvement
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.8462	.9576	52
RATER	1.00	Beauclair	3.0000	.0000	1
RATER	2.00	Mirmiran	3.0000	.0000	3
RATER	3.00	Song	2.7500	1.2583	4
RATER	4.00	Nardi	2.8409	.9870	44

Summaries of D14IMP Improvement
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	3.0000	.0000	.0000	1
2.00	Mirmiran	3.0000	.0000	.0000	3
3.00	Song	2.7500	1.2583	4.7500	4
4.00	Nardi	2.8409	.9870	41.8864	44

Within Groups Total		2.8462	.9857	46.6364	52

Criterion Variable D14IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1329	3	.0443	.0456	.9869
Within Groups	46.6364	48	.9716		
Eta = .0533		Eta Squared = .0028			

1248

721

FCE 20124/706 i .

(9.1.4.2) Summaries of D21IMP Improvement
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.7692	1.3227	52
RATER	1.00	Beauclair	3.0000	.0000	1
RATER	2.00	Mirmiran	3.0000	.0000	3
RATER	3.00	Song	3.0000	1.6330	4
RATER	4.00	Nardi	2.7273	1.3702	44

Summaries of D21IMP Improvement
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	3.0000	.0000	.0000	1
2.00	Mirmiran	3.0000	.0000	.0000	3
3.00	Song	3.0000	1.6330	8.0000	4
4.00	Nardi	2.7273	1.3702	80.7273	44
Within Groups Total		2.7692	1.3596	88.7273	52

Criterion Variable D21IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5035	3	.1678	.0908	.9648
Within Groups	88.7273	48	1.8485		
Eta = .0751		Eta Squared = .0056			

1249

722

FCE 20124/706 i

(9.1.4.2) Summaries of D28IMP Improvement
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.5769	1.5126	52
RATER	1.00	Beauclair	4.0000	.0000	1
RATER	2.00	Mirmiran	2.0000	1.0000	3
RATER	3.00	Song	3.2500	2.0616	4
RATER	4.00	Nardi	2.5227	1.5018	44

Summaries of D28IMP Improvement
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	4.0000	.0000	.0000	1
2.00	Mirmiran	2.0000	1.0000	2.0000	3
3.00	Song	3.2500	2.0616	12.7500	4
4.00	Nardi	2.5227	1.5018	96.9773	44

Within Groups Total		2.5769	1.5257	111.7273	52

Criterion Variable D28IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.9650	3	1.6550	.7110	.5502
Within Groups	111.7273	48	2.3277		

Eta = .2063 Eta Squared = .0425

1250

723

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(9.1.4.2) Summaries of D35IMP Improvement
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			2.4423	1.5893	52
RATER	1.00	Beauclair	4.0000	.0000	1
RATER	2.00	Mirmiran	2.0000	1.0000	3
RATER	3.00	Song	3.2500	2.0616	4
RATER	4.00	Nardi	2.3636	1.5861	44

Summaries of D35IMP Improvement
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Beauclair	4.0000	.0000	.0000	1	
2.00	Mirmiran	2.0000	1.0000	2.0000	3	
3.00	Song	3.2500	2.0616	12.7500	4	
4.00	Nardi	2.3636	1.5861	108.1818	44	

Within Groups Total			2.4423	1.6003	122.9318	52

Criterion Variable D35IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	5.8951	3	1.9650	.7673	.5180
Within Groups	122.9318	48	2.5611		
Eta = .2139		Eta Squared = .0458			

1251

724

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(9.1.4.2) Summaries of D42IMP Improvement
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.4423	1.5893	52
RATER	1.00	Beauclair	4.0000	.0000	1
RATER	2.00	Mirmiran	2.0000	1.0000	3
RATER	3.00	Song	3.2500	2.0616	4
RATER	4.00	Nardi	2.3636	1.5861	44

Summaries of D42IMP Improvement
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	4.0000	.0000	.0000	1
2.00	Mirmiran	2.0000	1.0000	2.0000	3
3.00	Song	3.2500	2.0616	12.7500	4
4.00	Nardi	2.3636	1.5861	108.1818	44

Within Groups Total		2.4423	1.6003	122.9318	52

Criterion Variable D42IMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	5.8951	3	1.9650	.7673	.5180
Within Groups	122.9318	48	2.5611		
Eta = .2139		Eta Squared = .0458			

1252

725

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(9.1.4.2) Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			16.9487	24.9937	52
RATER	1.00	Beauclair	24.0000	.0000	1
RATER	2.00	Mirmiran	-1.0000	43.3013	3
RATER	3.00	Song	-1.0000	.0000	4
RATER	4.00	Nardi	19.6439	24.3447	44

Summaries of D7T14CG Dy7 to Dy14 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1.00	Beauclair	24.0000	.0000	.0000	1	
2.00	Mirmiran	-1.0000	43.3013	3750.0000	3	
3.00	Song	-1.0000	.0000	.0000	4	
4.00	Nardi	19.6439	24.3447	25484.5328	44	

Within Groups Total			16.9487	24.6790	29234.5328	52

Criterion Variable D7T14CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2624.4415	3	874.8138	1.4364	.2438
Within Groups	29234.5328	48	609.0528		
Eta = .2870		Eta Squared = .0824			

1253

726

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(9.1.4.2) Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			19.6731	34.8312	52
RATER	1.00	Beauclair	24.0000	.0000	1
RATER	2.00	Mirmiran	-1.0000	43.3013	3
RATER	3.00	Song	-7.2500	12.5000	4
RATER	4.00	Nardi	23.4318	35.0525	44

Summaries of D7T21CG Dy7 to Dy21 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	24.0000	.0000	.0000	1
2.00	Mirmiran	-1.0000	43.3013	3750.0000	3
3.00	Song	-7.2500	12.5000	468.7500	4
4.00	Nardi	23.4318	35.0525	52833.0177	44

Within Groups Total		19.6731	34.4758	57051.7677	52

Criterion Variable D7T21CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4821.8969	3	1607.2990	1.3523	.2686
Within Groups	57051.7677	48	1188.5785		
Eta = .2792		Eta Squared = .0779			

1254

727

FCE 20124/706 i

(9.1.4.2) Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			26.7244	37.7297	52
RATER	1.00	Beauclair	-1.0000	.0000	1
RATER	2.00	Mirmiran	40.6667	14.4338	3
RATER	3.00	Song	-13.5000	25.0000	4
RATER	4.00	Nardi	30.0606	37.9703	44

Summaries of D7T28CG Dy7 to Dy28 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	-1.0000	.0000	.0000	1
2.00	Mirmiran	40.6667	14.4338	416.6667	3
3.00	Song	-13.5000	25.0000	1875.0000	4
4.00	Nardi	30.0606	37.9703	61994.9495	44

Within Groups Total		26.7244	36.5965	64286.6162	52

Criterion Variable D7T28CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	8313.5441	3	2771.1814	2.0691	.1167
Within Groups	64286.6162	48	1339.3045		
Eta = .3384		Eta Squared = .1145			

1255

728

FCE 20124/706 i

(9.1.4.2) Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of RATER

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			30.5705	40.0958	52
RATER	1.00	Beauclair	-1.0000	.0000	1
RATER	2.00	Mimiran	40.6667	14.4338	3
RATER	3.00	Song	-13.5000	25.0000	4
RATER	4.00	Nardi	34.6061	40.3218	44

Summaries of D7T35CG Dy7 to Dy35 %Change
By levels of RATER

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1.00	Beauclair	-1.0000	.0000	.0000	1
2.00	Mimiran	40.6667	14.4338	416.6667	3
3.00	Song	-13.5000	25.0000	1875.0000	4
4.00	Nardi	34.6061	40.3218	69911.6162	44

Within Groups Total		30.5705	38.7845	72203.2828	52

Criterion Variable D7T35CG

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	9787.9031	3	3262.6344	2.1690	.1039
Within Groups	72203.2828	48	1504.2351		
Eta = .3455		Eta Squared = .1194			

1256

729

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(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 7

NPTUP7 by DRUGRP Treatment Group

Page 1 of 1

	Row Pct Col Pct	DRUGRP		Row Total
		Reboxeti ne	Placebo	
		1	2	
NPTUP7				
Imp 1&2	1.00	100.0 7.4		2 3.8
Imp >2	2.00	50.0 92.6	50.0 100.0	50 96.2
	Column Total	27 51.9	25 48.1	52 100.0

Chi-Square	Value	DF	Significance
Pearson	1.92593	1	.16520
Continuity Correction	.44373	1	.50533
Likelihood Ratio	2.69565	1	.10062
Mantel-Haenszel test for linear association	1.88889	1	.16933
Fisher's Exact Test:			
One-Tail			.26471
Two-Tail			.49095
Minimum Expected Frequency -	.962		
Cells with Expected Frequency < 5 -	2 OF	4 (50.0%)	

1257

730

FCE 20124/706 i

(9.1.4.2)
 No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 14
 NPTUP14 by DRUGRP Treatment Group

Page 1 of 1

	Row Pct Col Pct	DRUGRP		Row Total
		Reboxeti ne	Placebo	
		1	2	
NPTUP14				
Imp 1&2	1.00	75.0 55.6	25.0 20.0	20 38.5
Imp >2	2.00	37.5 44.4	62.5 80.0	32 61.5
Column Total		27 51.9	25 48.1	52 100.0

Chi-Square	Value	DF	Significance
Pearson	6.93333	1	.00846
Continuity Correction	5.51248	1	.01888
Likelihood Ratio	7.17692	1	.00738
Mantel-Haenszel test for linear association	6.80000	1	.00912
Minimum Expected Frequency -	9.615		

1258

731

FCE 20124/706 i

(9.1.4.2)
 No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 21

NPTUP21 by DRUGRP Treatment Group

Page 1 of 1

	Row Pct Col Pct	DRUGRP		Row Total
		Reboxeti ne	Placebo	
		1	2	
NPTUP21				
Imp 1&2	1.00	79.2	20.8	24
		70.4	20.0	46.2
Imp >2	2.00	28.6	71.4	28
		29.6	80.0	53.8
Column Total		27	25	52
		51.9	48.1	100.0

Chi-Square	Value	DF	Significance
Pearson	13.25221	1	.00027
Continuity Correction	11.30289	1	.00077
Likelihood Ratio	13.94374	1	.00019
Mantel-Haenszel test for linear association	12.99735	1	.00031
Minimum Expected Frequency -	11.538		

1259

732

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 28

NPTUP28 by DRUGRP Treatment Group

Page 1 of 1

		DRUGRP		Row Total
		Reboxetine	Placebo	
Row Pct	Col Pct	1	2	
NPTUP28				
	1.00	75.0	25.0	28
Imp 1&2		77.8	28.0	53.8
	2.00	25.0	75.0	24
Imp >2		22.2	72.0	46.2
	Column Total	27	25	52
		51.9	48.1	100.0

Chi-Square	Value	DF	Significance
Pearson	12.94222	1	.00032
Continuity Correction	11.01675	1	.00090
Likelihood Ratio	13.52751	1	.00024
Mantel-Haenszel test for linear association	12.69333	1	.00037
Minimum Expected Frequency -	11.538		

1266

733

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 35

NPTUP35 by DRUGRP Treatment Group

		DRUGRP		Page 1 of 1
Row Pct	Col Pct	Reboxeti	Placebo	Row Total
		ne		
		1	2	
NPTUP35				
	1.00	72.4	27.6	29
Imp 1&2		77.8	32.0	55.8
	2.00	26.1	73.9	23
Imp >2		22.2	68.0	44.2
	Column Total	27	25	52
		51.9	48.1	100.0

Chi-Square	Value	DF	Significance
Pearson	11.02785	1	.00090
Continuity Correction	9.25010	1	.00235
Likelihood Ratio	11.44585	1	.00072
Mantel-Haenszel test for linear association	10.81577	1	.00101
Minimum Expected Frequency -	11.058		

1261

734

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 42

NPTUP42 by DRUGRP Treatment Group

Page 1 of 1

	Row Pct Col Pct	DRUGRP		Row Total
		Reboxeti ne	Placebo	
NPTUP42				
Imp 1&2	1.00	75.9 81.5	24.1 28.0	29 55.8
Imp >2	2.00	21.7 18.5	78.3 72.0	23 44.2
Column Total		27 51.9	25 48.1	52 100.0

Chi-Square	Value	DF	Significance
Pearson	15.05179	1	.00010
Continuity Correction	12.96174	1	.00032
Likelihood Ratio	15.87085	1	.00007
Mantel-Haenszel test for linear association	14.76233	1	.00012
Minimum Expected Frequency -	11.058		

1262

735

FCE 20124/706 i

(9.1.4.2)
 No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 7
 NPTUP7 by SEX

Page 1 of 1

		SEX		
Row Pct	Col Pct	Female	Male	Row Total
		0	1	
NPTUP7				
	1.00	50.0	50.0	2
Imp 1&2		4.2	3.6	3.8
	2.00	46.0	54.0	50
Imp >2		95.8	96.4	96.2
	Column	24	28	52
	Total	46.2	53.8	100.0

Chi-Square	Value	DF	Significance
Pearson	.01238	1	.91140
Continuity Correction	.00000	1	1.00000
Likelihood Ratio	.01235	1	.91152
Mantel-Haenszel test for linear association	.01214	1	.91226
Fisher's Exact Test:			
One-Tail			.71493
Two-Tail			1.00000
Minimum Expected Frequency -	.923		
Cells with Expected Frequency < 5 -	2 OF	4 (50.0%)	

1263

.736

FCE 20124/706 i

(9.1.4.2)
 No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 14

NPTUP14 by SEX

Page 1 of 1

		SEX		Row
Row Pct	Col Pct	Female	Male	Total
		0	1	
NPTUP14				
	1.00	55.0	45.0	20
Imp 1&2		45.8	32.1	38.5
	2.00	40.6	59.4	32
Imp >2		54.2	67.9	61.5
	Column	24	28	52
	Total	46.2	53.8	100.0

Chi-Square	Value	DF	Significance
Pearson	1.02336	1	.31172
Continuity Correction	.52667	1	.46801
Likelihood Ratio	1.02402	1	.31157
Mantel-Haenszel test for linear association	1.00368	1	.31642
Minimum Expected Frequency -	9.231		

1264

737

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 21

NPTUP21 by SEX

Page 1 of 1

		SEX		
		Female	Male	
Row Pct	Col Pct			Row Total
		0	1	
NPTUP21				
	1.00	54.2	45.8	24
Imp 1&2		54.2	39.3	46.2
	2.00	39.3	60.7	28
Imp >2		45.8	60.7	53.8
	Column Total	24	28	52
		46.2	53.8	100.0

Chi-Square	Value	DF	Significance
Pearson	1.15150	1	.28323
Continuity Correction	.63056	1	.42715
Likelihood Ratio	1.15460	1	.28259
Mantel-Haenszel test for linear association	1.12936	1	.28791

Minimum Expected Frequency - 11.077

1265

738

FCE 20124/706 i

(9.1.4.2)
 No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 28
 NPTUP28 by SEX

Page 1 of 1

		SEX		
Row Pct	Col Pct	Female	Male	Row Total
		0	1	
NPTUP28				
	1.00	50.0	50.0	28
Imp 1&2		58.3	50.0	53.8
	2.00	41.7	58.3	24
Imp >2		41.7	50.0	46.2
	Column Total	24	28	52
		46.2	53.8	100.0

Chi-Square	Value	DF	Significance
Pearson	.36111	1	.54789
Continuity Correction	.10364	1	.74751
Likelihood Ratio	.36179	1	.54751
Mantel-Haenszel test for linear association	.35417	1	.55176
Minimum Expected Frequency -	11.077		

1266

739

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 35

NPTUP35 by SEX

Page 1 of 1

		SEX		
Row Pct	Col Pct	Female	Male	Row Total
		0	1	
NPTUP35				
	1.00	48.3	51.7	29
Imp 1&2		58.3	53.6	55.8
	2.00	43.5	56.5	23
Imp >2		41.7	46.4	44.2
	Column Total	24	28	52
	Total	46.2	53.8	100.0

Chi-Square	Value	DF	Significance
Pearson	.11880	1	.73034
Continuity Correction	.00418	1	.94847
Likelihood Ratio	.11891	1	.73022
Mantel-Haenszel test for linear association	.11651	1	.73285

Minimum Expected Frequency - 10.615

1267

740

FCE 20124/706 i .

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 42

NPTUP42 by SEX

Page 1 of 1

		SEX		
		Female	Male	
Row Pct	Col Pct			Row Total
		0	1	
NPTUP42				
	1.00	48.3	51.7	29
Imp 1&2		58.3	53.6	55.8
	2.00	43.5	56.5	23
Imp >2		41.7	46.4	44.2
	Column Total	24	28	52
		46.2	53.8	100.0

Chi-Square	Value	DF	Significance
Pearson	.11880	1	.73034
Continuity Correction	.00418	1	.94847
Likelihood Ratio	.11891	1	.73022
Mantel-Haenszel test for linear association	.11651	1	.73285

Minimum Expected Frequency - 10.615

1258

741

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 7

NPTUP7 by COUNTRY

Page 1 of 1

		COUNTRY		Row
		Canada	Brazil	Total
Row Pct	Col Pct			
		1.00	2.00	
NPTUP7				
	1.00	100.0		2
Imp 1&2		25.0		3.8
	2.00	12.0	88.0	50
Imp >2		75.0	100.0	96.2
	Column	8	44	52
	Total	15.4	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	11.44000	1	.00072
Continuity Correction	5.67864	1	.01717
Likelihood Ratio	7.95709	1	.00479
Mantel-Haenszel test for linear association	11.22000	1	.00081
Fisher's Exact Test:			
One-Tail			.02112
Two-Tail			.02112
Minimum Expected Frequency -	.308		
Cells with Expected Frequency < 5 -	2 OF	4 (50.0%)	

1269

742

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 14

NPTUP14 by COUNTRY

Page 1 of 1

		COUNTRY		Row Total
		Canada	Brazil	
Row Pct	Col Pct			
		1.00	2.00	
NPTUP14				
	1.00	5.0	95.0	20
Imp 1&2		12.5	43.2	38.5
	2.00	21.9	78.1	32
Imp >2		87.5	56.8	61.5
	Column Total	8	44	52
	Total	15.4	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	2.69233	1	.10083
Continuity Correction	1.55206	1	.21283
Likelihood Ratio	3.08842	1	.07885
Mantel-Haenszel test for linear association	2.64055	1	.10417
Fisher's Exact Test:			
One-Tail			.10343
Two-Tail			.13244
Minimum Expected Frequency -	3.077		
Cells with Expected Frequency < 5 -	2 OF	4 (50.0%)	

1270

743

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 21

NPTUP21 by COUNTRY

Page 1 of 1

		COUNTRY		Row Total
		Canada	Brazil	
Row Pct	Col Pct			
		1.00	2.00	
NPTUP21				
	1.00	4.2	95.8	24
Imp 1&2		12.5	52.3	46.2
	2.00	25.0	75.0	28
Imp >2		87.5	47.7	53.8
	Column Total	8	44	52
	Total	15.4	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	4.30871	1	.03792
Continuity Correction	2.85694	1	.09098
Likelihood Ratio	4.84497	1	.02773
Mantel-Haenszel test for linear association	4.22585	1	.03981
Fisher's Exact Test:			
One-Tail			.04189
Two-Tail			.05575
Minimum Expected Frequency -	3.692		
Cells with Expected Frequency < 5 -	2 OF	4 (50.0%)	

1271

744

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 28

NPTUP28 by COUNTRY

Page 1 of 1

		COUNTRY		Row
Row Pct	Col Pct	Canada	Brazil	Total
		1.00	2.00	
NPTUP28				
	1.00	10.7	89.3	28
Imp 1&2		37.5	56.8	53.8
	2.00	20.8	79.2	24
Imp >2		62.5	43.2	46.2
	Column	8	44	52
	Total	15.4	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	1.01650	1	.31335
Continuity Correction	.38778	1	.53347
Likelihood Ratio	1.01808	1	.31297
Mantel-Haenszel test for linear association	.99696	1	.31805
Fisher's Exact Test:			
One-Tail			.26649
Two-Tail			.44656
Minimum Expected Frequency -	3.692		
Cells with Expected Frequency < 5 -	2 OF	4 (50.0%)	

1272

745

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 35

NPTUP35 by COUNTRY

Page 1 of 1

		COUNTRY		Row
Row Pct	Col Pct	Canada	Brazil	Total
		1.00	2.00	
NPTUP35				
	1.00	10.3	89.7	29
Imp 1&2		37.5	59.1	55.8
	2.00	21.7	78.3	23
Imp >2		62.5	40.9	44.2
	Column	8	44	52
	Total	15.4	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	1.27927	1	.25803
Continuity Correction	.55370	1	.45681
Likelihood Ratio	1.27416	1	.25899
Mantel-Haenszel test for linear association	1.25467	1	.26266
Fisher's Exact Test:			
One-Tail			.22795
Two-Tail			.44105
Minimum Expected Frequency -	3.538		
Cells with Expected Frequency < 5 -	2 OF	4 (50.0%)	

1273

746

FCE 20124/706 i .

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 42

NPTUP42 by COUNTRY

Page 1 of 1

		COUNTRY		Row
Row Pct	Col Pct	Canada	Brazil	Total
		1.00	2.00	
NPTUP42				
	1.00	10.3	89.7	29
Imp 1&2		37.5	59.1	55.8
	2.00	21.7	78.3	23
Imp >2		62.5	40.9	44.2
	Column	8	44	52
	Total	15.4	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	1.27927	1	.25803
Continuity Correction	.55370	1	.45681
Likelihood Ratio	1.27416	1	.25899
Mantel-Haenszel test for linear association	1.25467	1	.26266
Fisher's Exact Test:			
One-Tail			.22795
Two-Tail			.44105
Minimum Expected Frequency -	3.538		
Cells with Expected Frequency < 5 -	2 OF	4 (50.0%)	

1274

747

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 7

NPTUP7 by AGEGRP Age Group

Page 1 of 1

		AGEGRP			Row
		(18-37)	(38-49)	(50+)	Total
Row Pct	Col Pct	1.00	2.00	3.00	
NPTUP7					
1.00	50.0	50.0			2
Imp 1&2	5.3	5.0			3.8
2.00	36.0	38.0	26.0		50
Imp >2	94.7	95.0	100.0		96.2
Column Total		19	20	13	52
		36.5	38.5	25.0	100.0

Chi-Square	Value	DF	Significance
Pearson	.69516	2	.70640
Likelihood Ratio	1.17855	2	.55473
Mantel-Haenszel test for linear association	.50123	1	.47896

Minimum Expected Frequency - .500
 Cells with Expected Frequency < 5 - 3 OF 6 (50.0%)

1275

748

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 14

NPTUP14 by AGEGRP Age Group

Page 1 of 1

		AGEGRP			Row
		(18-37)	(38-49)	(50+)	Total
Row Pct	Col Pct				
		1.00	2.00	3.00	
NPTUP14					
	1.00	40.0	35.0	25.0	20
Imp 1&2		42.1	35.0	38.5	38.5
	2.00	34.4	40.6	25.0	32
Imp >2		57.9	65.0	61.5	61.5
	Column	19	20	13	52
	Total	36.5	38.5	25.0	100.0

Chi-Square	Value	DF	Significance
Pearson	.20783	2	.90130
Likelihood Ratio	.20793	2	.90126
Mantel-Haenszel test for linear association	.06344	1	.80114

Minimum Expected Frequency - 5.000

1276

749

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(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 21

NPTUP21 by AGEGRP Age Group

Page 1 of 1

		AGEGRP			Row
		(18-37)	(38-49)	(50+)	Total
Row Pct	Col Pct	1.00	2.00	3.00	
NPTUP21					
	1.00	33.3	37.5	29.2	24
Imp 1&2		42.1	45.0	53.8	46.2
	2.00	39.3	39.3	21.4	28
Imp >2		57.9	55.0	46.2	53.8
	Column	19	20	13	52
	Total	36.5	38.5	25.0	100.0

Chi-Square	Value	DF	Significance
Pearson	.44555	2	.80029
Likelihood Ratio	.44501	2	.80051
Mantel-Haenszel test for linear association	.39457	1	.52991
Minimum Expected Frequency -	6.000		

1277

750

FCE 20124/706 i .

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 28

NPTUP28 by AGEGRP Age Group

Page 1 of 1

		AGEGRP			
		(18-37)	(38-49)	(50+)	
Row Pct	Col Pct				Row Total
		1.00	2.00	3.00	
NPTUP28					
	1.00	35.7	39.3	25.0	28
Imp 1&2		52.6	55.0	53.8	53.8
	2.00	37.5	37.5	25.0	24
Imp >2		47.4	45.0	46.2	46.2
	Column Total	19	20	13	52
		36.5	38.5	25.0	100.0

Chi-Square	Value	DF	Significance
Pearson	.02199	2	.98906
Likelihood Ratio	.02199	2	.98906
Mantel-Haenszel test for linear association	.00671	1	.93470
Minimum Expected Frequency -	6.000		

1278

751

FCE 20124/706 i .

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 35

NPTUP35 by AGEGRP Age Group

Page 1 of 1

		AGEGRP			Row
		(18-37)	(38-49)	(50+)	Total
Row Pct	Col Pct				
		1.00	2.00	3.00	
NPTUP35					
	1.00	37.9	37.9	24.1	29
Imp 1&2		57.9	55.0	53.8	55.8
	2.00	34.8	39.1	26.1	23
Imp >2		42.1	45.0	46.2	44.2
	Column Total	19	20	13	52
		36.5	38.5	25.0	100.0

Chi-Square	Value	DF	Significance
Pearson	.05909	2	.97089
Likelihood Ratio	.05915	2	.97086
Mantel-Haenszel test for linear association	.05429	1	.81575
Minimum Expected Frequency -	5.750		

1279

752

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 42

NPTUP42 by AGEGRP Age Group

Page 1 of 1

		AGEGRP			Row
		(18-37)	(38-49)	(50+)	Total
Row Pct	Col Pct	1.00	2.00	3.00	
NPTUP42					
	1.00	37.9	34.5	27.6	29
Imp 1&2		57.9	50.0	61.5	55.8
	2.00	34.8	43.5	21.7	23
Imp >2		42.1	50.0	38.5	44.2
	Column	19	20	13	52
	Total	36.5	38.5	25.0	100.0

Chi-Square	Value	DF	Significance
Pearson	.48008	2	.78660
Likelihood Ratio	.48041	2	.78647
Mantel-Haenszel test for linear association	.01522	1	.90182

Minimum Expected Frequency - 5.750

1280

753

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(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 7

NPTUP7 by SUBFORM DSM-III-R Subform

Page 1 of 1

		SUBFORM				Row
Row Pct	Col Pct	Sing.Epi	Recurr.	Rec.-Mod	Rec.Sv.w	Total
		1.00	2.00	3.00	4.00	
				.Sv.	o.Pf	
NPTUP7						
	1.00		50.0	50.0		2
Imp 1&2			4.5	100.0		3.8
	2.00	54.0	42.0		4.0	50
Imp >2		100.0	95.5		100.0	96.2
	Column	27	22	1	2	52
	Total	51.9	42.3	1.9	3.8	100.0

Chi-Square	Value	DF	Significance
Pearson	26.18909	3	.00001
Likelihood Ratio	8.81853	3	.03180
Mantel-Haenszel test for linear association	3.38628	1	.06574

Minimum Expected Frequency = .038
 Cells with Expected Frequency < 5 = 6 OF 8 (75.0%)

1281

754

FCE 20124/706 i

(9.1.4.2)
 No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 14

NPTUP14 by SUBFORM DSM-III-R Subform

Page 1 of 1

		SUBFORM				Row
Row Pct	Col Pct	Sing.Epi	Recurr.	Rec.-Mod .Sv.	Rec.Sv.w o.Pf	Total
		1.00	2.00	3.00	4.00	
NPTUP14						
	1.00	50.0	50.0			20
Imp 1&2		37.0	45.5			38.5
	2.00	53.1	37.5	3.1	6.3	32
Imp >2		63.0	54.5	100.0	100.0	61.5
	Column Total	27	22	1	2	52
		51.9	42.3	1.9	3.8	100.0

Chi-Square	Value	DF	Significance
Pearson	2.35269	3	.50250
Likelihood Ratio	3.38232	3	.33635
Mantel-Haenszel test for linear association	.36744	1	.54441

Minimum Expected Frequency - .385
 Cells with Expected Frequency < 5 - 4 OF 8 (50.0%)

1282

755

FCE 20124/706 i .

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 21

NPTUP21 by SUBFORM DSM-III-R Subform

Page 1 of 1

	Row Pct Col Pct	SUBFORM				Row Total
		Sing.Epi	Recurr.	Rec.-Mod .Sv.	Rec.Sv.w o.Pf	
NPTUP21		1.00	2.00	3.00	4.00	
Imp 1&2	1.00	58.3	41.7			24
		51.9	45.5			46.2
Imp >2	2.00	46.4	42.9	3.6	7.1	28
		48.1	54.5	100.0	100.0	53.8
Column Total		27	22	1	2	52
		51.9	42.3	1.9	3.8	100.0

Chi-Square	Value	DF	Significance
Pearson	2.92849	3	.40278
Likelihood Ratio	4.07000	3	.25400
Mantel-Haenszel test for linear association	2.18711	1	.13917

Minimum Expected Frequency = .462
 Cells with Expected Frequency < 5 = 4 OF 8 (50.0%)

1283

.756

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 28

NPTUP28 by SUBFORM DSM-III-R Subform

Page 1 of 1

SUBFORM	Row Pct	SUBFORM				Row Total
	Col Pct	Sing.Epi	Recurr.	Rec.-Mod .Sv.	Rec.Sv.w o.Pf	
NPTUP28		1.00	2.00	3.00	4.00	
Imp 1&2	1.00	53.6	39.3	3.6	3.6	28
		55.6	50.0	100.0	50.0	53.8
Imp >2	2.00	50.0	45.8		4.2	24
		44.4	50.0		50.0	46.2
Column Total		27	22	1	2	52
		51.9	42.3	1.9	3.8	100.0

Chi-Square	Value	DF	Significance
Pearson	1.03175	3	.79357
Likelihood Ratio	1.41232	3	.70265
Mantel-Haenszel test for linear association	.00350	1	.95283

Minimum Expected Frequency = .462
 Cells with Expected Frequency < 5 = 4 OF 8 (50.0%)

1284

757

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 35

NPTUP35 by SUBFORM DSM-III-R Subform

Page 1 of 1

		SUBFORM				Row
Row Pct	Col Pct	Sing.Epi	Recurr.	Rec.-Mod	Rec.Sv.w	Total
		1.00	2.00	3.00	4.00	
NPTUP35						
Imp 1&2	1.00	55.2	37.9	3.4	3.4	29
		59.3	50.0	100.0	50.0	55.8
Imp >2	2.00	47.8	47.8		4.3	23
		40.7	50.0		50.0	44.2
	Column Total	27	22	1	2	52
		51.9	42.3	1.9	3.8	100.0

Chi-Square	Value	DF	Significance
Pearson	1.25026	3	.74098
Likelihood Ratio	1.62373	3	.65402
Mantel-Haenszel test for linear association	.07955	1	.77791

Minimum Expected Frequency = .442
 Cells with Expected Frequency < 5 = 4 OF 8 (50.0%)

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1285

.750

FCE 20124/706 i

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 42

NPTUP42 by SUBFORM DSM-III-R Subform

Page 1 of 1

		SUBFORM				Row
Row Pct	Col Pct	Sing.Epi	Recurr.	Rec.-Mod Sv.	Rec.Sv.w o.Pf	Total
		1.00	2.00	3.00	4.00	
NPTUP42						
	1.00	58.6	34.5	3.4	3.4	29
Imp 1&2		63.0	45.5	100.0	50.0	55.8
	2.00	43.5	52.2		4.3	23
Imp >2		37.0	54.5		50.0	44.2
	Column Total	27	22	1	2	52
		51.9	42.3	1.9	3.8	100.0

Chi-Square	Value	DF	Significance
Pearson	2.93542	3	.50577
Likelihood Ratio	2.71022	3	.43849
Mantel-Haenszel test for linear association	.44621	1	.50414

Minimum Expected Frequency = .442
 Cells with Expected Frequency < 5 = 4 OF 8 (50.0%)

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FCE 20124/706 i . . .

(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 7

NPTUP7 by RATER

Page 1 of 1

		RATER				
		Beauclai	Mimiran	Song	Nardi	
Row Pct	Col Pct	1.00	2.00	3.00	4.00	Row Total
NPTUP7						
	1.00		50.0	50.0		2
Imp 1&2			33.3	25.0		3.8
	2.00	2.0	4.0	6.0	88.0	50
Imp >2		100.0	66.7	75.0	100.0	96.2
	Column Total	1	3	4	44	52
		1.9	5.8	7.7	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	13.69333	3	.00335
Likelihood Ratio	8.63669	3	.03453
Mantel-Haenszel test for linear association	7.62069	1	.00577

Minimum Expected Frequency = .038
 Cells with Expected Frequency < 5 = 7 OF 8 (87.5%)

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(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 14

NPTUP14 by RATER

Page 1 of 1

		RATER				
		Beauclai	Mirmiran	Song	Nardi	
Row Pct	Col Pct	1.00	2.00	3.00	4.00	Row Total
NPTUP14						
Imp 1&2	1.00			5.0	95.0	20
				25.0	43.2	38.5
Imp >2	2.00	3.1	9.4	9.4	78.1	32
		100.0	100.0	75.0	56.8	61.5
	Column Total	1	3	4	44	52
		1.9	5.8	7.7	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	3.22045	3	.35887
Likelihood Ratio	4.61806	3	.20200
Mantel-Haenszel test for linear association	3.04828	1	.08082

Minimum Expected Frequency - .385
 Cells with Expected Frequency < 5 - 6 OF 8 (75.0%)

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(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 21

NPTUP21 by RATER

Page 1 of 1

		RATER				
Row Pct	Col Pct	Beauclai	Mirmiran	Song	Nardi	Row Total
NPTUP21		1.00	2.00	3.00	4.00	
Imp 1&2	1.00			4.2	95.8	24
				25.0	52.3	46.2
Imp >2	2.00	3.6	10.7	10.7	75.0	28
		100.0	100.0	75.0	47.7	53.8
	Column Total	1	3	4	44	52
		1.9	5.8	7.7	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	4.81169	3	.18612
Likelihood Ratio	6.37462	3	.09474
Mantel-Haenszel test for linear association	4.53612	1	.03319

Minimum Expected Frequency - .462
 Cells with Expected Frequency < 5 - 6 OF 8 (75.0%)

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(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 28

NPTUP28 by RATER

Page 1 of 1

		RATER				
Row Pct	Col Pct	Beauclai	Mirmiran	Song	Nardi	Row Total
		1.00	2.00	3.00	4.00	
NPTUP28						
	1.00		7.1	3.6	89.3	28
Imp 1&2			66.7	25.0	56.8	53.8
	2.00	4.2	4.2	12.5	79.2	24
Imp >2		100.0	33.3	75.0	43.2	46.2
	Column Total	1	3	4	44	52
		1.9	5.8	7.7	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	2.86075	3	.41360
Likelihood Ratio	3.28533	3	.34969
Mantel-Haenszel test for linear association	.72578	1	.39425

Minimum Expected Frequency = .462
 Cells with Expected Frequency < 5 = 6 OF 8 (75.0%)

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(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 35

NPTUP35 by RATER

Page 1 of 1

		RATER				
Row Pct	Col Pct	Beauclai	Mimiran	Song	Nardi	Row Total
NPTUP35		1.00	2.00	3.00	4.00	
Imp 1&2	1.00		6.9	3.4	89.7	29
			66.7	25.0	59.1	55.8
Imp >2	2.00	4.3	4.3	13.0	78.3	23
		100.0	33.3	75.0	40.9	44.2
	Column Total	1	3	4	44	52
		1.9	5.8	7.7	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	3.13734	3	.37093
Likelihood Ratio	3.54140	3	.31543
Mantel-Haenszel test for linear association	.92545	1	.33605

Minimum Expected Frequency - .442
 Cells with Expected Frequency < 5 - 6 OF 8 (75.0%)

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(9.1.4.2)

No. Pts. Very (1) and Much (2) Improved vs No. Pts. Improved (>2) - Day 42

NPTUP42 by RATER

Page 1 of 1

		RATER				Row Total
Row Pct	Col Pct	Beauclai	Mimiran	Song	Nardi	
		1.00	2.00	3.00	4.00	
NPTUP42						
	1.00		6.9	3.4	89.7	29
Imp 1&2			66.7	25.0	59.1	55.8
	2.00	4.3	4.3	13.0	78.3	23
Imp >2		100.0	33.3	75.0	40.9	44.2
	Column Total	1	3	4	44	52
	Total	1.9	5.8	7.7	84.6	100.0

Chi-Square	Value	DF	Significance
Pearson	3.13734	3	.37093
Likelihood Ratio	3.54140	3	.31543
Mantel-Haenszel test for linear association	.92545	1	.33605
Minimum Expected Frequency -	.442		
Cells with Expected Frequency < 5 -	6 OF	8 (75.0%)	

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APPENDIX 20

NOSS: Day 0

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FCE 20124/706 i

(9.2.1.1) SYMNO Symptom # - Reboxetine - Day 0

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
none	0	27	93.1	93.1	93.1
headache	8	1	3.4	3.4	96.6
dizziness	12	1	3.4	3.4	100.0
Total		29	100.0	100.0	

SYMNO Symptom # - Placebo - Day 0

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
none	0	25	80.6	80.6	80.6
insomnia	4	1	3.2	3.2	83.9
constipation	10	1	3.2	3.2	87.1
dizziness	12	2	6.5	6.5	93.5
agitation	32	1	3.2	3.2	96.8
sexual disturb.	46	1	3.2	3.2	100.0
Total		31	100.0	100.0	

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FCE 20124/706 i

(9.2.1.1) SEV Severity - Reboxetine - Day 0

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
mild	0	2	6.9	100.0	100.0
	.	27	93.1	Missing	
		-----	-----	-----	
	Total	29	100.0	100.0	

SEV Severity - Placebo - Day 0

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
mild	0	2	6.5	33.3	33.3
moderate	1	2	6.5	33.3	66.7
severe	2	2	6.5	33.3	100.0
	.	25	80.6	Missing	
		-----	-----	-----	
	Total	31	100.0	100.0	

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FCE 20124/706 i

(9.2.1.1) RPT Reported - Reboxetine - Day 0

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Spon.	0	2	6.9	100.0	100.0
	.	27	93.1	Missing	
	Total	29	100.0	100.0	

RPT Reported - Placebo - Day 0

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Spon.	0	2	6.5	33.3	33.3
Upon Inq.	1	4	12.9	66.7	100.0
	.	25	80.6	Missing	
	Total	31	100.0	100.0	

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APPENDIX 21

NOSS: Clinical Trial

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FCE 20124/706 i

(9.2.1.2.1) SYMNO Symptom #: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
hypotension	1	3	1.4	1.4	1.4
dry mouth	2	68	31.5	31.5	32.9
drowsiness	3	2	.9	.9	33.8
insomnia	4	20	9.3	9.3	43.1
sweating	7	18	8.3	8.3	51.4
headache	8	3	1.4	1.4	52.8
constipation	10	17	7.9	7.9	60.6
dizziness	12	3	1.4	1.4	62.0
vomiting	21	6	2.8	2.8	64.8
blurred vision	22	19	8.8	8.8	73.6
pruritis	26	1	.5	.5	74.1
agitation	32	1	.5	.5	74.5
tremor	34	20	9.3	9.3	83.8
decr.appetite	38	11	5.1	5.1	88.9
urinary ret.	44	6	2.8	2.8	91.7
sexual disturb.	46	15	6.9	6.9	98.6
hypomania	50	2	.9	.9	99.5
cold extremities	93	1	.5	.5	100.0
Total		216	100.0	100.0	
Valid cases	216	Missing cases	0		

FCE 20124/706 i

(9.2.1.2.1) SYMNO Symptom #: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
dry mouth	2	16	29.6	29.6	29.6
drowsiness	3	2	3.7	3.7	33.3
headache	8	6	11.1	11.1	44.4
constipation	10	6	11.1	11.1	55.6
dizziness	12	2	3.7	3.7	59.3
diarrhea	19	3	5.6	5.6	64.8
vomiting	21	1	1.9	1.9	66.7
blurred vision	22	1	1.9	1.9	68.5
lassitude	28	2	3.7	3.7	72.2
agitation	32	2	3.7	3.7	75.9
tremor	34	9	16.7	16.7	92.6
sexual disturb.	46	2	3.7	3.7	96.3
urinary incont.	51	2	3.7	3.7	100.0
	Total	54	100.0	100.0	

Valid cases 54 Missing cases 0

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(9.2.1.2.2) RPT Reported: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Spon.	0	143	66.2	67.5	67.5
Upon Inq.	1	69	31.9	32.5	100.0
	.	4	1.9	Missing	
	Total	216	100.0	100.0	

Valid cases 212 Missing cases 4

RPT Reported: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Spon.	0	39	72.2	72.2	72.2
Upon Inq.	1	15	27.8	27.8	100.0
	Total	54	100.0	100.0	

Valid cases 54 Missing cases 0

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(9.2.1.2.2) C R O S S T A B U L A T I O N

RPT Reported by GROUP

Page 1 of 1

RPT	Count	GROUP		Row Total
		RBX 1	PBO 2	
Spon.	0	143	40	183 68.5
Upon Inq.	1	69	15	84 31.5
	Column Total	212	55	267
		79.4	20.6	100.0

Chi-Square	Value	DF	Significance
Pearson	.56342	1	.45289
Continuity Correction	.34536	1	.55675
Likelihood Ratio	.57453	1	.44847
Mantel-Haenszel test for linear association	.56131	1	.45373

Minimum Expected Frequency = 17.303

Number of Missing Observations: 10

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(9.2.1.2.5) - - - - - O N E W A Y - - - - -

Variable DURDY Dur.-Days

By Variable GROUP

Analysis of Variance

Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.
Between Groups	1	1174.1347	1174.1347	18.1658	.0000
Within Groups	264	17063.4931	64.6344		
Total	265	18237.6278			

Group	Count	Mean	Standard Deviation	Standard Error	95 Pct Conf Int	for Mean
Grp 1	216	10.2176	8.8135	.5997	9.0356 To	11.3996
Grp 2	50	4.8400	2.7207	.3848	4.0668 To	5.6132
Total	266	9.2068	8.2959	.5087	8.2053 To	10.2083

Group	Minimum	Maximum
Grp 1	1.0000	39.0000
Grp 2	1.0000	11.0000
Total	1.0000	39.0000

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(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Hypotension

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	33.3	33.3	33.3
	2	1	33.3	33.3	66.7
	3	1	33.3	33.3	100.0
	Total	3	100.0	100.0	
Mean	2.000	Median	2.000		

DURDY Dur.-Days: Reboxetine - Dry Mouth

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	5	7.4	7.4	7.4
	2	7	10.3	10.3	17.6
	3	2	2.9	2.9	20.6
	4	5	7.4	7.4	27.9
	5	8	11.8	11.8	39.7
	6	4	5.9	5.9	45.6
	7	3	4.4	4.4	50.0
	8	5	7.4	7.4	57.4
	9	2	2.9	2.9	60.3
	10	1	1.5	1.5	61.8
	11	3	4.4	4.4	66.2
	12	6	8.8	8.8	75.0
	13	2	2.9	2.9	77.9
	14	1	1.5	1.5	79.4
	15	3	4.4	4.4	83.8
	16	1	1.5	1.5	85.3
	18	1	1.5	1.5	86.8
	19	4	5.9	5.9	92.6
	20	1	1.5	1.5	94.1
	23	1	1.5	1.5	95.6
	24	1	1.5	1.5	97.1
	25	1	1.5	1.5	98.5
	26	1	1.5	1.5	100.0
	Total	68	100.0	100.0	
Mean	9.059	Median	7.500		
Valid cases	68	Missing cases	0		

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(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Drowsiness

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	4	1	50.0	50.0	50.0
	5	1	50.0	50.0	100.0
	Total	2	100.0	100.0	
Mean	4.500	Median	4.500		
Valid cases	2	Missing cases	0		

DURDY Dur.-Days: Reboxetine - Insomnia

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	3	15.0	15.0	15.0
	2	2	10.0	10.0	25.0
	3	1	5.0	5.0	30.0
	4	2	10.0	10.0	40.0
	5	2	10.0	10.0	50.0
	6	1	5.0	5.0	55.0
	7	3	15.0	15.0	70.0
	8	1	5.0	5.0	75.0
	9	1	5.0	5.0	80.0
	10	1	5.0	5.0	85.0
	13	2	10.0	10.0	95.0
	22	1	5.0	5.0	100.0
	Total	20	100.0	100.0	
Mean	6.500	Median	5.500		
Valid cases	20	Missing cases	0		

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(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Sweating

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	1	5.6	5.6	5.6
	3	3	16.7	16.7	22.2
	4	1	5.6	5.6	27.8
	6	2	11.1	11.1	38.9
	8	1	5.6	5.6	44.4
	10	2	11.1	11.1	55.6
	14	1	5.6	5.6	61.1
	17	2	11.1	11.1	72.2
	22	1	5.6	5.6	77.8
	24	1	5.6	5.6	83.3
	29	1	5.6	5.6	88.9
	31	1	5.6	5.6	94.4
	38	1	5.6	5.6	100.0
	Total	18	100.0	100.0	
Mean	13.722	Median	10.000		
Valid cases	18	Missing cases	0		

DURDY Dur.-Days: Reboxetine - Headache

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	33.3	33.3	33.3
	4	1	33.3	33.3	66.7
	5	1	33.3	33.3	100.0
	Total	3	100.0	100.0	
Mean	3.333	Median	4.000		
Valid cases	3	Missing cases	0		

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(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Constipation

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	5.9	5.9	5.9
	2	1	5.9	5.9	11.8
	3	2	11.8	11.8	23.5
	5	1	5.9	5.9	29.4
	6	2	11.8	11.8	41.2
	7	1	5.9	5.9	47.1
	8	1	5.9	5.9	52.9
	10	1	5.9	5.9	58.8
	12	1	5.9	5.9	64.7
	14	1	5.9	5.9	70.6
	16	1	5.9	5.9	76.5
	21	1	5.9	5.9	82.4
	22	1	5.9	5.9	88.2
	28	1	5.9	5.9	94.1
	30	1	5.9	5.9	100.0
	Total	17	100.0	100.0	

Mean 11.412 Median 8.000

Valid cases 17 Missing cases 0

DURDY Dur.-Days: Reboxetine - Dizziness

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	2	66.7	66.7	66.7
	4	1	33.3	33.3	100.0
	Total	3	100.0	100.0	

Mean 2.667 Median 2.000

Valid cases 3 Missing cases 0

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(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Vomiting

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	4	66.7	66.7	66.7
	4	1	16.7	16.7	83.3
	7	1	16.7	16.7	100.0
	Total	6	100.0	100.0	
Mean	3.167	Median	2.000		
Valid cases	6	Missing cases	0		

DURDY Dur.-Days: Reboxetine - Blurred Vision

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	5.3	5.3	5.3
	2	3	15.8	15.8	21.1
	4	1	5.3	5.3	26.3
	5	2	10.5	10.5	36.8
	6	1	5.3	5.3	42.1
	9	2	10.5	10.5	52.6
	10	1	5.3	5.3	57.9
	11	1	5.3	5.3	63.2
	16	2	10.5	10.5	73.7
	18	1	5.3	5.3	78.9
	23	2	10.5	10.5	89.5
	25	1	5.3	5.3	94.7
	28	1	5.3	5.3	100.0
	Total	19	100.0	100.0	
Mean	11.316	Median	9.000		
Valid cases	19	Missing cases	0		

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(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Pruritus

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	7	1	100.0	100.0	100.0
	Total	1	100.0	100.0	

Mean 7.000 Median 7.000

Valid cases 1 Missing cases 0

DURDY Dur.-Days: Reboxetine - Agitation

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	3	1	100.0	100.0	100.0
	Total	1	100.0	100.0	

Mean 3.000 Median 3.000

Valid cases 1 Missing cases 0

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(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Tremor

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	5.0	5.0	5.0
	2	1	5.0	5.0	10.0
	3	2	10.0	10.0	20.0
	4	1	5.0	5.0	25.0
	6	3	15.0	15.0	40.0
	7	1	5.0	5.0	45.0
	9	1	5.0	5.0	50.0
	10	1	5.0	5.0	55.0
	11	1	5.0	5.0	60.0
	12	1	5.0	5.0	65.0
	13	1	5.0	5.0	70.0
	17	1	5.0	5.0	75.0
	20	1	5.0	5.0	80.0
	24	1	5.0	5.0	85.0
	26	1	5.0	5.0	90.0
	27	1	5.0	5.0	95.0
	30	1	5.0	5.0	100.0

Total 20 100.0 100.0

Mean 11.850 Median 9.500

Valid cases 20 Missing cases 0

DURDY Dur.-Days: Reboxetine - Decreased Appetite

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	2	18.2	18.2	18.2
	4	1	9.1	9.1	27.3
	6	1	9.1	9.1	36.4
	11	1	9.1	9.1	45.5
	13	1	9.1	9.1	54.5
	18	1	9.1	9.1	63.6
	20	1	9.1	9.1	72.7
	21	1	9.1	9.1	81.8
	28	1	9.1	9.1	90.9
	35	1	9.1	9.1	100.0

Total 11 100.0 100.0

Mean 14.545 Median 13.000

Valid cases 11 Missing cases 0

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(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Urinary Retention

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	4	1	16.7	16.7	16.7
	6	1	16.7	16.7	33.3
	8	1	16.7	16.7	50.0
	13	1	16.7	16.7	66.7
	22	1	16.7	16.7	83.3
	29	1	16.7	16.7	100.0
	Total	6	100.0	100.0	
Mean	13.667	Median	10.500		
Valid cases	6	Missing cases	0		

DURDY Dur.-Days: Reboxetine - Sexual Disturbance

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	6.7	6.7	6.7
	2	1	6.7	6.7	13.3
	3	1	6.7	6.7	20.0
	5	1	6.7	6.7	26.7
	7	1	6.7	6.7	33.3
	9	1	6.7	6.7	40.0
	11	1	6.7	6.7	46.7
	16	1	6.7	6.7	53.3
	18	1	6.7	6.7	60.0
	23	1	6.7	6.7	66.7
	25	1	6.7	6.7	73.3
	30	1	6.7	6.7	80.0
	32	1	6.7	6.7	86.7
	37	1	6.7	6.7	93.3
	39	1	6.7	6.7	100.0
	Total	15	100.0	100.0	
Mean	17.200	Median	16.000		
Valid cases	15	Missing cases	0		

1310

783

FCE 20124/706 i

(9.2.1.2.5) DURDY Dur.-Days: Reboxetine - Hypomania

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	3	1	100.0	100.0	100.0
	Total	1	100.0	100.0	
Mean	3.000	Median	3.000		
Valid cases	1	Missing cases	0		

DURDY Dur.-Days: Reboxetine - Cold Extremities

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	100.0	100.0	100.0
	Total	1	100.0	100.0	
Mean	1.000	Median	1.000		
Valid cases	1	Missing cases	0		

FCE 20124/706 i

(9.2.1.2.5) DURDY Dur.-Days: Placebo - Dry Mouth

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	1	6.3	6.3	6.3
	3	3	18.8	18.8	25.0
	4	1	6.3	6.3	31.3
	5	1	6.3	6.3	37.5
	6	3	18.8	18.8	56.3
	7	2	12.5	12.5	68.8
	8	1	6.3	6.3	75.0
	9	2	12.5	12.5	87.5
	10	2	12.5	12.5	100.0
	Total	16	100.0	100.0	

Mean 6.125 Median 6.000

Valid cases 16 Missing cases 0

DURDY Dur.-Days: Placebo - Drowsiness

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	1	50.0	100.0	100.0
	.	1	50.0	Missing	
	Total	2	100.0	100.0	

Mean 2.000 Median 2.000

Valid cases 1 Missing cases 1

FCE 20124/706 i

(9.2.1.2.5) DURDY Dur.-Days: Placebo - Headache

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	2	33.3	40.0	40.0
	3	1	16.7	20.0	60.0
	4	2	33.3	40.0	100.0
	.	1	16.7	Missing	
	Total	6	100.0	100.0	

Mean 2.600 Median 3.000

Valid cases 5 Missing cases 1

DURDY Dur.-Days: Placebo - Constipation

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	16.7	16.7	16.7
	4	1	16.7	16.7	33.3
	5	1	16.7	16.7	50.0
	7	1	16.7	16.7	66.7
	8	1	16.7	16.7	83.3
	9	1	16.7	16.7	100.0
	Total	6	100.0	100.0	

Mean 5.667 Median 6.000

Valid cases 6 Missing cases 0

DURDY Dur.-Days: Placebo - Dizziness

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	3	1	50.0	50.0	50.0
	6	1	50.0	50.0	100.0
	Total	2	100.0	100.0	

Mean 4.500 Median 4.500

Valid cases 2 Missing cases 0

1313
786

FCE 20124/706 i

(9.2.1.2.5) DURDY Dur.-Days: Placebo - Diarrhea

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	1	33.3	33.3	33.3
	3	1	33.3	33.3	66.7
	4	1	33.3	33.3	100.0
	Total	3	100.0	100.0	
Mean	3.000	Median	3.000		
Valid cases	3	Missing cases	0		

DURDY Dur.-Days: Placebo - Vomiting

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	3	1	100.0	100.0	100.0
	Total	1	100.0	100.0	
Mean	3.000	Median	3.000		
Valid cases	1	Missing cases	0		

DURDY Dur.-Days: Placebo - Blurred Vision

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	.	1	100.0	Missing	
	Total	1	100.0	100.0	
Valid cases	0	Missing cases	1		

FCE 20124/706 i

(9.2.1.2.5) DURDY Dur.-Days: Placebo - Lassitude

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	5	1	50.0	100.0	100.0
	.	1	50.0	Missing	
	Total	2	100.0	100.0	
Mean	5.000	Median	5.000		
Valid cases	1	Missing cases	1		

DURDY Dur.-Days: Placebo - Agitation

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	1	1	50.0	50.0	50.0
	3	1	50.0	50.0	100.0
	Total	2	100.0	100.0	
Mean	2.000	Median	2.000		
Valid cases	2	Missing cases	0		

DURDY Dur.-Days: Placebo - Tremor

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	2	2	22.2	22.2	22.2
	3	2	22.2	22.2	44.4
	5	1	11.1	11.1	55.6
	6	1	11.1	11.1	66.7
	9	2	22.2	22.2	88.9
	11	1	11.1	11.1	100.0
	Total	9	100.0	100.0	
Mean	5.556	Median	5.000		
Valid cases	9	Missing cases	0		

1315

788

FCE 20124/706 i

(9.2.1.2.5) DURDY Dur.-Days: Placebo - Sexual Disturbance

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	3	1	50.0	50.0	50.0
	4	1	50.0	50.0	100.0
	Total	2	100.0	100.0	
Mean	3.500	Median	3.500		
Valid cases	2	Missing cases	0		

DURDY Dur.-Days: Placebo - Urinary Incontinence

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	3	1	50.0	50.0	50.0
	5	1	50.0	50.0	100.0
	Total	2	100.0	100.0	
Mean	4.000	Median	4.000		
Valid cases	2	Missing cases	0		

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(9.2.1.2.6) SEV Severity by GROUP

Page 1 of 1

SEV	Count	GROUP		Row Total
		RBX	PBO	
mild	0	172	38	210 77.5
moderate	1	31	16	47 17.3
severe	2	13	1	14 5.2
	Column Total	216	55	271
	Total	79.7	20.3	100.0

Chi-Square	Value	DF	Significance
Pearson	7.61651	2	.02219
Likelihood Ratio	7.34220	2	.02545
Mantel-Haenszel test for linear association	.57818	1	.44703

Minimum Expected Frequency = 2.841
 Cells with Expected Frequency < 5 = 1 OF 6 (16.7%)

Number of Missing Observations: 0

1317

790

FCE 20124/706 i

(9.2.1.2.7) RQRX Required Rx: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	0	103	47.7	47.7	47.7
No	1	113	52.3	52.3	100.0
Total		216	100.0	100.0	

Valid cases 216 Missing cases 0

RQRX Required Rx: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Yes	0	26	48.1	48.1	48.1
No	1	28	51.9	51.9	100.0
Total		54	100.0	100.0	

Valid cases 54 Missing cases 0

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(9.2.1.2.7) C R O S S T A B U L A T I O N

RQRX Required Rx by GROUP

Page 1 of 1

RQRX	Count	GROUP		Row Total
		RBX 1	PBO 2	
Yes	0	103	26	129 47.8
No	1	113	28	141 52.2
	Column Total	216 80.0	54 20.0	270 100.0

Chi-Square	Value	DF	Significance
Pearson	.00371	1	.95142
Continuity Correction	.00000	1	1.00000
Likelihood Ratio	.00371	1	.95144
Mantel-Haenszel test for linear association	.00370	1	.95151

Minimum Expected Frequency = 25.800

Number of Missing Observations: 0

FCE 20124/706 i

(9.2.1.2.9) Summaries of FOLDUR Follow-up Dur.
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.6667	1.1547	3
GROUP	1		3.6667	1.1547	3

Total Cases = 271
Missing Cases = 268 OR 98.9 PCT.

Summaries of FOLDUR Follow-up Dur.
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		3.6667	1.1547	2.6667	3

Within Groups Total		3.6667	1.1547	2.6667	3

Criterion Variable FOLDUR
Fewer than two groups - Analysis of Variance cancelled

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FCE 20124/706 i

(9.2.1.2.10) OTCM Outcome: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Full	0	35	16.2	100.0	100.0
	.	181	83.8	Missing	
		Total	216	100.0	100.0
Valid cases	35	Missing cases	181		

OTCM Outcome: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Full	0	15	27.8	93.8	93.8
w/Seq.	1	1	1.9	6.3	100.0
	.	38	70.4	Missing	
		Total	54	100.0	100.0
Valid cases	16	Missing cases	38		

FCE 20124/706 i

(9.2.1.2.10) C R O S S T A B U L A T I O N

OTCM Outcome by GROUP

Page 1 of 1

OTCM	Count	GROUP		Row Total
		RBX 1	PBO 2	
Full	0	35	15	50
w/Seq.	1		1	1
		35	16	51
Column Total		68.6	31.4	100.0

Chi-Square	Value	DF	Significance
Pearson	2.23125	1	.13524
Continuity Correction	.16438	1	.68515
Likelihood Ratio	2.36258	1	.12428
Mantel-Haenszel test for linear association	2.18750	1	.13913
Fisher's Exact Test:			
One-Tail			.31373
Two-Tail			.31373

Minimum Expected Frequency = .314
 Cells with Expected Frequency < 5 = 2 OF 4 (50.0%)

Number of Missing Observations: 219

1322

795

FCE 20124/706 i

(9.2.1.2.11) RELMED Relation.-Med.: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Unknown	0	5	2.3	2.3	2.3
Poss./Doubt.	1	17	7.9	7.9	10.2
Probable	2	49	22.7	22.7	32.9
Certain	3	145	67.1	67.1	100.0
Total		216	100.0	100.0	
Valid cases	216	Missing cases	0		

RELMED Relation.-Med.: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Unknown	0	1	1.9	1.9	1.9
Poss./Doubt.	1	17	31.5	32.1	34.0
Probable	2	15	27.8	28.3	62.3
Certain	3	20	37.0	37.7	100.0
.	.	1	1.9	Missing	
Total		54	100.0	100.0	
Valid cases	53	Missing cases	1		

FCE 20124/706 i

(9.2.1.2.11) C R O S S T A B U L A T I O N

RELMED Relation.-Med. by GROUP

Page 1 of 1

RELMED	Count	GROUP		Row Total
		RBX 1	PBO 2	
Unknown	0	5	1	6 2.2
Poss./Doubt.	1	17	17	34 12.6
Probable	2	49	15	64 23.8
Certain	3	145	20	165 61.3
Column Total		216	53	269
		80.3	19.7	100.0

Chi-Square	Value	DF	Significance
Pearson	26.32096	3	.00001
Likelihood Ratio	22.86569	3	.00004
Mantel-Haenszel test for linear association	18.62428	1	.00002
Minimum Expected Frequency -	1.182		
Cells with Expected Frequency < 5 -	2 OF	8 (25.0%)	

Number of Missing Observations: 1

1324

797

FCE 20124/706 i

(9.2.1.2.12) COURSE: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Clear/Cont.	0	32	14.8	15.2	15.2
Persist/Cont.	1	163	75.5	77.3	92.4
Persist/Low.Dose	3	9	4.2	4.3	96.7
Perm.Stop	5	7	3.2	3.3	100.0
.	.	5	2.3	Missing	
Total		216	100.0	100.0	
Valid cases	211	Missing cases	5		

COURSE: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Clear/Cont.	0	12	22.2	22.6	22.6
Persist/Cont.	1	39	72.2	73.6	96.2
Perm.Stop	5	2	3.7	3.8	100.0
.	.	1	1.9	Missing	
Total		54	100.0	100.0	
Valid cases	53	Missing cases	1		

FCE 20124/706 i

(9.2.1.2.12) C R O S S T A B U L A T I O N

COURSE by GROUP

Page 1 of 1

COURSE	Count	GROUP		Row Total
		RBX 1	PBO 2	
Clear/Cont.	0	32	12	44 16.7
Persist/Cont.	1	163	39	202 76.5
Persist/Low.Dose	3	9		9 3.4
Perm.Stop	5	7	2	9 3.4
	Column Total	211	53	264
		79.9	20.1	100.0

Chi-Square	Value	DF	Significance
Pearson	3.78129	3	.28607
Likelihood Ratio	5.44770	3	.14180
Mantel-Haenszel test for linear association	1.00204	1	.31682

Minimum Expected Frequency = 1.807
 Cells with Expected Frequency < 5 = 2 OF 8 (25.0%)

Number of Missing Observations: 6

1326

799

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APPENDIX 22

Vital Signs in Two Treatment Groups

1327

800

FCE 20124/706 i

(9.2.2.1.1) MLOR1SY o.r.am l.sys - Morning Lying Systolic Out-of-Range:
Day 1 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MLOR1SY o.r.am l.sys - Morning Lying Systolic Out-of-Range:
Day 1 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR1SY o.r.am s.sys - Morning Standing Systolic Out-of-Range:
Day 1 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR1SY o.r.am s.sys - Morning Standing Systolic Out-of-Range:
Day 1 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	.00	26	92.9	96.3	96.3
	1.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
Total		28	100.0	100.0	

Valid cases 27 Missing cases 1

1328

801

FCE 20124/706 i

(9.2.2.1.1) ELOR1SY o.r.pm s.sys - Evening Lying Systolic Out-of-Range:
Day 1 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ELOR1SY o.r.pm s.sys - Evening Lying Systolic Out-of-Range:
Day 1 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR1SY o.r.pm s.sys - Evening Standing Systolic Out-of-Range:
Day 1 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR1SY o.r.pm s.sys - Evening Standing Systolic Out-of-Range:
Day 1 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

1329

802

FCE 20124/706 i

(9.2.2.1.1) MLOR2SY o.r.am l.sys - Morning Lying Systolic Out-of-Range:
Day 2 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MLOR2SY o.r.am l.sys - Morning Lying Systolic Out-of-Range:
Day 2 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR2SY o.r.am s.sys - Morning Standing Systolic Out-of-Range:
Day 2 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR2SY o.r.am s.sys - Morning Standing Systolic Out-of-Range:
Day 2 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

FCE 20124/706 i

(9.2.2.1.1) ELOR2SY o.r.pm s.sys - Evening Lying Systolic Out-of-Range:
Day 2 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ELOR2SY o.r.pm s.sys - Evening Lying Systolic Out-of-Range:
Day 2 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR2SY o.r.pm s.sys - Evening Standing Systolic Out-of-Range:
Day 2 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR2SY o.r.pm s.sys - Evening Standing Systolic Out-of-Range:
Day 2 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

1331

804

FCE 20124/706 i

(9.2.2.1.1) MLOR3SY o.r.am l.sys - Morning Lying Systolic Out-of-Range:
Day 3 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	89.3	89.3
Yes	1.00	3	10.7	10.7	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MLOR3SY o.r.am l.sys - Morning Lying Systolic Out-of-Range:
Day 3 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR3SY o.r.am s.sys - Morning Standing Systolic Out-of-Range:
Day 3 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR3SY o.r.am s.sys - Morning Standing Systolic Out-of-Range:
Day 3 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

1332

805

FCE 20124/706 i

(9.2.2.1.1) ELOR3SY o.r.pm s.sys - Evening Lying Systolic Out-of-Range:
Day 3 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	89.3	89.3
Yes	1.00	3	10.7	10.7	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ELOR3SY o.r.pm s.sys - Evening Lying Systolic Out-of-Range: Day 3 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	96.3	96.3
Yes	1.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

ESOR3SY o.r.pm s.sys - Evening Standing Systolic Out-of-Range:
Day 3 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR3SY o.r.pm s.sys - Evening Standing Systolic Out-of-Range:
Day 3 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	92.6	92.6
Yes	1.00	2	7.1	7.4	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

FCE 20124/706 i

(9.2.2.1.1) MLOR4SY o.r.am l.sys - Morning Lying Systolic Out-of-Range: Day 4 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	89.3	89.3
Yes	1.00	3	10.7	10.7	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MLOR4SY o.r.am l.sys - Morning Lying Systolic Out-of-Range: Day 4 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	96.2	96.2
Yes	1.00	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

MSOR4SY o.r.am s.sys - Morning Standing Systolic Out-of-Range: Day 4 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	28	100.0	100.0	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR4SY o.r.am s.sys - Morning Standing Systolic Out-of-Range: Day 4 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	24	85.7	92.3	92.3
Yes	1.00	2	7.1	7.7	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

FCE 20124/706 i

(9.2.2.1.1) ELOR4SY o.r.pm s.sys - Evening lying Systolic Out-of-Range: Day 4 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	92.6	92.6
Yes	1.00	2	7.1	7.4	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

ELOR4SY o.r.pm s.sys - Evening lying Systolic Out-of-Range: Day 4 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	100.0	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

ESOR4SY o.r.pm s.sys - Evening Standing Systolic Out-of-Range: Day 4 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	96.3	96.3
Yes	1.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

ESOR4SY o.r.pm s.sys - Evening Standing Systolic Out-of-Range: Day 4 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	96.2	96.2
Yes	1.00	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

FCE 20124/706 i

(9.2.2.1.1) HYP01 Dy1 a.m.syschg - A.M. Systolic B.P. Changes: RBX Day 1

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	3	10.7	10.7	10.7
	-2.00	1	3.6	3.6	14.3
	.00	5	17.9	17.9	32.1
	2.00	2	7.1	7.1	39.3
	5.00	11	39.3	39.3	78.6
	6.00	1	3.6	3.6	82.1
	10.00	3	10.7	10.7	92.9
	12.00	1	3.6	3.6	96.4
	14.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

HYP02 Dy1 p.m.syschg - P.M. Systolic B.P. Changes: RBX Day 1

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	3	10.7	10.7	10.7
	-4.00	1	3.6	3.6	14.3
	.00	4	14.3	14.3	28.6
	4.00	1	3.6	3.6	32.1
	5.00	10	35.7	35.7	67.9
	10.00	5	17.9	17.9	85.7
	16.00	2	7.1	7.1	92.9
	20.00	1	3.6	3.6	96.4
	30.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

FCE 20124/706 i

(9.2.2.1.1) HYPO3 Dy2 a.m.syschg - A.M. Systolic B.P. Changes: RBX Day 2

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	3	10.7	10.7	10.7
	.00	5	17.9	17.9	28.6
	4.00	1	3.6	3.6	32.1
	5.00	9	32.1	32.1	64.3
	10.00	6	21.4	21.4	85.7
	14.00	1	3.6	3.6	89.3
	20.00	1	3.6	3.6	92.9
	22.00	1	3.6	3.6	96.4
	30.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

HYPO4 Dy2 p.m.syschg - P.M. Systolic B.P. Changes: RBX Day 2

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	1	3.6	3.6	3.6
	.00	7	25.0	25.0	28.6
	4.00	1	3.6	3.6	32.1
	5.00	8	28.6	28.6	60.7
	8.00	1	3.6	3.6	64.3
	10.00	8	28.6	28.6	92.9
	20.00	1	3.6	3.6	96.4
	24.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

FCE 20124/706 i

(9.2.2.1.1) HYP05 Dy3 a.m.syschg - A.M. Systolic B.P. Changes: RBX Day 3

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	2	7.1	7.1	7.1
	5.00	15	53.6	53.6	60.7
	8.00	1	3.6	3.6	64.3
	10.00	6	21.4	21.4	85.7
	16.00	1	3.6	3.6	89.3
	22.00	1	3.6	3.6	92.9
	24.00	1	3.6	3.6	96.4
	56.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

HYP06 Dy3 p.m.syschg - P.M. Systolic B.P. Changes: RBX Day 3

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	6	21.4	21.4	21.4
	.00	6	21.4	21.4	42.9
	5.00	7	25.0	25.0	67.9
	10.00	3	10.7	10.7	78.6
	18.00	1	3.6	3.6	82.1
	20.00	3	10.7	10.7	92.9
	24.00	1	3.6	3.6	96.4
	76.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

FCE 20124/706 i

(9.2.2.1.1) HYP07 Dy4 a.m.syschg - A.M. Systolic B.P. Changes: RBX Day 4

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	3	10.7	10.7	10.7
	.00	3	10.7	10.7	21.4
	5.00	12	42.9	42.9	64.3
	6.00	1	3.6	3.6	67.9
	10.00	4	14.3	14.3	82.1
	18.00	2	7.1	7.1	89.3
	20.00	1	3.6	3.6	92.9
	26.00	1	3.6	3.6	96.4
	40.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

HYP08 Dy4 p.m.syschg - P.M. Systolic B.P. Changes: RBX Day 4

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-20.00	1	3.6	3.7	3.7
	-5.00	2	7.1	7.4	11.1
	.00	4	14.3	14.8	25.9
	5.00	16	57.1	59.3	85.2
	20.00	3	10.7	11.1	96.3
	30.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

FCE 20124/706 i

(9.2.2.1.1) HYP01 Dy1 a.m.syschg - A.M. Systolic B.P. Changes: PBO Day 1

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-10.00	1	3.6	3.7	3.7
	-8.00	1	3.6	3.7	7.4
	-6.00	1	3.6	3.7	11.1
	-5.00	4	14.3	14.8	25.9
	.00	6	21.4	22.2	48.1
	5.00	11	39.3	40.7	88.9
	6.00	1	3.6	3.7	92.6
	8.00	1	3.6	3.7	96.3
	20.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

HYP02 Dy1 p.m.syschg - P.M. Systolic B.P. Changes: PBO Day 1

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-10.00	1	3.6	3.6	3.6
	-5.00	6	21.4	21.4	25.0
	.00	13	46.4	46.4	71.4
	5.00	5	17.9	17.9	89.3
	8.00	1	3.6	3.6	92.9
	10.00	1	3.6	3.6	96.4
	16.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

FCE 20124/706 i

(9.2.2.1.1) HYP03 Dy2 a.m.syschg - A.M. Systolic B.P. Changes: PBO Day 2

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	5	17.9	17.9	17.9
	-4.00	1	3.6	3.6	21.4
	.00	5	17.9	17.9	39.3
	2.00	1	3.6	3.6	42.9
	4.00	2	7.1	7.1	50.0
	5.00	11	39.3	39.3	89.3
	10.00	2	7.1	7.1	96.4
	14.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

HYP04 Dy2 p.m.syschg - P.M. Systolic B.P. Changes: PBO Day 2

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-8.00	1	3.6	3.6	3.6
	-5.00	8	28.6	28.6	32.1
	-4.00	1	3.6	3.6	35.7
	.00	10	35.7	35.7	71.4
	5.00	3	10.7	10.7	82.1
	6.00	1	3.6	3.6	85.7
	8.00	1	3.6	3.6	89.3
	10.00	2	7.1	7.1	96.4
	16.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

FCE 20124/706 i

(9.2.2.1.1) HYP05 Dy3 a.m.syschg - A.M. Systolic B.P. Changes: PBO Day 3

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	6	21.4	21.4	21.4
	-4.00	1	3.6	3.6	25.0
	.00	7	25.0	25.0	50.0
	4.00	1	3.6	3.6	53.6
	5.00	7	25.0	25.0	78.6
	6.00	1	3.6	3.6	82.1
	10.00	2	7.1	7.1	89.3
	14.00	1	3.6	3.6	92.9
	15.00	1	3.6	3.6	96.4
	24.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

HYP06 Dy3 p.m.syschg - P.M. Systolic B.P. Changes: PBO Day 3

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-12.00	1	3.6	3.7	3.7
	-5.00	3	10.7	11.1	14.8
	-2.00	1	3.6	3.7	18.5
	.00	11	39.3	40.7	59.3
	2.00	1	3.6	3.7	63.0
	5.00	10	35.7	37.0	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

FCE 20124/706 i

(9.2.2.1.1) HYP07 Dy4 a.m.syschg - A.M. Systolic B.P. Changes: PBO Day 4

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	4	14.3	15.4	15.4
	-2.00	1	3.6	3.8	19.2
	.00	7	25.0	26.9	46.2
	4.00	2	7.1	7.7	53.8
	5.00	8	28.6	30.8	84.6
	6.00	1	3.6	3.8	88.5
	10.00	3	10.7	11.5	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

HYP08 Dy4 p.m.syschg - P.M. Systolic B.P. Changes: PBO Day 4

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-5.00	2	7.1	7.7	7.7
	-2.00	1	3.6	3.8	11.5
	.00	6	21.4	23.1	34.6
	4.00	1	3.6	3.8	38.5
	5.00	15	53.6	57.7	96.2
	10.00	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

FCE 20124/706 i

(9.2.2.1.2) MLOR1DI o.r.am l.dia - Morning Lying Diastolic Out-of-Range:
Day 1 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MLOR1DI o.r.am l.dia - Morning Lying Diastolic Out-of-Range:
Day 1 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	28	100.0	100.0	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR1DI o.r.am s.dia - Morning Standing Diastolic Out-of-Range:
Day 1 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR1DI o.r.am s.dia - Morning Standing Diastolic Out-of-Range:
Day 1 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	92.6	92.6
Yes	1.00	2	7.1	7.4	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

FCE 20124/706 i

(9.2.2.1.2) ELOR1DI o.r.pm s.dia - Evening Lying Diastolic Out-of-Range:
Day 1 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	89.3	89.3
Yes	1.00	3	10.7	10.7	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ELOR1DI o.r.pm s.dia - Evening Lying Diastolic Out-of-Range:
Day 1 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	28	100.0	100.0	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR1DI o.r.pm s.dia - Evening Standing Diastolic Out-of-Range:
Day 1 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	89.3	89.3
Yes	1.00	3	10.7	10.7	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR1DI o.r.pm s.dia - Evening Standing Diastolic Out-of-Range:
Day 1 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

1345

FCE 20124/706 i

(9.2.2.1.2) MLOR2DI o.r.am l.dia - Morning Lying Diastolic Out-of-Range:
Day 2 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MLOR2DI o.r.am l.dia - Morning Lying Diastolic Out-of-Range:
Day 2 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR2DI o.r.am s.dia - Morning Standing Diastolic Out-of-Range:
Day 2 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR2DI o.r.am s.dia - Morning Standing Diastolic Out-of-Range:
Day 2 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	89.3	89.3
Yes	1.00	3	10.7	10.7	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

FCE 20124/706 i

(9.2.2.1.2) ELOR2DI o.r.pm s.dia - Evening Lying Diastolic Out-of-Range:
Day 2 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ELOR2DI o.r.pm s.dia - Evening Lying Diastolic Out-of-Range:
Day 2 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR2DI o.r.pm s.dia - Evening Standing Diastolic Out-of-Range:
Day 2 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

ESOR2DI o.r.pm s.dia - Evening Standing Diastolic Out-of-Range:
Day 2 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	89.3	89.3
Yes	1.00	3	10.7	10.7	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

FCE 20124/706 i

(9.2.2.1.2) MLOR3DI o.r.am l.dia - Morning Lying Diastolic Out-of-Range:
Day 3 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MLOR3DI o.r.am l.dia - Morning Lying Diastolic Out-of-Range:
Day 3 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	28	100.0	100.0	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR3DI o.r.am s.dia - Morning Standing Diastolic Out-of-Range:
Day 3 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR3DI o.r.am s.dia - Morning Standing Diastolic Out-of-Range:
Day 3 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

1348

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FCE 20124/706 i

(9.2.2.1.2) ELOR3DI o.r.pm s.dia - Evening Lying Diastolic Out-of-Range:
Day 3 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	24	85.7	85.7	85.7
Yes	1.00	4	14.3	14.3	100.0
Total		28	100.0	100.0	
Valid cases	28	Missing cases	0		

ELOR3DI o.r.pm s.dia - Evening Lying Diastolic Out-of-Range:
Day 3 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	96.3	96.3
Yes	1.00	1	3.6	3.7	100.0
.	.	1	3.6	Missing	
Total		28	100.0	100.0	
Valid cases	27	Missing cases	1		

ESOR3DI o.r.pm s.dia - Evening Standing Diastolic Out-of-Range:
Day 3 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	27	96.4	96.4	96.4
Yes	1.00	1	3.6	3.6	100.0
Total		28	100.0	100.0	
Valid cases	28	Missing cases	0		

ESOR3DI o.r.pm s.dia - Evening Standing Diastolic Out-of-Range:
Day 3 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	92.6	92.6
Yes	1.00	2	7.1	7.4	100.0
.	.	1	3.6	Missing	
Total		28	100.0	100.0	
Valid cases	27	Missing cases	1		

FCE 20124/706 i

(9.2.2.1.2) MLOR4DI o.r.am l.dia - Morning Lying Diastolic Out-of-Range:
Day 4 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	89.3	89.3
Yes	1.00	3	10.7	10.7	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MLOR4DI o.r.am l.dia - Morning Lying Diastolic Out-of-Range:
Day 4 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	96.2	96.2
Yes	1.00	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

MSOR4DI o.r.am s.dia - Morning Standing Diastolic Out-of-Range:
Day 4 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	92.9	92.9
Yes	1.00	2	7.1	7.1	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MSOR4DI o.r.am s.dia - Morning Standing Diastolic Out-of-Range:
Day 4 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	100.0	100.0
Yes	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

823 1350

FCE 20124/706 i

(9.2.2.1.2) ELOR4DI o.r.pm s.dia - Evening Lying Diastolic Out-of-Range:
Day 4 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	92.6	92.6
Yes	1.00	2	7.1	7.4	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

ELOR4DI o.r.pm s.dia - Evening Lying Diastolic Out-of-Range:
Day 4 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	100.0	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

ESOR4DI o.r.pm s.dia - Evening Standing Diastolic Out-of-Range:
Day 4 RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	25	89.3	92.6	92.6
Yes	1.00	2	7.1	7.4	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

ESOR4DI o.r.pm s.dia - Evening Standing Diastolic Out-of-Range:
Day 4 PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	.00	26	92.9	100.0	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

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(9.2.2.1.3) HRCHG1 a.m.1y.H.R.Chg.Dy1-2 : RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-16.15	1	3.6	3.6	3.6
	-13.50	1	3.6	3.6	7.1
	-12.11	1	3.6	3.6	10.7
	-11.53	1	3.6	3.6	14.3
	-9.82	1	3.6	3.6	17.9
	-6.88	1	3.6	3.6	21.4
	-6.71	1	3.6	3.6	25.0
	-6.56	1	3.6	3.6	28.6
	-4.23	1	3.6	3.6	32.1
	-3.78	2	7.1	7.1	39.3
	-1.00	5	17.9	17.9	57.1
	.47	1	3.6	3.6	60.7
	2.75	1	3.6	3.6	64.3
	4.15	1	3.6	3.6	67.9
	4.26	1	3.6	3.6	71.4
	5.25	1	3.6	3.6	75.0
	6.58	1	3.6	3.6	78.6
	6.89	1	3.6	3.6	82.1
	7.33	3	10.7	10.7	92.9
	9.00	1	3.6	3.6	96.4
	9.26	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28				
Missing cases	0				

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(9.2.2.1.3) HRCHG1 a.m. 1y.H.R.Chg.Dy1-2: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-21.00	1	3.6	3.6	3.6
	-17.13	1	3.6	3.6	7.1
	-12.43	1	3.6	3.6	10.7
	-7.67	1	3.6	3.6	14.3
	-7.45	1	3.6	3.6	17.9
	-5.29	2	7.1	7.1	25.0
	-4.33	1	3.6	3.6	28.6
	-4.23	1	3.6	3.6	32.1
	-3.63	1	3.6	3.6	35.7
	-2.25	1	3.6	3.6	39.3
	-1.00	5	17.9	17.9	57.1
	1.50	1	3.6	3.6	60.7
	1.56	1	3.6	3.6	64.3
	1.78	2	7.1	7.1	71.4
	3.76	1	3.6	3.6	75.0
	5.98	1	3.6	3.6	78.6
	6.32	1	3.6	3.6	82.1
	7.24	1	3.6	3.6	85.7
	8.68	1	3.6	3.6	89.3
	12.16	1	3.6	3.6	92.9
	16.14	1	3.6	3.6	96.4
	23.62	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

1353

826

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(9.2.2.1.3) HRCHG2 a.m. 1y.H.R.Chg.Dy1-3: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-16.79	1	3.6	3.6	3.6
	-13.50	1	3.6	3.6	7.1
	-11.00	1	3.6	3.6	10.7
	-10.38	1	3.6	3.6	14.3
	-10.09	1	3.6	3.6	17.9
	-9.82	2	7.1	7.1	25.0
	-7.06	1	3.6	3.6	28.6
	-6.88	1	3.6	3.6	32.1
	-6.71	1	3.6	3.6	35.7
	-3.78	2	7.1	7.1	42.9
	-1.00	4	14.3	14.3	57.1
	.03	1	3.6	3.6	60.7
	1.63	1	3.6	3.6	64.3
	1.78	2	7.1	7.1	71.4
	2.13	1	3.6	3.6	75.0
	2.23	1	3.6	3.6	78.6
	4.00	1	3.6	3.6	82.1
	4.56	2	7.1	7.1	89.3
	6.69	1	3.6	3.6	92.9
	10.11	1	3.6	3.6	96.4
	12.89	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

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(9.2.2.1.3) HRCHG2 a.m. |y.H.R.Chg.Dy1-3: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-31.00	1	3.6	3.6	3.6
	-23.58	1	3.6	3.6	7.1
	-17.67	1	3.6	3.6	10.7
	-13.90	1	3.6	3.6	14.3
	-9.57	1	3.6	3.6	17.9
	-8.89	1	3.6	3.6	21.4
	-8.50	1	3.6	3.6	25.0
	-8.14	1	3.6	3.6	28.6
	-7.67	1	3.6	3.6	32.1
	-7.45	1	3.6	3.6	35.7
	-4.33	1	3.6	3.6	39.3
	-4.13	1	3.6	3.6	42.9
	-3.78	1	3.6	3.6	46.4
	-1.00	3	10.7	10.7	57.1
	.22	1	3.6	3.6	60.7
	1.56	1	3.6	3.6	64.3
	1.78	1	3.6	3.6	67.9
	2.23	1	3.6	3.6	71.4
	3.65	1	3.6	3.6	75.0
	4.56	1	3.6	3.6	78.6
	6.14	1	3.6	3.6	82.1
	6.50	1	3.6	3.6	85.7
	9.53	1	3.6	3.6	89.3
	10.43	1	3.6	3.6	92.9
	14.29	1	3.6	3.6	96.4
	24.38	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases		28			
Missing cases		0			

1355

828

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(9.2.2.1.3) HRCHG3 a.m.ly.H.R.Chg.Dy1-4: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-26.00	1	3.6	3.6	3.6
	-24.33	1	3.6	3.6	7.1
	-21.59	1	3.6	3.6	10.7
	-19.18	1	3.6	3.6	14.3
	-13.50	1	3.6	3.6	17.9
	-11.53	1	3.6	3.6	21.4
	-9.33	1	3.6	3.6	25.0
	-6.88	1	3.6	3.6	28.6
	-6.56	1	3.6	3.6	32.1
	-5.17	1	3.6	3.6	35.7
	-4.03	1	3.6	3.6	39.3
	-3.94	1	3.6	3.6	42.9
	-3.86	1	3.6	3.6	46.4
	-1.00	5	17.9	17.9	64.3
	.03	1	3.6	3.6	67.9
	.32	1	3.6	3.6	71.4
	1.50	1	3.6	3.6	75.0
	1.78	1	3.6	3.6	78.6
	3.17	1	3.6	3.6	82.1
	4.13	1	3.6	3.6	85.7
	4.26	1	3.6	3.6	89.3
	4.56	1	3.6	3.6	92.9
	7.33	2	7.1	7.1	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

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(9.2.2.1.3) HRCHG3 a.m.ly.H.R.Chg.Dy1-4: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-31.00	1	3.6	3.8	3.8
	-21.00	1	3.6	3.8	7.7
	-17.13	1	3.6	3.8	11.5
	-12.43	2	7.1	7.7	19.2
	-11.00	1	3.6	3.8	23.1
	-10.68	2	7.1	7.7	30.8
	-8.89	1	3.6	3.8	34.6
	-8.50	1	3.6	3.8	38.5
	-7.67	1	3.6	3.8	42.3
	-5.88	1	3.6	3.8	46.2
	-1.00	4	14.3	15.4	61.5
	1.33	1	3.6	3.8	65.4
	1.38	1	3.6	3.8	69.2
	1.78	1	3.6	3.8	73.1
	3.76	1	3.6	3.8	76.9
	4.71	1	3.6	3.8	80.8
	6.69	1	3.6	3.8	84.6
	12.16	1	3.6	3.8	88.5
	14.29	1	3.6	3.8	92.3
	29.00	1	3.6	3.8	96.2
	30.45	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases		26			
Missing cases		2			

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(9.2.2.1.3) HRCHG4 a.m.st.H.R.Chg.Dy1-2: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-28.78	1	3.6	3.6	3.6
	-22.05	1	3.6	3.6	7.1
	-13.12	1	3.6	3.6	10.7
	-12.43	1	3.6	3.6	14.3
	-10.09	1	3.6	3.6	17.9
	-8.14	1	3.6	3.6	21.4
	-7.85	1	3.6	3.6	25.0
	-7.45	1	3.6	3.6	28.6
	-5.11	1	3.6	3.6	32.1
	-3.78	1	3.6	3.6	35.7
	-3.70	1	3.6	3.6	39.3
	-2.43	1	3.6	3.6	42.9
	-2.05	1	3.6	3.6	46.4
	-1.00	4	14.3	14.3	60.7
	.43	1	3.6	3.6	64.3
	1.70	1	3.6	3.6	67.9
	1.86	1	3.6	3.6	71.4
	2.66	1	3.6	3.6	75.0
	5.49	1	3.6	3.6	78.6
	6.35	1	3.6	3.6	82.1
	7.11	1	3.6	3.6	85.7
	7.33	1	3.6	3.6	89.3
	7.75	1	3.6	3.6	92.9
	9.53	2	7.1	7.1	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

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(9.2.2.1.3) HRCHG4 a.m.st.H.R.Chg.Dy1-2: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-29.21	1	3.6	3.8	3.8
	-21.59	1	3.6	3.8	7.7
	-13.50	1	3.6	3.8	11.5
	-6.26	1	3.6	3.8	15.4
	-5.76	1	3.6	3.8	19.2
	-3.70	1	3.6	3.8	23.1
	-1.00	6	21.4	23.1	46.2
	.59	1	3.6	3.8	50.0
	1.63	1	3.6	3.8	53.8
	2.13	1	3.6	3.8	57.7
	2.57	1	3.6	3.8	61.5
	2.66	1	3.6	3.8	65.4
	3.00	1	3.6	3.8	69.2
	3.05	1	3.6	3.8	73.1
	3.65	1	3.6	3.8	76.9
	4.41	1	3.6	3.8	80.8
	5.06	1	3.6	3.8	84.6
	7.11	1	3.6	3.8	88.5
	10.90	1	3.6	3.8	92.3
	12.51	1	3.6	3.8	96.2
	15.67	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26	Missing cases	2		

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(9.2.2.1.3) HRCHG5 a.m.st.H.R.Chg.Dy1-3: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-32.58	1	3.6	3.6	3.6
	-31.56	1	3.6	3.6	7.1
	-16.15	1	3.6	3.6	10.7
	-13.12	1	3.6	3.6	14.3
	-12.43	1	3.6	3.6	17.9
	-6.71	1	3.6	3.6	21.4
	-6.45	1	3.6	3.6	25.0
	-5.17	1	3.6	3.6	28.6
	-3.86	2	7.1	7.1	35.7
	-2.37	1	3.6	3.6	39.3
	-1.00	3	10.7	10.7	50.0
	1.70	2	7.1	7.1	57.1
	2.66	1	3.6	3.6	60.7
	3.11	1	3.6	3.6	64.3
	3.29	1	3.6	3.6	67.9
	4.00	1	3.6	3.6	71.4
	4.41	1	3.6	3.6	75.0
	5.49	1	3.6	3.6	78.6
	7.33	2	7.1	7.1	85.7
	9.53	1	3.6	3.6	89.3
	10.43	1	3.6	3.6	92.9
	12.68	1	3.6	3.6	96.4
	14.79	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

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(9.2.2.1.3) HRCHG5 a.m.st.H.R.Chg.Dy1-3: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-29.21	1	3.6	3.8	3.8
	-19.75	1	3.6	3.8	7.7
	-15.52	1	3.6	3.8	11.5
	-9.11	1	3.6	3.8	15.4
	-8.35	1	3.6	3.8	19.2
	-7.67	1	3.6	3.8	23.1
	-7.32	1	3.6	3.8	26.9
	-7.25	1	3.6	3.8	30.8
	-6.41	1	3.6	3.8	34.6
	-2.19	1	3.6	3.8	38.5
	-1.00	4	14.3	15.4	53.8
	.35	1	3.6	3.8	57.7
	.59	1	3.6	3.8	61.5
	1.44	1	3.6	3.8	65.4
	1.63	1	3.6	3.8	69.2
	1.67	1	3.6	3.8	73.1
	2.03	1	3.6	3.8	76.9
	3.65	1	3.6	3.8	80.8
	4.41	1	3.6	3.8	84.6
	7.43	1	3.6	3.8	88.5
	8.52	1	3.6	3.8	92.3
	9.81	1	3.6	3.8	96.2
	11.50	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26				
Missing cases		2			

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(9.2.2.1.3) HRCHG6 a.m.st.H.R.Chg.Dy1-4: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-45.74	1	3.6	3.6	3.6
	-16.15	1	3.6	3.6	7.1
	-15.29	2	7.1	7.1	14.3
	-14.68	1	3.6	3.6	17.9
	-9.57	1	3.6	3.6	21.4
	-9.22	1	3.6	3.6	25.0
	-9.11	1	3.6	3.6	28.6
	-8.14	1	3.6	3.6	32.1
	-6.56	1	3.6	3.6	35.7
	-4.03	2	7.1	7.1	42.9
	-1.00	4	14.3	14.3	57.1
	.30	1	3.6	3.6	60.7
	.43	1	3.6	3.6	64.3
	.82	1	3.6	3.6	67.9
	1.94	1	3.6	3.6	71.4
	2.23	1	3.6	3.6	75.0
	4.56	1	3.6	3.6	78.6
	6.14	1	3.6	3.6	82.1
	6.32	1	3.6	3.6	85.7
	6.89	1	3.6	3.6	89.3
	7.33	1	3.6	3.6	92.9
	10.84	1	3.6	3.6	96.4
	11.50	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

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(9.2.2.1.3) HRCHG6 a.m.st.H.R.Chg.Dy1-4: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-19.75	1	3.6	4.2	4.2
	-18.95	1	3.6	4.2	8.3
	-12.29	1	3.6	4.2	12.5
	-12.11	1	3.6	4.2	16.7
	-9.11	2	7.1	8.3	25.0
	-8.81	1	3.6	4.2	29.2
	-6.00	1	3.6	4.2	33.3
	-5.76	2	7.1	8.3	41.7
	-4.57	1	3.6	4.2	45.8
	-4.13	1	3.6	4.2	50.0
	-3.70	1	3.6	4.2	54.2
	-1.00	3	10.7	12.5	66.7
	.11	1	3.6	4.2	70.8
	.52	1	3.6	4.2	75.0
	1.63	1	3.6	4.2	79.2
	3.05	1	3.6	4.2	83.3
	4.56	1	3.6	4.2	87.5
	4.81	1	3.6	4.2	91.7
	7.43	1	3.6	4.2	95.8
	12.51	1	3.6	4.2	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	
Valid cases	24				
Missing cases		4			

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(9.2.2.1.3) HRCHG7 p.m.ly.H.R.Chg.Dy1-2: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-12.76	1	3.6	3.6	3.6
	-8.81	1	3.6	3.6	7.1
	-8.69	2	7.1	7.1	14.3
	-7.06	1	3.6	3.6	17.9
	-6.56	1	3.6	3.6	21.4
	-6.41	1	3.6	3.6	25.0
	-4.33	1	3.6	3.6	28.6
	-3.78	1	3.6	3.6	32.1
	-3.70	1	3.6	3.6	35.7
	-1.00	1	3.6	3.6	39.3
	1.70	2	7.1	7.1	46.4
	1.94	1	3.6	3.6	50.0
	2.33	1	3.6	3.6	53.6
	3.00	1	3.6	3.6	57.1
	4.00	1	3.6	3.6	60.7
	4.26	1	3.6	3.6	64.3
	4.41	1	3.6	3.6	67.9
	4.56	1	3.6	3.6	71.4
	5.25	1	3.6	3.6	75.0
	8.00	1	3.6	3.6	78.6
	8.33	1	3.6	3.6	82.1
	8.59	1	3.6	3.6	85.7
	9.53	1	3.6	3.6	89.3
	9.81	1	3.6	3.6	92.9
	14.71	1	3.6	3.6	96.4
	15.00	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

1364

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(9.2.2.1.3) HRCHG7 p.m.ly.H.R.Chg.Dy1-2: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-14.64	1	3.6	3.6	3.6
	-12.76	1	3.6	3.6	7.1
	-11.34	1	3.6	3.6	10.7
	-10.68	1	3.6	3.6	14.3
	-9.11	1	3.6	3.6	17.9
	-7.45	1	3.6	3.6	21.4
	-6.88	1	3.6	3.6	25.0
	-4.85	1	3.6	3.6	28.6
	-3.94	1	3.6	3.6	32.1
	-3.44	1	3.6	3.6	35.7
	-2.61	1	3.6	3.6	39.3
	-1.00	3	10.7	10.7	50.0
	.27	1	3.6	3.6	53.6
	.32	1	3.6	3.6	57.1
	1.38	1	3.6	3.6	60.7
	1.94	1	3.6	3.6	64.3
	2.33	1	3.6	3.6	67.9
	2.57	1	3.6	3.6	71.4
	2.66	1	3.6	3.6	75.0
	2.70	1	3.6	3.6	78.6
	3.69	1	3.6	3.6	82.1
	5.06	1	3.6	3.6	85.7
	5.85	1	3.6	3.6	89.3
	8.52	1	3.6	3.6	92.9
	10.11	1	3.6	3.6	96.4
	17.42	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

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(9.2.2.1.3) HRCHG8 p.m.ly.H.R.Chg.Dy1-3:RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-16.15	1	3.6	3.6	3.6
	-13.00	1	3.6	3.6	7.1
	-12.76	1	3.6	3.6	10.7
	-10.38	1	3.6	3.6	14.3
	-9.82	1	3.6	3.6	17.9
	-7.67	1	3.6	3.6	21.4
	-6.41	1	3.6	3.6	25.0
	-3.78	1	3.6	3.6	28.6
	-1.00	7	25.0	25.0	53.6
	.33	1	3.6	3.6	57.1
	1.70	1	3.6	3.6	60.7
	1.78	1	3.6	3.6	64.3
	4.26	1	3.6	3.6	67.9
	4.56	1	3.6	3.6	71.4
	5.00	1	3.6	3.6	75.0
	6.69	1	3.6	3.6	78.6
	7.22	1	3.6	3.6	82.1
	8.38	1	3.6	3.6	85.7
	9.81	2	7.1	7.1	92.9
	10.43	1	3.6	3.6	96.4
	20.05	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28				
Missing cases	0				

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FCE 20124/706 i

(9.2.2.1.3) HRCHG8 p.m.ly.H.R.Chg.Dy1-3: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-41.32	1	3.6	3.7	3.7
	-13.82	1	3.6	3.7	7.4
	-12.76	1	3.6	3.7	11.1
	-11.29	1	3.6	3.7	14.8
	-10.09	1	3.6	3.7	18.5
	-7.90	1	3.6	3.7	22.2
	-7.67	1	3.6	3.7	25.9
	-6.88	1	3.6	3.7	29.6
	-5.88	1	3.6	3.7	33.3
	-4.95	1	3.6	3.7	37.0
	-4.70	1	3.6	3.7	40.7
	-4.13	1	3.6	3.7	44.4
	-3.94	1	3.6	3.7	48.1
	-3.70	1	3.6	3.7	51.9
	-1.00	8	28.6	29.6	81.5
	.27	1	3.6	3.7	85.2
	1.74	1	3.6	3.7	88.9
	4.56	1	3.6	3.7	92.6
	10.90	1	3.6	3.7	96.3
	17.42	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases	27				
Missing cases	1				

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FCE 20124/706 i

(9.2.2.1.3) HRCHG9 p.m.1y.H.R.Chg.Dy1-4: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-19.18	1	3.6	3.7	3.7
	-16.63	1	3.6	3.7	7.4
	-15.71	1	3.6	3.7	11.1
	-11.00	1	3.6	3.7	14.8
	-7.94	1	3.6	3.7	18.5
	-4.85	1	3.6	3.7	22.2
	-1.00	6	21.4	22.2	44.4
	1.56	1	3.6	3.7	48.1
	1.63	1	3.6	3.7	51.9
	2.33	1	3.6	3.7	55.6
	3.05	1	3.6	3.7	59.3
	3.11	1	3.6	3.7	63.0
	4.88	1	3.6	3.7	66.7
	5.25	1	3.6	3.7	70.4
	5.67	1	3.6	3.7	74.1
	6.00	1	3.6	3.7	77.8
	7.11	1	3.6	3.7	81.5
	7.33	1	3.6	3.7	85.2
	12.16	1	3.6	3.7	88.9
	12.51	1	3.6	3.7	92.6
	13.29	1	3.6	3.7	96.3
	15.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases	27				
Missing cases	1				

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FCE 20124/706 i

(9.2.2.1.3) HRCHG9 p.m.ly.H.R.Chg.Dy1-4: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-18.65	1	3.6	4.0	4.0
	-17.13	1	3.6	4.0	8.0
	-13.50	1	3.6	4.0	12.0
	-11.34	1	3.6	4.0	16.0
	-11.29	1	3.6	4.0	20.0
	-9.82	1	3.6	4.0	24.0
	-8.69	1	3.6	4.0	28.0
	-7.33	1	3.6	4.0	32.0
	-4.33	1	3.6	4.0	36.0
	-4.03	1	3.6	4.0	40.0
	-3.94	2	7.1	8.0	48.0
	-3.44	1	3.6	4.0	52.0
	-3.38	1	3.6	4.0	56.0
	-2.22	1	3.6	4.0	60.0
	-1.00	3	10.7	12.0	72.0
	.32	1	3.6	4.0	76.0
	2.23	1	3.6	4.0	80.0
	5.85	1	3.6	4.0	84.0
	6.14	1	3.6	4.0	88.0
	7.33	1	3.6	4.0	92.0
	10.90	1	3.6	4.0	96.0
	14.79	1	3.6	4.0	100.0
	.	3	10.7	Missing	
	Total	28	100.0	100.0	
Valid cases	25	Missing cases	3		

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FCE 20124/706 i

(9.2.2.1.3) HRCHG10 p.m.st.H.R.Chg.Dy1-2: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-15.52	1	3.6	3.7	3.7
	-12.11	1	3.6	3.7	7.4
	-9.82	1	3.6	3.7	11.1
	-8.14	1	3.6	3.7	14.8
	-7.85	1	3.6	3.7	18.5
	-6.00	1	3.6	3.7	22.2
	-3.78	1	3.6	3.7	25.9
	-3.50	1	3.6	3.7	29.6
	-2.23	1	3.6	3.7	33.3
	-1.00	1	3.6	3.7	37.0
	.64	1	3.6	3.7	40.7
	1.63	1	3.6	3.7	44.4
	1.70	1	3.6	3.7	48.1
	1.86	1	3.6	3.7	51.9
	3.62	1	3.6	3.7	55.6
	4.63	1	3.6	3.7	59.3
	4.71	1	3.6	3.7	63.0
	5.41	1	3.6	3.7	66.7
	6.69	1	3.6	3.7	70.4
	6.89	2	7.1	7.4	77.8
	7.33	1	3.6	3.7	81.5
	7.96	1	3.6	3.7	85.2
	9.81	1	3.6	3.7	88.9
	10.11	1	3.6	3.7	92.6
	13.47	1	3.6	3.7	96.3
	20.05	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases	27				
Missing cases	1				

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FCE 20124/706 i

(9.2.2.1.3) HRCHG10 p.m.st.H.R.Chg.Dy1-2: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-30.73	1	3.6	3.7	3.7
	-19.18	1	3.6	3.7	7.4
	-14.51	1	3.6	3.7	11.1
	-12.48	1	3.6	3.7	14.8
	-11.45	1	3.6	3.7	18.5
	-11.00	1	3.6	3.7	22.2
	-7.33	1	3.6	3.7	25.9
	-5.69	1	3.6	3.7	29.6
	-4.45	1	3.6	3.7	33.3
	-4.33	1	3.6	3.7	37.0
	-4.23	1	3.6	3.7	40.7
	-3.86	1	3.6	3.7	44.4
	-3.63	1	3.6	3.7	48.1
	-2.27	1	3.6	3.7	51.9
	-1.00	2	7.1	7.4	59.3
	.56	1	3.6	3.7	63.0
	1.41	1	3.6	3.7	66.7
	1.44	1	3.6	3.7	70.4
	2.17	1	3.6	3.7	74.1
	2.23	1	3.6	3.7	77.8
	3.11	1	3.6	3.7	81.5
	4.33	1	3.6	3.7	85.2
	5.10	1	3.6	3.7	88.9
	7.33	2	7.1	7.4	96.3
	16.95	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases		27			
Missing cases			1		

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FCE 20124/706 i

(9.2.2.1.3) HRCHG11 p.m.st.H.R.Chg.Dy1-3: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-23.58	1	3.6	3.7	3.7
	-14.24	1	3.6	3.7	7.4
	-12.43	1	3.6	3.7	11.1
	-9.89	1	3.6	3.7	14.8
	-9.20	1	3.6	3.7	18.5
	-6.26	1	3.6	3.7	22.2
	-5.17	1	3.6	3.7	25.9
	-3.86	1	3.6	3.7	29.6
	-2.85	1	3.6	3.7	33.3
	-2.37	1	3.6	3.7	37.0
	-1.00	4	14.3	14.8	51.9
	.43	1	3.6	3.7	55.6
	1.70	1	3.6	3.7	59.3
	1.82	1	3.6	3.7	63.0
	2.85	1	3.6	3.7	66.7
	3.62	1	3.6	3.7	70.4
	4.26	1	3.6	3.7	74.1
	5.67	1	3.6	3.7	77.8
	6.41	1	3.6	3.7	81.5
	6.69	1	3.6	3.7	85.2
	6.89	1	3.6	3.7	88.9
	7.33	1	3.6	3.7	92.6
	9.45	1	3.6	3.7	96.3
	14.79	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases	27				
Missing cases	1				

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(9.2.2.1.3) HRCHG11 p.m.st.H.R.Chg.Dy1-3: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-22.62	1	3.6	3.8	3.8
	-19.18	1	3.6	3.8	7.7
	-17.42	1	3.6	3.8	11.5
	-14.51	1	3.6	3.8	15.4
	-13.66	1	3.6	3.8	19.2
	-12.11	1	3.6	3.8	23.1
	-10.68	1	3.6	3.8	26.9
	-10.38	1	3.6	3.8	30.8
	-8.23	1	3.6	3.8	34.6
	-6.71	1	3.6	3.8	38.5
	-6.00	1	3.6	3.8	42.3
	-4.45	1	3.6	3.8	46.2
	-4.28	1	3.6	3.8	50.0
	-3.63	1	3.6	3.8	53.8
	-3.53	1	3.6	3.8	57.7
	-2.59	1	3.6	3.8	61.5
	-2.37	1	3.6	3.8	65.4
	-1.00	2	7.1	7.7	73.1
	.33	1	3.6	3.8	76.9
	.56	1	3.6	3.8	80.8
	1.38	1	3.6	3.8	84.6
	1.78	1	3.6	3.8	88.5
	2.66	1	3.6	3.8	92.3
	11.20	1	3.6	3.8	96.2
	16.95	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26				
Missing cases	2				

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FCE 20124/706 i

(9.2.2.1.3) HRCHG12 p.m.st.H.R.Chg.Dy1-4: RBX

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-23.58	1	3.6	3.8	3.8
	-18.65	1	3.6	3.8	7.7
	-15.29	2	7.1	7.7	15.4
	-12.48	1	3.6	3.8	19.2
	-12.11	1	3.6	3.8	23.1
	-6.26	1	3.6	3.8	26.9
	-5.11	1	3.6	3.8	30.8
	-2.85	1	3.6	3.8	34.6
	-1.00	1	3.6	3.8	38.5
	.23	1	3.6	3.8	42.3
	.35	1	3.6	3.8	46.2
	1.56	2	7.1	7.7	53.8
	1.78	1	3.6	3.8	57.7
	2.95	1	3.6	3.8	61.5
	3.23	1	3.6	3.8	65.4
	4.26	2	7.1	7.7	73.1
	4.71	1	3.6	3.8	76.9
	5.15	1	3.6	3.8	80.8
	6.50	1	3.6	3.8	84.6
	9.53	1	3.6	3.8	88.5
	9.83	1	3.6	3.8	92.3
	12.43	1	3.6	3.8	96.2
	12.89	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26				
Missing cases		2			

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FCE 20124/706 i

(9.2.2.1.3) HRCHG12 p.m.st.H.R.Chg.Dy1-4: PBO

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	-25.32	1	3.6	4.0	4.0
	-19.18	1	3.6	4.0	8.0
	-17.42	1	3.6	4.0	12.0
	-16.87	1	3.6	4.0	16.0
	-14.51	1	3.6	4.0	20.0
	-10.68	1	3.6	4.0	24.0
	-10.38	1	3.6	4.0	28.0
	-8.59	1	3.6	4.0	32.0
	-5.11	1	3.6	4.0	36.0
	-4.66	1	3.6	4.0	40.0
	-4.61	1	3.6	4.0	44.0
	-4.45	1	3.6	4.0	48.0
	-4.33	1	3.6	4.0	52.0
	-4.28	1	3.6	4.0	56.0
	-1.00	1	3.6	4.0	60.0
	1.63	1	3.6	4.0	64.0
	1.86	1	3.6	4.0	68.0
	2.13	1	3.6	4.0	72.0
	3.00	1	3.6	4.0	76.0
	3.76	1	3.6	4.0	80.0
	4.56	1	3.6	4.0	84.0
	6.32	1	3.6	4.0	88.0
	6.69	1	3.6	4.0	92.0
	7.86	1	3.6	4.0	96.0
	15.67	1	3.6	4.0	100.0
	.	3	10.7	Missing	
	Total	28	100.0	100.0	
Valid cases	25	Missing cases	3		

FCE 20124/706 i

(9.2.2.2.1) Summaries of T2MLSYS Day 0 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			122.1607	15.5864	56
DRUGRP	1		123.6071	13.7041	28
DRUGRP	2		120.7143	17.3991	28
Total Cases =					56

Summaries of T2MLSYS Day 0 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		123.6071	13.7041	5070.6786	28
2		120.7143	17.3991	8173.7143	28
Within Groups Total		122.1607	15.6610	13244.3929	56

Criterion Variable T2MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	117.1607	1	117.1607	.4777	.4924
Within Groups	13244.3929	54	245.2665		
Eta = .0936		Eta Squared = .0088			

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FCE 20124/706 i

(9.2.2.2.1) Summaries of T3MLSYS Day 1 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			123.6964	13.5471	56
DRUGRP	1		125.1429	12.3430	28
DRUGRP	2		122.2500	14.7363	28
Total Cases =		56			

Summaries of T3MLSYS Day 1 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		125.1429	12.3430	4113.4286	28
2		122.2500	14.7363	5863.2500	28
Within Groups Total		123.6964	13.5924	9976.6786	56

Criterion Variable T3MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	117.1607	1	117.1607	.6341	.4293
Within Groups	9976.6786	54	184.7533		
Eta = .1077		Eta Squared = .0116			

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(9.2.2.2.1) Summaries of T4MLSYS Day 2 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			123.9643	14.1896	56
DRUGRP	1		124.7857	12.5738	28
DRUGRP	2		123.1429	15.8318	28
Total Cases =					56

Summaries of T4MLSYS Day 2 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		124.7857	12.5738	4268.7143	28
2		123.1429	15.8318	6767.4286	28
Within Groups Total		123.9643	14.2959	11036.1429	56

Criterion Variable T4MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	37.7857	1	37.7857	.1849	.6689
Within Groups	11036.1429	54	204.3730		
Eta = .0584		Eta Squared = .0034			

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(9.2.2.2.1) Summaries of T5MLSYS Day 3 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		124.7321	13.7807	56
DRUGRP	1	125.2143	11.4838	28
DRUGRP	2	124.2500	15.9528	28
Total Cases = 56				

Summaries of T5MLSYS Day 3 A.M. Ly.Sys.
By Levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	125.2143	11.4838	3560.7143	28
2	124.2500	15.9528	6871.2500	28

Within Groups Total	124.7321	13.8991	10431.9643	56

Criterion Variable T5MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	13.0179	1	13.0179	.0674	.7962
Within Groups	10431.9643	54	193.1845		
Eta = .0353 Eta Squared = .0012					

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FCE 20124/706 i

(9.2.2.2.1) Summaries of T6MLSYS Day 4 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			122.6296	10.9670	54
DRUGRP	1		123.8929	11.8301	28
DRUGRP	2		121.2692	10.0062	26
Total Cases = 56					
Missing Cases = 2 OR 3.6 PCT.					

Summaries of T6MLSYS Day 4 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		123.8929	11.8301	3778.6786	28
2		121.2692	10.0062	2503.1154	26

Within Groups Total		122.6296	10.9911	6281.7940	54

Criterion Variable T6MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	92.7986	1	92.7986	.7682	.3848
Within Groups	6281.7940	52	120.8037		
Eta = .1207 Eta Squared = .0146					

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853

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(9.2.2.2.1) Summaries of T7MLSYS Day 5 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			120.9038	8.4720	52
DRUGRP	1		122.3704	9.8103	27
DRUGRP	2		119.3200	6.5747	25
Total Cases = 56					
Missing Cases = 4 OR 7.1 PCT.					

Summaries of T7MLSYS Day 5 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		122.3704	9.8103	2502.2963	27
2		119.3200	6.5747	1037.4400	25

Within Groups Total		120.9038	8.4140	3539.7363	52

Criterion Variable T7MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	120.7829	1	120.7829	1.7061	.1975
Within Groups	3539.7363	50	70.7947		
Eta = .1816 Eta Squared = .0330					

1381

854

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(9.2.2.2.1) Summaries of T8MLSYS Day 6 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			121.5094	11.2705	53
DRUGRP	1		123.5926	12.8580	27
DRUGRP	2		119.3462	9.0948	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T8MLSYS Day 6 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		123.5926	12.8580	4298.5185	27
2		119.3462	9.0948	2067.8846	26

Within Groups Total		121.5094	11.1728	6366.4031	53

Criterion Variable T8MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	238.8421	1	238.8421	1.9133	.1726
Within Groups	6366.4031	51	124.8314		
Eta = .1902 Eta Squared = .0362					

1382

855

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(9.2.2.2.1) Summaries of T9MLSYS Day 7 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			121.3091	11.8757	55
DRUGRP	1		122.8571	14.1963	28
DRUGRP	2		119.7037	8.8527	27
Total Cases = 56					
Missing Cases = 1 OR 1.8 PCT.					

Summaries of T9MLSYS Day 7 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		122.8571	14.1963	5441.4286	28
2		119.7037	8.8527	2037.6296	27

Within Groups Total		121.3091	11.8792	7479.0582	55

Criterion Variable T9MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	136.6873	1	136.6873	.9686	.3295
Within Groups	7479.0582	53	141.1143		
Eta = .1340		Eta Squared = .0179			

1383

856

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(9.2.2.2.1) Summaries of T10MLSYS Day 10 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			120.4906	10.3749	53
DRUGRP	1		120.4074	10.0164	27
DRUGRP	2		120.5769	10.9332	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T10MLSYS Day 10 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		120.4074	10.0164	2608.5185	27
2		120.5769	10.9332	2988.3462	26

Within Groups Total		120.4906	10.4758	5596.8647	53

Criterion Variable T10MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.3806	1	.3806	.0035	.9533
Within Groups	5596.8647	51	109.7424		
Eta = .0082 Eta Squared = .0001					

1384

857

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(9.2.2.2.1) Summaries of T11MLSYS Day 14 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			121.4717	11.3555	53
DRUGRP	1		122.8148	12.4747	27
DRUGRP	2		120.0769	10.1190	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T11MLSYS Day 14 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		122.8148	12.4747	4046.0741	27
2		120.0769	10.1190	2559.8462	26

Within Groups Total		121.4717	11.3810	6605.9202	53

Criterion Variable T11MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	99.2873	1	99.2873	.7665	.3854
Within Groups	6605.9202	51	129.5278		
Eta = .1217 Eta Squared = .0148					

1385

858

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(9.2.2.2.1) Summaries of T12MLSYS Day 21 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			121.6600	10.8602	50
DRUGRP	1		123.0000	11.8491	26
DRUGRP	2		120.2083	9.7177	24
Total Cases = 56					
Missing Cases = 6 OR 10.7 PCT.					

Summaries of T12MLSYS Day 21 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		123.0000	11.8491	3510.0000	26
2		120.2083	9.7177	2171.9583	24

Within Groups Total		121.6600	10.8800	5681.9583	50

Criterion Variable T12MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	97.2617	1	97.2617	.8216	.3692
Within Groups	5681.9583	48	118.3741		
Eta = .1297 Eta Squared = .0168					

1386

859

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(9.2.2.2.1) Summaries of T13MLSYS Day 28 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		121.9429	11.0079	35
DRUGRP	1	122.4400	12.4401	25
DRUGRP	2	120.7000	6.5328	10
Total Cases = 56				
Missing Cases = 21 OR 37.5 PCT.				

Summaries of T13MLSYS Day 28 A.M. Ly.Sys.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	122.4400	12.4401	3714.1600	25
2	120.7000	6.5328	384.1000	10

Within Groups Total	121.9429	11.1440	4098.2600	35

Criterion Variable T13MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	21.6257	1	21.6257	.1741	.6792
Within Groups	4098.2600	33	124.1897		
Eta = .0725 Eta Squared = .0052					

1387

860

FILE: 20124/2009 i

(9.2.2.2.1) Summaries of T14MLSYS Day 35 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			121.5938	10.3015	32
DRUGRP	1		122.5455	11.5541	22
DRUGRP	2		119.5000	6.8516	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T14MLSYS Day 35 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		122.5455	11.5541	2803.4545	22
2		119.5000	6.8516	422.5000	10

Within Groups Total		121.5938	10.3698	3225.9545	32

Criterion Variable T14MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	63.7642	1	63.7642	.5930	.4473
Within Groups	3225.9545	30	107.5318		
Eta = .1392		Eta Squared = .0194			

1388

861

POB 20124/706 i

(9.2.2.2.1) Summaries of T15MLSYS Day 42 A.M. Ly.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			122.0313	9.0178	32
DRUGRP	1		122.1364	9.5334	22
DRUGRP	2		121.8000	8.2435	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T15MLSYS Day 42 A.M. Ly.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		122.1364	9.5334	1908.5909	22
2		121.8000	8.2435	611.6000	10

Within Groups Total		122.0313	9.1655	2520.1909	32

Criterion Variable T15MLSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.7778	1	.7778	.0093	.9240
Within Groups	2520.1909	30	84.0064		
Eta = .0176 Eta Squared = .0003					

1388

862

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(9.2.2.2.1) * * A N A L Y S I S O F V A R I A N C E * * *

T15MLSYS Day 42 A.M. Ly.Sys.
 BY DRUGRP
 WITH T2MLSYS Day 0 A.M. Ly.Sys.

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	1409.417	1	1409.417	39.165	.000
T2MLSYS	1409.417	1	1409.417	39.165	.000
Main Effects	67.939	1	67.939	1.888	.180
DRUGRP	67.939	1	67.939	1.888	.180
Explained	1477.356	2	738.678	20.526	.000
Residual	1043.613	29	35.987		
Total	2520.969	31	81.322		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1390

863

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(9.2.2.2.2) Summaries of T2MSSYS Day 0 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			120.0179	14.7728	56
DRUGRP	1		121.3214	12.8411	28
DRUGRP	2		118.7143	16.6174	28
Total Cases =		56			

Summaries of T2MSSYS Day 0 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		121.3214	12.8411	4452.1071	28
2		118.7143	16.6174	7455.7143	28
Within Groups Total		120.0179	14.8498	11907.8214	56

Criterion Variable T2MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	95.1607	1	95.1607	.4315	.5140
Within Groups	11907.8214	54	220.5152		
Eta = .0890		Eta Squared = .0079			

1391

864

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(9.2.2.2.2) Summaries of T3MSSYS Day 1 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			120.3273	12.2188	55
DRUGRP	1		121.4286	12.0537	28
DRUGRP	2		119.1852	12.5116	27
Total Cases = 56					
Missing Cases = 1 OR 1.8 PCT.					

Summaries of T3MSSYS Day 1 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		121.4286	12.0537	3922.8571	28
2		119.1852	12.5116	4070.0741	27

Within Groups Total		120.3273	12.2805	7992.9312	55

Criterion Variable T3MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	69.1779	1	69.1779	.4587	.5012
Within Groups	7992.9312	53	150.8100		
Eta = .0926 Eta Squared = .0086					

1392

865

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(9.2.2.2.2) Summaries of T4MSSYS Day 2 A.M. St.Sys.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		119.5000	14.0376	56
DRUGRP	1	118.3571	12.8617	28
DRUGRP	2	120.6429	15.2733	28
Total Cases =	56			

Summaries of T4MSSYS Day 2 A.M. St.Sys.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	118.3571	12.8617	4466.4286	28
2	120.6429	15.2733	6298.4286	28
Within Groups Total	119.5000	14.1191	10764.8571	56

Criterion Variable T4MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	73.1429	1	73.1429	.3669	.5472
Within Groups	10764.8571	54	199.3492		
Eta = .0822		Eta Squared = .0067			

1393

866

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(9.2.2.2.2) Summaries of T5MSSYS Day 3 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			118.7500	12.5398	56
DRUGRP	1		116.2500	12.1156	28
DRUGRP	2		121.2500	12.6714	28
Total Cases =		56			

Summaries of T5MSSYS Day 3 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		116.2500	12.1156	3963.2500	28
2		121.2500	12.6714	4335.2500	28

Within Groups Total		118.7500	12.3966	8298.5000	56

Criterion Variable T5MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	350.0000	1	350.0000	2.2775	.1371
Within Groups	8298.5000	54	153.6759		

Eta = .2012 Eta Squared = .0405

1394

867

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(9.2.2.2.2) Summaries of T6MSSYS Day 4 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			117.5370	10.2602	54
DRUGRP	1		116.2857	8.6746	28
DRUGRP	2		118.8846	11.7587	26
Total Cases = 56					
Missing Cases = 2 OR 3.6 PCT.					

Summaries of T6MSSYS Day 4 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		116.2857	8.6746	2031.7143	28
2		118.8846	11.7587	3456.6538	26

Within Groups Total		117.5370	10.2735	5488.3681	54

Criterion Variable T6MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	91.0578	1	91.0578	.8627	.3573
Within Groups	5488.3681	52	105.5455		
Eta = .1278 Eta Squared = .0163					

1395

868

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(9.2.2.2.2) Summaries of T7MSSYS Day 5 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			115.8077	8.9903	52
DRUGRP	1		115.2222	10.1502	27
DRUGRP	2		116.4400	7.7032	25
Total Cases = 56					
Missing Cases = 4 OR 7.1 PCT.					

Summaries of T7MSSYS Day 5 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		115.2222	10.1502	2678.6667	27
2		116.4400	7.7032	1424.1600	25

Within Groups Total		115.8077	9.0585	4102.8267	52

Criterion Variable T7MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	19.2503	1	.19.2503	.2346	.6303
Within Groups	4102.8267	50	82.0565		
Eta = .0683		Eta Squared = .0047			

1396

869

FCE 20124/706 i

(9.2.2.2.2) Summaries of T8MSSYS Day 6 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			116.9615	11.2598	52
DRUGRP	1		115.1852	12.2004	27
DRUGRP	2		118.8800	10.0388	25
Total Cases = 56					
Missing Cases = 4 OR 7.1 PCT.					

Summaries of T8MSSYS Day 6 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		115.1852	12.2004	3870.0741	27
2		118.8800	10.0388	2418.6400	25

Within Groups Total		116.9615	11.2149	6288.7141	52

Criterion Variable T8MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	177.2090	1	177.2090	1.4089	.2408
Within Groups	6288.7141	50	125.7743		
Eta = .1655 Eta Squared = .0274					

1387

870

FCE 20124/706 i

(9.2.2.2.2) Summaries of T9MSSYS Day 7 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			116.3519	11.6443	54
DRUGRP	1		114.8571	12.4088	28
DRUGRP	2		117.9615	10.7684	26
Total Cases = 56					
Missing Cases = 2 OR 3.6 PCT.					

Summaries of T9MSSYS Day 7 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		114.8571	12.4088	4157.4286	28
2		117.9615	10.7684	2898.9615	26

Within Groups Total		116.3519	11.6490	7056.3901	54

Criterion Variable T9MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	129.9247	1	129.9247	.9574	.3324
Within Groups	7056.3901	52	135.6998		
Eta = .1345 Eta Squared = .0181					

1398

871

FCE 20124/706 i

(9.2.2.2.2) Summaries of T10MSSYS Day 10 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			115.6792	10.2371	53
DRUGRP	1		114.4444	9.8384	27
DRUGRP	2		116.9615	10.6751	26
Total Cases =	56				
Missing Cases =	3 OR	5.4 PCT.			

Summaries of T10MSSYS Day 10 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		114.4444	9.8384	2516.6667	27
2		116.9615	10.6751	2848.9615	26
Within Groups Total		115.6792	10.2571	5365.6282	53

Criterion Variable T10MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	83.9190	1	83.9190	.7976	.3760
Within Groups	5365.6282	51	105.2084		
Eta = .1241		Eta Squared = .0154			

1399

872

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(9.2.2.2.2) Summaries of T11MSSYS Day 14 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			117.6792	10.7949	53
DRUGRP	1		116.4444	11.5969	27
DRUGRP	2		118.9615	9.9578	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T11MSSYS Day 14 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		116.4444	11.5969	3496.6667	27
2		118.9615	9.9578	2478.9615	26

Within Groups Total		117.6792	10.8245	5975.6282	53

Criterion Variable T11MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	83.9190	1	83.9190	.7162	.4013
Within Groups	5975.6282	51	117.1692		
Eta = .1177 Eta Squared = .0138					

1400

873

FCE 20124/706 i

(9.2.2.2.2) Summaries of T12MSSYS Day 21 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			117.0200	10.1890	50
DRUGRP	1		115.6154	11.3034	26
DRUGRP	2		118.5417	8.8119	24
Total Cases = 56					
Missing Cases = 6 OR 10.7 PCT.					

Summaries of T12MSSYS Day 21 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		115.6154	11.3034	3194.1538	26
2		118.5417	8.8119	1785.9583	24

Within Groups Total		117.0200	10.1859	4980.1122	50

Criterion Variable T12MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	106.8678	1	106.8678	1.0300	.3152
Within Groups	4980.1122	48	103.7523		
Eta = .1449 Eta Squared = .0210					

1401

874

FCE 20124/706 i

(9.2.2.2.2) Summaries of T13MSSYS Day 28 A.M. St.Sys.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		116.2571	9.9657	35
DRUGRP	1	115.8400	11.3750	25
DRUGRP	2	117.3000	5.3344	10
Total Cases = 56				
Missing Cases = 21 OR 37.5 PCT.				

Summaries of T13MSSYS Day 28 A.M. St.Sys.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	115.8400	11.3750	3105.3600	25
2	117.3000	5.3344	256.1000	10

Within Groups Total	116.2571	10.0927	3361.4600	35

Criterion Variable T13MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15.2257	1	15.2257	.1495	.7015
Within Groups	3361.4600	33	101.8624		
Eta = .0671 Eta Squared = .0045					

1402

875

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(9.2.2.2.2) Summaries of T14MSSYS Day 35 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			115.3125	7.8224	32
DRUGRP	1		115.2273	7.4765	22
DRUGRP	2		115.5000	8.9598	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T14MSSYS Day 35 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		115.2273	7.4765	1173.8636	22
2		115.5000	8.9598	722.5000	10

Within Groups Total		115.3125	7.9506	1896.3636	32

Criterion Variable T14MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.5114	1	.5114	.0081	.9289
Within Groups	1896.3636	30	63.2121		
Eta = .0164 Eta Squared = .0003					

1403

876

FCE 20124/706 i

(9.2.2.2.2) Summaries of T15MSSYS Day 42 A.M. St.Sys.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			117.1563	11.1619	32
DRUGRP	1		116.7727	11.7349	22
DRUGRP	2		118.0000	10.3280	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T15MSSYS Day 42 A.M. St.Sys.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		116.7727	11.7349	2891.8636	22
2		118.0000	10.3280	960.0000	10

Within Groups Total		117.1563	11.3312	3851.8636	32

Criterion Variable T15MSSYS

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	10.3551	1	10.3551	.0807	.7784
Within Groups	3851.8636	30	128.3955		
Eta = .0518 Eta Squared = .0027					

1404

877

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(9.2.2.2.2) * * A N A L Y S I S O F V A R I A N C E * * *

T15MSSYS Day 42 A.M. St.Sys.
 BY DRUGRP
 WITH T2MSSYS Day 0 A.M. St.Sys.

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	1728.376	1	1728.376	25.816	.000
T2MSSYS	1728.376	1	1728.376	25.816	.000
Main Effects	192.267	1	192.267	2.872	.101
DRUGRP	192.267	1	192.267	2.872	.101
Explained	1920.643	2	960.321	14.344	.000
Residual	1941.576	29	66.951		
Total	3862.219	31	124.588		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1405

873

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(9.2.2.2.3) Summaries of T2MLDIA Day 0 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			77.2321	9.8756	56
DRUGRP	1		78.8571	10.6309	28
DRUGRP	2		75.6071	8.9540	28
Total Cases =		56			

Summaries of T2MLDIA Day 0 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		78.8571	10.6309	3051.4286	28
2		75.6071	8.9540	2164.6786	28

Within Groups Total		77.2321	9.8283	5216.1071	56

Criterion Variable T2MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	147.8750	1	147.8750	1.5309	.2213
Within Groups	5216.1071	54	96.5946		
Eta = .1660					Eta Squared = .0276

1406

879

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(9.2.2.2.3) Summaries of T3MLDIA Day 1 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			78.5893	8.9010	56
DRUGRP	1		78.7500	10.3553	28
DRUGRP	2		78.4286	7.3557	28
Total Cases =		56			

Summaries of T3MLDIA Day 1 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		78.7500	10.3553	2895.2500	28
2		78.4286	7.3557	1460.8571	28
Within Groups Total		78.5893	8.9816	4356.1071	56

Criterion Variable T3MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.4464	1	1.4464	.0179	.8940
Within Groups	4356.1071	54	80.6687		
Eta = .0182		Eta Squared = .0003			

1407

380

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(9.2.2.2.3) Summaries of T4MLDIA Day 2 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			78.3571	9.4473	56
DRUGRP	1		78.9286	10.9068	28
DRUGRP	2		77.7857	7.8851	28
Total Cases =		56			

Summaries of T4MLDIA Day 2 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		78.9286	10.9068	3211.8571	28
2		77.7857	7.8851	1678.7143	28
Within Groups Total		78.3571	9.5166	4890.5714	56

Criterion Variable T4MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	18.2857	1	18.2857	.2019	.6550
Within Groups	4890.5714	54	90.5661		
Eta = .0610		Eta Squared = .0037			

1408

881

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(9.2.2.2.3) Summaries of T5MLDIA Day 3 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		77.5179	9.7812	56
DRUGRP	1	78.3929	10.8469	28
DRUGRP	2	76.6429	8.6974	28
Total Cases = 56				

Summaries of T5MLDIA Day 3 A.M. Ly.Dia.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	78.3929	10.8469	3176.6786	28
2	76.6429	8.6974	2042.4286	28

Within Groups Total	77.5179	9.8311	5219.1071	56

Criterion Variable T5MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	42.8750	1	42.8750	.4436	.5082
Within Groups	5219.1071	54	96.6501		
Eta = .0903 Eta Squared = .0081					

1409

882

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(9.2.2.2.3) Summaries of T6MLDIA Day 4 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			78.9074	9.8790	54
DRUGRP	1		80.1071	11.7074	28
DRUGRP	2		77.6154	7.4516	26
Total Cases =	56				
Missing Cases =	2 OR	3.6 PCT.			

Summaries of T6MLDIA Day 4 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		80.1071	11.7074	3700.6786	28
2		77.6154	7.4516	1388.1538	26

Within Groups Total		78.9074	9.8925	5088.8324	54

Criterion Variable T6MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	83.7046	1	83.7046	.8553	.3593
Within Groups	5088.8324	52	97.8622		
Eta = .1272 Eta Squared = .0162					

1410

883

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(9.2.2.2.3) Summaries of T7MLDIA Day 5 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			78.0385	8.3689	52
DRUGRP	1		79.4815	9.5086	27
DRUGRP	2		76.4800	6.7831	25
Total Cases = 56					
Missing Cases = 4 OR 7.1 PCT.					

Summaries of T7MLDIA Day 5 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		79.4815	9.5086	2350.7407	27
2		76.4800	6.7831	1104.2400	25

Within Groups Total		78.0385	8.3126	3454.9807	52

Criterion Variable T7MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	116.9423	1	116.9423	1.6924	.1993
Within Groups	3454.9807	50	69.0996		
Eta = .1809 Eta Squared = .0327					

1411

884

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(9.2.2.2.3) Summaries of T8MLDIA Day 6 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			77.3208	9.0973	53
DRUGRP	1		78.7037	9.4658	27
DRUGRP	2		75.8846	8.6456	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T8MLDIA Day 6 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		78.7037	9.4658	2329.6296	27
2		75.8846	8.6456	1868.6538	26

Within Groups Total		77.3208	9.0730	4198.2835	53

Criterion Variable T8MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	105.2637	1	105.2637	1.2787	.2634
Within Groups	4198.2835	51	82.3193		
Eta = .1564 Eta Squared = .0245					

1412

885

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(9.2.2.2.3) Summaries of T9MLDIA Day 7 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			75.6545	9.0579	55
DRUGRP	1		76.8571	10.1497	28
DRUGRP	2		74.4074	7.7621	27
Total Cases = 56					
Missing Cases = 1 OR 1.8 PCT.					

Summaries of T9MLDIA Day 7 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		76.8571	10.1497	2781.4286	28
2		74.4074	7.7621	1566.5185	27

Within Groups Total		75.6545	9.0574	4347.9471	55

Criterion Variable T9MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	82.4893	1	82.4893	1.0055	.3205
Within Groups	4347.9471	53	82.0367		
Eta = .1365 Eta Squared = .0186					

1413

886

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(9.2.2.2.3) Summaries of T10MLDIA Day 10 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			77.2075	8.1414	53
DRUGRP	1		77.7778	9.7323	27
DRUGRP	2		76.6154	6.2166	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T10MLDIA Day 10 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		77.7778	9.7323	2462.6667	27
2		76.6154	6.2166	966.1538	26

Within Groups Total		77.2075	8.1995	3428.8205	53

Criterion Variable T10MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	17.8965	1	17.8965	.2662	.6081
Within Groups	3428.8205	51	67.2318		
Eta = .0721		Eta Squared = .0052			

1414

887

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(9.2.2.2.3) Summaries of T11MLDIA Day 14 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		76.5660	8.9260	53
DRUGRP	1	76.7407	10.5670	27
DRUGRP	2	76.3846	7.0375	26
Total Cases = 56				
Missing Cases = 3 OR 5.4 PCT.				

Summaries of T11MLDIA Day 14 A.M. Ly.Dia.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	76.7407	10.5670	2903.1852	27
2	76.3846	7.0375	1238.1538	26

Within Groups Total	76.5660	9.0113	4141.3390	53

Criterion Variable T11MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.6798	1	1.6798	.0207	.8862
Within Groups	4141.3390	51	81.2027		
Eta = .0201 Eta Squared = .0004					

1415

888

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(9.2.2.2.3) Summaries of T12MLDIA Day 21 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			78.0600	7.4681	50
DRUGRP	1		79.0000	8.9532	26
DRUGRP	2		77.0417	5.4412	24
Total Cases =		56			
Missing Cases =		6 OR	10.7 PCT.		

Summaries of T12MLDIA Day 21 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		79.0000	8.9532	2004.0000	26
2		77.0417	5.4412	680.9583	24
Within Groups Total		78.0600	7.4791	2684.9583	50

Criterion Variable T12MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	47.8617	1	47.8617	.8556	.3596
Within Groups	2684.9583	48	55.9366		
Eta = .1323		Eta Squared = .0175			

1416

389

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(9.2.2.2.3) Summaries of T13MLDIA Day 28 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			79.0857	9.0403	35
DRUGRP	1		79.2800	9.6804	25
DRUGRP	2		78.6000	7.6478	10
Total Cases = 56					
Missing Cases = 21 OR 37.5 PCT.					

Summaries of T13MLDIA Day 28 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		79.2800	9.6804	2249.0400	25
2		78.6000	7.6478	526.4000	10

Within Groups Total		79.0857	9.1708	2775.4400	35

Criterion Variable T13MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.3029	1	3.3029	.0393	.8441
Within Groups	2775.4400	33	84.1042		
Eta = .0345 Eta Squared = .0012					

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(9.2.2.2.3) Summaries of T14MLDIA Day 35 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			79.5313	7.6664	32
DRUGRP	1		79.6818	7.4090	22
DRUGRP	2		79.2000	8.6127	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T14MLDIA Day 35 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		79.6818	7.4090	1152.7727	22
2		79.2000	8.6127	667.6000	10

Within Groups Total		79.5313	7.7897	1820.3727	32

Criterion Variable T14MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.5960	1	1.5960	.0263	.8723
Within Groups	1820.3727	30	60.6791		
Eta = .0296		Eta Squared = .0009			

1418

891

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(9.2.2.2.3) Summaries of T15MLDIA Day 42 A.M. Ly.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			78.3438	8.5595	32
DRUGRP	1		78.9545	8.9575	22
DRUGRP	2		77.0000	7.8881	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T15MLDIA Day 42 A.M. Ly.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		78.9545	8.9575	1684.9545	22
2		77.0000	7.8881	560.0000	10

Within Groups Total		78.3438	8.6505	2244.9545	32

Criterion Variable T15MLDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	26.2642	1	26.2642	.3510	.5580
Within Groups	2244.9545	30	74.8318		
Eta = .1075		Eta Squared = .0116			

1419

892

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(9.2.2.2.3) * * A N A L Y S I S O F V A R I A N C E * * *

T15MLDIA Day 42 A.M. Ly.Dia.
 BY DRUGRP
 WITH T2MLDIA Day 0 A.M. Ly.Dia.

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	1398.209	1	1398.209	47.286	.000
T2MLDIA	1398.209	1	1398.209	47.286	.000
Main Effects	15.507	1	15.507	.524	.475
DRUGRP	15.507	1	15.507	.524	.475
Explained	1413.715	2	706.858	23.905	.000
Residual	857.503	29	29.569		
Total	2271.219	31	73.265		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1420

893

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(9.2.2.2.4) Summaries of T2MSDIA Day 0 A.M. St.Dia.
By Levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		75.4821	10.2283	56
DRUGRP	1	76.1429	10.9094	28
DRUGRP	2	74.8214	9.6535	28
Total Cases =				56

Summaries of T2MSDIA Day 0 A.M. St.Dia.
By Levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	76.1429	10.9094	3213.4286	28
2	74.8214	9.6535	2516.1071	28

Within Groups Total	75.4821	10.3006	5729.5357	56

Criterion Variable T2MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	24.4464	1	24.4464	.2304	.6332
Within Groups	5729.5357	54	106.1025		
Eta = .0652		Eta Squared = .0042			

1421

894

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(9.2.2.2.4) Summaries of T3MSDIA Day 1 A.M. St.Dia.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		76.3818	9.8967	55
DRUGRP	1	75.8571	10.2802	28
DRUGRP	2	76.9259	9.6473	27
Total Cases = 56				
Missing Cases = 1 OR 1.8 PCT.				

Summaries of T3MSDIA Day 1 A.M. St.Dia.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	75.8571	10.2802	2853.4286	28
2	76.9259	9.6473	2419.8519	27

Within Groups Total	76.3818	9.9748	5273.2804	55

Criterion Variable T3MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15.7014	1	15.7014	.1578	.6928
Within Groups	5273.2804	53	99.4959		
Eta = .0545 Eta Squared = .0030					

1422

895

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(9.2.2.2.4) Summaries of T4MSDIA Day 2 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			77.1250	9.9564	56
DRUGRP	1		76.5357	10.1379	28
DRUGRP	2		77.7143	9.9214	28
Total Cases =		56			

Summaries of T4MSDIA Day 2 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		76.5357	10.1379	2774.9643	28
2		77.7143	9.9214	2657.7143	28

Within Groups Total		77.1250	10.0302	5432.6786	56

Criterion Variable T4MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	19.4464	1	19.4464	.1933	.6619
Within Groups	5432.6786	54	100.6052		
Eta = .0597		Eta Squared = .0036			

1423

896

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(9.2.2.2.4) Summaries of T5MSDIA Day 3 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			75.5179	9.2991	56
DRUGRP	1		74.2500	10.0871	28
DRUGRP	2		76.7857	8.4299	28
Total Cases =		56			

Summaries of T5MSDIA Day 3 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		74.2500	10.0871	2747.2500	28
2		76.7857	8.4299	1918.7143	28
Within Groups Total		75.5179	9.2955	4665.9643	56

Criterion Variable T5MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	90.0179	1	90.0179	1.0418	.3120
Within Groups	4665.9643	54	86.4067		
Eta = .1376		Eta Squared = .0189			

1424

897

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(9.2.2.2.4) Summaries of T6MSDIA Day 4 A.M. St.Dia.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		74.7963	10.1002	54
DRUGRP	1	74.2143	11.4967	28
DRUGRP	2	75.4231	8.5284	26
Total Cases = 56				
Missing Cases = 2 OR 3.6 PCT.				

Summaries of T6MSDIA Day 4 A.M. St.Dia.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	74.2143	11.4967	3568.7143	28
2	75.4231	8.5284	1818.3462	26

Within Groups Total	74.7963	10.1783	5387.0604	54

Criterion Variable T6MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	19.6988	1	19.6988	.1901	.6646
Within Groups	5387.0604	52	103.5973		
Eta = .0604 Eta Squared = .0036					

1425

898

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(9.2.2.2.4) Summaries of T7MSDIA Day 5 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			75.3077	10.3138	52
DRUGRP	1		75.4815	12.5157	27
DRUGRP	2		75.1200	7.5018	25
Total Cases = 56					
Missing Cases = 4 OR 7.1 PCT.					

Summaries of T7MSDIA Day 5 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		75.4815	12.5157	4072.7407	27
2		75.1200	7.5018	1350.6400	25

Within Groups Total		75.3077	10.4148	5423.3807	52

Criterion Variable T7MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.6962	1	1.6962	.0156	.9010
Within Groups	5423.3807	50	108.4676		
Eta = .0177 Eta Squared = .0003					

1426

899

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(9.2.2.2.4) Summaries of T8MSDIA Day 6 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			74.8654	9.4683	52
DRUGRP	1		74.2593	10.8010	27
DRUGRP	2		75.5200	7.9536	25
Total Cases = 56					
Missing Cases = 4 OR 7.1 PCT.					

Summaries of T8MSDIA Day 6 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		74.2593	10.8010	3033.1852	27
2		75.5200	7.9536	1518.2400	25

Within Groups Total		74.8654	9.5409	4551.4252	52

Criterion Variable T8MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	20.6325	1	20.6325	.2267	.6361
Within Groups	4551.4252	50	91.0285		
Eta = .0672 Eta Squared = .0045					

1427

900

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(9.2.2.2.4) Summaries of T9MSDIA Day 7 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			75.0185	9.6280	54
DRUGRP	1		74.3214	9.7679	28
DRUGRP	2		75.7692	9.6096	26
Total Cases = 56					
Missing Cases = 2 OR 3.6 PCT.					

Summaries of T9MSDIA Day 7 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		74.3214	9.7679	2576.1071	28
2		75.7692	9.6096	2308.6154	26

Within Groups Total		75.0185	9.6921	4884.7225	54

Criterion Variable T9MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	28.2590	1	28.2590	.3008	.5857
Within Groups	4884.7225	52	93.9370		
Eta = .0758		Eta Squared = .0058			

1420

901

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(9.2.2.2.4) Summaries of T10MSDIA Day 10 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			74.7736	9.0907	53
DRUGRP	1		74.2963	9.7815	27
DRUGRP	2		75.2692	8.4785	26
Total Cases =	56				
Missing Cases =	3 OR	5.4 PCT.			

Summaries of T10MSDIA Day 10 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		74.2963	9.7815	2487.6296	27
2		75.2692	8.4785	1797.1154	26

Within Groups Total		74.7736	9.1659	4284.7450	53

Criterion Variable T10MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	12.5380	1	12.5380	.1492	.7009
Within Groups	4284.7450	51	84.0146		
Eta = .0540 Eta Squared = .0029					

1429

902

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(9.2.2.2.4) Summaries of T11MSDIA Day 14 A.M. St.Dia.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		74.3208	8.6018	53
DRUGRP	1	73.6296	8.2469	27
DRUGRP	2	75.0385	9.0619	26
Total Cases = 56				
Missing Cases = 3 OR 5.4 PCT.				

Summaries of T11MSDIA Day 14 A.M. St.Dia.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	73.6296	8.2469	1768.2963	27
2	75.0385	9.0619	2052.9615	26

Within Groups Total	74.3208	8.6560	3821.2578	53

Criterion Variable T11MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	26.2893	1	26.2893	.3509	.5562
Within Groups	3821.2578	51	74.9266		
Eta = .0827 Eta Squared = .0068					

1430

903

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(9.2.2.2.4) Summaries of T12MSDIA Day 21 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			75.4200	8.8065	50
DRUGRP	1		75.6538	9.3550	26
DRUGRP	2		75.1667	8.3649	24
Total Cases = 56					
Missing Cases = 6 OR 10.7 PCT.					

Summaries of T12MSDIA Day 21 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		75.6538	9.3550	2187.8846	26
2		75.1667	8.3649	1609.3333	24

Within Groups Total		75.4200	8.8943	3797.2179	50

Criterion Variable T12MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.9621	1	2.9621	.0374	.8474
Within Groups	3797.2179	48	79.1087		
Eta = .0279 Eta Squared = .0008					

1431

904

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(9.2.2.2.4) Summaries of T13MSDIA Day 28 A.M. St.Dia.
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		75.5143	9.5066	35
DRUGRP	1	74.7200	10.7142	25
DRUGRP	2	77.5000	5.4006	10
Total Cases = 56				
Missing Cases = 21 OR 37.5 PCT.				

Summaries of T13MSDIA Day 28 A.M. St.Dia.
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	74.7200	10.7142	2755.0400	25
2	77.5000	5.4006	262.5000	10

Within Groups Total	75.5143	9.5625	3017.5400	35

Criterion Variable T13MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	55.2029	1	55.2029	.6037	.4427
Within Groups	3017.5400	33	91.4406		
Eta = .1340 Eta Squared = .0180					

1432

905

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(9.2.2.2.4) Summaries of T14MSDIA Day 35 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			75.8750	8.6239	32
DRUGRP	1		75.7727	9.2989	22
DRUGRP	2		76.1000	7.3704	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T14MSDIA Day 35 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		75.7727	9.2989	1815.8636	22
2		76.1000	7.3704	488.9000	10

Within Groups Total		75.8750	8.7650	2304.7636	32

Criterion Variable T14MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.7364	1	.7364	.0096	.9227
Within Groups	2304.7636	30	76.8255		
Eta = .0179 Eta Squared = .0003					

1433

906

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(9.2.2.2.4) Summaries of T15MSDIA Day 42 A.M. St.Dia.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			74.4375	10.9602	32
DRUGRP	1		73.6364	12.3618	22
DRUGRP	2		76.2000	7.2234	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T15MSDIA Day 42 A.M. St.Dia.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		73.6364	12.3618	3209.0909	22
2		76.2000	7.2234	469.6000	10

Within Groups Total		74.4375	11.0735	3678.6909	32

Criterion Variable T15MSDIA

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	45.1841	1	45.1841	.3685	.5484
Within Groups	3678.6909	30	122.6230		
Eta = .1102 Eta Squared = .0121					

1434

907

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(9.2.2.2.4) * * A N A L Y S I S O F V A R I A N C E * * *

T15MSDIA Day 42 A.M. St.Dia.
 BY DRUGRP
 WITH T2MSDIA Day 0 A.M. St.Dia.

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2017.347	1	2017.347	36.452	.000
T2MSDIA	2017.347	1	2017.347	36.452	.000
Main Effects	101.606	1	101.606	1.836	.186
DRUGRP	101.606	1	101.606	1.836	.186
Explained	2118.954	2	1059.477	19.144	.000
Residual	1604.921	29	55.342		
Total	3723.875	31	120.125		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1435

908

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(9.2.2.2.5) Summaries of T2MLHR Day 0 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			74.7679	12.3303	56
DRUGRP	1		74.8571	13.4790	28
DRUGRP	2		74.6786	11.3139	28
Total Cases =		56			

Summaries of T2MLHR Day 0 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		74.8571	13.4790	4905.4286	28
2		74.6786	11.3139	3456.1071	28

Within Groups Total		74.7679	12.4436	8361.5357	56

Criterion Variable T2MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.4464	1	.4464	.0029	.9574
Within Groups	8361.5357	54	154.8433		
Eta = .0073 Eta Squared = .0001					

1436

909

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(9.2.2.2.5) Summaries of T3MLHR Day 1 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			74.9286	14.1458	56
DRUGRP	1		74.3929	10.9759	28
DRUGRP	2		75.4643	16.9279	28
Total Cases =		56			

Summaries of T3MLHR Day 1 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		74.3929	10.9759	3252.6786	28
2		75.4643	16.9279	7736.9643	28
Within Groups Total		74.9286	14.2658	10989.6429	56

Criterion Variable T3MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	16.0714	1	16.0714	.0790	.7798
Within Groups	10989.6429	54	203.5119		
Eta = .0382		Eta Squared = .0015			

1437

910

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(9.2.2.2.5) Summaries of T4MLHR Day 2 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			73.9643	10.4880	56
DRUGRP	1		74.1071	9.6661	28
DRUGRP	2		73.8214	11.4279	28
Total Cases =		56			

Summaries of T4MLHR Day 2 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		74.1071	9.6661	2522.6786	28
2		73.8214	11.4279	3526.1071	28

Within Groups Total		73.9643	10.5837	6048.7857	56

Criterion Variable T4MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.1429	1	1.1429	.0102	.9199
Within Groups	6048.7857	54	112.0146		

Eta = .0137 Eta Squared = .0002

1438

911

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(9.2.2.2.5) Summaries of T5MLHR Day 3 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			75.2500	11.7647	56
DRUGRP	1		75.1786	11.7853	28
DRUGRP	2		75.3214	11.9600	28
Total Cases =					56

Summaries of T5MLHR Day 3 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		75.1786	11.7853	3750.1071	28
2		75.3214	11.9600	3862.1071	28

Within Groups Total		75.2500	11.8729	7612.2143	56

Criterion Variable T5MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.2857	1	.2857	.0020	.9643
Within Groups	7612.2143	54	140.9669		
Eta = .0061		Eta Squared = .0000			

1439

912

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(9.2.2.2.5) Summaries of T6MLHR Day 4 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			75.7407	9.2720	54
DRUGRP	1		76.6429	10.5311	28
DRUGRP	2		74.7692	7.7836	26
Total Cases =		56			
Missing Cases =		2 OR	3.6 PCT.		

Summaries of T6MLHR Day 4 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		76.6429	10.5311	2994.4286	28
2		74.7692	7.7836	1514.6154	26

Within Groups Total		75.7407	9.3119	4509.0440	54

Criterion Variable T6MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	47.3264	1	47.3264	.5458	.4634
Within Groups	4509.0440	52	86.7124		
Eta = .1019 Eta Squared = .0104					

1440

913

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(9.2.2.2.5) Summaries of T7MLHR Day 5 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			74.0962	10.4492	52
DRUGRP	1		75.6667	10.6591	27
DRUGRP	2		72.4000	10.1571	25
Total Cases =	56				
Missing Cases =	4 OR	7.1 PCT.			

Summaries of T7MLHR Day 5 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		75.6667	10.6591	2954.0000	27
2		72.4000	10.1571	2476.0000	25

Within Groups Total		74.0962	10.4211	5430.0000	52

Criterion Variable T7MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	138.5192	1	138.5192	1.2755	.2641
Within Groups	5430.0000	50	108.6000		
Eta = .1577 Eta Squared = .0249					

1441

914

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(9.2.2.2.5) Summaries of T8MLHR Day 6 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			73.6226	10.1739	53
DRUGRP	1		74.6296	11.5730	27
DRUGRP	2		72.5769	8.5892	26
Total Cases =	56				
Missing Cases =	3 OR	5.4 PCT.			

Summaries of T8MLHR Day 6 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		74.6296	11.5730	3482.2963	27
2		72.5769	8.5892	1844.3462	26

Within Groups Total		73.6226	10.2198	5326.6425	53

Criterion Variable T8MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	55.8104	1	55.8104	.5344	.4681
Within Groups	5326.6425	51	104.4440		
Eta = .1018 Eta Squared = .0104					

1442

915

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(9.2.2.2.5) Summaries of T9MLHR Day 7 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			73.5273	9.9272	55
DRUGRP	1		73.8214	11.2745	28
DRUGRP	2		73.2222	8.5139	27
Total Cases =		56			
Missing Cases =		1 OR	1.8 PCT.		

Summaries of T9MLHR Day 7 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		73.8214	11.2745	3432.1071	28
2		73.2222	8.5139	1884.6667	27

Within Groups Total		73.5273	10.0158	5316.7738	55

Criterion Variable T9MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.9353	1	4.9353	.0492	.8253
Within Groups	5316.7738	53	100.3165		
Eta = .0305		Eta Squared = .0009			

1443

916

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(9.2.2.2.5) Summaries of T10MLHR Day 10 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			72.6038	9.4061	53
DRUGRP	1		73.1111	10.3490	27
DRUGRP	2		72.0769	8.4896	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T10MLHR Day 10 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		73.1111	10.3490	2784.6667	27
2		72.0769	8.4896	1801.8462	26

Within Groups Total		72.6038	9.4832	4586.5128	53

Criterion Variable T10MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	14.1664	1	14.1664	.1575	.6931
Within Groups	4586.5128	51	89.9316		
Eta = .0555 Eta Squared = .0031					

1444

917

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(9.2.2.2.5) Summaries of T11MLHR Day 14 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			73.0943	8.3649	53
DRUGRP	1		73.8148	8.9573	27
DRUGRP	2		72.3462	7.8074	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T11MLHR Day 14 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		73.8148	8.9573	2086.0741	27
2		72.3462	7.8074	1523.8846	26

Within Groups Total		73.0943	8.4133	3609.9587	53

Criterion Variable T11MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	28.5696	1	28.5696	.4036	.5281
Within Groups	3609.9587	51	70.7835		
Eta = .0886		Eta Squared = .0079			

1445

918

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(9.2.2.2.5) Summaries of T12MLHR Day 21 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			72.1000	8.6597	50
DRUGRP	1		72.7692	8.6686	26
DRUGRP	2		71.3750	8.7765	24
Total Cases = 56					
Missing Cases = 6 OR 10.7 PCT.					

Summaries of T12MLHR Day 21 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		72.7692	8.6686	1878.6154	26
2		71.3750	8.7765	1771.6250	24

Within Groups Total		72.1000	8.7205	3650.2404	50

Criterion Variable T12MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	24.2596	1	24.2596	.3190	.5748
Within Groups	3650.2404	48	76.0467		
Eta = .0813 Eta Squared = .0066					

1446

919

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(9.2.2.2.5) Summaries of T13MLHR Day 28 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		73.5714	9.1661	35
DRUGRP	1	73.6400	9.0179	25
DRUGRP	2	73.4000	10.0244	10
Total Cases = 56				
Missing Cases = 21 OR 37.5 PCT.				

Summaries of T13MLHR Day 28 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	73.6400	9.0179	1951.7600	25
2	73.4000	10.0244	904.4000	10

Within Groups Total	73.5714	9.3032	2856.1600	35

Criterion Variable T13MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.4114	1	.4114	.0048	.9454
Within Groups	2856.1600	33	86.5503		
Eta = .0120 Eta Squared = .0001					

1447

920

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(9.2.2.2.5) Summaries of T14MLHR Day 35 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			72.5313	7.8205	32
DRUGRP	1		72.8636	8.2248	22
DRUGRP	2		71.8000	7.2080	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T14MLHR Day 35 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		72.8636	8.2248	1420.5909	22
2		71.8000	7.2080	467.6000	10

Within Groups Total		72.5313	7.9335	1888.1909	32

Criterion Variable T14MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	7.7778	1	7.7778	.1236	.7276
Within Groups	1888.1909	30	62.9397		
Eta = .0640		Eta Squared = .0041			

1448

921

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(9.2.2.2.5) Summaries of T15MLHR Day 42 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			72.8438	7.0898	32
DRUGRP	1		73.3182	7.1540	22
DRUGRP	2		71.8000	7.2080	10
Total Cases =	56				
Missing Cases =	24	OR 42.9 PCT.			

Summaries of T15MLHR Day 42 A.M. Ly.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		73.3182	7.1540	1074.7727	22
2		71.8000	7.2080	467.6000	10

Within Groups Total		72.8438	7.1702	1542.3727	32

Criterion Variable T15MLHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15.8460	1	15.8460	.3082	.5829
Within Groups	1542.3727	30	51.4124		
Eta = .1008		Eta Squared = .0102			

1449

922

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(9.2.2.2.5) ** ANALYSIS OF VARIANCE ***

T15MLHR Day 42 A.M. Ly.Hrt.Rate
 BY DRUGRP
 WITH T2MLHR Day 0 A.M. Ly.Hrt.Rate

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	557.257	1	557.257	16.569	.000
T2MLHR	557.257	1	557.257	16.569	.000
Main Effects	25.622	1	25.622	.762	.390
DRUGRP	25.622	1	25.622	.762	.390
Explained	582.878	2	291.439	8.665	.001
Residual	975.340	29	33.632		
Total	1558.219	31	50.265		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1450

923

FCE 20124/706 i

(9.2.2.2.6) Summaries of T2MSHR Day 0 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			77.0714	13.8641	56
DRUGRP	1		77.7500	16.2381	28
DRUGRP	2		76.3929	11.2656	28
Total Cases =		56			

Summaries of T2MSHR Day 0 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		77.7500	16.2381	7119.2500	28
2		76.3929	11.2656	3426.6786	28

Within Groups Total		77.0714	13.9748	10545.9286	56

Criterion Variable T2MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	25.7857	1	25.7857	.1320	.7178
Within Groups	10545.9286	54	195.2950		
Eta = .0494		Eta Squared = .0024			

1451

924

FCE 20124/706 i

(9.2.2.2.6) Summaries of T3MSHR Day 1 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			76.5000	12.6785	54
DRUGRP	1		77.5714	15.1668	28
DRUGRP	2		75.3462	9.4697	26
Total Cases =	56				
Missing Cases =	2 OR	3.6 PCT.			

Summaries of T3MSHR Day 1 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		77.5714	15.1668	6210.8571	28
2		75.3462	9.4697	2241.8846	26

Within Groups Total		76.5000	12.7496	8452.7418	54

Criterion Variable T3MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	66.7582	1	66.7582	.4107	.5244
Within Groups	8452.7418	52	162.5527		
Eta = .0885 Eta Squared = .0078					

1452

925

FCE 20124/706 i

(9.2.2.2.6) Summaries of T4MSHR Day 2 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			77.1818	13.5661	55
DRUGRP	1		78.4286	14.6728	28
DRUGRP	2		75.8889	12.4602	27
Total Cases =	56				
Missing Cases =	1 OR	1.8 PCT.			

Summaries of T4MSHR Day 2 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		78.4286	14.6728	5812.8571	28
2		75.8889	12.4602	4036.6667	27

Within Groups Total		77.1818	13.6323	9849.5238	55

Criterion Variable T4MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	88.6580	1	88.6580	.4771	.4928
Within Groups	9849.5238	53	185.8401		
Eta = .0945 Eta Squared = .0089					

1453

926

FCE 20124/706 i

(9.2.2.2.6) Summaries of T5MSHR Day 3 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			77.4727	13.9707	55
DRUGRP	1		77.8929	16.2329	28
DRUGRP	2		77.0370	11.4606	27
Total Cases = 56					
Missing Cases = 1 OR 1.8 PCT.					

Summaries of T5MSHR Day 3 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		77.8929	16.2329	7114.6786	28
2		77.0370	11.4606	3414.9630	27

Within Groups Total		77.4727	14.0951	10529.6415	55

Criterion Variable T5MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	10.0676	1	10.0676	.0507	.8228
Within Groups	10529.6415	53	198.6725		
Eta = .0309 Eta Squared = .0010					

1454

927

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(9.2.2.2.6) Summaries of T6MSHR Day 4 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			78.3704	13.4042	54
DRUGRP	1		79.3571	16.0167	28
DRUGRP	2		77.3077	10.0788	26
Total Cases =	56				
Missing Cases =	2 OR	3.6 PCT.			

Summaries of T6MSHR Day 4 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		79.3571	16.0167	6926.4286	28
2		77.3077	10.0788	2539.5385	26

Within Groups Total		78.3704	13.4921	9465.9670	54

Criterion Variable T6MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	56.6256	1	56.6256	.3111	.5794
Within Groups	9465.9670	52	182.0378		
Eta = .0771 Eta Squared = .0059					

1455

928

FCE 20124/706 i

(9.2.2.2.6) Summaries of T7MSHR Day 5 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			76.4118	13.5147	51
DRUGRP	1		77.9231	15.2340	26
DRUGRP	2		74.8400	11.5639	25
Total Cases = 56					
Missing Cases = 5 OR 8.9 PCT.					

Summaries of T7MSHR Day 5 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		77.9231	15.2340	5801.8462	26
2		74.8400	11.5639	3209.3600	25

Within Groups Total		76.4118	13.5611	9011.2062	51

Criterion Variable T7MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	121.1468	1	121.1468	.6588	.4209
Within Groups	9011.2062	49	183.9022		
Eta = .1152 Eta Squared = .0133					

1456

929

FCE 20124/706 i

(9.2.2.2.6) Summaries of T8MSHR Day 6 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			75.9216	13.6965	51
DRUGRP	1		77.4615	16.2831	26
DRUGRP	2		74.3200	10.4591	25
Total Cases =	56				
Missing Cases =	5 OR	8.9 PCT.			

Summaries of T8MSHR Day 6 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		77.4615	16.2831	6628.4615	26
2		74.3200	10.4591	2625.4400	25
<hr/>					
Within Groups Total		75.9216	13.7425	9253.9015	51

Criterion Variable T8MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	125.7847	1	125.7847	.6660	.4184
Within Groups	9253.9015	49	188.8551		
Eta = .1158 Eta Squared = .0134					

1457

930

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(9.2.2.2.6) Summaries of T9MSHR Day 7 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			77.4074	14.4176	54
DRUGRP	1		78.5714	17.3278	28
DRUGRP	2		76.1538	10.6422	26
Total Cases =	56				
Missing Cases =	2 OR	3.6 PCT.			

Summaries of T9MSHR Day 7 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		78.5714	17.3278	8106.8571	28
2		76.1538	10.6422	2831.3846	26

Within Groups Total		77.4074	14.5035	10938.2418	54

Criterion Variable T9MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	78.7953	1	78.7953	.3746	.5432
Within Groups	10938.2418	52	210.3508		
Eta = .0846		Eta Squared = .0072			

1458

931

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(9.2.2.2.6) Summaries of T10MSHR Day 10 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			76.4340	15.1283	53
DRUGRP	1		77.8148	17.4423	27
DRUGRP	2		75.0000	12.4676	26
Total Cases =	56				
Missing Cases =	3 OR	5.4 PCT.			

Summaries of T10MSHR Day 10 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		77.8148	17.4423	7910.0741	27
2		75.0000	12.4676	3886.0000	26

Within Groups Total		76.4340	15.2084	11796.0741	53

Criterion Variable T10MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	104.9448	1	104.9448	.4537	.5036
Within Groups	11796.0741	51	231.2956		
Eta = .0939 Eta Squared = .0088					

1459

932

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(9.2.2.2.6) Summaries of T11MSHR Day 14 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			76.7925	13.5680	53
DRUGRP	1		77.5926	15.4876	27
DRUGRP	2		75.9615	11.4908	26
Total Cases =	56				
Missing Cases =	3 OR	5.4 PCT.			

Summaries of T11MSHR Day 14 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		77.5926	15.4876	6236.5185	27
2		75.9615	11.4908	3300.9615	26

Within Groups Total		76.7925	13.6751	9537.4801	53

Criterion Variable T11MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	35.2369	1	35.2369	.1884	.6661
Within Groups	9537.4801	51	187.0094		
Eta = .0607 Eta Squared = .0037					

1460

933

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(9.2.2.2.6) Summaries of T12MSHR Day 21 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			74.8400	13.0827	50
DRUGRP	1		75.9615	15.2617	26
DRUGRP	2		73.6250	10.4166	24
Total Cases =	56				
Missing Cases =	6	OR 10.7 PCT.			

Summaries of T12MSHR Day 21 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		75.9615	15.2617	5822.9615	26
2		73.6250	10.4166	2495.6250	24

Within Groups Total		74.8400	13.1645	8318.5865	50

Criterion Variable T12MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	68.1335	1	68.1335	.3931	.5336
Within Groups	8318.5865	48	173.3039		
Eta = .0901 Eta Squared = .0081					

1461

934

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(9.2.2.2.6) Summaries of T13MSHR Day 28 A.M. St.Hrt.Rate
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			76.8857	13.0153	35
DRUGRP	1		76.7200	14.3687	25
DRUGRP	2		77.3000	9.4405	10
Total Cases =	56				
Missing Cases =	21	OR	37.5	PCT.	

Summaries of T13MSHR Day 28 A.M. St.Hrt.Rate
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		76.7200	14.3687	4955.0400	25
2		77.3000	9.4405	802.1000	10

Within Groups Total		76.8857	13.2083	5757.1400	35

Criterion Variable T13MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	2.4029	1	2.4029	.0138	.9073
Within Groups	5757.1400	33	174.4588		
Eta = .0204		Eta Squared = .0004			

1462

935

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(9.2.2.2.6) Summaries of T14MSHR
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		75.7188	12.7234	32
DRUGRP	1	76.1818	14.6373	22
DRUGRP	2	74.7000	7.4841	10
Total Cases = 56				
Missing Cases = 24 OR 42.9 PCT.				

Summaries of T14MSHR
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	76.1818	14.6373	4499.2727	22
2	74.7000	7.4841	504.1000	10

Within Groups Total	75.7188	12.9143	5003.3727	32

Criterion Variable T14MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15.0960	1	15.0960	.0905	.7656
Within Groups	5003.3727	30	166.7791		
Eta = .0548 Eta Squared = .0030					

1463

936

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(9.2.2.2.6) Summaries of T15MSHR
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		74.6563	8.8632	32
DRUGRP	1	74.9091	9.3090	22
DRUGRP	2	74.1000	8.2388	10
Total Cases = 56				
Missing Cases = 24 OR 42.9 PCT.				

Summaries of T15MSHR
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	74.9091	9.3090	1819.8182	22
2	74.1000	8.2388	610.9000	10

Within Groups Total	74.6563	9.0013	2430.7182	32

Criterion Variable T15MSHR

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	4.5006	1	4.5006	.0555	.8153
Within Groups	2430.7182	30	81.0239		
Eta = .0430 Eta Squared = .0018					

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(9.2.2.2.6) * * A N A L Y S I S O F V A R I A N C E * * *

T15MSHR
 BY DRUGRP
 WITH T2MSHR Day 0 A.M. St.Hrt.Rate

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	1294.306	1	1294.306	33.557	.000
T2MSHR	1294.306	1	1294.306	33.557	.000
Main Effects	22.386	1	22.386	.580	.452
DRUGRP	22.386	1	22.386	.580	.452
Explained	1316.692	2	658.346	17.069	.000
Residual	1118.527	29	38.570		
Total	2435.219	31	78.555		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1465

938

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(9.2.2.2.7) Summaries of T2WT Day 0 Body Wt.(kg)
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			63.0066	13.5113	56
DRUGRP	1		63.2500	15.2634	28
DRUGRP	2		62.7632	11.7804	28
Total Cases = 56					

Summaries of T2WT Day 0 Body Wt.(kg)
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		63.2500	15.2634	6290.1900	28
2		62.7632	11.7804	3746.9730	28

Within Groups Total		63.0066	13.6335	10037.1630	56

Criterion Variable T2WT

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.3174	1	3.3174	.0178	.8942
Within Groups	10037.1630	54	185.8734		
Eta = .0182 Eta Squared = .0003					

1466

939

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(9.2.2.2.7) Summaries of T9WT Day 7 Body Wt.(kg)
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			62.5056	13.7047	54
DRUGRP	1		62.6714	14.9772	28
DRUGRP	2		62.3269	12.4839	26
Total Cases = 56					
Missing Cases = 2 OR 3.6 PCT.					

Summaries of T9WT Day 7 Body Wt.(kg)
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		62.6714	14.9772	6056.5771	28
2		62.3269	12.4839	3896.1712	26

Within Groups Total		62.5056	13.8347	9952.7483	54

Criterion Variable T9WT

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.6000	1	1.6000	.0084	.9275
Within Groups	9952.7483	52	191.3990		
Eta = .0127 Eta Squared = .0002					

1467

940

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(9.2.2.2.7) Summaries of T11WT Day 14 Body Wt.(kg)
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			63.3208	12.9062	53
DRUGRP	1		63.5704	14.6135	27
DRUGRP	2		63.0615	11.1459	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T11WT Day 14 Body Wt.(kg)
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		63.5704	14.6135	5552.4363	27
2		63.0615	11.1459	3105.8015	26

Within Groups Total		63.3208	13.0296	8658.2378	53

Criterion Variable T11WT

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.4293	1	3.4293	.0202	.8875
Within Groups	8658.2378	51	169.7694		
Eta = .0199 Eta Squared = .0004					

1468

941

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(9.2.2.2.7) Summaries of T12WT Day 21 Body Wt.(kg)
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			63.1420	12.6524	50
DRUGRP	1		64.5115	14.6250	26
DRUGRP	2		61.6583	10.2050	24
Total Cases = 56					
Missing Cases = 6 OR 10.7 PCT.					

Summaries of T12WT Day 21 Body Wt.(kg)
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		64.5115	14.6250	5347.2465	26
2		61.6583	10.2050	2395.2583	24

Within Groups Total		63.1420	12.7005	7742.5049	50

Criterion Variable T12WT

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	101.5969	1	101.5969	.6299	.4313
Within Groups	7742.5049	48	161.3022		
Eta = .1138 Eta Squared = .0130					

1469

942

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(9.2.2.2.7) Summaries of T13WT Day 28 Body Wt.(kg)
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			64.7400	13.0175	35
DRUGRP	1		65.1560	14.6319	25
DRUGRP	2		63.7000	8.2199	10
Total Cases = 56					
Missing Cases = 21 OR 37.5 PCT.					

Summaries of T13WT Day 28 Body Wt.(kg)
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		65.1560	14.6319	5138.2416	25
2		63.7000	8.2199	608.1000	10

Within Groups Total		64.7400	13.1959	5746.3416	35

Criterion Variable T13WT

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	15.1424	1	15.1424	.0870	.7699
Within Groups	5746.3416	33	174.1316		
Eta = .0513 Eta Squared = .0026					

1470

943

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(9.2.2.2.7) Summaries of T14WT Day 35 Body Wt.(kg)
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		64.4406	12.9304	32
DRUGRP	1	64.6636	14.7475	22
DRUGRP	2	63.9500	8.2477	10
Total Cases = 56				
Missing Cases = 24 OR 42.9 PCT.				

Summaries of T14WT Day 35 Body Wt.(kg)
By levels of DRUGRP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	64.6636	14.7475	4567.2909	22
2	63.9500	8.2477	612.2250	10

Within Groups Total	64.4406	13.1397	5179.5159	32

Criterion Variable T14WT

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	3.5013	1	3.5013	.0203	.8877
Within Groups	5179.5159	30	172.6505		
Eta = .0260 Eta Squared = .0007					

1471

944

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(9.2.2.2.7) Summaries of T15WT Day 42 Body Wt.(kg)
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			64.5719	13.1060	32
DRUGRP	1		64.8955	14.9979	22
DRUGRP	2		63.8600	8.1224	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T15WT Day 42 Body Wt.(kg)
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		64.8955	14.9979	4723.6495	22
2		63.8600	8.1224	593.7640	10

Within Groups Total		64.5719	13.3134	5317.4135	32

Criterion Variable T15WT

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	7.3711	1	7.3711	.0416	.8398
Within Groups	5317.4135	30	177.2471		
Eta = .0372 Eta Squared = .0014					

1472

945

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```
( 9.2.2.2.7 ) manova t2wt t9wt t11wt t12wt t13wt t14wt t15wt by drugrp(1,2)
/wsfactors=time (7)
/wsdesign=time
/design.
```

```
30 cases accepted.
0 cases rejected because of out-of-range factor values.
26 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
Source of Variation      SS      DF      MS      F      Sig of F
WITHIN CELLS             34392.07    28    1228.29
CONSTANT                 726258.87     1 726258.87    591.28     .000
DRUGRP                   55.00      1     55.00     .04     .834
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .00124
Chi-square approx. = 172.49906 with 20 D. F.
Significance = .000
```

```
Greenhouse-Geisser Epsilon = .29161
Huynh-Feldt Epsilon = .32057
Lower-bound Epsilon = .16667
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to univariate or split-plot or mixed-model approach to repeated measures. Epsilons may be used to adjust d.f. for the AVERAGED results.
```

1473

946

FCE 20124/706 i

(9.2.2.2.7) * * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. DRUGRP BY TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 10 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.21849	1.07173	6.00	23.00	.408
Hotellings	.27958	1.07173	6.00	23.00	.408
Wilks	.78151	1.07173	6.00	23.00	.408
Roys	.21849				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 10 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.38668	2.41680	6.00	23.00	.059
Hotellings	.63047	2.41680	6.00	23.00	.059
Wilks	.61332	2.41680	6.00	23.00	.059
Roys	.38668				

* * ANALYSIS OF VARIANCE -- DESIGN 1 * *

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	184.05	168	1.10		
TIME	41.41	6	6.90	6.30	.000
DRUGRP BY TIME	2.32	6	.39	.35	.907

1474

947

FCE 20124/706 i

(9.2.2.2.7) ** ANALYSIS OF VARIANCE ***

T15WT Day 42 Body Wt.(kg)
 BY DRUGRP
 WITH T2WT Day 0 Body Wt.(kg)

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	5195.958	1	5195.958	1169.656	.000
T2WT	5195.958	1	5195.958	1169.656	.000
Main Effects	.000	1	.000	.000	.998
DRUGRP	.000	1	.000	.000	.998
Explained	5195.958	2	2597.979	584.828	.000
Residual	128.827	29	4.442		
Total	5324.785	31	171.767		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1475

948

FCE 20124/706 i

(9.2.2.2.8) Summaries of T2TEMP Day 0 Body.Temp.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			36.6732	.2339	56
DRUGRP	1		36.6536	.1774	28
DRUGRP	2		36.6929	.2814	28
Total Cases = 56					

Summaries of T2TEMP Day 0 Body.Temp.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		36.6536	.1774	.8496	28
2		36.6929	.2814	2.1386	28

Within Groups Total		36.6732	.2352	2.9882	56

Criterion Variable T2TEMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0216	1	.0216	.3905	.5347
Within Groups	2.9882	54	.0553		
Eta = .0847 Eta Squared = .0072					

1476

949

FCE 20124/706 i

(9.2.2.2.8) Summaries of T9TEMP Day 7 Body.Temp.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			36.6407	.2088	54
DRUGRP	1		36.6250	.1756	28
DRUGRP	2		36.6577	.2419	26
Total Cases = 56					
Missing Cases = 2 OR 3.6 PCT.					

Summaries of T9TEMP Day 7 Body.Temp.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		36.6250	.1756	.8325	28
2		36.6577	.2419	1.4635	26

Within Groups Total		36.6407	.2101	2.2960	54

Criterion Variable T9TEMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0144	1	.0144	.3263	.5703
Within Groups	2.2960	52	.0442		
Eta = .0790		Eta Squared = .0062			

1477

950

FCE 20124/706 i

(9.2.2.2.8) Summaries of T11TEMP Day 14 Body.Temp.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			36.6264	.1923	53
DRUGRP	1		36.6037	.1931	27
DRUGRP	2		36.6500	.1924	26
Total Cases = 56					
Missing Cases = 3 OR 5.4 PCT.					

Summaries of T11TEMP Day 14 Body.Temp.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		36.6037	.1931	.9696	27
2		36.6500	.1924	.9250	26

Within Groups Total		36.6264	.1927	1.8946	53

Criterion Variable T11TEMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0284	1	.0284	.7642	.3861
Within Groups	1.8946	51	.0371		
Eta = .1215 Eta Squared = .0148					

1478

951

FCE 20124/706 i

(9.2.2.2.8) Summaries of T12TEMP Day 21 Body.Temp.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			36.6040	.1603	50
DRUGRP	1		36.5846	.1377	26
DRUGRP	2		36.6250	.1824	24
Total Cases = 56					
Missing Cases = 6 OR 10.7 PCT.					

Summaries of T12TEMP Day 21 Body.Temp.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		36.5846	.1377	.4738	26
2		36.6250	.1824	.7650	24

Within Groups Total		36.6040	.1607	1.2388	50

Criterion Variable T12TEMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0204	1	.0204	.7886	.3789
Within Groups	1.2388	48	.0258		
Eta = .1271 Eta Squared = .0162					

1479

952

FCE 20124/706 i

(9.2.2.2.8) Summaries of T13TEMP Day 28 Body.Temp.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			36.6086	.1669	35
DRUGRP	1		36.5840	.1650	25
DRUGRP	2		36.6700	.1636	10
Total Cases = 56					
Missing Cases = 21 OR 37.5 PCT.					

Summaries of T13TEMP Day 28 Body.Temp.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		36.5840	.1650	.6536	25
2		36.6700	.1636	.2410	10

Within Groups Total		36.6086	.1646	.8946	35

Criterion Variable T13TEMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0528	1	.0528	1.9487	.1720
Within Groups	.8946	33	.0271		
Eta = .2361 Eta Squared = .0558					

1480

953

FCE 20124/706 i

(9.2.2.2.8) Summaries of T14TEMP Day 35 Body.Temp.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			36.6000	.1414	32
DRUGRP	1		36.5955	.1362	22
DRUGRP	2		36.6100	.1595	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T14TEMP Day 35 Body.Temp.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		36.5955	.1362	.3895	22
2		36.6100	.1595	.2290	10

Within Groups Total		36.6000	.1436	.6185	32

Criterion Variable T14TEMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0015	1	.0015	.0705	.7924
Within Groups	.6185	30	.0206		
Eta = .0484 Eta Squared = .0023					

1481

954

FCE 20124/706 i

(9.2.2.2.8) Summaries of T15TEMP Day 42 Body.Temp.
By levels of DRUGRP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			36.5688	.1256	32
DRUGRP	1		36.5364	.0953	22
DRUGRP	2		36.6400	.1578	10
Total Cases = 56					
Missing Cases = 24 OR 42.9 PCT.					

Summaries of T15TEMP Day 42 Body.Temp.
By levels of DRUGRP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		36.5364	.0953	.1909	22
2		36.6400	.1578	.2240	10

Within Groups Total		36.5688	.1176	.4149	32

Criterion Variable T15TEMP

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0738	1	.0738	5.3391	.0279
Within Groups	.4149	30	.0138		
Eta = .3887		Eta Squared = .1511			

1482

955

FCE 20124/706 i

```
( 9.2.2.2.8 ) manova t2temp t9temp t11temp t12temp t13temp t14temp t15temp by
druggrp(1,2)
/wsfactors=time (7)
/wsdesign=time
/design.
```

```
30 cases accepted.
0 cases rejected because of out-of-range factor values.
26 cases rejected because of missing data.
2 non-empty cells.
```

```
1 design will be processed.
```

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests of Between-Subjects Effects.
```

```
Tests of Significance for T1 using UNIQUE sums of squares
```

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	2.37	28	.08		
CONSTANT	236276.42	1	236276.42	2791212.6	.000
DRUGRP	.22	1	.22	2.56	.121

```
** ANALYSIS OF VARIANCE -- DESIGN 1 **
```

```
Tests involving 'TIME' Within-Subject Effect.
```

```
Mauchly sphericity test, W = .41383
Chi-square approx. = 22.74403 with 20 D. F.
Significance = .302
```

```
Greenhouse-Geisser Epsilon = .79473
Huynh-Feldt Epsilon = 1.00000
Lower-bound Epsilon = .16667
```

```
AVERAGED Tests of Significance that follow multivariate tests are equivalent to
univariate or split-plot or mixed-model approach to repeated measures.
Epsilons may be used to adjust d.f. for the AVERAGED results.
```

1483

956

FCE 20124/706 i

(9.2.2.2.8) ** ANALYSIS OF VARIANCE -- DESIGN 1 **

EFFECT .. DRUGRP BY TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 10 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.18654	.87907	6.00	23.00	.526
Hotellings	.22932	.87907	6.00	23.00	.526
Wilks	.81346	.87907	6.00	23.00	.526
Roys	.18654				

** ANALYSIS OF VARIANCE -- DESIGN 1 **

EFFECT .. TIME

Multivariate Tests of Significance (S = 1, M = 2 , N = 10 1/2)

Test Name	Value	Approx. F	Hypoth. DF	Error DF	Sig. of F
Pillais	.12035	.52444	6.00	23.00	.784
Hotellings	.13681	.52444	6.00	23.00	.784
Wilks	.87965	.52444	6.00	23.00	.784
Roys	.12035				

** ANALYSIS OF VARIANCE -- DESIGN 1 **

Tests involving 'TIME' Within-Subject Effect.

AVERAGED Tests of Significance for MEAS.1 using UNIQUE sums of squares

Source of Variation	SS	DF	MS	F	Sig of F
WITHIN CELLS	.94	168	.01		
TIME	.01	6	.00	.42	.868
DRUGRP BY TIME	.03	6	.00	.89	.501

1484

957

FCE 20124/706 i

(9.2.2.2.8) * * A N A L Y S I S O F V A R I A N C E * * *

T15TEMP Day 42 Body.Temp.
 BY DRUGRP
 WITH T2TEMP Day 0 Body.Temp.

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	.225	1	.225	28.179	.000
T2TEMP	.225	1	.225	28.179	.000
Main Effects	.033	1	.033	4.113	.052
DRUGRP	.033	1	.033	4.113	.052
Explained	.258	2	.129	16.146	.000
Residual	.231	29	.008		
Total	.489	31	.016		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1485

958

FCE 20124/706 i

APPENDIX 23

Laboratory Tests in the Two Treatment Groups

1486

959

FCE 20124/706 i

(9.3.1.1) OR1HGB Dy0 HEMOGLOBIN: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	81.5	81.5
O.O.R.	1.00	5	17.9	18.5	100.0
	.	1	3.6	Missing	
Total		28	100.0	100.0	

Valid cases 27 Missing cases 1

OR2HGB Dy21 HGB

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	71.4	80.0	80.0
O.O.R.	1.00	5	17.9	20.0	100.0
	.	3	10.7	Missing	
Total		28	100.0	100.0	

Valid cases 25 Missing cases 3

OR3HGB Dy42 HGB

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	70.8	70.8
O.O.R.	1.00	7	25.0	29.2	100.0
	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

1487

960

FCE 20124/706 i

(9.3.1.1) OR1HGB Dy0 HEMOGLOBIN: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	77.8	84.0	84.0
O.O.R.	1.00	4	14.8	16.0	100.0
	.	2	7.4	Missing	
	Total	27	100.0	100.0	

Valid cases 25 Missing cases 2

OR2HGB Dy21 HGB

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	55.6	62.5	62.5
O.O.R.	1.00	9	33.3	37.5	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3HGB Dy42 HGB

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	7	25.9	77.8	77.8
O.O.R.	1.00	2	7.4	22.2	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1488

961

FCE 20124/706 i

(9.3.1.1) OR1HCT Dy0 HEMATOCRIT: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	92.9	96.3	96.3
O.O.R.	1.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
Total		28	100.0	100.0	

Valid cases 27 Missing cases 1

OR2HCT Dy21 HCT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	92.0	92.0
O.O.R.	1.00	2	7.1	8.0	100.0
	.	3	10.7	Missing	
Total		28	100.0	100.0	

Valid cases 25 Missing cases 3

OR3HCT Dy42 HCT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	71.4	83.3	83.3
O.O.R.	1.00	4	14.3	16.7	100.0
	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

1489

962

FCE 20124/706 i

(9.3.1.1) OR1HCT Dy0 HEMATOCRIT: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	85.2	92.0	92.0
O.O.R.	1.00	2	7.4	8.0	100.0
	.	2	7.4	Missing	
Total		27	100.0	100.0	

Valid cases 25 Missing cases 2

OR2HCT Dy21 HCT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	81.5	91.7	91.7
O.O.R.	1.00	2	7.4	8.3	100.0
	.	3	11.1	Missing	
Total		27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3HCT Dy42 HCT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	8	29.6	88.9	88.9
O.O.R.	1.00	1	3.7	11.1	100.0
	.	18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1490

963

FCE 20124/706 i

(9.3.1.1) OR1RBC Dy0 RED BLOOD CELLS: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	53.6	55.6	55.6
O.O.R.	1.00	12	42.9	44.4	100.0
	.	1	3.6	Missing	
Total		28	100.0	100.0	

Valid cases 27 Missing cases 1

OR2RBC Dy21 RBC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	68.0	68.0
O.O.R.	1.00	8	28.6	32.0	100.0
	.	3	10.7	Missing	
Total		28	100.0	100.0	

Valid cases 25 Missing cases 3

OR3RBC Dy42 RBC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	11	39.3	45.8	45.8
O.O.R.	1.00	13	46.4	54.2	100.0
	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

1491

964

FCE 20124/706 i

(9.3.1.1) OR1RBC Dy0 RED BLOOD CELLS: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	16	59.3	64.0	64.0
O.O.R.	1.00	9	33.3	36.0	100.0
.	.	2	7.4	Missing	
Total		27	100.0	100.0	

Valid cases 25 Missing cases 2

OR2RBC Dy21 RBC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	13	48.1	54.2	54.2
O.O.R.	1.00	11	40.7	45.8	100.0
.	.	3	11.1	Missing	
Total		27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3RBC Dy42 RBC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	4	14.8	44.4	44.4
O.O.R.	1.00	5	18.5	55.6	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1492

965

FCE 20124/706 i

(9.3.1.1) OR1WBC Dy0 WHITE BLOOD CELLS: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	16	57.1	57.1	57.1
O.O.R.	1.00	12	42.9	42.9	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

OR2WBC Dy21 WBC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	65.4	65.4
O.O.R.	1.00	9	32.1	34.6	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26	Missing cases	2		

OR3WBC Dy42 WBC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	53.6	62.5	62.5
O.O.R.	1.00	9	32.1	37.5	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	
Valid cases	24	Missing cases	4		

1493

966

FCE 20124/706 i

(9.3.1.1) OR1WBC Dy0 WHITE BLOOD CELLS: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	14	51.9	51.9	51.9
O.O.R.	1.00	13	48.1	48.1	100.0
Total		27	100.0	100.0	

Valid cases 27 Missing cases 0

OR2WBC Dy21 WBC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	14	51.9	53.8	53.8
O.O.R.	1.00	12	44.4	46.2	100.0
.	.	1	3.7	Missing	
Total		27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3WBC Dy42 WBC

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	5	18.5	55.6	55.6
O.O.R.	1.00	4	14.8	44.4	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1494

967

FCE 20124/706 i

(9.3.1.1) OR1NEUT Dy0 NEUTROPHILS: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	75.0	75.0
O.O.R.	1.00	7	25.0	25.0	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

OR2NEUT Dy21 NEUT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	88.5	88.5
O.O.R.	1.00	3	10.7	11.5	100.0
.	.	2	7.1	Missing	
Total		28	100.0	100.0	

Valid cases 26 Missing cases 2

OR3NEUT Dy42 NEUT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	19	67.9	79.2	79.2
O.O.R.	1.00	5	17.9	20.8	100.0
.	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

1495

968

FCE 20124/706 i

(9.3.1.1) OR1NEUT Dy0 NEUTROPHILS: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	74.1	74.1	74.1
O.O.R.	1.00	7	25.9	25.9	100.0
Total		27	100.0	100.0	
Valid cases	27	Missing cases	0		

OR2NEUT Dy21 NEUT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	16	59.3	61.5	61.5
O.O.R.	1.00	10	37.0	38.5	100.0
.	.	1	3.7	Missing	
Total		27	100.0	100.0	
Valid cases	26	Missing cases	1		

OR3NEUT Dy42 NEUT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	8	29.6	88.9	88.9
O.O.R.	1.00	1	3.7	11.1	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	
Valid cases	9	Missing cases	18		

1496

969

FCE 20124/706 i

(9.3.1.1) OR1LYMP Dy0 LYMPHOCYTES: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	14	50.0	50.0	50.0
O.O.R.	1.00	14	50.0	50.0	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

OR2LYMP Dy21 LYMP.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	53.6	57.7	57.7
O.O.R.	1.00	11	39.3	42.3	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26	Missing cases	2		

OR3LYMP Dy42 LYMP.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	12	42.9	50.0	50.0
O.O.R.	1.00	12	42.9	50.0	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	
Valid cases	24	Missing cases	4		

1497

970

FCE 20124/706 i

(9.3.1.1) OR1LYMP Dy0 LYMPHOCYTES: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	11	40.7	40.7	40.7
O.O.R.	1.00	16	59.3	59.3	100.0
Total		27	100.0	100.0	
Valid cases	27	Missing cases		0	

OR2LYMP Dy21 LYMP.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	34.6	34.6
O.O.R.	1.00	17	63.0	65.4	100.0
.	.	1	3.7	Missing	
Total		27	100.0	100.0	
Valid cases	26	Missing cases		1	

OR3LYMP Dy42 LYMP.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	5	18.5	55.6	55.6
O.O.R.	1.00	4	14.8	44.4	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	
Valid cases	9	Missing cases		18	

1498

971

FCE 20124/706 i

(9.3.1.1) OR1EOS Dy0 EOSINOPHILS: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	63.0	63.0
O.O.R.	1.00	10	35.7	37.0	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

OR2EOS Dy21 EOS.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	13	46.4	50.0	50.0
O.O.R.	1.00	13	46.4	50.0	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

OR3EOS Dy42 EOS.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	12	42.9	50.0	50.0
O.O.R.	1.00	12	42.9	50.0	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

1499

972

FCE 20124/706 i

(9.3.1.1) OR1EOS Dy0 EOSINOPHILS: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	55.6	55.6	55.6
O.O.R.	1.00	12	44.4	44.4	100.0
Total		27	100.0	100.0	
Valid cases	27	Missing cases		0	

OR2EOS Dy21 EOS.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	13	48.1	50.0	50.0
O.O.R.	1.00	13	48.1	50.0	100.0
.	.	1	3.7	Missing	
Total		27	100.0	100.0	
Valid cases	26	Missing cases		1	

OR3EOS Dy42 EOS.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	6	22.2	66.7	66.7
O.O.R.	1.00	3	11.1	33.3	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	
Valid cases	9	Missing cases		18	

1500

973

FCE 20124/706 i

(9.3.1.1) OR1MONO Dy0 MONOCYTES: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	10	35.7	35.7	35.7
O.O.R.	1.00	18	64.3	64.3	100.0
Total		28	100.0	100.0	

Valid cases 28 Missing cases 0

OR2MONO Dy21 MONO.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	12	42.9	46.2	46.2
O.O.R.	1.00	14	50.0	53.8	100.0
.	.	2	7.1	Missing	
Total		28	100.0	100.0	

Valid cases 26 Missing cases 2

OR3MONO Dy42 MONO.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	32.1	37.5	37.5
O.O.R.	1.00	15	53.6	62.5	100.0
.	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

1501

974

FCE 20124/706 i

(9.3.1.1) OR1MONO Dy0 MONOCYTES: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	12	44.4	44.4	44.4
O.O.R.	1.00	15	55.6	55.6	100.0
Total		27	100.0	100.0	
Valid cases	27	Missing cases	0		

OR2MONO Dy21 MONO.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	8	29.6	30.8	30.8
O.O.R.	1.00	18	66.7	69.2	100.0
.	.	1	3.7	Missing	
Total		27	100.0	100.0	
Valid cases	26	Missing cases	1		

OR3MONO Dy42 MONO.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	3	11.1	33.3	33.3
O.O.R.	1.00	6	22.2	66.7	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	
Valid cases	9	Missing cases	18		

1502

975

FCE 20124/706 i

(9.3.1.1) OR1BASO Dy0 BASOPHILS: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	27	96.4	100.0	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases	27	Missing cases	1		

OR2BASO Dy21 BASO.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	92.9	100.0	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26	Missing cases	2		

OR3BASO Dy42 BASO.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	85.7	100.0	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	
Valid cases	24	Missing cases	4		

1503

976

FCE 20124/706 i

(9.3.1.1) OR1BASO Dy0 BASOPHILS: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	27	100.0	100.0	100.0

	Total	27	100.0	100.0	
Valid cases	27	Missing cases	0		

OR2BASO Dy21 BASO.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	96.2	96.2
O.O.R.	1.00	1	3.7	3.8	100.0
	.	1	3.7	Missing	

	Total	27	100.0	100.0	
Valid cases	26	Missing cases	1		

OR3BASO Dy42 BASO.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	

	Total	27	100.0	100.0	
Valid cases	9	Missing cases	18		

1504

977

FCE 20124/706 i

(9.3.1.1) OR1PLAT Dy0 PLATELETS: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	28	100.0	100.0	100.0
		Total	28	100.0	100.0
Valid cases	28	Missing cases	0		

OR2PLAT Dy21 PLATE.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	88.5	88.5
O.O.R.	1.00	3	10.7	11.5	100.0
.	.	2	7.1	Missing	
		Total	28	100.0	100.0
Valid cases	26	Missing cases	2		

OR3PLAT Dy42 PLATE.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	95.8	95.8
O.O.R.	1.00	1	3.6	4.2	100.0
.	.	4	14.3	Missing	
		Total	28	100.0	100.0
Valid cases	24	Missing cases	4		

1505

978

FCE 20124/706 i

(9.3.1.1) OR1PLAT Dy0 PLATELETS: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	92.6	92.6
O.O.R.	1.00	2	7.4	7.4	100.0
	Total	27	100.0	100.0	
Valid cases	27	Missing cases	0		

OR2PLAT Dy21 PLATE.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	88.9	92.3	92.3
O.O.R.	1.00	2	7.4	7.7	100.0
	.	1	3.7	Missing	
	Total	27	100.0	100.0	
Valid cases	26	Missing cases	1		

OR3PLAT Dy42 PLATE.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	
Valid cases	9	Missing cases	18		

1506

979

FCE 20124/706 i

(9.3.1.2) OR1NA Dy0 NA+: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	75.0	75.0
O.O.R.	1.00	7	25.0	25.0	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

OR2NA Dy21 NA+

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	71.4	76.9	76.9
O.O.R.	1.00	6	21.4	23.1	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

OR3NA Dy42 NA+

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	18	64.3	75.0	75.0
O.O.R.	1.00	6	21.4	25.0	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

1507

980

FCE 20124/706 i

(9.3.1.2) OR1NA Dy0 NA+: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	77.8	77.8	77.8
O.O.R.	1.00	6	22.2	22.2	100.0
Total		27	100.0	100.0	
Valid cases	27	Missing cases	0		

OR2NA Dy21 NA+

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	81.5	84.6	84.6
O.O.R.	1.00	4	14.8	15.4	100.0
.	.	1	3.7	Missing	
Total		27	100.0	100.0	
Valid cases	26	Missing cases	1		

OR3NA Dy42 NA+

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	8	29.6	88.9	88.9
O.O.R.	1.00	1	3.7	11.1	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	
Valid cases	9	Missing cases	18		

1508

981

FCE 20124/706 i

(9.3.1.2) OR1K Dy0 K+: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	87.5	87.5
O.O.R.	1.00	3	10.7	12.5	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR2K Dy21 K+

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	91.7	91.7
O.O.R.	1.00	2	7.1	8.3	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR3K Dy42 K+

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	95.5	95.5
O.O.R.	1.00	1	3.6	4.5	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	

Valid cases 22 Missing cases 6

1509

982

FCE 20124/706 i

(9.3.1.2) OR1K Dy0 K+: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	85.2	95.8	95.8
O.O.R.	1.00	1	3.7	4.2	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	
Valid cases	24	Missing cases	3		

OR2K Dy21 K+

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	88.9	100.0	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	
Valid cases	24	Missing cases	3		

OR3K Dy42 K+

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	
Valid cases	9	Missing cases	18		

1510

983

FCE 20124/706 i

(9.3.1.2) OR1CL Dy0 CL-: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	91.7	91.7
O.O.R.	1.00	2	7.1	8.3	100.0
.	.	4	14.3	Missing	
Total		28	100.0	100.0	
Valid cases	24	Missing cases	4		

OR2CL Dy21 CL-

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	71.4	83.3	83.3
O.O.R.	1.00	4	14.3	16.7	100.0
.	.	4	14.3	Missing	
Total		28	100.0	100.0	
Valid cases	24	Missing cases	4		

OR3CL Dy42 CL-

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	95.5	95.5
O.O.R.	1.00	1	3.6	4.5	100.0
.	.	6	21.4	Missing	
Total		28	100.0	100.0	
Valid cases	22	Missing cases	6		

1511

984

FCE 20124/706 i

(9.3.1.2) OR1CL Dy0 CL-: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	74.1	83.3	83.3
O.O.R.	1.00	4	14.8	16.7	100.0
	.	3	11.1	Missing	
Total		27	100.0	100.0	
Valid cases	24	Missing cases	3		

OR2CL Dy21 CL-

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	81.5	91.7	91.7
O.O.R.	1.00	2	7.4	8.3	100.0
	.	3	11.1	Missing	
Total		27	100.0	100.0	
Valid cases	24	Missing cases	3		

OR3CL Dy42 CL-

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	8	29.6	88.9	88.9
O.O.R.	1.00	1	3.7	11.1	100.0
	.	18	66.7	Missing	
Total		27	100.0	100.0	
Valid cases	9	Missing cases	18		

FCE 20124/706 i

(9.3.1.2) OR1CA Dy0 CA++: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	95.8	95.8
O.O.R.	1.00	1	3.6	4.2	100.0
	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

OR2CA Dy21 CA++

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	71.4	83.3	83.3
O.O.R.	1.00	4	14.3	16.7	100.0
	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

OR3CA Dy42 CA++

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	71.4	90.9	90.9
O.O.R.	1.00	2	7.1	9.1	100.0
	.	6	21.4	Missing	
Total		28	100.0	100.0	

Valid cases 22 Missing cases 6

1513

986

FCE 20124/706 i

(9.3.1.2) OR1CA Dy0 CA++: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	77.8	87.5	87.5
O.O.R.	1.00	3	11.1	12.5	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR2CA Dy21 CA++

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	85.2	95.8	95.8
O.O.R.	1.00	1	3.7	4.2	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3CA Dy42 CA++

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1514

987

FCE 20124/706 i

(9.3.1.2) OR1P04 Dy0 P04: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	100.0	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	
Valid cases	22	Missing cases	6		

OR2P04 Dy21 P04

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	100.0	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	
Valid cases	22	Missing cases	6		

OR3P04 Dy42 P04

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	100.0	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	
Valid cases	22	Missing cases	6		

1515

988

FCE 20124/706 i

(9.3.1.2) OR1P04 Dy0 P04: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

OR2P04 Dy21 P04

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

OR3P04 Dy42 P04

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

FCE 20124/706 i

(9.3.1.2) OR1SGOT Dy0 SGOT: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	19	67.9	79.2	79.2
O.O.R.	1.00	5	17.9	20.8	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR2SGOT Dy21 SGOT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	87.5	87.5
O.O.R.	1.00	3	10.7	12.5	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR3SGOT Dy42 SGOT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	18	64.3	81.8	81.8
O.O.R.	1.00	4	14.3	18.2	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	

Valid cases 22 Missing cases 6

1517

990

FCE 20124/706 i

(9.3.1.2) OR1SGOT Dy0 SGOT: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	63.0	70.8	70.8
O.O.R.	1.00	7	25.9	29.2	100.0
.	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR2SGOT Dy21 SGOT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	55.6	62.5	62.5
O.O.R.	1.00	9	33.3	37.5	100.0
.	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3SGOT Dy42 SGOT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	7	25.9	77.8	77.8
O.O.R.	1.00	2	7.4	22.2	100.0
.	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1518

991

FCE 20124/706 i

(9.3.1.2) OR1SGPT Dy0 SGPT: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	70.8	70.8
O.O.R.	1.00	7	25.0	29.2	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR2SGPT Dy21 SGPT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	95.8	95.8
O.O.R.	1.00	1	3.6	4.2	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR3SGPT Dy42 SGPT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	77.3	77.3
O.O.R.	1.00	5	17.9	22.7	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	

Valid cases 22 Missing cases 6

1519

992

FCE 20124/706 i

(9.3.1.2) OR1SGPT Dy0 SGPT: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	14	51.9	58.3	58.3
O.O.R.	1.00	10	37.0	41.7	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR2SGPT Dy21 SGPT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	63.0	70.8	70.8
O.O.R.	1.00	7	25.9	29.2	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3SGPT Dy42 SGPT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	7	25.9	77.8	77.8
O.O.R.	1.00	2	7.4	22.2	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1520

993

FCE 20124/706 i

(9.3.1.2) OR1YGT Dy0 t GT: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	53.6	62.5	62.5
O.O.R.	1.00	9	32.1	37.5	100.0
.	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

OR2YGT Dy21 GAM.GT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	53.6	62.5	62.5
O.O.R.	1.00	9	32.1	37.5	100.0
.	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

OR3YGT Dy42 GAM.GT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	13	46.4	59.1	59.1
O.O.R.	1.00	9	32.1	40.9	100.0
.	.	6	21.4	Missing	
Total		28	100.0	100.0	

Valid cases 22 Missing cases 6

1521

994

FCE 20124/706 i

(9.3.1.2) OR1YGT Dy0 τ GT: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	15	55.6	62.5	62.5
O.O.R.	1.00	9	33.3	37.5	100.0
	.	3	11.1	Missing	
Total		27	100.0	100.0	

Valid cases 24 Missing cases 3

OR2YGT Dy21 GAM.GT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	10	37.0	41.7	41.7
O.O.R.	1.00	14	51.9	58.3	100.0
	.	3	11.1	Missing	
Total		27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3YGT Dy42 GAM.GT

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	7	25.9	77.8	77.8
O.O.R.	1.00	2	7.4	22.2	100.0
	.	18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1522

995

FCE 20124/706 i

(9.3.1.2) OR1BSG Dy0 BLOOD SUGAR: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	95.8	95.8
O.O.R.	1.00	1	3.6	4.2	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR2BSG Dy21 BLD.SUG.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	87.5	87.5
O.O.R.	1.00	3	10.7	12.5	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR3BSG Dy42 BLD.SUG.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	19	67.9	86.4	86.4
O.O.R.	1.00	3	10.7	13.6	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	

Valid cases 22 Missing cases 6

1523

996

FCE 20124/706 i

(9.3.1.2) OR1BSG Dy0 BLOOD SUGAR: PPlacebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	74.1	83.3	83.3
O.O.R.	1.00	4	14.8	16.7	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR2BSG Dy21 BLD.SUG.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	18	66.7	75.0	75.0
O.O.R.	1.00	6	22.2	25.0	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3BSG Dy42 BLD.SUG.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	7	25.9	77.8	77.8
O.O.R.	1.00	2	7.4	22.2	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1524

FCE 20124/706 i

(9.3.1.2) OR1ALKP Dy0 ALKALINE PHOSPHATASE: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	95.8	95.8
O.O.R.	1.00	1	3.6	4.2	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR2ALKP Dy21 ALK.PHOS.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	91.7	91.7
O.O.R.	1.00	2	7.1	8.3	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

OR3ALKP Dy42 ALK.PHOS.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	71.4	90.9	90.9
O.O.R.	1.00	2	7.1	9.1	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	

Valid cases 22 Missing cases 6

1525

998

FCE 20124/706 i

(9.3.1.2) OR1ALKP Dy0 ALKALINE PHOSPHATASE: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	81.5	91.7	91.7
O.O.R.	1.00	2	7.4	8.3	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR2ALKP Dy21 ALK.PHOS.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	88.9	100.0	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3ALKP Dy42 ALK.PHOS.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	7	25.9	77.8	77.8
O.O.R.	1.00	2	7.4	22.2	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1526

999

FCE 20124/706 i

(9.3.1.2) OR1BUN Dy0 BUN: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	95.8	95.8
O.O.R.	1.00	1	3.6	4.2	100.0
	.	4	14.3	Missing	

Total		28	100.0	100.0	
Valid cases	24	Missing cases	4		

OR2BUN Dy21 BUN

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	91.7	91.7
O.O.R.	1.00	2	7.1	8.3	100.0
	.	4	14.3	Missing	

Total		28	100.0	100.0	
Valid cases	24	Missing cases	4		

OR3BUN Dy42 BUN

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	95.5	95.5
O.O.R.	1.00	1	3.6	4.5	100.0
	.	6	21.4	Missing	

Total		28	100.0	100.0	
Valid cases	22	Missing cases	6		

1527

1000

FCE 20124/706 i

(9.3.1.2) OR1BUN Dy0 BUN: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	81.5	91.7	91.7
O.O.R.	1.00	2	7.4	8.3	100.0
.	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR2BUN Dy21 BUN

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	88.9	100.0	100.0
.	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3BUN Dy42 BUN

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	8	29.6	88.9	88.9
O.O.R.	1.00	1	3.7	11.1	100.0
.	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1528

1001

FCE 20124/706 i

(9.3.1.2) OR1CRET Dy0 CREATININE: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	70.8	70.8
O.O.R.	1.00	7	25.0	29.2	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	
Valid cases	24	Missing cases	4		

OR2CRET Dy21 CREAT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	70.8	70.8
O.O.R.	1.00	7	25.0	29.2	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	
Valid cases	24	Missing cases	4		

OR3CRET Dy42 CREAT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	10	35.7	45.5	45.5
O.O.R.	1.00	12	42.9	54.5	100.0
	.	6	21.4	Missing	
	Total	28	100.0	100.0	
Valid cases	22	Missing cases	6		

1529

1002

FCE 20124/706 i

(9.3.1.2) OR1CRET Dy0 CREATININE: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	16	59.3	66.7	66.7
O.O.R.	1.00	8	29.6	33.3	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR2CRET Dy21 CREAT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	11	40.7	45.8	45.8
O.O.R.	1.00	13	48.1	54.2	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3CRET Dy42 CREAT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	4	14.8	44.4	44.4
O.O.R.	1.00	5	18.5	55.6	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1530

1003

FCE 20124/706 i

(9.3.1.2) OR1URAC Dy0 URIC ACID: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	89.3	92.6	92.6
O.O.R.	1.00	2	7.1	7.4	100.0
	.	1	3.6	Missing	
Total		28	100.0	100.0	

Valid cases 27 Missing cases 1

OR2URAC Dy21 UR.ACID

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	88.0	88.0
O.O.R.	1.00	3	10.7	12.0	100.0
	.	3	10.7	Missing	
Total		28	100.0	100.0	

Valid cases 25 Missing cases 3

OR3URAC Dy42 UR.ACID

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	91.7	91.7
O.O.R.	1.00	2	7.1	8.3	100.0
	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

1531

1004

FCE 20124/706 i

(9.3.1.2) OR1URAC Dy0 URIC ACID: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	85.2	92.0	92.0
O.O.R.	1.00	2	7.4	8.0	100.0
	.	2	7.4	Missing	
	Total	27	100.0	100.0	

Valid cases 25 Missing cases 2

OR2URAC Dy21 UR.ACID

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	81.5	91.7	91.7
O.O.R.	1.00	2	7.4	8.3	100.0
	.	3	11.1	Missing	
	Total	27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3URAC Dy42 UR.ACID

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	8	29.6	88.9	88.9
O.O.R.	1.00	1	3.7	11.1	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1532

1005

FCE 20124/706 i

(9.3.1.2) OR1TBIL Dy0 TOTAL BILIRUBIN: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	92.9	92.9	92.9
O.O.R.	1.00	2	7.1	7.1	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

OR2TBIL Dy21 TOT.BIL.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	92.9	96.3	96.3
O.O.R.	1.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

OR3TBIL Dy42 TOT.BIL.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	91.7	91.7
O.O.R.	1.00	2	7.1	8.3	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

1533

1006

FCE 20124/706 i

(9.3.1.2) OR1TBIL Dy0 TOTAL BILIRUBIN: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	96.3	96.3	96.3
O.O.R.	1.00	1	3.7	3.7	100.0
	Total	27	100.0	100.0	

Valid cases 27 Missing cases 0

OR2TBIL Dy21 TOT.BIL.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	96.2	96.2
O.O.R.	1.00	1	3.7	3.8	100.0
	.	1	3.7	Missing	
	Total	27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3TBIL Dy42 TOT.BIL.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	8	29.6	88.9	88.9
O.O.R.	1.00	1	3.7	11.1	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1534

1007

FCE 20124/706 i

(9.3.1.2) OR1TPRO Dy0 TOTAL PROTEIN: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	75.0	75.0
O.O.R.	1.00	7	25.0	25.0	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

OR2TPRO Dy21 TOT.PROT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	81.5	81.5
O.O.R.	1.00	5	17.9	18.5	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

OR3TPRO Dy42 TOT.PROT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	87.5	87.5
O.O.R.	1.00	3	10.7	12.5	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	

Valid cases 24 Missing cases 4

1535

1008

FCE 20124/706 i

(9.3.1.2) OR1TPRO Dy0 TOTAL PROTEIN: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	85.2	85.2	85.2
O.O.R.	1.00	4	14.8	14.8	100.0
	Total	27	100.0	100.0	

Valid cases 27 Missing cases 0

OR2TPRO Dy21 TOT.PROT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	88.9	92.3	92.3
O.O.R.	1.00	2	7.4	7.7	100.0
		1	3.7	Missing	
	Total	27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3TPRO Dy42 TOT.PROT.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
		18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1536

1009

FCE 20124/706 i

(9.3.1.2) OR1BALB Dy0 BLOOD ALBUMIN: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	28	100.0	100.0	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

OR2BALB Dy21 BLD.ALBU.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	27	96.4	100.0	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases	27	Missing cases	1		

OR3BALB Dy42 BLD.ALBU.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	85.7	100.0	100.0
	.	4	14.3	Missing	
	Total	28	100.0	100.0	
Valid cases	24	Missing cases	4		

1537

1010

FCE 20124/706 i

(9.3.1.2) OR1BALB Dy0 BLOOD ALBUMIN: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	92.6	92.6
O.O.R.	1.00	2	7.4	7.4	100.0
Total		27	100.0	100.0	

Valid cases 27 Missing cases 0

OR2BALB Dy21 BLD.ALBU.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	96.2	96.2
O.O.R.	1.00	1	3.7	3.8	100.0
Total		27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3BALB Dy42 BLD.ALBU.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1538

1011

FCE 20124/706 i

(9.3.1.2) OR1CHOL Dy0 CHOLESTEROL: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	18	64.3	66.7	66.7
O.O.R.	1.00	9	32.1	33.3	100.0
	.	1	3.6	Missing	
Total		28	100.0	100.0	

Valid cases 27 Missing cases 1

OR2CHOL Dy21 CHOLEST.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	60.7	68.0	68.0
O.O.R.	1.00	8	28.6	32.0	100.0
	.	3	10.7	Missing	
Total		28	100.0	100.0	

Valid cases 25 Missing cases 3

OR3CHOL Dy42 CHOLEST.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	14	50.0	58.3	58.3
O.O.R.	1.00	10	35.7	41.7	100.0
	.	4	14.3	Missing	
Total		28	100.0	100.0	

Valid cases 24 Missing cases 4

1539

1012

FCE 20124/706 i

(9.3.1.2) OR1CHOL Dy0 CHOLESTEROL: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	19	70.4	76.0	76.0
O.O.R.	1.00	6	22.2	24.0	100.0
.	.	2	7.4	Missing	
Total		27	100.0	100.0	

Valid cases 25 Missing cases 2

OR2CHOL Dy21 CHOLEST.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	17	63.0	70.8	70.8
O.O.R.	1.00	7	25.9	29.2	100.0
.	.	3	11.1	Missing	
Total		27	100.0	100.0	

Valid cases 24 Missing cases 3

OR3CHOL Dy42 CHOLEST.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	7	25.9	77.8	77.8
O.O.R.	1.00	2	7.4	22.2	100.0
.	.	18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1540

1013

FCE 20124/706 i

(9.3.1.2) OR1TRIG Dy0 TRIGLYCERIDES: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	85.7	85.7	85.7
O.O.R.	1.00	4	14.3	14.3	100.0
Total		28	100.0	100.0	
Valid cases	28	Missing cases	0		

OR2TRIG Dy21 TRIGLY.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	80.8	80.8
O.O.R.	1.00	5	17.9	19.2	100.0
	.	2	7.1	Missing	
Total		28	100.0	100.0	
Valid cases	26	Missing cases	2		

OR3TRIG Dy42 TRIGLY.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	18	64.3	75.0	75.0
O.O.R.	1.00	6	21.4	25.0	100.0
	.	4	14.3	Missing	
Total		28	100.0	100.0	
Valid cases	24	Missing cases	4		

1541

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FCE 20124/706 i

(9.3.1.2) OR1TRIG Dy0 TRIGLYCERIDES: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	77.8	77.8	77.8
O.O.R.	1.00	6	22.2	22.2	100.0
Total		27	100.0	100.0	

Valid cases 27 Missing cases 0

OR2TRIG Dy21 TRIGLY.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	20	74.1	76.9	76.9
O.O.R.	1.00	6	22.2	23.1	100.0
		1	3.7	Missing	
Total		27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3TRIG Dy42 TRIGLY.

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	6	22.2	66.7	66.7
O.O.R.	1.00	3	11.1	33.3	100.0
		18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1542

1015

FCE 20124/706 i

(9.3.1.2) OR1GA1 Dy0 GLOBULINS α -1: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	92.9	96.3	96.3
O.O.R.	1.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

OR2GA1 Dy21 GLOB.A-1

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	92.9	100.0	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

OR3GA1 Dy42 GLOB.A-1

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	100.0	100.0
	.	5	17.9	Missing	
	Total	28	100.0	100.0	

Valid cases 23 Missing cases 5

1543

1016

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(9.3.1.2) OR1GA1 Dy0 GLOBULINS α-1: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	96.2	96.2
O.O.R.	1.00	1	3.7	3.8	100.0
	.	1	3.7	Missing	
Total		27	100.0	100.0	

Valid cases 26 Missing cases 1

OR2GA1 Dy21 GLOB.A-1

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	96.2	96.2
O.O.R.	1.00	1	3.7	3.8	100.0
	.	1	3.7	Missing	
Total		27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3GA1 Dy42 GLOB.A-1

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1544

1017

FCE 20124/706 i

(9.3.1.2) OR1GA1 Dy0 GLOBULINS α -2: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	92.9	96.3	96.3
O.O.R.	1.00	1	3.6	3.7	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

OR2GA2 Dy21 GLOB.A-2

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	89.3	96.2	96.2
O.O.R.	1.00	1	3.6	3.8	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	

Valid cases 26 Missing cases 2

OR3GA2 Dy42 GLOB.A-2

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	21	75.0	91.3	91.3
O.O.R.	1.00	2	7.1	8.7	100.0
	.	5	17.9	Missing	
	Total	28	100.0	100.0	

Valid cases 23 Missing cases 5

1545

1018

FCE 20124/706 i

(9.3.1.2) OR1GA1 Dy0 GLOBULINS α-2: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	88.9	92.3	92.3
O.O.R.	1.00	2	7.4	7.7	100.0
	.	1	3.7	Missing	
	Total	27	100.0	100.0	

Valid cases 26 Missing cases 1

OR2GA2 Dy21 GLOB.A-2

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	85.2	88.5	88.5
O.O.R.	1.00	3	11.1	11.5	100.0
	.	1	3.7	Missing	
	Total	27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3GA2 Dy42 GLOB.A-2

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1546

1019

FCE 20124/706 i

(9.3.1.2) OR1BETA Dy0 GLOBULINS B: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	27	96.4	100.0	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases	27	Missing cases	1		

OR2BETA Dy21 GLOB.BETA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	85.7	92.3	92.3
O.O.R.	1.00	2	7.1	7.7	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26	Missing cases	2		

OR3BETA Dy42 GLOB.BETA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	22	78.6	95.7	95.7
O.O.R.	1.00	1	3.6	4.3	100.0
	.	5	17.9	Missing	
	Total	28	100.0	100.0	
Valid cases	23	Missing cases	5		

1547

1020

FCE 20124/706 i

(9.3.1.2) OR1BETA Dy0 GLOBULINS β: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	85.2	88.5	88.5
O.O.R.	1.00	3	11.1	11.5	100.0
	.	1	3.7	Missing	
Total		27	100.0	100.0	

Valid cases 26 Missing cases 1

OR2BETA Dy21 GLOB.BETA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	24	88.9	92.3	92.3
O.O.R.	1.00	2	7.4	7.7	100.0
	.	1	3.7	Missing	
Total		27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3BETA Dy42 GLOB.BETA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	7	25.9	77.8	77.8
O.O.R.	1.00	2	7.4	22.2	100.0
	.	18	66.7	Missing	
Total		27	100.0	100.0	

Valid cases 9 Missing cases 18

1548

1021

FCE 20124/706 i

(9.3.1.2) OR1GGAM Dy0 GLOBULINS τ: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	27	96.4	100.0	100.0
	.	1	3.6	Missing	
	Total	28	100.0	100.0	
Valid cases	27	Missing cases	1		

OR2GGAM Dy21 GLOB.GAMMA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	26	92.9	100.0	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26	Missing cases	2		

OR3GGAM Dy42 GLOB.GAMMA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	23	82.1	100.0	100.0
	.	5	17.9	Missing	
	Total	28	100.0	100.0	
Valid cases	23	Missing cases	5		

1010

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FCE 20124/706 i

(9.3.1.2) OR1GGAM Dy0 GLOBULINS τ: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	96.2	96.2
O.O.R.	1.00	1	3.7	3.8	100.0
	.	1	3.7	Missing	
	Total	27	100.0	100.0	

Valid cases 26 Missing cases 1

OR2GGAM Dy21 GLOB.GAMMA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	25	92.6	96.2	96.2
O.O.R.	1.00	1	3.7	3.8	100.0
	.	1	3.7	Missing	
	Total	27	100.0	100.0	

Valid cases 26 Missing cases 1

OR3GGAM Dy42 GLOB.GAMMA

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
W.N.L.	.00	9	33.3	100.0	100.0
	.	18	66.7	Missing	
	Total	27	100.0	100.0	

Valid cases 9 Missing cases 18

1550

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APPENDIX 24

Total Population: Benefit/Risk Ratio

1551

1024

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Transformation procedure for Efficacy Index (EI):		
Score	Therapeutic Effect	Side Effects
01	Marked	None
02	Marked	Do not significantly interfere
03	Marked	Significantly interfere
04	Marked	Outweigh therapeutic effect
05	Moderate	None
06	Moderate	Do not significantly interfere
07	Moderate	Significantly interfere
08	Moderate	Outweigh therapeutic effect
09	Minimal	None
10	Minimal	Do not significantly interfere
11	Minimal	Significantly interfere
12	Minimal	Outweigh therapeutic effect
13	Unchanged/Worse	None
14	Unchanged/Worse	Do not significantly interfere
15	Unchanged/Worse	Significantly interfere
16	Unchanged/Worse	Outweigh therapeutic effect

1552

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(9.4) Summaries of D7E1 Dy7 Efficacy Index
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.0164	.5049	56
GROUP	1	.9671	.5106	28
GROUP	2	1.0657	.5036	28
Total Cases = 56				

Summaries of D7E1 Dy7 Efficacy Index
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	.9671	.5106	7.0390	28
2	1.0657	.5036	6.8469	28

Within Groups Total	1.0164	.5071	13.8859	56

Criterion Variable D7E1

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1360	1	.1360	.5290	.4702
Within Groups	13.8859	54	.2571		
Eta = .0985 Eta Squared = .0097					

1553

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(9.4) Summaries of D14EI Dy14 Efficacy Index
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			1.5417	.7809	52
GROUP	1		1.5962	.7876	26
GROUP	2		1.4873	.7857	26
Total Cases =	56				
Missing Cases =	4 OR	7.1 PCT.			

Summaries of D14EI Dy14 Efficacy Index
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		1.5962	.7876	15.5096	26
2		1.4873	.7857	15.4347	26

Within Groups Total		1.5417	.7867	30.9443	52

Criterion Variable D14EI

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.1540	1	.1540	.2489	.6201
Within Groups	30.9443	50	.6189		
Eta = .0704 Eta Squared = .0050					

1554

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(9.4) Summaries of D21E1 Dy21 Efficacy Index
By levels of GROUP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population				
		1.8300	.9589	51
GROUP	1	1.9935	.9633	26
GROUP	2	1.6600	.9434	25
Total Cases = 56				
Missing Cases = 5 OR 8.9 PCT.				

Summaries of D21E1 Dy21 Efficacy Index
By levels of GROUP

Value Label	Mean	Std Dev	Sum of Sq	Cases
1	1.9935	.9633	23.1978	26
2	1.6600	.9434	21.3600	25

Within Groups Total	1.8300	.9536	44.5578	51

Criterion Variable D21E1

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.4172	1	1.4172	1.5585	.2178
Within Groups	44.5578	49	.9093		
Eta = .1756 Eta Squared = .0308					

1555

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(9.4) Summaries of D28E1 Dy28 Efficacy Index
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			2.6760	1.1662	35
GROUP	1		2.5464	1.2378	25
GROUP	2		3.0000	.9428	10
Total Cases =		56			
Missing Cases =		21 OR 37.5 PCT.			

Summaries of D28E1 Dy28 Efficacy Index
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		2.5464	1.2378	36.7740	25
2		3.0000	.9428	8.0000	10

Within Groups Total		2.6760	1.1648	44.7740	35

Criterion Variable D28E1

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	1.4697	1	1.4697	1.0832	.3055
Within Groups	44.7740	33	1.3568		
Eta = .1783 Eta Squared = .0318					

1556

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(9.4) Summaries of D35E1 Dy35 Efficacy Index
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population					
			3.0441	1.1439	34
GROUP	1		2.9375	1.2186	24
GROUP	2		3.3000	.9487	10
Total Cases = 56					
Missing Cases = 22 OR 39.3 PCT.					

Summaries of D35E1 Dy35 Efficacy Index
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases	
1		2.9375	1.2186	34.1563	24	
2		3.3000	.9487	8.1000	10	

Within Groups Total			3.0441	1.1491	42.2563	34

Criterion Variable D35E1

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.9276	1	.9276	.7024	.4082
Within Groups	42.2563	32	1.3205		
Eta = .1466		Eta Squared = .0215			

1557

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(9.4) Summaries of D42EI Dy42 Efficacy Index
By levels of GROUP

Variable	Value	Label	Mean	Std Dev	Cases
For Entire Population			3.2656	1.0775	32
GROUP	1		3.2955	1.1197	22
GROUP	2		3.2000	1.0328	10
Total Cases =	56				
Missing Cases =	24 OR	42.9 PCT.			

Summaries of D42EI Dy42 Efficacy Index
By levels of GROUP

Value	Label	Mean	Std Dev	Sum of Sq	Cases
1		3.2955	1.1197	26.3295	22
2		3.2000	1.0328	9.6000	10

Within Groups Total		3.2656	1.0944	35.9295	32

Criterion Variable D42EI

Analysis of Variance

Source	Sum of Squares	D.F.	Mean Square	F	Sig.
Between Groups	.0626	1	.0626	.0523	.8207
Within Groups	35.9295	30	1.1977		
Eta = .0417 Eta Squared = .0017					

1558

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(9.4) * * * A N A L Y S I S O F V A R I A N C E * * *

BY D42EI Dy42 Efficacy Index
 GROUP
 WITH D7EI Dy7 Efficacy Index

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Covariates	2.412	1	2.412	2.108	.157
D7EI	2.412	1	2.412	2.108	.157
Main Effects	.396	1	.396	.346	.561
GROUP	.396	1	.396	.346	.561
Explained	2.808	2	1.404	1.227	.308
Residual	33.184	29	1.144		
Total	35.992	31	1.161		

56 Cases were processed.
 24 Cases (42.9 PCT) were missing.

1559

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APPENDIX 25

Indirect Indicators
of Efficacy at Termination

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(9.5.1) Summaries of TDUR Trial Duration
By levels of DRUGRP

Variable	Value Label	Mean	Std Dev	Cases
For Entire Population		32.6071	12.0570	56
DRUGRP	1	38.1429	9.2725	28
DRUGRP	2	27.0714	12.1073	28
Total Cases =				56

*** ANALYSIS OF VARIANCE ***

TDUR Trial Duration
BY DRUGRP

Source of Variation	Sum of Squares	DF	Mean Square	F	Signif of F
Main Effects	1716.071	1	1716.071	14.758	.000
DRUGRP	1716.071	1	1716.071	14.758	.000
Explained	1716.071	1	1716.071	14.758	.000
Residual	6279.286	54	116.283		
Total	7995.357	55	145.370		

56 Cases were processed.
0 Cases (.0 PCT) were missing.

1561

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(9.5.2) DISP - Disposition at Termination: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Remain.Hosp	1.00	14	50.0	51.9	51.9
Discharged	2.00	13	46.4	48.1	100.0
.	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

DISP - Disposition at Termination: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Remain.Hosp	1.00	22	78.6	81.5	81.5
Discharged	2.00	4	14.3	14.8	96.3
Other	3.00	1	3.6	3.7	100.0
.	.	1	3.6	Missing	
	Total	28	100.0	100.0	

Valid cases 27 Missing cases 1

1562

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(9.5.2) C R O S S T A B U L A T I O N

DISP by DRUGRP

Page 1 of 1

Count	DRUGRP		Row Total
	RBX	PBO	
1.00	14	22	36
Remain.Hosp			66.7
2.00	13	4	17
Discharged			31.5
3.00		1	1
Other			1.9
Column Total	27	27	54
Total	50.0	50.0	100.0

Chi-Square	Value	DF	Significance
Pearson	7.54248	2	.02302
Likelihood Ratio	8.19579	2	.01661
Mantel-Haenszel test for linear association	3.35964	1	.06681

Minimum Expected Frequency = .500
 Cells with Expected Frequency < 5 = 2 OF 6 (33.3%)

Number of Missing Observations: 2

1563

1036

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(9.5.2) VAR1 Disposition & Meds: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Hosp.w/meds	1.00	6	21.4	23.1	23.1
Hosp.wo/meds	2.00	8	28.6	30.8	53.8
Dcd w/meds	3.00	1	3.6	3.8	57.7
Dcd wo/meds	4.00	11	39.3	42.3	100.0
.	.	2	7.1	Missing	
Total		28	100.0	100.0	
Valid cases	26	Missing cases	2		

VAR1 Disposition & Meds: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Hosp.w/meds	1.00	18	64.3	69.2	69.2
Hosp.wo/meds	2.00	4	14.3	15.4	84.6
Dcd w/meds	3.00	1	3.6	3.8	88.5
Dcd wo/meds	4.00	3	10.7	11.5	100.0
.	.	2	7.1	Missing	
Total		28	100.0	100.0	
Valid cases	26	Missing cases	2		

1564

1037

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(9.5.2) C R O S S T A B U L A T I O N

VAR1 Disposition & Meds by DRUGRP

Count DRUGRP Page 1 of 1

VAR1	Count	DRUGRP		Row
		1	2	Total
1.00	6	18	24	46.2
Hosp.w/meds				
2.00	8	4	12	23.1
Hosp.wo/meds				
3.00	1	1	2	3.8
Dcd w/meds				
4.00	11	3	14	26.9
Dcd wo/meds				
Column	26	26	52	
Total	50.0	50.0	100.0	

Chi-Square	Value	DF	Significance
Pearson	11.90476	3	.00772
Likelihood Ratio	12.49806	3	.00586
Mantel-Haenszel test for linear association	9.45695	1	.00210

Minimum Expected Frequency = 1.000
 Cells with Expected Frequency < 5 = 2 OF 8 (25.0%)

Number of Missing Observations: 4

1565

1038

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FCE 20124/706 i

(9.5.2) MEDS Presc.New Meds by DRUGRP

Page 1 of 1

Count	DRUGRP		Row Total
	RBX 1	PBO 2	
MEDS 1.00 Yes	7	19	26 49.1
MEDS 2.00 No	19	8	27 50.9
Column Total	26 49.1	27 50.9	53 100.0

Chi-Square	Value	DF	Significance
Pearson	10.00464	1	.00156
Continuity Correction	8.34165	1	.00387
Likelihood Ratio	10.34969	1	.00129
Mantel-Haenszel test for linear association	9.81587	1	.00173

Minimum Expected Frequency = 12.755

Number of Missing Observations: 3

1566

1039

FCE 20124/706 i

(9.5.2) MEDSPR Meds.Prescribed in Hospital: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
		22	78.6	78.6	78.6
	Ativan	1	3.6	3.6	82.1
	DESIPRAM	1	3.6	3.6	85.7
	FLUOXETI	1	3.6	3.6	89.3
	IMIPRAMI	3	10.7	10.7	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

MEDSPR Meds.Prescribed in Hospital: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
		10	35.7	35.7	35.7
	Ativan	1	3.6	3.6	39.3
	Capoten	1	3.6	3.6	42.9
	IMIPRAMI	8	28.6	28.6	71.4
	Imiprami	6	21.4	21.4	92.9
	Librium/ fluoxeti	1	3.6	3.6	96.4
		1	3.6	3.6	100.0
	Total	28	100.0	100.0	

Valid cases 28 Missing cases 0

1567

1040

FCE 20124/706 i

(9.5.2) PRDCMEDS DC Meds Prescribed: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
None		28	100.0	100.0	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

PRDCMEDS DC Meds Prescribed: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
		27	96.4	96.4	96.4
	Imiprami	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

1568

1041

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(9.5.3) FINCON Final Conclusions: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Def.No	0	3	10.7	12.0	12.0
Inclin.No	1	1	3.6	4.0	16.0
Undecided	2	1	3.6	4.0	20.0
Inclin.Yes	3	1	3.6	4.0	24.0
Def.Yes	4	19	67.9	76.0	100.0
.	.	3	10.7	Missing	
Total		28	100.0	100.0	
Valid cases	25	Missing cases	3		

FINCON Final Conclusions: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Def.No	0	14	50.0	58.3	58.3
Inclin.No	1	3	10.7	12.5	70.8
Undecided	2	1	3.6	4.2	75.0
Inclin.Yes	3	2	7.1	8.3	83.3
Def.Yes	4	4	14.3	16.7	100.0
.	.	4	14.3	Missing	
Total		28	100.0	100.0	
Valid cases	24	Missing cases	4		

1569

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APPENDIX 26

Indirect Indicators
of Efficacy at Follow-up

1570

1043

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(9.6) DAY of Assessment: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	14	1	3.6	3.6	3.6
	42	1	3.6	3.6	7.1
	49	4	14.3	14.3	21.4
	56	1	3.6	3.6	25.0
	70	11	39.3	39.3	64.3
	72	9	32.1	32.1	96.4
	74	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

DAY of Assessment: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
	5	2	7.1	7.1	7.1
	42	5	17.9	17.9	25.0
	49	10	35.7	35.7	60.7
	52	3	10.7	10.7	71.4
	70	4	14.3	14.3	85.7
	72	3	10.7	10.7	96.4
	77	1	3.6	3.6	100.0
	Total	28	100.0	100.0	
Valid cases	28	Missing cases	0		

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(9.6.2) ONMEDS Antid.Meds: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	20	71.4	76.9	76.9
Yes	1	6	21.4	23.1	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26	Missing cases	2		

ONMEDS Antid.Meds: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
No	0	7	25.0	26.9	26.9
Yes	1	19	67.9	73.1	100.0
	.	2	7.1	Missing	
	Total	28	100.0	100.0	
Valid cases	26	Missing cases	2		

1572

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(9.6.2) C R O S S T A B U L A T I O N

ONMEDS Antid.Meds by DRUGRP

Page 1 of 1

Count	DRUGRP		Row
	RBX	PBO	Total
ONMEDS			
No	0	27	27 51.9
Yes	1	24	25 48.1
Column Total	26	26	52 100.0

Chi-Square	Value	DF	Significance
Pearson	13.01926	1	.00031
Continuity Correction	11.09333	1	.00087
Likelihood Ratio	13.63015	1	.00022
Mantel-Haenszel test for linear association	12.76889	1	.00035

Minimum Expected Frequency = 12.500

Number of Missing Observations: 4

1573

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(9.6.3) PCON Pres.Condit. at Follow-up: Reboxetine

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Outpt.	0	21	75.0	80.8	80.8
Inpt.	1	2	7.1	7.7	88.5
DCd	2	3	10.7	11.5	100.0
.	.	2	7.1	Missing	
Total		28	100.0	100.0	
Valid cases	26	Missing cases	2		

PCON Pres.Condit. at Follow-up: Placebo

Value Label	Value	Frequency	Percent	Valid Percent	Cum Percent
Outpt.	0	21	75.0	80.8	80.8
Inpt.	1	4	14.3	15.4	96.2
DCd	2	1	3.6	3.8	100.0
.	.	2	7.1	Missing	
Total		28	100.0	100.0	
Valid cases	26	Missing cases	2		

1574

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(9.6.3) C R O S S T A B U L A T I O N

PCON Pres.Condit. by DRUGRP

Page 1 of 1

PCON	Count	DRUGRP		Row Total
		RBX 1	PBO 2	
0	42	21	21	42
Outpt.	80.8			
1	6	2	4	6
Inpt.	11.5			
2	4	3	1	4
DCd	7.7			
Column Total	52	26	26	52
	100.0	50.0	50.0	100.0

Chi-Square	Value	DF	Significance
Pearson	1.66667	2	.43460
Likelihood Ratio	1.72609	2	.42187
Mantel-Haenszel test for linear association	.21519	1	.64273

Minimum Expected Frequency = 2.000
 Cells with Expected Frequency < 5 = 4 OF 6 (66.7%)

Number of Missing Observations: 4

1575

1048

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APPENDIX 27

Ethical Committee Approval

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A copy of the Ethical Committee Approval is archived in the Study Master File

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124

CTN: 20124/ADE 091

Phase II Placebo-Controlled Clinical Study with Reboxetine in Major Depressions.

ADDENDUM TO REPORT NO. 706/i BASED ON THE ANALYSES OF DATA COLLECTED BY CODE-DD IN THE BRAZILIAN SUBSAMPLE OF THE STUDY

INVESTIGATOR: Dr. Marcio Versiani
Dr. A. E. Nardi

MONITOR: Dr. Alcione Moraes de Souza

REPORTING: Dr. Thomas A. Ban
Olaf K. Fjetland
A. Dubini

A. Dubini

July 14, 95
Date

Alcione Dubini
Signature

Pharmacia CNS

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REBOXETINE - PROTOCOL ADE 091

ADDENDUM

SYNOPSIS

Name of Company: Pharmacia	Individual study Table referring to part IV of the dossier	(For national authority use only)
Name of finished product:	Ref.:	
Name of active ingredient(s): Reboxetine	Vol.:	
	Page:	
Title of the study: Phase II Placebo-Controlled Clinical Study with Reboxetine in Major Depressions - ADDENDUM -		
Investigators: Dr. Marcio Versiani, Dr. A.E. Nardi		
Study centres:*		
Publication (reference):*		
Study period:*	Clinical Phase:*	
Objectives:*		
Methodology:*		
Number of subject (total and for each treatment):*		
Diagnosis and criteria for inclusion: *		
Test product:*	mode of administration:*	batch no.:*
Duration of treatment:*		
Reference therapy:*	batch no.:*	
Criteria for evaluation:*		
Statistical methods:*		
<p>Summary- Conclusions : CODE-DD was administered prior to commencement of treatment to all 44 patients included in the Brazilian sample of a placebo-controlled (PBO), multinational clinical trial with reboxetine (RBX). The two treatment groups were comparable in all but eight variables. Significantly more patients displayed the diagnosis of pure depression and the variables genetically pure, body misperceptions, decreased appetite and time still in the RBX than in the PBO group, whereas significantly more patients displayed the diagnosis of sporadic depression and variables impairment of social adaptation and early insomnia in the PBO- than in the RBX- treated group.</p> <p>Analyses of data revealed that the presence of insidious onset, bodily misperceptions and feelings of impoverishment and/or the absence of diurnal variation had a negative effect on the therapeutic response to RBX, and that the presence of depersonalisation and self-incrimination had a negative effect, while the presence of precipitating factor with temporal connection and hypochondriasis had a positive effect on responsiveness to PBO.</p> <p>It was noted that in 33 of the 39 diagnosis-based populations in which at least 5 patients were included in each treatment group, treatment with reboxetine was superior to treatment with placebo and that in the remaining 6 populations (never represented with more than 10 patients per treatment group) treatment with RBX and treatment with PBO were equal.</p>		

* see Synopsis of report no.7061

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2. INTRODUCTION

The Composite Diagnostic Evaluation of Depressive Disorders (CODE-DD)* includes a diagnostic assessment scale (RSDD, based on 90 characteristic variables of depressive illness, scored as present or absent) and a severity assessment subscale (RSASDD based on 40 of the above mentioned variables). The instrument, by specially devided algorithms, provides diagnoses within 25 systems of diagnostic classification of depressive disorders simultaneously. The classifications were selected on the basis of their relevance to the conceptual development of the different forms and subforms of depressive illness.

This report is based on the analyses of data collected by the administration of CODE-DD to 44 patients with the clinical diagnosis of major depression (DSM-III-R). The 44 patients constituted the total population of the Brazilian sample of a multinational double-blind, placebo-controlled clinical trial with reboxetine conducted at three centers in two countries (Brazil and Canada) in a total of 56 patients. The analysis has been limited to the CODE-DD data from the Brazilian sample, to focus more homogeneous, single-centre population.

CODE-DD was administered only once to each patient prior to the commencement of treatment with reboxetine and/or placebo. Because of this, in the efficacy analyses changes in the HAMD total score from Day 0 to Day 43 were employed.

The five parts of this report are:

1. Description of Population
2. Exploration of Symptoms
3. Exploration of Diagnoses
4. Correspondence Between Severity Scores
5. Raw Data Listing

* Comparative Diagnostic Evaluation of Depressive Disorders Code-DD. Ban T A, Brentwood, TN: JM Productions, Inc. 1989

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PART ONE:

DESCRIPTION OF POPULATION

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Part One consists of two sections of which, in the first one, the total population is characterised and, in the second, the comparability of the two treatment groups is discussed.

Description of the population in Part One is based on the introductory section of CODE-DD, which is not an integral part of the composite diagnostic evaluation.

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Characteristic of Total Population

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The total population of this study of 44 hospitalised patients with the clinical diagnosis of major depression (DSM-III-R) in Rio de Janeiro.

As shown in Table 1, there was an equal distribution of males (22 patients - 50%) and females (22 patients - 50%), ranging in age from 18 to 58 years, with a mean age of 39.9 years.

In terms of personal characteristic, as shown in Table 2, with the exception of 1, all patients were high school graduates, including 13 (29.5%) patients with a university degree; and nearly one-half (19 - 43.2%) of the patients were professionals. The majority (28 - 63.6%) of the patients were married.

In terms of patients characteristics - as shown in Table 2 -- more than one half (25 - 56.8%) of the patients had seen a physician for their depression prior to present hospitalisation, but less than one half (19 - 43.2%) had prior pharmacologic treatment for their depression. Only 2 (4.5%) of the patients had prior hospitalisation for depression and none received electro-convulsive treatment in the past.

In terms of their past non-psychiatric medical history -- as shown also in Table 2 -- more than one-half (25 - 56.8%) of the patients had prior surgical intervention: and of the 22 females, 5 (22.7%) had hysterectomy or tubal ligation. It was noted that 15 (68.2%) of the 22 female patients were not of childbearing potential.

In terms of depressive characteristics -- as shown in Table 2 -- 13 (29.5%) of the patients were tearful at the time of the diagnostic evaluation; 6 (13.6%) displayed Veraguti's fold; and 4 (9.1%) displayed Omega sign.

Table 1
Sex and Age Distribution in the Total Population

	Sex				Age		
	Males		Females		Mean	S.D.	Range
	N	%	N	%			
Total Population	22	50.0	22	50.0	39.9	10.9	18-59

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Table 2
Description of Personal and Patient Characteristics

Variables	N	%	Variables	N	%
Marital Status			Prior ECT		
Married/Common Law	28	63.6	No	44	100
Divorced/Separated	2	4.5	Surgical Intervention		
Widow(er)	2	4.5	Yes	25	56.8
Single	12	27.3	No	19	43.2
Highest Grade			Hysterectomy/ Tubal Ligation***		
High School	30	68.2	Yes	5	22.7
University Degree	13	29.5	No	17	77.3
Missing Data	1	2.3	Childbearing Potential***		
Occupation			Yes	7	31.8
Skilled Worker	11	25.0	No	15	68.2
Professional*	19	43.2	Omega Sign		
Housewife	6	13.6	Yes	4	9.1
Secretary	5	11.4	No	40	90.9
Student	3	6.8	Veraguth's Folds		
Prior Hospitalisation			Yes	6	13.6
Yes**	2	4.5	No	38	86.4
No	42	95.5	Tearful		
Prior Dr. Visit			Yes	13	29.5
Yes	25	56.8	No	31	70.5
No	19	43.2			
Prior Treatment with Medication					
Yes	19	43.2			
No	25	56.8			

* Included under professional were the following: engineer, lawyer, nurse, nursing assistant, bank clerk, business woman, music professor, university professor, seller, translator, teacher and administrative worker.

** The age of 1 patient at the time of prior hospitalisation was 40 years and of the other it was 31.

*** Percentages are based on the female subsample.

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Comparability of Treatment Groups

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Table 4 (cont.)
Comparability of Personal and Patient Characteristics in Two Treatment Groups.

Variables	RBX		PBO		Level of Significance
	N	%	N	%	
Prior Dr. Visit					
Yes	11	50.0	14	63.6	p = .361
No	11	50.0	8	36.4	
Prior Treatment with Medication					
Yes	8	36.4	11	50.0	p = .361
No	14	63.6	11	50.0	
Prior Ect					
No	22	100.0	22	100.0	N/A
Surgical Intervention					
Yes	16	72.7	9	40.9	p = .047*
No	6	17.3	13	59.1	
Hysterectomy/ Tubal Ligation					
Yes	2	18.2	3	27.3	p = .269
No	9	81.8	8	72.7	
Childbearing Potential					
Yes	2	18.2	5	45.5	p = .170
No	9	81.8	6	54.5	
Omega Sign					
Yes	2	9.1	2	9.1	p = 1.000
No	20	90.9	20	90.9	
Veraguth's Folds					
Yes	5	22.7	1	4.5	p = .079
No	17	77.3	21	95.5	
Tearful					
Yes	6	27.3	7	31.8	p = .741
No	16	72.7	15	68.2	

* Statistically Significant.

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PART TWO:
EXPLORATION OF SYMPTOMS

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Exploration of symptoms, i.e., symptom-based analyses, was conducted in four steps, with the aim of establishing:

1. symptom structure of depressive illness in study population;
2. comparability of symptom display in two treatment- (i.e., reboxetine and placebo) groups;
3. responsiveness of symptom-based population; and
4. comparative responsiveness of symptom-based populations to treatment

To render the 90 variables accessible for symptom-based analyses, the variable “medical illness” was split into two variables, i.e., “medical psychiatric illness” and “medical non-psychiatric illness”; the variable “temporal connection” was split into four variables, i.e., “medical non-psychiatric illness with temporal connection”, “medical psychiatric illness with temporal connection”, “treatment with mood depressant medication with temporal connection”, and “precipitating factors with temporal connection”; and the variables “genetically sporadic and insidious onset” were added to the cluster “predisposing factors” and “onset”, respectively. With these changes the 90 variable of the RSDD was transformed into 96 (72 dichotomous symptom, 18 dichotomous non-symptom and 6 comparative) new variables, which are as follows:

Cluster	Number		Variable	Specification
	Old	New		
Predisposing Factors	1	1	Genetically on Spectrum	Comparative of 1 vs 2 vs 3
	2	2	Genetically pure	Comparative of 1 vs 2 vs 3
	3	3	Genetically sporadic	Comparative of 1 vs 2 vs 3
	3	4	Impairment of social adaptation in past	Dichotomous non-symptom
Etiologic Factors	4	5	Medical non-psychiatric illness	Dichotomous non-symptom
	4	6	Medical psychiatric illness	Dichotomous non-symptom
	5	7	Treatment with mood depressant medication	Dichotomous non-symptom
	6	8	Precipitating factor	Dichotomous non-symptom
	7	9	Medical non-psychiatric illness with temporal connection	Dichotomous non-symptom
	7	10	Medical non-psychiatric illness with temporal connection	Dichotomous non-symptom
	7	11	Treatment with mood depressant medication with temporal connection	Dichotomous non-symptom
	7	12	Precipitating factor with temporal connection	Dichotomous non-symptom
Determinating Structure	8	13	Early Onset	Dichotomous non-symptom
	9	14	Acute Onset	Comparative of 14 vs 15 vs 16
A. Onset	10	15	Subacute Onset	Comparative of 14 vs 15 vs 16
		16		Comparative of 14 vs 15 vs 16

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Symptom Structure of Depressive Illness in Study Population

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To establish the basic structure and the symptom structure of depressive illness in the population studied the number and percentage of patients displaying each of the new variables in the total population was identified (Tables 5-22); and variables relevant to the basic structure (Table 23) and variables relevant to the symptom structure (Table 24) were ranked separately.

In terms of the basic structure of depressive illness, as shown in Table from 5 to 7, it was noted that in 37 (84.1%) of the patients the onset of depression was acute (22-50%) or subacute (15 -34.1%); and in nearly one-half (21 -47.7%) of the patients the depressive disorder was genetically pure. In only 4 (9.1%) patients was the depressive illness of early onset; and in only 7 (15.9%) patients was precipitating factor with temporal connection present.

In terms of the symptom structure, it was noted that 31 of the 72 variables were present in at least 75% of the 44 patients, with 13 symptoms -- including the four present in 100% -- present in at least 90%.

Table 5
Predisposing Factors: Number and Percentage of Patients in Total Population
(P=Present; A=Absent)

Variable	N	%
Genetically on Spectrum	8	18.2
Genetically Pure	21	47.7
Genetically Sporadic	15	34.1
P-Impairment of Social Adaptation in Past	8	18.2
A-Impairment of Social Adaptation in Past	36	81.8

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Table 7
Onset: Number and Percentage
of Patients in Total Population

Variable	N	%
P-Early onset	4	9.1
A-Early onset	40	90.9
Acute onset	22	50.0
Subacute onset	15	34.1
Insidious onset	7	15.9

Table 8
Disturbance of Attention and Memory: Number and Percentage
of Patients in Total Population

Variable	N	%
Disturbance of concentration	41	93.2

Table 9
Disorders of Perception: Number and Percentage
of Patients in Total Population

Variable	N	%
Hallucinations	0	0.0
Bodily misperceptions	7	15.9

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Table 10
Formal Disorders of Thought: Number and Percentage
of Patients in Total Population

Variable	N	%
Rumination	38	86.4
Retarded thinking	33	75.0
Inhibited thinking	0	0.0
Constricted thinking	34	77.3
Tangential thinking	1	2.3
Incoherence	1	2.3

Table 11
Delusions: Number and Percentage
of Patients in Total Population

Variable	N	%
Ideas of reference	2	4.5
Delusions	0	0.0

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Table 12
Disorders of the Experience of the Self: Number and Percentage
of Patients in Total Population

Variable	N	%
Thought broadcasting	0	0.0
Thought withdrawal	0	0.0
Thought insertion	0	0.0
Other feelings of alien influence	0	0.0
Derealization	25	56.8
Depersonalisation	31	70.5

Table 13
Phobias and Compulsion: Number and Percentage
of Patients in Total Population

Variable	N	%
Hypochondriasis	27	64.1
Suspiciousness	7	15.9
Phobias	25	56.8
Obsessive thoughts	15	34.1

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Table 14
Disturbance of Affect: Number and Percentage
of Patients in Total Population

Variable	N	%
Anxious mood	43	97.7
Reactive mood changes	21	47.7
Depressed mood	44	100.0
Unmotivated depressed mood	31	70.5
Depressive evaluations	42	95.5
Parathymia	1	2.3
Anxiety	44	100.0
Dysphoria	41	93.2
Unmotivated dysphoria	28	63.6
Constricted affect	38	86.4
Anhedonia	33	75.0
Apathetic indifference	24	54.5
Feeling of loss of feeling	33	75.0
Feelings of inadequacy	39	88.6
Feelings of guilt	29	65.9
Feelings of impoverishment	15	34.1
Lack of interest	33	75.0
Displeasure	39	88.6
Hopelessness	37	84.1
Self-incrimination	19	43.2

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Table 14 (cont.)
Disturbance of Affect: Number and Percentage
of Patients in Total Population

Variable	N	%
Irritability	39	88.6
Hostility	39	70.5
Vegetative manifestations	16	36.4
Asthenia	44	100.0
Corporization	14	31.8
Felt loss of vitality	41	93.2
Disturbance of vital balance	36	81.8
Complaintiveness	33	75.0
Driven complaintiveness	15	34.1

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Table 15
Disorders of Drive and Psychomotility: Number and Percentage
of Patients in Total Population

Variable	N	%
Lack of drive	42	95.5
Decreased sex drive	39	88.6
Loss of desire to live	30	68.2
Suicidal tendencies	11	25.0
Histrionics	5	11.4
Motor restlessness	7	15.9
Abulia	38	86.4
Motor retardation	32	72.7
Negativism	1	2.3
Parakinesis	1	2.3

Table 16
Circadian Disturbances: Number and Percentage
of Patients in Total Population

Variable	N	%
Diurnal variations	31	70.5
Worse in the morning	25	56.8

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Table 17
Disturbances of Sleep and Vigilance: Number and Percentage
of Patients in Total Population

Variable	N	%
Early insomnia	40	90.9
Middle insomnia	35	79.5
Late insomnia	42	95.5
Hypersomnia	1	2.3

Table 18
Appetite Disturbances: Number and Percentage
of Patients in Total Population

Variable	N	%
Decreased appetite	37	84.1
Excessive appetite	3	6.8

Table 19
Miscellaneous Symptoms: Number and Percentage
of Patients in Total Population

Variable	N	%
Indecisiveness	41	93.2
Time still	35	79.5
Mood congruent psychotic symptoms	1	2.3

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Table 20
Course: Number and Percentage
of Patients in Total Population

Variable	N	%
P-first episode	25	56.8
A-first episode	19	43.2
P-manic/hypomanic episode in past	0	0.0
A-manic/hypomanic episode in past	44	100.0
P-seasonal pattern*	0	0.0
A-seasonal pattern*	19	100.0
P-prolonged duration	8	18.2
A-prolonged duration	36	81.8
P-continuous presence in past	0	0.0
A-continuous presence in past	44	100.0
P-responsiveness to somatic treatment in past*	17	89.5
A-responsiveness to somatic treatment in past*	2	10.5

* based on total of 19 (100%) patients

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Table 23
Rank Order, With Number and Percentage of Patients in Total Population Displaying Each Non-Symptom Variable

Rank N	Variable Non-Symptom	Total	
		N	%
1	A-medical non-psychiatric illness	44	100.0
1	A-medical psychiatric illness	44	100.0
1	A-treatment with mood depressant medication	44	100.0
1	A-medical non-psychiatric illness w/temporal connection	44	100.0
1	A-medical psychiatric illness w/temporal connection	44	100.0
1	A-treatment with mood depressant medication/temporal connection	44	100.0
1	A-Manic/Hypomanic episode in past	44	100.0
1	A-continuous presence in past	44	100.0
1	A-excessive alcohol consumption	44	100.0
10	P-full recovery in past*	18	94.7
10	A-Early onset	40	90.9
12	A-impairment of social adaptation in past	36	81.8
12	A-precipitating factor	36	81.8
12	A-prolonged duration	36	81.8
15	P-first episode	25	56.8
16	Acute onset	22	50.0
17	Genetically pure	21	47.7
18	A-first episode (recurrent)	19	43.2
18	A-seasonal pattern*	19	100.0
20	P-responsiveness to somatic treatment in past*	17	89.5
21	Genetically sporadic	15	34.1
21	Subacute onset	15	34.1
23	Genetically on spectrum	8	18.2
23	P-impairment of social adaptation in past	8	18.2
23	P-precipitating factor	8	18.2
23	P-prolonged duration	8	18.2
27	Insidious onset	7	15.9
27	P-precipitating factor w/temporal connection	7	15.9
29	P-early onset	4	9.1
30	A-responsiveness to somatic treatment in past*	2	10.5
31	A-fully recovery in past*	1	5.3

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Table 23 (cont.)
Rank Order, With Number and Percentage of Patients in Total Population Displaying Each Non-Symptom Variable

Rank N	Variable Non-Symptom	Total	
		N	%
32	P-medical non-psychiatric illness	0	0.0
32	P-medical psychiatric illness	0	0.0
32	P-treatment with mood depressant medication	0	0.0
32	P-medical non-psychiatric illness w/temporal connection	0	0.0
32	P-medical psychiatric illness w/temporal connection	0	0.0
32	P-treatment with mood depressant medication/temporal connection	0	0.0
32	P-Manic/Hypomanic episode in past	0	0.0
32	P-seasonal pattern*	0	0.0
32	P-continuous presence in past	0	0.0
32	P-excessive alcohol consumption	0	0.0

* Based on a total of 19 (100%) patients (P=Present; A= Absent)

Table 24
Rank Order, with Number and Percentage of Patients in Total Population Displaying Each Symptom Variable

Rank N	Variable Symptom	Total	
		N	%
1	Depressed mood	44	100.0
1	Anxiety	44	100.0
1	Asthemia	44	100.0
1	Impairment of social adaptation	44	100.0
5	Anxious mood	43	97.7
6	Depressive evaluation	42	95.5
6	Lack of drive	42	95.5
6	Late insomnia	42	95.5
9	Disturbance of concentration	41	93.2
9	Dysphoria	41	93.2
9	Felt loss of vitality	41	93.2
9	Indecisiveness	41	93.2
13	Early insomnia	40	90.9
14	Feelings of inadequacy	39	88.6
14	Displeasure	39	88.6
14	Irritability	39	88.6
14	Decreased sex drive	39	88.6

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Table 24 (cont.)
Rank Order, with Number and Percentage of Patients in Total Population Displaying Each Symptom Variable

Rank N	Variable Symptom	Total	
		N	%
18	Rumination	38	86.4
18	Constricted affect	38	86.4
18	Abulia	38	86.4
21	Hopelessness	37	84.1
21	Decreased appetite	37	84.1
23	Disturbance of vital balance	36	81.8
24	Middle insomnia	35	79.5
24	Time still	35	79.5
26	Constricted thinking	34	77.3
27	Retarded thinking	33	75.0
27	Anhedonia	33	75.0
27	Feeling of loss of feeling	33	75.0
27	Lack of interest	33	75.0
27	Complaintiveness	33	75.0
32	Motor retardation	32	72.5
33	Depersonalisation	31	70.5
33	Unmotivated depressed mood	31	70.5
33	Hostility	31	70.5
33	Diurnal variations	31	70.5
37	Loss of desire to live	30	68.2
38	Feeling of guilt	29	65.9
39	Unmotivated dysphoria	28	63.6
40	Hypochondriasis	27	64.1
41	Derealization	25	56.8
41	Phobias	25	56.8
41	Worse in the morning	25	56.8
44	Apathetic indifference	24	54.5
45	Reactive mood changes	21	47.7
46	Self-incrimination	19	43.2
47	Vegetative manifestations	16	36.4

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Table 24 (cont.)
Rank Order, with Number and Percentage of Patients in Total Population Displaying Each Symptom Variable

Rank N	Variable Symptom	Total	
		N	%
48	Obsessive thoughts	15	34.1
48	Feelings of impoverishment	15	34.1
48	Driven complaintiveness	15	34.1
51	Corporization	14	31.8
52	Suicidal tendencies	11	25.0
53	Bodily misperceptions	7	15.9
53	Suspiciousness	7	15.9
53	Motor restlessness	7	15.9
56	Histrionics	5	11.4
57	Excessive appetite	3	6.8
58	Ideas of reference	2	4.5
59	Tangential thinking	1	2.3
59	Incoherence	1	2.3
59	Parathymia	1	2.3
59	Negativism	1	2.3
59	Parakinesis	1	2.3
59	Hypersomnia	1	2.3
59	Mood congruent psychotic symptoms	1	2.3
66	Hallucinations	0	0.0
66	Inhibited thinking	0	0.0
66	Delusions	0	0.0
66	Thought broadcasting	0	0.0
66	Thought withdrawal	0	0.0
66	Thought insertion	0	0.0
66	Other feelings of alien influence	0	0.0

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Comparability of Symptom Display in Two Treatment Groups

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Comparability of symptom display in the two treatment groups was examined in terms of number and percentage of patients displaying each new RSDD variable in each treatment group. A clinical difference in symptom display between the two treatment groups was expressed by numbers from 1 (0-99%) through 2 (100-199%) to 3 (200% or more). For the detection of statistically significant differences in number of patients displaying one or another variable between the two treatment groups, chi-squares analyses were employed. As a result, it was found that there were statistically significant differences between the two treatment groups on six variables. This was to the effect that patients were significantly more often genetically pure in the RBX than in the PBO group, and patients in the RBX group also displayed more frequently bodily misperceptions, decreased appetite and time still than in the PBO group. On the other hand, impairment of social adaptation and early insomnia were significantly more present in the PBO than in the RBX group. There were clinically significant (2 or 3) differences between the two groups on seven variables. (This was to the effect that three (genetically pure, bodily misperceptions, and corporization) variables were more often present in the RBX than in the PBO group, whereas four variables (genetically sporadic, impairment of social adaptation in past, precipitating factor with temporal connection and early onset) were more often present in the PBO than in the RBX group.

Table 25
Comparability of Two Treatment Groups in Terms of the 96 New CODE Variables

Variable No.	Variable Name	RBX		PBO		Differences	
		N	%	N	%	Clin.	Stat.
1	Genetically on spectrum	4	18.2	4	18.2	-	-
2	Genetically pure	14	63.5	7	31.8	2	p=.035
3	Genetically sporadic	4	18.2	11	50.0	2	-
4	Impairment of social adaptation in past	0	0.0	8	36.4	3	p=.002
5	Medical non-psychiatric illness	0	0.0	0	0.0	-	-
6	Medical psychiatric illness	0	0.0	0	0.0	-	-
7	Treatment with mood depressant medication	0	0.0	0	0.0	-	-
8	Precipitating factor	3	13.6	5	22.7	1	-
9	Medical non-psychiatric illness w/temporal connection	0	0.0	0	0.0	-	-
10	Medical psychiatric illness w/temporal connection	0	0.0	0	0.0	-	-
11	Treatment w/mood depressant medication w/temporal connection	0	0.0	0	0.0	-	-
12	Precipitating factor w/temporal connection	2	9.1	5	22.7	2	-
13	Early onset	1	4.5	3	13.6	3	-
14	Acute onset	9	40.9	13	59.1	1	-
15	Subacute onset	9	40.9	6	27.3	1	-
16	Insidious onset	4	18.2	3	13.6	1	-
17	Disturbance of concentration	21	95.5	20	90.9	1	-
18	Hallucination	0	0.0	0	0.0	-	-

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Table 25 (cont.)
Comparability of Two Treatment Groups in Terms of the 96 New CODE Variables

Variable No.	Name	RBX		PBO		Differences	
		N	%	N	%	Clin.	Stat.
19	Bodily misperception	6	27.3	1	4.5	3	p=.039
20	Rumination	19	86.4	19	86.4	-	-
21	Retarded thinking	17	77.3	16	72.7	1	-
22	Inhibited thinking	0	0.0	0	0.0	-	-
23	Constricted thinking	19	86.4	16	68.2	1	-
24	Tangential thinking	0	0.0	1	4.5	1	-
25	Incoherence	0	0.0	1	4.5	1	-
26	Ideas of reference	2	9.1	0	0.0	1	-
27	Delusions	0	0.0	0	0.0	-	-
28	Thought broadcasting	0	0.0	0	0.0	-	-
29	Thought withdrawal	0	0.0	0	0.0	-	-
30	Thought insertion	0	0.0	0	0.0	-	-
31	Other feelings of alien influence	0	0.0	0	0.0	-	-
32	Derealization	13	59.1	12	54.5	1	-
33	Depersonalisation	17	77.3	14	63.6	1	-
34	Hypochondriasis	14	63.6	13	59.1	1	-
35	Suspiciousness	4	18.2	3	13.6	1	-
36	Phobias	12	54.5	13	59.1	1	-
37	Obsessive thoughts	8	36.4	7	31.8	1	-
38	Anxious mood	21	95.5	22	100.0	1	-
39	Reactive mood changes	12	54.5	9	40.9	1	-
40	Depressed mood	22	100.0	22	100.0	-	-
41	Unmotivated depressed mood	15	68.2	16	77.0	1	-
42	Depressive evaluation	21	95.5	21	95.5	-	-
43	Parathymia	0	0.0	1	4.5	1	-
44	Anxiety	22	100.0	22	100.0	-	-
45	Dysphoria	21	95.5	20	90.9	1	-
46	Unmotivated dysphoria	13	59.1	15	68.2	1	-
47	Constricted affects	19	86.4	19	86.4	-	-
48	Anhedonia	16	72.7	17	77.3	1	-
49	Apathetic indifference	13	59.1	11	50.0	1	-

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Table 25 (cont.)
Comparability of Two Treatment Groups in Terms of the 96 New CODE Variables

Variable No.	Name	RBX		PBO		Differences	
		N	%	N	%	Clin.	Stat.
81	Late insomnia	20	90.9	22	100.0	1	-
82	Hypersomnia	1	4.5	0	0.0	1	-
83	Decreased appetite	21	95.5	16	72.7	1	p=.039
84	Excessive appetite	0	0.0	3	13.6	1	-
85	Indecisiveness	20	90.9	21	95.5	1	-
86	Time still	21	95.5	14	63.6	1	-
87	Mood congruent psychotic symptoms	0	0.0	1	4.5	1	-
88	First episode	13	59.1	12	54.5	1	-
89	Manic/Hypomanic episode in past	0	0.0	0	0.0	-	-
90	Seasonal pattern	0	0.0	0	0.0	-	-
91	Prolonged duration	5	22.7	3	13.6	1	-
92	Continuous presence in past	0	0.0	0	0.0	-	-
93	Responsiveness to somatic treatment in past	8	36.4	9	40.9	1	-
94	Full recovery in past	8	36.4	10	45.5	1	-
95	Excessive alcohol consumption	0	0.0	0	0.0	-	-
96	Impairment of social adaptation	22	100.0	22	100.0	-	-

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Responsiveness of Symptom-Based Populations

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Symptom-based population is defined as the subpopulation within the total population in which a particular symptom is present (P) or absent (A). Responsiveness of symptom-based populations was examined by measuring the actual and percentile changes (with the level of statistical --t-test--significance) in HAMD total scores from Day 0 to Day 42 (Table 26); and relative consideration of number of patients included in symptom-based populations and level of statistical significance) from the highest (most responsive) to the lowest (least responsive) (Table 27).

Table 26
Responsiveness of Symptom-Based Population as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance.
(P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Genetically on spectrum	8	35.63	21.37	14.26	40.0	p=.051
Genetically pure	21	36.19	17.86	18.33	50.6	p=.000
Genetically sporadic	15	36.00	25.87	10.13	28.1	p=.023
Acute onset	22	36.23	25.00	11.23	31.0	p=.004
Subacute onset	15	36.47	15.60	20.87	57.2	p=.000
Insidious onset	7	34.86	21.43	13.43	38.5	p=.125
P-Impairment of social adaptation in past	8	34.38	24.88	9.50	27.6	p=.094
A-Impairment of social adaptation in past	36	36.47	20.42	16.05	44.0	p=.000
P-Precipitating factor	8	38.25	29.88	8.37	21.9	p=.233
A- Precipitating factor	36	35.61	19.31	16.37	45.8	p=.000
P-Precipitating factor w/temporal connection	7	38.14	32.86	5.28	13.8	p=.433
A- Precipitating factor w/temporal connection	37	35.70	19.03	16.67	46.7	p=.000
P-Early onset	4	35.00	29.50	5.5	15.7	p=.396
A-Early onset (late onset)	40	36.20	20.40	15.8	43.6	p=.000
P-Disturbance of concentration	41	36.07	21.15	14.92	41.4	p=.000
A-Disturbance of concentration	3	36.33	22.33	14.00	38.5	p=.259
P-Bodily misperceptions	7	33.71	25.29	8.42	25.0	p=.188
A-Bodily misperceptions	37	36.54	20.46	16.08	44.0	p=.000
P-Rumination	38	35.74	21.18	14.56	40.7	p=.000
A-Rumination	6	38.33	21.50	16.83	43.9	p=.072
P-Retarded thinking	33	36.30	22.36	13.94	38.4	p=.000
A-Retarded thinking	11	35.45	17.82	17.63	48.7	p=.003
P-Constricted thinking	34	36.24	20.24	16.00	44.2	p=.000
A-Constricted thinking	10	35.60	24.60	11.00	30.9	p=.046

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Table 26 (continue)

Responsiveness of Symptom-Based Population as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance.

(P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Tangential thinking	1	33.00	40.00	-7.00	-21.2	N/A
A-Tangential thinking	43	36.16	20.79	15.37	42.5	p=.000
P-Incoherence	1	33.00	40.00	-7.00	-21.2	N/A
A-Incoherence	43	36.16	20.79	15.37	42.5	p=.000
P-Ideas of reference	2	37.50	8.50	29.00	77.3	p=.066
A-Ideas of reference	42	36.02	21.83	14.19	39.4	p=.000
P-Derealization	25	36.36	21.24	15.12	41.6	p=.000
A-Derealization	19	35.74	21.21	14.56	40.7	p=.002
P-Depersonalisation	31	35.68	22.84	12.84	36.0	p=.000
A-Depersonalisation	13	37.08	17.38	19.70	53.1	p=.000
P-Hypochondriasis	27	36.63	19.42	17.21	47.0	p=.000
A-Hypochondriasis	17	35.24	24.12	11.12	31.6	p=.016
P-Suspiciousness	7	37.14	27.29	9.85	26.5	p=.242
A-Suspiciousness	37	35.89	20.08	15.81	44.1	p=.000
P-Phobias	25	35.92	21.00	14.92	41.5	p=.000
A-Phobias	19	36.32	21.53	14.79	40.7	p=.001
P-Obsessive thoughts	15	36.93	20.93	16.00	43.3	p=.004
A-Obsessive thoughts	29	35.66	21.38	14.28	40.0	p=.000
P-Anxious mood	43	36.12	21.35	14.77	40.9	p=.000
A-Anxious mood	1	35.00	16.00	19.00	54.3	N/A
P-Reactive mood changes	21	36.05	17.57	18.48	51.3	p=.000
A-Reactive mood changes	23	36.13	24.57	11.56	32.0	p=.004
P-Unmotivated depressed mood	31	35.68	20.65	15.03	42.1	p=.000
A-Unmotivated depressed mood	13	37.08	22.62	14.46	39.0	p=.009
P-Depressive evaluations	42	36.10	21.95	14.18	39.3	p=.000
A-Depressive evaluations	2	36.00	6.00	30.00	83.3	p=.063
P-Parathymia	1	33.0	40.0	-7.00	-21.2	N/A
A-Parathymia	43	36.16	20.79	15.37	42.5	p=.000
P-Dysphoria	41	35.95	21.32	14.63	40.7	p=.000
A-Dysphoria	3	38.00	20.00	18.00	47.4	p=.261
P-Unmotivated dysphoria	28	35.68	19.86	15.82	44.3	p=.000
A-Unmotivated dysphoria	16	36.81	23.36	13.45	36.5	p=.007
P-Constricted affect	38	36.16	21.58	14.58	40.3	p=.000
A-Constricted affect	6	35.67	19.00	16.67	46.7	p=.039
P-Anhedonia	33	36.45	21.30	15.15	41.6	p=.000
A-Anhedonia	11	35.00	21.00	14.00	40.0	p=.022
P-Apathetic indifference	24	36.17	20.88	15.29	42.3	p=.000
A-Apathetic indifference	20	36.00	21.65	14.35	39.9	p=.001
P-Feeling of loss of feeling	33	36.03	22.88	13.15	36.5	p=.000
A-Feeling of loss of feeling	11	36.27	16.27	20.00	55.1	p=.001

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Table 26 (continue)

Responsiveness of Symptom-Based Population as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance. (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Feelings of inadequacy	39	36.15	19.44	16.71	46.2	p=.000
A-Feelings of inadequacy	5	35.60	35.20	0.40	1.1	p=.953
P-Feelings of guilt	29	36.83	20.48	16.35	44.4	p=.000
A-Feelings of guilt	15	34.67	22.67	12.00	34.6	p=.016
P-Feelings of impoverishment	15	35.40	26.93	8.47	23.9	p=.068
A-Feelings of impoverishment	29	36.45	18.28	18.17	49.8	p=.000
P-Lack of interest	33	36.30	19.97	16.33	45.0	p=.000
A-Lack of interest	11	35.45	25.00	10.45	29.5	p=.058
P-Displeasure	39	36.33	22.03	14.30	39.4	p=.000
A-Displeasure	5	34.20	15.00	19.20	56.1	p=.052
P-Hopelessness	37	36.05	23.19	12.86	35.7	p=.000
A-Hopelessness	7	36.29	10.86	25.43	70.1	p=.001
P-Self-incrimination	19	36.95	21.68	15.27	41.3	p=.001
A-Self-incrimination	25	35.44	20.88	14.56	41.1	p=.000
P-Irritability	39	36.15	20.44	15.71	43.5	p=.000
A-Irritability	5	35.60	27.40	8.20	23.0	p=.250
P-Hostility	15	36.93	20.93	16.00	43.3	p=.004
A-Hostility	13	36.85	21.85	15.00	40.7	p=.006
P-Vegetative manifestations	16	36.50	19.25	17.25	47.3	p=.000
A-Vegetative manifestations	28	35.86	22.36	13.50	37.6	p=.000
P-Corporization	14	37.00	19.29	17.71	47.9	p=.001
A-Corporization	30	35.67	22.13	13.54	38.0	p=.000
P-Felt loss of vitality	41	36.00	21.29	14.71	40.9	p=.000
A-Felt loss of vitality	3	37.33	20.33	17.00	45.5	p=.296
P-Disturbance of vital balance	36	36.56	22.67	13.89	38.0	p=.000
A-Disturbance of vital balance	8	34.00	14.75	19.25	56.6	p=.015
P-Complaintiveness	33	36.52	22.42	14.10	38.6	p=.000
A-Complaintiveness	11	34.82	17.64	17.18	49.3	p=.004
P-Driven complaintiveness	15	35.73	21.27	14.46	40.5	p=.004
A-Driven complaintiveness	29	36.28	21.21	15.07	41.5	p=.000
P-Lack of drive	42	35.90	21.83	14.07	39.2	p=.000
A-Lack of drive	2	40.00	8.50	31.50	78.8	p=.110
P-Decreased sex drive	39	36.15	21.15	15.00	41.5	p=.000
A-Decreased sex drive	5	35.60	21.80	13.80	38.8	p=.154
P-Loss of desire to live	30	36.73	21.10	15.63	42.6	p=.000
A-Loss of desire to live	14	34.71	21.50	13.21	38.1	p=.009
P-Suicidal tendencies	11	37.00	15.91	21.09	57.0	p=.000
A-Suicidal tendencies	33	35.79	23.00	12.79	35.7	p=.000
P-Histrionics	5	35.40	16.40	19.00	53.7	p=.057
A-Histrionics	39	36.18	21.85	14.33	39.6	p=.000

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Table 26 (continue)

Responsiveness of Symptom-Based Population as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance. (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Motor restlessness	7	36.86	26.86	10.00	27.1	p=.220
A-Motor restlessness	37	35.95	20.16	15.79	43.9	p=.000
P-Abulia	38	36.24	20.53	15.71	43.3	p=.000
A-Abulia	6	35.17	25.67	9.50	27.0	p=.288
P-Motor retardation	32	36.13	20.66	15.47	42.8	p=.000
A-Motor retardation	12	36.00	22.75	13.25	36.8	p=.025
P-Negativism	1	33.00	40.00	-7.00	-21.2	N/A
A-Negativism	43	36.16	20.79	15.37	42.5	p=.000
P-Parakinesis	1	33.00	40.00	-7.00	-21.2	N/A
A-Parakinesis	43	36.16	20.79	15.37	42.5	p=.000
P-Diurnal variations	31	36.77	19.55	17.22	46.8	p=.000
A-Diurnal variations	13	34.46	25.23	9.23	26.8	p=.072
P-Worse in the morning	25	36.64	18.24	18.40	50.2	p=.000
A-Worse in the morning	19	35.37	25.16	10.21	28.9	p=.019
P-Early insomnia	40	36.20	22.73	13.47	37.2	p=.000
A-Early insomnia	4	35.00	6.25	28.75	82.1	p=.000
P-Middle insomnia	35	36.46	21.86	14.60	40.0	p=.000
A-Middle insomnia	9	34.67	18.78	15.89	45.8	p=.023
P-Late insomnia	42	36.17	21.48	14.69	40.6	p=.000
A-Late insomnia	2	34.50	16.00	18.50	53.6	p=.329
P-Hypersomnia	1	34.00	5.00	29.00	85.3	N/A
A-Hypersomnia	43	36.14	21.60	14.54	40.2	p=.000
P-Decreased appetite	37	36.16	20.78	15.38	42.5	p=.000
A-Decreased appetite	7	35.71	23.57	12.14	34.0	p=.096
P-Excessive appetite	3	35.00	21.67	13.33	38.1	p=.260
A-Excessive appetite	41	36.17	21.20	14.97	41.4	p=.000
P-Indecisiveness	41	36.05	20.88	15.17	42.1	p=.000
A-Indecisiveness	3	36.67	26.00	10.67	29.1	p=.348
P-Time still	35	36.29	18.94	17.35	47.8	p=.000
A-Time still	9	35.33	30.11	5.22	14.8	p=.328
P-Mood congruent psychotic symptoms	1	33.00	40.00	-7.00	-21.2	N/A
A- Mood congruent psychotic symptoms	43	36.16	20.79	15.37	42.5	p=.000
P-First episode	25	36.76	21.56	15.20	41.3	p=.000
A-First episode (recurrent)	19	35.21	20.79	14.42	41.0	p=.001
P-Prolonged duration	8	34.88	22.13	12.75	36.6	p=.093
A-Prolonged duration	36	36.36	21.03	15.33	42.2	p=.000

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Table 26 (continue)

Responsiveness of Symptom-Based Population as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance. (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Responsiveness to somatic treatment in past	17	34.94	22.06	12.88	36.9	p=.005
A-Responsiveness to somatic treatment in past	2	37.50	10.00	27.50	73.3	p=.058
P-Fully recovery in past	18	35.28	21.44	13.84	39.2	p=.002
A-Fully recovery in past	1	34.00	9.00	25.00	73.5	N/A

Table 27

Rank Order of Responsiveness - With Consideration of Number of Patients Included in Sample - in Terms of Percentage Change in Total Scores of HAMD from Day 0 to Day 42 in Symptom-Based Populations. (Populations in Which the Change Reached the Accepted Level of Statistical Significance - $p < /- .05$ - are marked by an asterisk*.) (P=Present; A=Absent)

Rank No.	Population	Percentage of change	N.
1	P-Hypersomnia	85.3	1
2	A-Depressive evaluations	83.3	2
3	A-Early insomnia*	82.1	4
4	A-Lack of drive	78.8	2
5	P-Idea of reference	77.3	2
6	A-Full recovery in past	73.5	1
7	A-Responsiveness to somatic treatment in past	73.3	2
8	A-Hopelessness*	70.1	7
9	Subacute onset*	57.2	15
10	P-Suicidal tendencies*	57.0	11
11	A-Disturbance of vital balance*	56.6	8
12	A-Displeasure	56.1	5
13	A-Feeling of loss of feeling*	55.1	11
14	A-Anxious mood	54.3	1
15	P-Histrionics	53.7	5
16	A-Late Insomnia	53.6	2
17	A-Depersonalisation*	53.1	13
18	P-Reactive mood changes*	51.3	21
19	Genetically pure	50.6	21
20	P-Worse in the morning*	50.2	25
21	A-Feelings of impoverishment*	49.8	29
22	A-Complaintiveness*	49.3	11
23	A-Retarded thinking	48.7	11

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Table 27 (cont.)

Rank Order of Responsiveness - With Consideration of Number of Patients Included in Sample - in Terms of Percentage Change in Total Scores of HAMD from Day 0 to Day 42 in Symptom-Based Populations. (Populations in Which the Change Reached the Accepted Level of Statistical Significance - $p = < /- .05$ - are marked by an asterisk*.) (P=Present; A=Absent)

Rank No.	Population	Percentage of change	N.
24	P-Corporization*	47.9	14
25	P-Time still*	47.8	35
26	A-Dysphoria	47.4	3
27	P-Vegetative manifestations*	47.3	16
28	P-Hypochondriasis*	47.0	27
29	P-Diurnal variations*	46.8	31
30	A-Precipitating factor/w temporal connection*	46.7	37
30	A-Constricted affect*	46.7	6
32	P-Feelings of inadequacy*	46.2	39
33	A-Precipitating factor*	45.8	36
33	A-Middle insomnia*	45.8	9
35	A-Felt loss of vitality	45.5	3
36	P-Lack of interest*	45.0	33
37	P-Feelings of guilt*	44.4	29
38	P-Unmotivated dysphoria*	44.3	28
39	P-Constricted thinking*	44.2	34
40	A-Suspiciousness*	44.1	37
41	A-Bodily misperceptions*	44.0	37
41	A-Impairment of social adaptation in past*	44.0	36
43	A-Motor restlessness*	43.9	37
43	A-Rumination	43.9	6
45	A-Early onset (late onset)	43.6	40
46	P-Irritability*	43.5	39
47	P-Obsessive thoughts*	43.3	15
47	P-Abulia*	43.3	38
49	P-Motor retardation*	42.8	32
50	P-Loss of desire to live*	42.6	30
51	A-Tangential thinking*	42.5	43
51	A-Incoherence*	42.5	43
51	A-Parathymia*	42.5	43
51	A-Negativism*	42.5	43
51	A-Parakinesis*	42.5	43
51	P-Decrease appetite*	42.5	37
51	A-Mood congruent psychotic symptoms*	42.5	43
58	P-Apathetic indifference*	42.3	24
59	A-Prolonged duration*	42.2	36
60	P-Unmotivated depressed mood*	42.1	31
60	P-Indecisiveness*	42.1	41
62	P-Derealization*	41.6	25

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Table 27 (cont.)

Rank Order of Responsiveness - With Consideration of Number of Patients Included in Sample - in Terms of Percentage Change in Total Scores of HAMD from Day 0 to Day 42 in Symptom-Based Populations. (Populations in Which the Change Reached the Accepted Level of Statistical Significance - $p = < /- .05$ - are marked by an asterisk*). (P=Present; A=Absent)

Rank No.	Population	Percentage of change	N.
62	P-Anhedonia*	41.6	33
64	P-Phobias*	41.5	25
64	A-Driven complaintiveness*	41.5	29
64	P-Decreased sex drive*	41.5	39
67	P-Disturbance of concentration*	41.4	41
67	P-Hostility*	41.4	31
67	A-Excessive appetite*	41.4	41
70	P-Self-incrimination*	41.3	19
70	P-First episode*	41.3	25
72	A-Self-incrimination*	41.1	25
73	A-First episode (recurrent)*	41.0	19
74	P-Anxious mood*	40.9	43
74	P-Felt loss of vitality*	40.9	41
76	P-Rumination*	40.7	38
76	A-Derealization*	40.7	19
76	A-Phobia*	40.7	19
76	P-Disphoria*	40.7	41
76	A-Hostility*	40.7	13
81	P-Late insomnia*	40.6	42
82	P-Driven complaintiveness*	40.5	15
83	P-Constricted affect*	40.3	38
84	A-Hypersomnia*	40.2	43
85	A-Obsessive thoughts*	40.0	29
85	A-Anhedonia*	40.0	11
85	P-Middle insomnia*	40.0	35
85	Genetically on spectrum	40.0	8
89	A-Apathetic indifference*	39.9	20
90	A-Histrionics*	39.6	39
91	A-Ideas of reference*	39.4	42
91	P-Displeasure*	39.4	39
93	P-Depressive evaluations*	39.3	42
94	P-Lack of drive*	39.2	42
94	P-Full recovery in past	39.2	18
96	A-Unmotivated depressed mood*	39.0	13
97	A-Decreased sex drive	38.8	5
98	P-Complaintiveness*	38.6	33
99	Insidious onset	38.5	7
99	A-Disturbance of concentration	38.5	3
101	P-Retarded thinking*	38.4	33

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Table 27 (cont.)

Rank Order of Responsiveness - With Consideration of Number of Patients Included in Sample - in Terms of Percentage Change in Total Scores of HAMD from Day 0 to Day 42 in Symptom-Based Populations. (Populations in Which the Change Reached the Accepted Level of Statistical Significance - $p < /- .05$ - are marked by an asterisk*.) (P=Present; A=Absent)

Rank No.	Population	Percentage of change	N.
102	A-Loss of desire to live*	38.1	14
102	P-Excessive appetite	38.1	3
104	A-Corporization*	38.0	30
104	P-Disturbance of vital balance*	38.0	36
106	A-Vegetative manifestations*	37.6	28
107	P-Early insomnia*	37.2	40
108	P-Responsive to somatic treatment in past*	36.9	17
109	A-Motor retardation*	36.8	12
110	P-Prolonged duration	36.6	8
111	P-Feeling of loss feeling*	36.5	33
112	P-Depersonalization*	36.0	31
113	A-Unmotivated dysphoria*	35.8	16
114	P-Hopelessness*	35.7	37
114	A-Suicidal tendencies*	35.7	33
116	A-Feelings of guilt*	34.6	15
117	A-Decreased appetite*	34.0	7
118	A-Reactive mood changes*	32.0	23
119	A-Hypochondriasis*	31.6	17
120	Acute onset*	31.0	22
121	A-Constricted thinking*	30.9	10
122	A-Lack of interest	29.5	11
123	A-Indecisiveness	29.1	3
124	A-Worse in the morning*	28.9	19
125	Genetically sporadic*	28.1	15
126	P-Impairment of social adaptation in past	27.6	8
127	P-Motor restlessness	27.1	7
128	A-Abulia	27.0	6
129	A-Diurnal variations	26.8	13
130	P-Suspiciousness	26.5	7
131	P-Bodily misperceptions	25.0	7
132	P-Feeling of impoverishment	23.9	15
133	A-Irritability	23.0	5
134	P-Precipitating factor	21.9	8
135	P-Early onset	15.7	4
136	A-Time still	14.8	9
137	P-Precipitating factor w/temporal connection	13.8	7
138	A-Feeling of inadequacy	1.1	5
139	P-Tangential thinking	-21.2	1
139	P-Incoherence	-21.2	1

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Table 27 (cont.)

Rank Order of Responsiveness - With Consideration of Number of Patients Included in Sample - in Terms of Percentage Change in Total Scores of HAMD from Day 0 to Day 42 in Symptom-Based Populations. (Populations in Which the Change Reached the Accepted Level of Statistical Significance - $p = < /- .05$ - are marked by an asterisk*.)
(P=Present; A=Absent)

Rank No.	Population	Percentage of change	N.
139	P-Parathymia	-21.2	1
139	P-Negativism	-21.2	1
139	P-Parakinesis	-21.2	1
139	P-Mood congruent psychotic symptoms	-21.2	1

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Comparative Responsiveness of Symptom-Based Populations to Treatment

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Responsiveness of symptom-based populations in the RBX- (Table 28) and PBO- (Table 29) treated groups was examined separately by measuring the actual and percentile change, with level of statistical - t-test - significance in HAMD total scores from Day 0 to Day 42; and differential responsiveness was measured by comparing the level of statistical significance between the two treatment groups in each symptom-based population (Table 30). Of the 144 symptom-based populations, as shown in Table 30, in 126 therapeutic responsiveness was greater (as measured by the level of statistical significance of the changes from Day 0 to Day 42) in the RBX- than in the PBO-treated group; in 11 symptom-based populations responsiveness in the two treatment groups was equal; and in seven symptom-based populations responsiveness was greater in the PBO-treated than in the RBX-treated group.

Table 28

Responsiveness to RBX in Symptom-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test). (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Genetically on spectrum	4	36.50	15.75	20.75	56.8	p=.097
Genetically pure	14	36.79	10.00	26.79	72.8	p=.000
Genetically sporadic	4	37.50	11.25	26.25	70.0	p=.023
Acute onset	9	36.56	12.56	24.00	65.6	p=.001
Subacute onset	9	37.89	8.56	29.33	77.4	p=.000
Insidious onset	7	35.25	14.15	21.10	59.9	p=.122
P-Impairment of social adaptation in past	0	-	-	-	-	N/A
A-Impairment of social adaptation in past	22	36.86	11.27	25.59	69.4	p=.000
P-Precipitating factor	3	38.33	8.67	29.66	77.4	p=.002
A- Precipitating factor	19	36.63	11.68	24.95	68.1	p=.000
P-Precipitating factor w/temporal connection	2	38.00	8.50	29.50	77.6	p=.054
A- Precipitating factor w/temporal connection	20	36.75	11.55	25.20	68.6	p=.000
P-Early onset	1	34.00	39.00	-5.00	-14.7	N/A
A-Early onset (late onset)	21	37.00	9.95	27.05	73.1	p=.000
P-Disturbance of concentration	21	36.95	11.57	25.38	68.7	p=.000
A-Disturbance of concentration	1	35.00	5.00	30.00	85.7	N/A
P-Bodily misperceptions	6	33.50	22.67	10.83	32.3	p=.135
A-Bodily misperceptions	16	38.13	7.00	31.13	81.6	p=.000
P-Rumination	19	36.63	12.00	24.63	67.2	p=.000
A-Rumination	3	38.33	6.67	31.66	82.6	p=.012
P-Retarded thinking	17	37.06	11.65	25.41	68.6	p=.000
A-Retarded thinking	5	36.20	10.00	26.23	72.4	p=.005
P-Constricted thinking	19	36.89	10.95	25.94	70.3	p=.000
A-Constricted thinking	3	36.67	13.33	23.34	63.6	p=.095

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Table 28 (continue)

Responsiveness to RBX in Symptom-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test). (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Tangential thinking	0	-	-	-	-	N/A
A-Tangential thinking	22	36.86	11.27	25.59	69.4	p=.000
P-Incoherence	0	-	-	-	-	N/A
A-Incoherence	22	36.86	11.27	25.59	69.4	p=.000
P-Ideas of reference	2	37.50	8.50	29.00	77.3	p=.066
A-Ideas of reference	20	36.80	11.55	25.25	68.6	p=.000
P-Derealization	13	37.08	9.15	27.93	75.3	p=.000
A-Derealization	9	36.56	14.33	22.23	60.8	p=.004
P-Depersonalisation	17	36.59	12.71	23.88	65.3	p=.000
A-Depersonalisation	5	37.80	6.40	31.40	83.1	p=.000
P-Hypochondriasis	14	37.14	12.07	25.07	67.5	p=.000
A-Hypochondriasis	8	36.38	9.88	26.50	72.8	p=.000
P-Suspiciousness	4	38.00	16.75	21.25	55.9	p=.124
A-Suspiciousness	18	36.61	10.06	26.55	72.5	p=.000
P-Phobias	12	37.00	11.17	25.83	69.8	p=.000
A-Phobias	10	36.70	11.40	25.30	68.9	p=.000
P-Obsessive thoughts	8	37.63	7.00	30.63	81.4	p=.000
A-Obsessive thoughts	14	36.43	13.71	22.72	62.4	p=.000
P-Anxious mood	21	36.95	11.05	25.90	70.1	p=.000
A-Anxious mood	1	35.00	16.00	19.00	54.3	N/A
P-Reactive mood changes	12	37.17	10.92	26.25	70.6	p=.000
A-Reactive mood changes	10	36.50	11.70	24.80	67.9	p=.000
P-Unmotivated depressed mood	15	36.93	11.60	25.33	68.6	p=.000
A-Unmotivated depressed mood	7	36.71	10.57	26.14	71.2	p=.000
P-Depressive evaluations	21	36.81	11.57	25.24	68.6	p=.000
A-Depressive evaluations	1	38.00	5.00	33.00	86.8	N/A
P-Parathymia	0	-	-	-	-	N/A
A-Parathymia	22	36.86	11.27	25.59	69.4	p=.000
P-Dysphoria	21	36.76	11.48	25.28	68.8	p=.000
A-Dysphoria	1	39.00	7.00	32.00	82.1	N/A
P-Unmotivated dysphoria	13	37.00	9.85	27.15	73.4	p=.000
A-Unmotivated dysphoria	9	36.67	13.33	23.34	63.6	p=.001
P-Constricted affect	19	36.79	11.05	25.74	70.0	p=.000
A-Constricted affect	3	37.33	12.67	24.66	66.1	p=.104
P-Anhedonia	16	37.63	10.00	27.63	73.4	p=.000
A-Anhedonia	6	34.83	14.67	20.16	57.9	p=.030
P-Apathetic indifference	13	36.92	10.62	26.30	71.2	p=.000
A-Apathetic indifference	9	36.78	12.22	24.56	66.8	p=.001
P-Feeling of loss of feeling	16	36.38	11.94	24.44	67.2	p=.000
A-Feeling of loss of feeling	6	38.17	9.50	28.67	75.1	p=.001

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Table 28 (continue)

Responsiveness to RBX in Symptom-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test). (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Feelings of inadequacy	21	36.89	11.29	25.60	69.4	p=.000
A-Feelings of inadequacy	1	37.00	11.00	26.00	70.3	N/A
P-Feelings of guilt	17	36.82	13.06	23.76	64.5	p=.000
A-Feelings of guilt	5	37.00	5.20	31.80	85.9	p=.000
P-Feelings of impoverishment	6	34.33	19.17	15.16	44.2	p=.086
A-Feelings of impoverishment	16	37.81	8.31	29.50	78.0	p=.000
P-Lack of interest	16	37.38	9.38	28.00	74.9	p=.000
A-Lack of interest	6	35.50	16.33	19.17	54.0	p=.031
P-Displeasure	18	37.22	10.33	26.89	72.2	p=.000
A-Displeasure	4	35.25	15.50	19.75	56.0	p=.099
P-Hopelessness	18	36.68	12.39	24.29	66.2	p=.000
A-Hopelessness	4	37.75	6.25	31.50	83.4	p=.000
P-Self-incrimination	11	37.63	9.27	28.36	75.4	p=.000
A-Self-incrimination	11	36.09	13.27	22.82	63.2	p=.001
P-Irritability	20	36.95	10.50	26.45	71.6	p=.000
A-Irritability	2	36.00	19.00	17.00	47.2	p=.310
P-Hostility	15	36.40	11.27	25.13	69.0	p=.000
A-Hostility	7	37.86	11.29	26.57	70.2	p=.000
P-Vegetative manifestations	6	37.67	8.17	29.50	80.4	p=.000
A-Vegetative manifestations	16	35.56	12.44	24.12	66.0	p=.000
P-Corporization	10	36.80	13.40	23.40	63.6	p=.000
A-Corporization	12	36.92	9.50	27.42	74.3	p=.000
P-Felt loss of vitality	20	36.80	11.55	25.25	68.6	p=.000
A-Felt loss of vitality	2	37.50	8.50	29.00	77.3	p=.066
P-Disturbance of vital balance	16	37.75	11.50	26.25	69.5	p=.000
A-Disturbance of vital balance	6	34.50	10.67	23.83	69.1	p=.014
P-Complaintiveness	16	37.13	11.88	25.25	68.0	p=.000
A-Complaintiveness	6	36.17	9.67	26.50	73.3	p=.001
P-Driven complaintiveness	7	37.43	9.29	28.14	75.2	p=.000
A-Driven complaintiveness	15	36.60	12.20	24.40	66.7	p=.000
P-Lack of drive	20	36.55	11.55	25.00	68.4	p=.000
A-Lack of drive	2	40.00	8.50	31.50	78.8	p=.110
P-Decreased sex drive	19	36.95	11.42	25.53	69.1	p=.000
A-Decreased sex drive	3	36.33	10.33	26.00	71.6	p=.023
P-Loss of desire to live	15	37.47	9.87	27.60	73.7	p=.000
A-Loss of desire to live	7	35.57	14.29	21.28	59.8	p=.011
P-Suicidal tendencies	7	37.00	8.66	28.14	76.1	p=.000
A-Suicidal tendencies	15	36.80	12.40	24.40	66.3	p=.000
P-Histrionics	2	40.00	8.50	31.50	78.8	p=.110
A-Histrionics	20	36.55	11.55	25.00	68.4	p=.000

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Table 28 (continue)

Responsiveness to RBX in Symptom-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test). (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Motor restlessness	3	38.33	8.67	29.66	77.4	p=.032
A-Motor restlessness	19	36.63	11.68	24.95	68.1	p=.000
P-Abulia	18	37.06	9.50	27.56	74.4	p=.000
A-Abulia	4	36.00	19.25	16.75	46.5	p=.203
P-Motor retardation	17	36.59	12.24	24.35	66.5	p=.000
A-Motor retardation	5	37.80	8.00	29.80	86.5	p=.001
P-Negativism	0	-	-	-	-	N/A
A-Negativism	22	36.86	11.27	25.59	69.4	p=.000
P-Parakinesis	0	-	-	-	-	N/A
A-Parakinesis	22	36.86	11.27	25.59	69.4	p=.000
P-Diurnal variations	16	37.88	9.00	28.88	75.2	p=.000
A-Diurnal variations	6	34.17	17.33	16.84	49.3	p=.074
P-Worse in the morning	13	37.85	9.23	28.62	75.6	p=.000
A-Worse in the morning	9	35.44	14.22	21.22	59.9	p=.004
P-Early insomnia	18	37.28	12.39	24.89	66.8	p=.000
A-Early insomnia	4	35.00	6.25	28.75	82.1	p=.000
P-Middle insomnia	19	36.84	12.00	24.84	67.4	p=.000
A-Middle insomnia	3	37.00	6.67	30.33	82.0	p=.001
P-Late insomnia	20	37.10	10.80	26.30	70.9	p=.000
A-Late insomnia	2	34.50	16.00	18.50	53.6	p=.329
P-Hypersomnia	1	34.00	5.00	29.00	85.3	N/A
A-Hypersomnia	21	37.00	11.57	25.43	68.7	p=.000
P-Decreased appetite	21	36.86	11.29	25.57	69.4	p=.000
A-Decreased appetite	1	37.00	11.00	26.00	70.3	N/A
P-Excessive appetite	0	-	-	-	-	N/A
A-Excessive appetite	22	36.86	11.27	25.59	69.4	p=.000
P-Indecisiveness	20	36.95	10.55	26.40	71.4	p=.000
A-Indecisiveness	2	36.00	18.50	17.50	48.6	p=.317
P-Time still	21	36.95	11.57	25.38	68.7	p=.000
A-Time still	1	35.00	5.00	30.00	85.7	N/A
P-Mood congruent psychotic symptoms	0	-	-	-	-	N/A
A- Mood congruent psychotic symptoms	22	36.86	11.27	25.59	69.4	p=.000
P-First episode	13	37.62	7.92	29.70	78.9	p=.000
A-First episode (recurrent)	9	35.78	16.11	19.67	55.00	p=.008
P-Prolonged duration	5	35.20	17.00	18.20	51.7	p=.084
A-Prolonged duration	17	37.35	9.58	27.77	74.4	p=.000

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Table 28 (continue)

Responsiveness to RBX in Symptom-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test). (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Responsiveness to somatic treatment in past	8	36.00	17.00	19.00	52.8	p=.019
A-Responsiveness to somatic treatment in past	1	34.00	9.00	25.00	73.5	N/A
P-Fully recovery in past	8	36.00	17.00	19.00	52.8	p=.019
A-Fully recovery in past	1	34.00	9.00	25.00	73.5	N/A

Table 29

Responsiveness to PBO in Symptom-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test). (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Genetically on spectrum	4	34.75	27.00	7.75	22.3	p=.416
Genetically pure	7	35.00	33.57	1.43	4.1	p=.797
Genetically sporadic	11	35.73	31.18	4.55	12.73	p=.063
Acute onset	13	36.00	33.62	2.38	6.6	p=.467
Subacute onset	6	34.33	26.17	8.16	23.8	p=.263
Insidious onset	3	34.33	30.67	3.66	10.7	p=.774
P-Impairment of social adaptation in past	8	34.38	24.88	9.50	27.6	p=0.94
A-Impairment of social adaptation in past	14	35.86	34.79	1.07	3.0	p=.752
P-Precipitating factor	5	38.20	42.60	-4.40	-11.5	p=.002
A- Precipitating factor	17	34.47	27.82	6.65	19.3	p=.072
P-Precipitating factor w/temporal connection	5	38.20	42.60	-4.40	-11.5	p=.002
A- Precipitating factor w/temporal connection	17	34.47	27.82	6.65	19.3	p=.072
P-Early onset	3	35.33	26.33	9.00	25.5	p=.279
A-Early onset (late onset)	19	35.32	31.95	3.37	9.5	p=.300
P-Disturbance of concentration	20	35.15	31.20	3.95	11.2	p=.215
A-Disturbance of concentration	2	37.00	31.00	6.00	16.2	p=.549
P-Bodily misperceptions	1	35.00	41.00	-6.00	-17.1	N/A
A-Bodily misperceptions	21	35.33	30.71	4.62	13.1	p=.131

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Table 29 (continue)

Responsiveness to PBO in Symptom-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test). (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Rumination	19	34.84	30.37	4.47	12.8	p=.176
A-Rumination	3	38.33	36.33	2.00	5.2	p=.788
P-Retarded thinking	16	35.50	33.75	1.75	4.9	p=.578
A-Retarded thinking	6	34.83	24.33	10.53	30.1	p=.144
P-Constricted thinking	15	35.40	32.00	3.40	9.6	p=.355
A-Constricted thinking	7	35.14	29.43	5.71	16.2	p=.293
P-Tangential thinking	1	33.00	40.00	-7.00	-21.2	N/A
A-Tangential thinking	21	35.43	30.76	4.67	13.2	p=.126
P-Incoherence	1	33.00	40.00	-7.00	-21.2	N/A
A-Incoherence	21	35.43	30.76	4.67	13.2	p=.126
P-Ideas of reference	0	-	-	-	-	N/A
A-Ideas of reference	22	35.32	31.18	4.14	11.7	p=.159
P-Derealization	12	35.58	34.33	1.25	3.5	p=.692
A-Derealization	10	35.00	27.40	7.60	21.7	p=.162
P-Depersonalisation	14	34.57	35.14	-0.57	-1.6	p=.837
A-Depersonalisation	8	36.63	24.25	12.38	33.8	p=.049
P-Hypochondriasis	13	36.08	27.31	8.77	24.3	p=.052
A-Hypochondriasis	9	34.22	36.78	-2.56	-7.5	p=.339
P-Suspiciousness	3	36.00	41.33	-5.33	-14.8	p=.026
A-Suspiciousness	19	35.21	29.58	5.63	16.0	p=.091
P-Phobias	13	34.92	30.08	4.84	13.9	p=.225
A-Phobias	9	35.89	32.78	3.11	8.7	p=.509
P-Obsessive thoughts	7	36.14	36.86	-0.72	-2.0	p=.879
A-Obsessive thoughts	15	34.93	28.53	6.40	18.3	p=.092
P-Anxious mood	22	35.32	31.18	4.14	11.7	p=.159
A-Anxious mood	0	-	-	-	-	N/A
P-Reactive mood changes	9	34.56	26.44	8.12	23.5	p=.100
A-Reactive mood changes	13	35.85	34.46	1.39	3.9	p=.713
P-Unmotivated depressed mood	16	34.50	29.13	5.37	15.6	p=.136
A-Unmotivated depressed mood	6	37.50	36.67	0.83	2.2	p=.880
P-Depressive evaluations	21	35.38	32.33	3.05	8.6	p=.280
A-Depressive evaluations	1	34.00	7.00	27.00	79.4	N/A
P-Parathymia	1	34.00	7.00	27.00	79.4	N/A
A-Parathymia	21	35.43	30.76	4.67	13.2	p=.126
P-Dysphoria	20	35.10	31.65	3.45	9.8	p=.242
A-Dysphoria	2	37.50	26.50	11.00	29.3	p=.617
P-Unmotivated dysphoria	15	34.53	28.53	6.00	17.4	p=.116
A-Unmotivated dysphoria	7	37.00	36.86	0.14	0.4	p=.976
P-Constricted affect	19	35.53	32.11	3.42	9.6	p=.292
A-Constricted affect	3	34.00	25.33	8.67	25.5	p=.311

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Table 29 (continue)

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Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Anhedonia	17	35.35	31.94	3.41	9.6	p=.288
A-Anhedonia	5	35.20	28.60	6.60	18.8	p=.415
P-Apathetic indifference	11	35.27	33.00	2.27	6.4	p=.591
A-Apathetic indifference	11	35.36	39.36	6.00	17.0	p=.168
P-Feeling of loss of feeling	17	35.71	33.18	2.53	7.1	p=.446
A-Feeling of loss of feeling	5	34.00	24.40	9.60	28.2	p=.174
P-Feelings of inadequacy	18	35.33	28.94	6.39	18.1	p=.065
A-Feelings of inadequacy	4	35.25	41.25	-6.00	-17.0	p=.007
P-Feelings of guilt	12	36.83	31.00	5.83	15.8	p=.212
A-Feelings of guilt	10	33.50	31.40	2.10	6.3	p=.558
P-Feelings of impoverishment	9	36.11	32.11	4.00	11.1	p=.457
A-Feelings of impoverishment	13	34.77	30.54	4.23	12.2	p=.240
P-Lack of interest	17	35.29	29.94	5.35	15.2	p=.139
A-Lack of interest	5	35.40	35.43	0.00	0.0	p=1.000
P-Displeasure	21	35.57	32.05	3.52	9.9	p=.239
A-Displeasure	1	30.00	13.00	17.00	56.7	N/A
P-Hopelessness	19	35.47	33.42	2.05	5.8	p=.466
A-Hopelessness	3	34.33	17.00	17.33	50.5	p=.199
P-Self-incrimination	8	36.00	38.75	-2.75	-7.6	p=.376
A-Self-incrimination	14	34.93	26.86	8.07	23.1	p=.054
P-Irritability	19	35.32	30.89	4.43	12.5	p=.177
A-Irritability	3	35.33	33.00	2.33	6.6	p=.780
P-Hostility	16	35.19	30.06	5.13	14.6	p=.169
A-Hostility	6	35.67	34.17	1.50	4.2	p=.758
P-Vegetative manifestations	10	35.80	25.90	9.90	27.7	p=.057
A-Vegetative manifestations	12	34.92	35.58	-0.66	-1.9	p=.832
P-Corporization	4	37.50	34.00	3.50	9.3	p=.644
A-Corporization	18	34.83	30.56	4.27	12.3	p=.200
P-Felt loss of vitality	21	35.24	30.57	4.67	13.3	p=.126
A-Felt loss of vitality	1	37.00	44.00	-7.00	-18.9	N/A
P-Disturbance of vital balance	20	35.60	31.60	4.00	11.2	p=.200
A-Disturbance of vital balance	2	32.50	27.00	5.50	16.9	p=.716
P-Complaintiveness	17	35.94	32.35	3.57	9.9	p=.293
A-Complaintiveness	5	33.20	27.20	6.00	18.1	p=.376
P-Driven complaintiveness	8	34.25	31.75	2.50	7.3	p=.598
A-Driven complaintiveness	14	35.93	30.86	5.07	14.1	p=.197
P-Lack of drive	22	35.32	31.18	4.14	11.7	p=.159
A-Lack of drive	0	-	-	-	-	N/A
P-Decreased sex drive	20	35.40	30.40	5.00	14.1	p=.117
A-Decreased sex drive	2	34.50	39.00	-4.50	-13.0	p=.421

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Table 29 (continue)

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Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-Loss of desire to live	15	36.00	32.33	3.67	10.2	p=.321
A-Loss of desire to live	7	33.86	28.71	5.15	15.2	p=.339
P-Suicidal tendencies	4	37.00	28.25	8.75	23.6	p=.366
A-Suicidal tendencies	18	34.94	31.83	3.11	8.9	p=.318
P-Histrionics	3	32.33	31.67	10.66	33.0	p=.344
A-Histrionics	19	35.79	32.68	3.11	8.7	p=.317
P-Motor restlessness	4	35.75	40.50	-4.75	-13.3	p=.064
A-Motor restlessness	18	35.22	29.11	6.11	17.3	p=.080
P-Abulia	20	35.50	30.45	5.05	14.2	p=.114
A-Abulia	2	33.55	38.50	-4.95	-14.8	p=.242
P-Motor retardation	15	35.60	30.20	5.40	15.2	p=.155
A-Motor retardation	7	34.71	33.29	1.42	4.1	p=.772
P-Negativism	1	33.00	40.00	-7.00	-21.2	N/A
A-Negativism	21	35.43	30.76	4.67	13.2	p=.126
P-Parakinesia	1	33.00	40.00	-7.00	-21.2	N/A
A-Parakinesia	21	35.43	30.76	4.67	13.2	p=.126
P-Diurnal variations	15	35.60	30.80	4.80	13.5	p=.193
A-Diurnal variations	7	34.71	32.00	2.71	7.8	p=.615
P-Worse in the morning	12	35.33	28.00	7.33	20.7	p=.099
A-Worse in the morning	10	35.30	35.00	0.30	0.8	p=.938
P-Early insomnia	22	35.32	31.18	4.14	11.7	p=.159
A-Early insomnia	0	-	-	-	-	N/A
P-Middle insomnia	16	36.00	33.56	2.44	6.8	p=.431
A-Middle insomnia	6	33.50	24.83	8.67	25.9	p=.255
P-Late insomnia	22	35.32	31.18	4.14	11.7	p=.159
A-Late insomnia	0	-	-	-	-	N/A
P-Hypersomnia	0	-	-	-	-	N/A
A-Hypersomnia	22	35.32	31.18	4.14	11.7	p=.159
P-Decreased appetite	16	35.25	33.25	2.00	5.7	p=.507
A-Decreased appetite	6	35.50	25.67	9.83	27.7	p=.205
P-Excessive appetite	3	35.00	21.67	13.33	38.1	p=.260
A-Excessive appetite	19	35.37	32.68	2.69	7.6	p=.375
P-Indecisiveness	21	35.19	30.71	4.48	12.7	p=.145
A-Indecisiveness	1	38.00	41.00	-3.00	-7.9	N/A
P-Time still	14	35.29	30.00	5.29	15.0	p=.181
A-Time still	8	35.38	33.25	2.13	6.0	p=.648
P-Mood congruent psychotic symptoms	1	33.00	40.00	-7.00	-21.2	N/A
A- Mood congruent psychotic symptoms	21	35.43	30.76	4.67	13.2	p=.162

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Table 29 (continue)

Responsiveness to PBO in Symptom-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test). (P=Present; A=Absent)

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
P-First episode	12	35.83	36.33	-0.50	-1.4	p=.869
A-First episode (recurrent)	10	34.70	25.00	9.70	28.0	p=.070
P-Prolonged duration	3	34.33	30.67	3.66	10.7	p=.774
A-Prolonged duration	19	35.47	31.26	4.21	11.9	p=.170
P-Responsiveness to somatic treatment in past	9	34.00	26.56	7.44	21.9	p=.146
A-Responsiveness to somatic treatment in past	1	41.00	11.00	30.00	73.2	N/A
P-Fully recovery in past	10	34.70	25.00	9.70	28.0	p=.070
A-Fully recovery in past	0	-	-	-	-	N/A

Table 30

Level of Statistical Significance of the Change in HAMD Total Scores from Day 0 to Day 42 on the 144 Symptom-Based Populations in the RBX-and PBO-Treated Groups. Populations With Statistically Significant ($p < .05$) Changes Only With RBX are Marked with an Asterisk (*) and Only with PBO are Marked with a Plus (+). (P=Present; A=Absent)

Population	Reboxetine		Placebo		Comp.
	N	L.S.	N	L.S.	
Genetically on spectrum	4	p=.097	4	p=.416	R>P
Genetically pure*	14	p=.000	7	p=.797	R>P
Genetically sporadic	4	p=.023	11	p=.263	R>P
Acute onset*	9	p=.001	13	p=.467	R>P
Subacute onset*	9	p=.000	6	p=.263	R>P
Insidious onset	7	p=.122	3	p=.744	R>P
P-Impairment of social adaptation in past	0	N/A	8	p=.094	P>R
A-Impairment of social adaptation in past*	22	p=.000	14	p=.752	R>P
P- Precipitating factor	3	p=.002	5	p=.002	R=P
A- Precipitating factor*	19	p=.000	17	p=0.72	R>P
P- Precipitating factor w/temporal connect. +	2	p=.054	5	p=.002	P>R
A- Precipitating factor w/temporal connect *	20	p=.000	17	p=0.72	R>P
P-Early onset	1	N/A	3	p=.279	P>R
A-Early onset (late onset)*	21	p=.000	19	p=.300	R>P
P-Disturbance of concentration*	21	p=.000	20	p=.215	R>P
A-Disturbance of concentration	1	N/A	2	p=.549	P>R

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Table 30 (continue)

Level of Statistical Significance of the Change in HAMD Total Scores from Day 0 to Day 42 on the 144 Symptom-Based Populations in the RBX-and PBO-Treated Groups. Populations With Statistically Significant ($p < .05$) Changes Only With RBX are Marked with an Asterisk (*) and Only with PBO are Marked with a Plus (+). (P=Present; A=Absent)

Population	Reboxetine		Placebo		Comp.
	N	L.S.	N	L.S.	
P-Bodily misperceptions	6	p=.135	1	N/A	R>P
A-Bodily misperceptions*	16	p=.000	21	p=.131	R>P
P-Rumination*	19	p=.000	19	p=.176	R>P
A-Rumination*	3	p=.012	3	p=.788	R>P
P-Retarded thinking*	17	p=.000	16	p=.578	R>P
A-Retarded thinking*	5	p=.005	6	p=.144	R>P
P-Constricted thinking*	19	p=.000	15	p=.355	R>P
A-Constricted thinking*	3	p=.095	7	p=.293	R>P
P-Tangential thinking	0	N/A	1	N/A	R=P
A-Tangential thinking*	22	p=.000	21	p=.126	R>P
P-Incoherence	0	N/A	1	N/A	R=P
A-Incoherence*	22	p=.000	21	p=.126	R>P
P-Ideas of reference	2	p=.066	0	N/A	R>P
A-Ideas of reference*	20	p=.000	22	p=.159	R>P
P-Derealization*	13	p=.000	12	p=.692	R>P
A-Derealization*	9	p=.004	10	p=.162	R>P
P-Depersonalization*	17	p=.000	14	p=.837	R>P
A-Depersonalization*	5	p=.000	8	p=.049	R>P
P-Hypochondriasis*	14	p=.000	13	p=.052	R>P
A-Hypochondriasis*	8	p=.000	9	p=.339	R>P
P-Suspiciousness +	4	p=.124	3	p=.026	P>R
A-Suspiciousness*	18	p=.000	19	p=.091	R>P
P-Phobias*	12	p=.000	13	p=.225	R>P
A-Phobias*	10	p=.000	9	p=.509	R>P
P-Obsessive thoughts*	8	p=.000	7	p=.879	R>P
A-Obsessive thoughts*	14	p=.000	15	p=.092	R>P
P-Anxious mood*	21	p=.000	22	p=.159	R>P
A-Anxious mood	1	N/A	0	N/A	R=P
P-Reactive mood changes*	12	p=.000	9	p=.100	R>P
A-Reactive mood changes*	10	p=.000	13	p=.713	R>P
P-Unmotivated depressed mood*	15	p=.000	16	p=.136	R>P
A-Unmotivated depressed mood*	7	p=.000	6	p=.880	R>P
P-Depressive evaluations*	21	p=.000	21	p=.280	R>P
A-Depressive evaluations	1	N/A	1	N/A	R=P

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Table 30 (continue)

Level of Statistical Significance of the Change in HAMD Total Scores from Day 0 to Day 42 on the 144 Symptom-Based Populations in the RBX-and PBO-Treated Groups. Populations With Statistically Significant ($p < .05$) Changes Only With RBX are Marked with an Asterisk (*) and Only with PBO are Marked with a Plus (+). (P=Present; A=Absent)

Population	Reboxetine		Placebo		Comp.
	N	L.S.	N	L.S.	
P-Parathymia	0	N/A	1	N/A	R=P
A-Parathymia*	22	p=.000	21	p=.126	R>P
P-Dysphoria*	21	p=.000	20	p=.242	R>P
A-Dysphoria	1	N/A	2	p=.617	P>R
P-Unmotivated dysphoria*	13	p=.000	15	p=.116	R>P
A-Unmotivated dysphoria*	9	p=.001	7	p=.976	p=.976
P-Constricted affect*	19	p=.000	19	p=.292	R>P
A-Constricted affect	3	p=.104	3	p=.311	R>P
P-Anhedonia*	16	p=.000	17	p=.288	R>P
A-Anhedonia*	6	p=.030	5	p=.415	R>P
P-Apathetic indifference*	13	p=.000	11	p=.591	R>P
A-Apathetic indifference*	9	p=.001	11	p=.168	R>P
P-Feeling of loss of feeling*	16	p=.000	17	p=.446	R>P
A-Feeling of loss of feeling*	6	p=.001	5	p=.174	R>P
P-Feelings of inadequacy*	21	p=.000	18	p=.065	R>P
A-Feelings of inadequacy+	1	N/A	4	p=.007	P>R
P-Feelings of guilt*	17	p=.000	12	p=.212	R>P
A-Feelings of guilt*	5	p=.000	10	p=.558	R>P
P-Feelings of impoverishment	6	p=.086	9	p=.457	R>P
A-Feelings of impoverishment*	16	p=.000	13	p=.240	R>P
P-Lack of interest*	16	p=.000	17	p=.139	R>P
A-Lack of interest*	6	p=.031	5	p=1.000	R>P
P-Displeasure*	18	p=.000	21	p=.239	R>P
A-Displeasure	4	p=.099	1	N/A	R>P
P-Hopelessness*	18	p=.000	19	p=.466	R>P
A-Hopelessness*	4	p=.000	3	p=.199	R>P
P-Self-incrimination*	11	p=.000	8	p=.376	R>P
A-Self-incrimination*	11	p=.001	14	p=.054	R>P
P-Irritability*	20	p=.000	19	p=.177	R>P
A-Irritability	2	p=.310	3	p=.780	R>P
P-Hostility*	15	p=.000	16	p=.169	R>P
A-Hostility*	7	p=.000	6	p=.758	R>P
P-Vegetative manifestations*	6	p=.000	10	p=.057	R>P
A-Vegetative manifestations*	16	p=.000	12	p=.842	R>P
P-Corporization*	10	p=.000	4	p=.644	R>P
A-Corporization*	12	p=.000	18	p=.200	R>P

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Table 30 (continue)

Level of Statistical Significance of the Change in HAMD Total Scores from Day 0 to Day 42 on the 144 Symptom-Based Populations in the RBX-and PBO-Treated Groups. Populations With Statistically Significant ($p < .05$) Changes Only With RBX are Marked with an Asterisk (*) and Only with PBO are Marked with a Plus (+). (P=Present; A=Absent)

Population	Reboxetine		Placebo		Comp.
	N	L.S.	N	L.S.	
P-Felt loss of vitality*	20	p=.000	21	p=.126	R>P
A-Felt loss of vitality	2	p=.066	1	N/A	R>P
P-Disturbance of vital balance*	16	p=.000	20	p=.200	R>P
A-Disturbance of vital balance*	6	p=.014	2	p=.716	R>P
P-Complaintiveness*	16	p=.000	17	p=.293	R>P
A-Complaintiveness*	6	p=.001	5	p=.376	R>P
P-Driven complaintiveness*	7	p=.000	8	p=.598	R>P
A-Driven complaintiveness*	15	p=.000	14	p=.197	R>P
P-Lack of drive*	20	p=.000	22	p=.159	R>P
A-Lack of drive	2	p=.110	0	N/A	R>P
P-Decreased sex drive*	19	p=.000	20	p=.117	R>P
A-Decreased sex drive*	3	p=.023	2	p=.421	R>P
P-Loss of desire to live*	15	p=.000	15	p=.321	R>P
A-Loss of desire to live*	7	p=.011	7	p=.339	R>P
P-Suicidal tendencies*	7	p=.000	4	p=.366	R>P
A-Suicidal tendencies*	15	p=.000	18	p=.316	R>P
P-Histrionics	2	p=.110	3	p=.344	R>P
A-Histrionics*	20	p=.000	19	p=.317	R>P
P-Motor restlessness*	3	p=.032	4	p=.064	R>P
A-Motor restlessness*	19	p=.000	18	p=.080	R>P
P-Abulia*	18	p=.000	20	p=.114	R>P
A-Abulia	4	p=.203	2	p=.242	R>P
P-Motor retardation*	17	p=.000	15	p=.155	R>P
A-Motor retardation*	5	p=.001	7	p=.772	R>P
P-Negativism	0	N/A	1	N/A	R=P
A-Negativism*	22	p=.000	21	p=.126	R>P
P-Parakinesis	0	N/A	1	N/A	R>P
A-Parakinesis*	22	p=.000	21	p=.126	R>P
P-Diurnal variations*	16	p=.000	15	p=.193	R>P
A-Diurnal variations	6	p=.074	7	p=.615	R>P
P-Worse in the morning*	13	p=.000	12	p=.099	R>P
A-Worse in the morning*	9	p=.004	10	p=.938	R>P
P-Early insomnia*	18	p=.000	22	p=.159	R>P
A-Early insomnia*	4	p=.000	0	N/A	R>P
P-Middle insomnia*	19	p=.000	16	p=.431	R>P
A-Middle insomnia*	3	p=.001	6	p=.255	R>P
P-Late insomnia*	20	p=.000	22	p=.159	R>P
A-Late insomnia	2	p=.329	0	N/A	R>P

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Table 30 (continue)

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Population	Means		Change		Level of Significance
	Before	After	Actual	%	
P-Hypersomnia	1	N/A	0	N/A	R=P
A-Hypersomnia*	21	p=.000	22	p=.159	R>P
P-Decreased appetite*	21	p=.000	16	p=.507	R>P
A-Decreased appetite	1	N/A	6	p=.205	P>R
P-Excessive appetite	0	N/A	3	p=.260	P>R
A-Excessive appetite*	22	p=.000	19	p=.375	R>P
P-Indecisiveness*	20	p=.000	21	p=.145	R>P
A-Indecisiveness	2	p=.317	1	N/A	R>P
P-Time still*	21	p=.000	14	p=.181	R>P
A-Time still	1	N/A	8	p.648	P>R
P-Mood congruent psychotic symptoms	0	N/A	1	N/A	R=P
A- Mood congruent psychotic symptoms*	22	p=.000	21	p=.126	R>P
P-First episode*	13	p=.000	12	p=.869	R>P
A-First episode (recurrent)*	9	p=.008	10	p=.070	R>P
P-Prolonged duration	5	p=.084	3	p=.774	R>P
A-Prolonged duration*	17	p=.000	19	p=.170	R>P
P-Responsiveness to somatic treatment in past*	8	p=.019	9	p=.146	R>P
A-Responsiveness to somatic treatment in past	1	N/A	1	N/A	R=P
P-Fully recovery in past*	8	p=.019	10	p=.070	R>P
A-Fully recovery in past	1	N/A	0	N/A	R=P

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PART THREE:

EXPLORATION OF DIAGNOSES

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Exploration of diagnoses, i.e., diagnosis-based analyses, were conducted in six steps:

1. diagnostic structure of study population;
2. comparability of diagnoses in two treatment groups;
3. responsiveness of diagnosis-based populations;
4. comparative responsiveness of diagnosis-based populations to treatment;
5. differential responsiveness of selected diagnosis-based populations to treatment; and
6. inclusiveness of classifications.

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Diagnostic Structure of Study Population

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To establish the diagnostic structure of the study population, the number and percentage of patients displaying each diagnostic form and subform in each of the 25 systems of classification included in CODE-DD in the total population was identified (Table 31); and each diagnostic form (Table 32) and subform (Table 33) were ranked separately, and together (Table 34).

Table 31
Number and Percentage of Patients With Different Forms and Subform of Diagnoses Within 25 Systems of Classification in the Total Population

System of Classification/Diagnoses	N	%
KRAEPELIN		
Depressive State	37	84.1
Melancholia Simplex	35	79.5
Melancholia Gravis	2	4.5
SCHNEIDER		
Vital Depression	43	97.7
Reactive Depression	1	2.3
LEHONARD		
Pure Melancholia	19	43.2
Definite Pure Melancholia	18	40.9
Probable Pure Melancholia	1	2.3
Pure Depression		
Self-torturing (pure) Depression	1	2.3
Non-participatory (pure) Depression	2	4.5
Mixed Depression	21	47.7
Mixed (Complete) Depression	18	40.9
Mixed (Incomplete) Depression	3	6.8
VIENNA		
Endogenomorphic-Depressive Axial Syndrome	31	70.5
ICD-10		
Depressive Episode	44	100.0
Severe	25	56.8
Recurrent Severe	19	43.2
LEWIS		
Melancholia	44	100.0
Definite	40	90.0
Probable	4	9.1
HAMILTON		
Retarded Depression	35	79.5
Agitated Depression	7	15.9
KILOH		
Endogenous Depression	44	100.0
PILOWSKY		
Class A/Neurotic Depression	1	2.3
Class B/ Endogenous Depression	43	97.7

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Table 31 (continue)
Number and Percentage of Patients With Different Forms and Subform of Diagnoses Within 25 Systems of Classification in the Total Population

System of Classification/Diagnoses	N	%
Mendels		
Endogenous Depression	44	100.00
Definite	35	79.5
Probable	6	13.6
Possible	3	6.8
FOULDS		
Neurotic Depression	42	95.5
Psychotic Depression	1	2.3
Dysthymic Depression	1	2.3
OVERALL		
Type A/ Anxious Depression	10	22.7
Type B/ Hostile Depression	2	4.5
Type C/ Retarded Depression	22	50.0
PAYKEL		
Group4 A/ Psychotic Depression	44	100.0
RASKIN		
Type 1/ Agitated Depression	1	2.3
Type 2/ Neurotic Depression	2	4.5
Type 3/ Endogenous Depression	40	90.9
CATEGO		
Class R/ Retarded Depression	44	100.0
ROBINS		
Primary Affective Depressive Disorder	41	93.2
ST. LOUIS		
Definite Primary Depression	44	100.0
WINOKUR		
Pure Depression	21	47.7
Sporadic Depression	15	34.1
Depressive Spectrum Disease	8	18.2
RDC		
Definite Major Depressive Disorder (DMDD)	42	95.5
DMDD, Primary, Retarded, Incapacitating, Definite		
Endogenous	11	25.0
DMDD, Primary, Retarded, Incapacitating, Definite		
Endogenous, Situational	6	14.0
DMDD, Primary, Retarded, Incapacitating, Definite		
Endogenous, Agitated	6	14.0
DMDD, Primary, Retarded, Incapacitating, Definite		
Endogenous, Situational, Agitated	1	2.3

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Table 31 (continue)
Number and Percentage of Patients With Different Forms and Subform of Diagnoses Within 25 Systems of Classification in the Total Population

RDC		
Definite Major Depressive Disorder (DMDD)	42	95.5
DMDD, Primary, Retarded, Incapacitating, Definite		
Endogenous	11	25.0
DMDD, Primary, Retarded, Incapacitating, Definite		
Endogenous, Situational	6	14.0
DMDD, Primary, Retarded, Incapacitating, Definite		
Endogenous, Agitated	6	14.0
DMDD, Primary, Incapacitating, Definite		
Endogenous, Situational, Agitated	1	2.3
DMDD, Primary, Retarded, Incapacitating, Probable		
Endogenous	1	2.3
DMDD, Recurrent, Primary, Incapacitating, Definite		
Endogenous	17	38.6
Probable major Depressive Disorder (PMDD)	1	2.3
PMDD, Recurrent, Primary, Incapacitating, Definite		
Endogenous	1	2.3
DSM-III-R		
Major Depressive Episode (MDE)	44	100.0
MDE, Single Episode, Severe	4	9.1
MDE, Single Episode, Severe, Melancholic	19	43.2
MDE, Single Episode, Severe, Melancholic, Chronic	2	4.5
MDE, Recurrent, Severe	1	2.3
MDE, Recurrent, Severe, melancholic	11	25.0
MDE, Recurrent, Severe, melancholic, Chronic	5	11.4
MDE, Recurrent, Moderate, melancholic	1	2.3
MDE, Recurrent, moderate, Chronic	1	2.3
TAYLOR		
Endogenous Depression	44	100.0
KLEIN		
Endogenomorphic Depression	36	81.8
Chronic Neurotic Dysphoria	3	6.8
Acute Dysphoria	1	2.3
POLLITT		
Psychological Type S Depression	44	100.0
KIELHOLZ		
Endogenous (Etiologic) Depression	35	79.5
Endogenous Periodic	17	38.6
Endogenous	18	40.9
Psychogenic (Etiologic) Depression	9	20.1
Reactive	7	15.9
Neurotic	2	4.5

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Table 31(continue)
Number and Percentages of Patients With different Forms and Subform of Diagnoses Within 25 Systems of Classification in the Total Population

System of Classification/Diagnoses	N	%
COMPOSITE		
Reactive Depressive Disorder	7	15.9
Depressive Illness	1	2.3
Vital Depression	11	25.0
Vital Depressive State	3	6.8
Vital Depressive State Pure	2	4.5
Vital Depressive State Pure Chronic Atypical	1	2.3
Vital Depressive Illness Pure	2	4.5
Vital Depressive Illness Chronic	1	2.3
Vital Depressive Illness Chronic Atypical	1	2.3
Vital Depressive Illness Pure Chronic Atypical	1	2.3
ENDOGENOUS DEPRESSION		
Endogenous Depressive State	5	11.4
Endogenous Depressive State Pure	6	13.6
Endogenous Depressive State Chronic Atypical	1	2.3
Endogenous Depressive Illness	5	11.4
Endogenous Depressive Illness Pure	4	9.1
Endogenous Depressive Illness Chronic Atypical	1	2.3
Endogenous Depressive Illness Pure Chronic Atypical	2	4.5

Table 32
Rank Order of Diagnostic Forms in Total Population

Rank	System	Diagnostic Form	N	%
1	ICD-10	Depressive Episode	44	100.0
1	Lewis	Melancholia	44	100.0
1	Kiloh	Endogenous Depression	44	100.0
1	Mendels	Endogenous Depression	44	100.0
1	Paykel	Group/4A Psychotic Depression	44	100.0
1	CATEGO	Class R/ Retarded Depression	44	100.0
1	St. Louis	Definite Primary Depression	44	100.0
1	DSM-III-R	Major Depressive Episode	44	100.0
1	Taylor	Endogenous Depression	44	100.0
1	Pollitt	Psychological Type S Depression	44	100.0
11	Schneider	Vital Depression	43	97.7
11	Pilowsky	Class B/ Endogenous Depression	43	97.7
13	Foulds	Neurotic Depression	42	95.5
13	RDC	Definite Major Depressive Disorder	42	95.5

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Table 32 (continue)
Rank Order of Diagnostic Forms in Total Population

Rank	System	Diagnostic Form	N	%
15	Robins	Primary Affective (Depressive) Disorder	41	93.2
16	Raskin	Type 3/ Endogenous Depression	40	90.9
17	Kraepelin	Depressive State	37	84.1
18	Klein	Endogenomorphic Depression	36	81.8
19	Hamilton	Retarded Depression	35	79.5
19	Kielholz	Endogenous (Etiologic) Depression	35	79.5
21	Vienna	Endogenomorphic-Depressive Axial Syndr.	31	70.5
22	Composite	Endogenous Depression	24	54.6
23	Overall	Type C/ Retarded Depression	22	50.0
24	Leonhard	Mixed Depression	21	47.7
24	Winokur	Pure Depression	21	47.7
26	Leonhard	Pure Melancholia	19	43.2
27	Winokur	Sporadic Depression	15	34.1
28	Composite	Vital Depression	11	25.0
29	Overall	Type A/ Anxious Depression	10	22.7
30	Kielholz	Psychogenetic (Etiologic) Depression	9	20.1
31	Winokur	Depressive Spectrum Disease	8	18.2
32	Hamilton	Agitated Depression	7	15.9
32	Composite	Reactive Depressive Disorder	7	15.9
34	Leonhard	Pure Depression	3	6.8
34	Klein	Chronic Neurotic Dysphoria	3	6.8
36	Overall	Type B/ Hostile Depression	2	4.5
36	Raskin	Type 2/Neurotic Depression	2	4.5
37	Schneider	Reactive Depression	1	2.3
37	Pilowsky	Class A/ Neurotic Depression	1	2.3
37	Foulds	Psychotic Depression	1	2.3
37	Foulds	Dysthymic Depression	1	2.3
37	Raskin	Type 1 Agitated Depression	1	2.3
37	RDC	Probable Major Depressive Disorder	1	2.3
37	Klein	Acute Dysphoria	1	2.3
37	Composite	Depressive Illness	1	2.3

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Table 33
Rank Order of Diagnostic Subforms in Total Population

Rank	System	Diagnostic Subform	N	%
1	Lewis	Definite Melancholia	40	90.9
2	Kraepelin	Depressive State-Melancholia Simplex	35	79.5
2	Mendels	Definite Endogenous Depression	35	79.5
4	ICD-10	Severe Depressive Episode	25	56.8
5	ICD-10	Recurrent Severe Depressive Episode	19	43.2
5	DSM-III-R	MDE, Single Episode, Severe, Melancholic	19	43.2
7	Leonhard	Definite Pure Melancholia	18	40.9
7	Leonhard	Mixed (Complete) Depression	18	40.9
7	Kielholz	Endogenous Depression	18	40.9
10	RDC	DMDD, Recurrent, Primary, Incapacitating, Definite Endogenous	17	38.6
10	Kielholz	Endogenous Periodic Depression	17	38.6
12	RDC	DMDD, Primary, Retarded, Incapacitating, Definite Endogenous	11	25.0
12	DSM-III-R	MDE, Recurrent, Severe, Melancholic	11	25.0
14	Kielholz	Psychogenic Reactive Depression	7	15.9
15	RDC	DMDD, Primary, Retarded, Incapacitating, Definite Endogenous, Situational	6	13.6
15	RDC	DMDD, Primary, Retarded, Incapacitating, Definite Endogenous, Agitated	6	13.6
15	Mendels	Probable Endogenous Depression	6	13.6
15	Composite	Endogenous Depressive State Pure	6	13.6
19	DSM-III-R	MDE, Recurrent, Severe, Melancholic, Chr.	5	11.4
19	Composite	Endogenous Depressive State	5	11.4
19	Composite	Endogenous Depressive Illness	5	11.4
22	Lewis	Probable Melancholia	4	9.1
22	DSM-III-R	MDE, Single Episode, Severe	4	9.1
22	Composite	Endogenous Depressive Illness Pure	4	9.1
25	Leonhard	Mixed (Incomplete) Depression	3	6.8
25	Mendels	Possible Endogenous Depression	3	6.8
25	Composite	Vital Depressive State	3	6.8
28	Kraepelin	Depressive State-Melancholia Gravis	2	4.5
28	Leonhard	Non-participatory (Pure) Depression	2	4.5
28	DSM-III-R	MDE, Single Episode, Severe, Melancholic, Chronic	2	4.5
28	Kielholz	Psychogenic Neurotic Depression	2	4.5
28	Composite	Vital Depressive State Pure	2	4.5
28	Composite	Vital Depressive Illness Pure	2	4.5
28	Composite	Endogenous Depressive Ill. Pure Chr. Atyp.	2	4.5
35	Leonhard	Probable Pure Melancholia	1	2.3
35	Leonhard	Self-torturing (pure) Depression	1	2.3
35	RDC	DMDD, Primary, Incapacitating, Definite Endogenous, Situational, Agitated	1	2.3

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Table 34
Rank Order of Diagnostic Forms and Subforms in Total Population

Rank	System	Diagnostic Forms and Subforms	N	%
1	ICD-10	Depressive Episode	44	100.0
1	Lewis	Melancholia	44	100.0
1	Kiloh	Endogenous Depression	44	100.0
1	Mendels	Endogenous Depression	44	100.0
1	Paykel	Group 4A/ Psychotic Depression	44	100.0
1	CATEGO	Class R/ Retarded Depression	44	100.0
1	St. Louis	Definite Primary Depression	44	100.0
1	DSM-III-R	Major Depressive Episode	44	100.0
1	Taylor	Endogenous Depression	44	100.0
1	Pollitt	Psychological Type S Depression	44	100.0
11	Schneider	Vital Depression	43	97.7
11	Pilowsky	Class B/ Endogenous Depression	43	97.7
13	Foulds	Neurotic Depression	42	95.5
13	RDC	Definite Major Depressive Disorder	42	95.5
15	Robins	Primary Affective (Depressive) Disorder	41	93.2
16	Lewis	Definite Melancholia	40	90.9
16	Raskin	Type 3/Endogenous Depression	40	90.9
18	Kraepelin	Depressive State	37	84.1
19	Klein	Endogenomorphic Depression	36	81.8
20	Kraepelin	Depressive State-Melancholia simplex	35	79.5
20	Hamilton	Retarded Depression	35	79.5
20	Mendels	Definite Endogenous Depression	35	79.5
20	Kielholz	Endogenous (Etiologic) Depression	35	79.5
24	Vienna	Endogenomorphic-Depressive Axial Synd.	31	70.5
25	ICD-10	Severe Depressive Episode	25	56.8
26	Composite	Endogenous Depression	24	54.6
27	Overall	Type C/ Retarded Depression	22	50.0
28	Leonhard	Mixed Depression	21	47.7
28	Winokur	Pure Depression	21	47.7
30	Leonhard	Pure Melancholia	19	43.2
30	ICD-10	Recurrent Severe Depression Episode	19	43.2
30	DSM-III-R	MDE, Single Episode, Severe, Melancholic	19	43.2
33	Leonhard	Definite Pure Melancholia	18	40.9
33	Leonhard	Mixed (Complete) Depression	18	40.9
33	Kielholz	Endogenous Depression	18	40.9
36	RDC	DMDD, Recurrent, Primary, Incapacitating, Definite Endogenous	17	38.6
36	Kielholz	Endogenous Periodic Depression	17	38.6
38	Winokur	Sporadic Depression	15	34.1
39	RDC	DMDD, Primary, Retarded, Incapacitating, Definite Endogenous	11	25.0
39	DSM-III-R	MDE, Recurrent, Severe, Melancholic	11	25.0
39	Composite	Vital Depression	11	25.0

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Table 34 (continue)
Rank Order of Diagnostic Forms and Subforms in Total Population

Rank	System	Diagnostic Forms and Subforms	N	%
42	Overall	Type A/ Anxious Depression	10	22.7
43	Kielholz	Psychogenic (Etiologic) Depression	9	20.1
44	Winokur	Depressive Spectrum Disease	8	18.2
45	Hamilton	Agitated Depression	7	15.9
45	Kielholz	Psychogenic Reactive Depression	7	15.9
45	Composite	Reactive Depressive Disorder	7	15.9
48	RDC	DMDD, Primary Retarded, Incapacitating, Definite Endogenous, Situational	6	13.6
48	RDC	DMDD, Primary Retarded, Incapacitating, Definite Endogenous, Agitated	6	13.6
48	Mendels	Probable Endogenous Depression	6	13.6
48	Composite	Endogenous Depressive State Pure	6	13.6
52	DSM-III-R	MDE, Recurrent, Severe, Melancholic, Chr.	5	11.4
52	Composite	Endogenous Depressive State	5	11.4
52	Composite	Endogenous Depressive Illness	5	11.4
55	Lewis	Probable Melancholia	4	9.1
55	DSM-III-R	MDE, Single Episode, Severe	4	9.1
55	Composite	Endogenous Depressive Illness Pure	4	9.1
58	Leonhard	Pure Depression	3	6.8
58	Leonhard	Mixed (Incomplete) Depression	3	6.8
58	Mendels	Possible Endogenous Depression	3	6.8
58	Klein	Chronic Neurotic Dysphoria	3	6.8
58	Composite	Vital Depressive State	3	6.8
63	Kraepelin	Depressive State-Melancholia Gravis	2	4.5
63	Leonhard	Non-participatory (Pure) Depression	2	4.5
63	DSM-III-R	MDE, Single Episode, Severe, Melancholic, Chronic	2	4.5
63	Overall	Type B/ Hostile Depression	2	4.5
63	Raskin	Type 2/ Neurotic Depression	2	4.5
63	Kielholz	Psychogenic Neurotic Depression	2	4.5
63	Composite	Vital Depressive State Pure	2	4.5
63	Composite	Vital Depressive Illness Pure	2	4.5
63	Composite	Endogenous Depressive Ill. Pure Chr. Atyp.	2	4.5
71	Schneider	Reactive Depression	1	2.3
71	Leonhard	Probable Pure Melancholia	1	2.3
71	Leonhard	Self-torturing (Pure) Depression	1	2.3
71	Pilowsky	Class/A Neurotic Depression	1	2.3
71	Foulds	Psychotic Depression	1	2.3
71	Foulds	Dysthymic Depression	1	2.3
71	Raskin	Type 1/ Agitated Depression	1	2.3
71	RDC	Probable Major Depressive Disorder	1	2.3

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Table 34 (continue)
Rank Order of Diagnostic Forms and Subforms in Total Population

Rank	System	Diagnostic Forms and Subforms	N	%
71	RDC	DMDD, Primary, Incapacitating, Definite Endogenous, Situational, Agitated	1	2.3
71	RDC	DMDD, Primary, Retarded, Incapacitating, Probable Endogenous,	1	2.3
71	RDC	PMDD, Recurrent, Primary, Incapacitating, Definite Endogenous	1	2.3
71	DSM-III-R	MDE, Recurrent, Severe	1	2.3
71	DSM-III-R	MDE, Recurrent, Moderate, Melancholic	1	2.3
71	DSM-III-R	MDE, Recurrent, Moderate, Chronic	1	2.3
71	Klein	Acute Dysphoria	1	2.3
71	Composite	Depressive Illness	1	2.3
71	Composite	Vital Depressive St. Pure Chr. Atypical	1	2.3
71	Composite	Vital Depressive Illness Chronic	1	2.3
71	Composite	Vital Depressive Ill. Chronic Atypical	1	2.3
71	Composite	Vital Depressive Ill. Pure Chr. Atypical	1	2.3
71	Composite	Endogenous Depressive St. Chr. Atypical	1	2.3
71	Composite	Endogenous Depressive Ill. Chr. Atypical	1	2.3

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Comparability of Diagnoses in Two Treatment Groups

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Comparability of two treatment-based populations in terms of diagnostic forms and subforms was examined. As a result, it was found that of the 93 diagnostic forms and subforms only in two was there a statistically significant difference between the two treatment groups: there were significantly more patients with pure depression in Winokur's classification in the RBX than in the PBO group, whereas there were significantly more patients with sporadic depression in Winokur's classification in the PBO group than in the RBX group.

Table 35
Comparability of Two Treatment-Based Populations in Terms of Diagnostic Forms and Subforms.

*Statistically Significant Difference Between the Two Treatment Groups.

No.	Diagnostic Forms and Subforms	RBX		PBO		DIFFERENCES	
		N	%	N	%		Stat.
1	Kraepelin Depressive State	20	90.9	17	77.3	-	p=.216
2	Kraepelin Depressive State Melancholia Gravis	2	9.1	0	0.0	1	p=.148
3	Kraepelin Depressive State Melancholia Simplex	18	81.8	17	77.3	-	p=.709
4	Schneider Reactive Depression	0	0.0	1	4.5	1	p=.312
5	Schneider Vital Depression	22	100.0	21	95.4	-	p=.312
6	Leonhard Pure Melancholia	10	45.5	9	40.9	-	p=.761
7	Leonhard Pure Melancholia Definite	10	45.5	8	36.4	-	p=.540
8	Leonhard Pure Melancholia Probable	0	0.0	1	4.5	1	p=.312
9	Leonhard Pure Depression	2	9.1	1	4.5	1	p=.550
10	Leonhard Pure Depression Self-torturing	1	4.5	0	0.0	1	p=.312
11	Leonhard Pure Depression Non-participatory	1	4.5	1	4.5	-	p=1.000
12	Leonhard Mixed Depression	9	40.9	12	54.5	-	p=.365
13	Leonhard Mixed Depression Complete	8	36.4	10	45.5	-	p=.540
14	Leonhard Mixed Depression Incomplete	1	4.5	2	9.1	1	p=.550
15	Vienna Endogenomorphic-Depressive Axial Syndrome	16	72.7	15	68.2	-	P=.741
16	ICD-10 Depressive Episode	22	100.0	22	100.0	-	N/A
17	ICD-10 Depressive Episode Severe	13	59.1	12	54.5	-	p=.761
18	ICD-10 Depressive Episode Recurrent Severe	9	40.9	10	45.5	-	p=.761
19	Lewis Melancholia	22	100.0	22	100.0	-	N/A
20	Lewis Melancholia Definite	20	90.9	20	90.9	-	p=1.000
19	Lewis Melancholia	22	100.0	22	100.0	-	N/A
21	Lewis Melancholia Probable	2	9.1	2	9.1	-	p=1.000
22	Hamilton Retarded Depression	18	81.8	17	77.3	-	p=.708
23	Hamilton Agitated Depression	2	9.1	5	22.7	-	p=.216
24	Kiloh Endogenous Depression	22	100.0	22	100.0	-	N/A
25	Pilowsky Class A/ Neurotic Depression	1	4.5	0	0.0	1	p=.312
26	Pilowsky Class B/ Endogenous Depression	21	95.4	22	100.0	-	p=.312
27	Mendels Endogenous Depression	22	100.0	22	100.0	-	N/A
28	Mendels Endogenous Depression Definite	19	86.4	16	72.7	-	p=.262
29	Mendels Endogenous Depression Probable	2	9.1	4	18.2	1	p=.380
30	Mendels Endogenous Depression Possible	1	4.5	2	9.1	1	p=.550
31	Foulds Neurotic Depression	22	100.0	20	90.9	-	p=.148
32	Foulds Psychotic Depression	0	0.0	1	4.5	1	p=.312
33	Foulds Dysthymic Depression	0	0.0	1	4.5	1	p=.312
34	Overall Type A/ Anxious Depression	4	18.2	6	27.3	-	p=.472
35	Overall Type B/ Hostile Depression	1	4.5	1	4.5	-	p=1.000
36	Overall Type C/ Retarded Depression	13	59.1	9	40.9	-	p=.228
37	Paykel Group 4A/ Psychotic Depression	22	100.0	22	100.0	-	N/A
38	Rask in Type 1/ Agitated Depression	1	4.5	0	0.0	1	p=.312
39	Rask in Type 2/ Neurotic Depression	1	4.5	1	4.5	-	p=1.000
40	Rask in Type 3/ Endogenous Depression	20	90.9	20	90.9	-	p=1.000

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Table 35 (continue)
Comparability of Two Treatment-Based Populations in Terms of Diagnostic Forms and Subforms.

*Statistically Significant Difference Between the Two Treatment Groups.

No.	Diagnostic Forms and Subforms	RBX		PBO		DIFFERENCES	
		N	%	N	%		Stat.
41	CATEGO Class R/ Retarded Depression	22	100.0	22	100.0	-	N/A
42	Robin Primary Affective (Depressive) Disorder	21	95.4	20	90.9	-	p=.550
43	St. Louis Definite Primary Depression	22	100.0	220	100.0	-	N/A
44	Winokur Pure Depression*	14	63.6	7	31.8	2	p=.035
45	Winokur Sporadic Depression*	4	18.2	11	50.0	2	p=.026
46	Winokur Depressive Spectrum Disease	4	18.2	4	18.2	-	p=1.000
47	RDC Major Depressive Disorder Definite	22	100.0	20	90.9	-	p=.148
48	RDC, DMDD, Primary, Retarded, Incapacitating, Definite Endogenous	7	31.8	4	18.2	-	p=.296
49	RDC, DMDD, Primary, Retarded, Incapacitating, Definite Endogenous, Situational	2	9.1	4	18.2	2	p=.380
50	RDC, DMDD, Primary, Retarded, Incapacitating, Definite Endogenous, Agitated	3	13.6	3	13.6	-	p=1.000
51	RDC, DMDD, Primary, Incapacitating, Definite Endogenous, Situational, Agitated	0	0.0	1	4.5	1	p=.312
52	RDC, DMDD, Primary, Retarded, Incapacitating, Probable Endogenous	1	4.5	0	0.0	1	p=.312
53	RDC, DMDD, Recurrent, Primary, Incapacitating, Definite Endogenous	9	40.9	8	36.4	-	p=.757
54	RDC Major Depressive Disorder Probable	0	0.0	1	4.5	1	p=.312
55	RDC, PMDD, Recurrent, Primary, Incapacitating, Definite Endogenous	0	0.0	1	4.5	1	p=.312
56	DSM-III-R Major Depressive Episode	22	100.0	22	100.0	-	N/A
57	DSM-III-R, MDE, Single Episode, Severe	2	9.1	2	9.1	-	p=1.000
58	DSM-III-R, MDE, Single Episode, Severe, Melancholic	9	40.9	10	45.5	-	p=.761
59	DSM-III-R, MDE, Single Episode, Severe, Melancholic, Chronic	2	9.1	0	0.0	1	p=.148
60	DSM-III-R, MDE, Recurrent, Severe	0	0.0	1	4.5	1	p=.312
61	DSM-III-R, MDE, Recurrent, Severe, Melancholic	6	27.3	5	22.7	-	p=.728
62	DSM-III-R, MDE, Recurrent, Severe, Melancholic, Chronic	3	13.6	2	9.1	-	p=.635
63	DSM-III-R, MDE, Recurrent, Moderate, Melancholic	0	0.0	4	18.2	4.5	p=.312
64	DSM-III-R, MDE, Recurrent, Moderate, Chronic	0	0.0	1	4.5	1	p=.312
65	Taylor Endogenous Depression	22	100.0	22	100.0	-	N/A
66	Klein Endogenous Depression	18	81.8	18	81.8	-	p=1.000
67	Klein Chronic Neurotic Dysphoria	2	9.1	1	4.5	1	p=.550
68	Klein Acute Dysphoria	0	0.0	1	4.5	1	p=.312
69	Pollitt Physiological Type S Depression	22	100.0	22	100.0	-	N/A
70	Kielholz Endogenous (Etiologic) Depression	20	90.9	15	68.2	-	p=.062
71	Kielholz Endogenous Periodic Depression	9	40.9	8	36.4	-	p=.757
72	Kielholz Endogenous Depression	11	50.0	7	31.8	-	p=.220
73	Kielholz Psychogenic (Etiologic) Depression	2	9.1	7	31.8	3	p=.062
74	Kielholz Psychogenic Reactive Depression	2	9.1	5	22.7	2	p=.216
75	Kielholz Psychogenic Neurotic Depression	0	0.0	2	9.1	1	p=.148
76	Composite Reactive Depression Disorder	2	9.1	5	22.7	2	p=.216
77	Composite Depressive Illness	0	0.0	1	4.5	1	p=.312
78	Composite Vital Depression	6	27.3	5	22.7	-	p=.728
79	Composite Vital Depressive State	1	4.5	2	9.1	2	p=.550
80	Composite Vital Depressive State Pure	2	9.1	0	0.0	1	p=.148
81	Composite Vital Depressive State Pure Chronic Atypical	1	4.5	0	0.0	1	p=.312
82	Composite Vital Depressive Illness Pure	1	4.5	1	4.5	-	p=1.000

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Table 35 (continue)
Comparability of Two Treatment-Based Populations in Terms of Diagnostic Forms and Subforms.

*Statistically Significant Difference Between the Two Treatment Groups.

No.	Diagnostic Forms and Subforms	RBX		PBO		DIFFERENCES	
		N	%	N	%		Stat.
83	Composite Vital Depressive Illness Chronic	1	4.5	0	0.0	1	p=.312
84	Composite Vital Depressive Illness Chronic Atypical	0	0.0	1	4.5	1	p=.312
85	Composite Vital Depressive Illness Pure Chronic Atypical	0	0.0	1	4.5	1	p=.312
86	Composite Endogenous Depression	14	63.6	10	45.5	-	p=.226
87	Composite Endogenous Depressive State	1	4.5	4	18.2	3	p=.154
88	Composite Endogenous Depressive State Pure	5	22.7	1	4.5	3	p=.079
89	Composite Endogenous Depressive State Chronic Atypical	1	4.5	0	0.0	1	p=.312
90	Composite Endogenous Depressive Illness	2	9.1	3	13.6	-	p=.635
91	Composite Endogenous Depressive Illness Pure	3	13.6	1	4.5	3	p=.294
92	Composite Endogenous Depressive Illness Chronic Atypical	1	4.5	0	0.0	1	p=.312
93	Composite Endogenous Depressive Illness Pure Chronic Atypical	1	4.5	1	4.5	-	p=1.000

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Responsiveness of Diagnosis-Based Populations

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Responsiveness of diagnosis-based population was examined by measuring the actual and percentile changes (with the level of statistical - t-test - significance) in HAMD total scores from Day 0 to Day 42 (Table 36); and relative responsiveness was established by ranking percentile changes (with consideration of number of patients included in diagnosis-based populations and level of statistical significance) from the highest (most responsive) to the lowest (least responsive) (Table 37).

Table 36
Responsiveness of Diagnosis-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance.

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Kraepelin in Depressive State	37	35.70	19.03	18.47	51.7	p=.000
Kraepelin in Melancholia Gravis	2	34.50	18.00	16.50	47.8	p=.303
Kraepelin in Melancholia Simplex	35	35.77	19.09	16.68	46.6	p=.000
Schneider Reactive Depression	1	42.00	45.00	-3.00	-7.1	N/A
Schneider Vital Depression	43	35.95	20.67	15.28	42.5	p=.000
Leonhard Pure Melancholia	19	35.79	23.89	11.90	33.2	p=.008
Leonhard Definite Pure Melancholia	18	35.89	23.17	12.72	35.4	p=.006
Leonhard Probable Pure Melancholia	1	34.00	37.00	-3.00	-8.8	N/A
Leonhard Pure Depression	3	34.00	24.33	9.67	28.4	p=.462
Leonhard Self-torturing Pure Depression	1	35.00	27.00	8.00	22.9	N/A
Leonhard Non-participatory Pure Depression	2	33.50	23.00	10.50	31.3	p=.671
Leonhard Mixed Depression	21	36.71	19.14	17.57	47.9	p=.000
Leonhard Mixed Complete Depr	18	36.67	19.50	17.17	46.8	p=.000
Leonhard Mixed Incomplete Depr.	3	37.00	17.00	20.00	54.1	p=.144
Vienna Endogenomorphic-Depr. Axial Syndrome	31	36.77	19.55	17.22	46.8	p=.000
ICD-10 Depressive Episode	44	36.09	21.23	14.86	41.2	p=.000
ICD-10 Severe Depressive Episode	25	36.76	21.56	15.20	41.3	p=.000
ICD-10 Rec. Sev. Depressive Epis.	19	35.21	20.79	14.12	41.0	p=.001
Lewis Melancholia	44	36.09	21.23	14.86	41.2	p=.000
Lewis Probable Melancholia	4	33.25	15.00	18.25	54.9	p=.098
Lewis Definite Melancholia	40	36.38	21.85	14.53	39.9	p=.000
Hamilton Retarded Depression	35	36.16	20.60	15.56	43.0	p=.000
Hamilton Agitated Depression	7	36.14	27.43	8.71	24.1	p=.269
Kiloh Endogenous Depression	44	36.09	21.23	14.86	41.2	p=.000
Pilowsky Class A/Neurotic Depr.	1	35.0	5.0	30.00	85.7	N/A
Pilowsky Class B/ Endogen. Depr.	43	36.11	21.61	14.50	40.2	p=.000
Mendels Endogenous Depression	44	36.09	21.23	14.86	41.2	p=.000
Mendels Possible Endogen. Depr.	3	36.67	29.00	7.67	20.9	p=.547
Mendels Probable Endogen. Depr.	6	34.50	20.33	14.17	41.1	p=.121

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Table 36 (continue)

Responsiveness of Diagnosis-Based Populations as measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance.

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Mendels Definite Endogen. Depr.	35	36.31	20.71	15.60	43.0	p=.121
Foulds Psychotic Depression	1	33.00	40.00	-7.00	-21.2	N/A
Foulds Neurotic Depression	42	36.21	20.38	15.83	43.7	p=.000
Foulds Dysthymic Depression	1	34.00	38.00	-4.00	-11.8	N/A
Overall Type A/ Anxious Depression	10	37.00	22.50	14.50	39.2	p=.000
Overall Type B/ Hostile Depression	2	32.50	38.50	-6.00	-18.5	p=.205
Overall Type C/Retarded Depression	22	36.55	16.55	20.00	54.7	p=.000
Paykel Group 4A/Psychotic Depr.	44	36.09	21.23	14.86	41.2	p=.000
Raskin Type 1/Agitated Depr.	1	34.00	5.00	29.00	85.3	N/A
Raskin Type 2/Neurotic Depr.	2	34.00	9.00	25.00	73.5	p=0.197
Raskin Type 3/Endogenous Depr.	40	36.33	22.60	13.73	37.8	p=.000
CATEGO Class R/Retarded Depr.	44	36.09	21.23	14.86	41.2	p=.000
Robins Primary Affective (Depressive) Disorder	41	36.27	20.76	15.51	42.8	p=.000
St. Louis Definite Primary Depr.	44	36.09	21.23	14.86	41.2	p=.000
Winokur Pure Depression	21	36.19	17.86	21.33	58.9	p=.000
Winokur Sporadic Depression	15	36.20	25.87	10.33	28.5	p=.000
Winokur Depr. Spectrum Disease	8	35.63	21.38	14.25	40.0	p=.051
RDC Definite Major Depr. Disorder	42	36.21	20.40	15.81	43.7	p=.000
RDC, DMDD, Primary, Retarded Incap., Def. Endogenous	11	36.45	17.73	18.72	51.4	p=.001
RDC, DMDD, Ret., Incap., Def. Endogenous, Situational	6	37.67	30.67	7.00	18.6	p=.373
RDC, DMDD, Primary, Incap., Def. Endog., Sit., Agitated	1	41.00	46.00	-5.00	-12.2	N/A
RDC, DMDD, Primary, Retarded Incap., Probable Endogenous	1	34.00	5.00	29.00	85.3	N/A
RDC, DMDD, Recurrent, Primary, Incap., Definite Endogenous	17	35.41	18.71	16.70	47.2	p=.000
RDC Probable Major Depr. Disorder	1	34.00	37.00	-3.00	-8.8	N/A
RDC, PMDD, Recurrent, Primary, Incap., Definite Endogenous	1	34.00	37.00	-3.00	-8.8	N/A
DSM-III-R Maj. Depressive Epis.	44	36.09	21.23	14.86	41.2	p=0.000
DSM, MDE, Single Epis., Severe, Melancholic	19	37.00	24.26	12.74	34.4	p=.006
DSM, MDE, Single Epis., Severe, Melancholic, Chronic	2	34.50	5.00	29.57	85.5	p=.075
DSM MDE, Recurrent, Severe	1	30.00	13.00	17.00	56.7	N/A
DSM, MDE, Recurrent, Severe, Melancholic	11	35.91	16.18	19.73	54.9	p=.001

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Table 36 (continue)

Responsiveness of Diagnosis-Based Populations as measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance.

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
DSM, MDE, Recurrent, Severe, Melancholic, Chronic	5	35.40	25.20	10.20	28.8	p=.283
DSM, MDE, Recurrent, Moderate, Melancholic	1	34.00	37.00	-3.00	-8.8	N/A
DSM, MDE, Recurrent, Moderate, Chronic	1	33.00	41.00	-8.00	-24.2	N/A
Taylor Endogenous Depression	44	36.09	21.23	14.86	41.2	p=.000
Klein Endogenomorphic Depr.	36	36.61	20.17	16.44	44.9	p=.000
Klein Chronic Neurotic Dysphoria	3	33.00	35.67	-2.67	-8.1	p=.667
Klein Acute dysphoria	1	38.00	41.00	-3.00	-7.9	N/A
Klein Acute dysphoria	1	38.00	41.00	-3.00	-7.9	N/A
Pollitt Physiolog. Type S Depr.	44	36.09	21.33	14.86	41.2	p=.000
Kielholz Endogen. (Etiol) Depr.	35	35.94	19.54	16.40	45.6	p=.000
Kielholz Endogen. Periodic Depr.	17	35.65	22.06	13.59	38.1	p=.004
Kielholz Endogenous Depression	18	36.22	17.17	19.05	52.6	p=.000
Kielholz Psycho (Etiol.) Depr.	9	36.67	27.78	8.89	24.2	p=.139
Kielholz Psycho Reactive Depr.	7	38.14	32.86	5.28	13.8	p=.433
Kielholz Psycho Neurotic Depr.	2	31.50	10.00	21.54	68.3	p=.131
Composite Reactive Depr. Disorder	7	38.14	32.86	5.28	13.8	p=.433
Composite Depressive Illness	1	30.00	13.00	17.00	56.7	N/A
Composite Vital Depression	11	35.45	13.91	21.54	60.8	p=.000
Composite Vital Depr. State	3	36.67	12.67	24.00	65.4	p=.052
Composite Vital Depr. State Pure	2	38.50	5.50	33.00	85.7	p=.077
Composite Vital Depr. State Pure	2	38.50	5.50	33.00	85.7	p=.077
Composite Vital Depr. State Pure Chronic Atypical	1	37.00	4.00	33.00	89.2	N/A
Composite Vit. Depr. Illness Pure	2	32.50	12.50	20.00	61.5	p=.295
Composite Vit. Depr. Ill. Chr.	1	35.00	27.00	8.00	22.9	N/A
Composite Vit. Depr. Ill. Chr. Atyp.	1	33.00	7.00	26.00	78.8	N/A
Composite Vit. Depr. Illness Pure Chronic Atypical	1	33.00	41.00	-8.00	-24.2	N/A
Composite Endogenous Depression	24	36.17	20.75	15.42	42.6	p=0.000
Composite Endog. Depressive State	5	35.00	32.60	2.40	6.9	p=.750
Composite Endog. Depr. State Pure	6	36.83	14.50	22.33	60.6	p=.014
Composite Endog. Depr. State Chronic Atypical	1	32.00	6.00	26.00	81.3	N/A
Composite Endog. Depr. Illness	5	36.40	23.60	12.80	35.2	p=.160
Composite Endog. Depressive Illness Pure	4	37.25	8.00	29.25	78.5	p=.000

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Table 36 (continue)

Responsiveness of Diagnosis-Based Populations as measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42 with Level of Statistical Significance.

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Composite End. Depr. Illness Chronic Atypical	1	41.00	9.00	32.00	78.0	N/A
Composite End. Depr. Illness Pure Chronic Atypical	2	34.00	41.50	-7.50	-22.1	p= .042

Table 37

Rank Order of Responsiveness - With Consideration of Number of Patients Included in Sample - in Terms of Percentage Change in Total Scores of HAMD from Day 0 to Day 42 in Diagnosis-Based Populations. (Populations in Which the Change Reached the Accepted Level of Statistical Significance - $p = < / - .05$ - are marked by an asterisk*.) (P=Present; A=Absent)

Rank No.	Population	Percentage of change	N.
1	Composite Vital Depressive St. Pure Chr. Atyp	89.2	1
2	Pilowsky Class A/Neurotic Depression	85.7	1
2	Composite Vital Depressive State	85.7	2
4	DSM-III-R MDE, Single Episode, Severe	85.5	2
5	Raskin in type 1/Agitated Depression	85.3	1
5	RDC DMDD Prim, Retarded, Incap., Prob. Endog.	85.3	1
7	Composite Endogenous Depressive St. Chr. Atyp.	81.3	1
7	Composite Endogenous Depressive St. Chr. Atyp.	81.3	1
9	Composite Vit. Depressive Illness Chr. Atyp.	78.8	1
10	Composite Endogenous Depressive Illness Pure	78.5	4
11	Composite Endogenous Depressive Ill. Chr. Atyp	78.0	1
12	Raskin Type 2/Neurotic Depression	73.5	2
13	Kielholz Psychogenic Neurotic Depression	68.3	2
14	Composite Vital Depressive State	65.4	3
15	Composite Vital Depressive Illness Pure	61.5	2
16	Composite Vital Depression*	60.8	11
17	Composite Endogenous Depressive State Pure*	60.6	6
18	Winokur Pure Depression*	58.9	21
19	DSM MDE, Recurrent, Severe	56.7	1
19	Composite Depressive Illness	56.7	1
21	Lewis Probable Melancholia	54.9	4
21	DSM MDE, Recurrent, Severe, Melancholic*	54.9	11
23	Overall Type C/Retarded Depression*	54.7	22

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Table 37 (continue)

Rank Order of Responsiveness - With Consideration of Number of Patients Included in Sample - in Terms of Percentages Change in Total Scores of HAMD from Day 0 to Day 42 in Diagnosis-Based Populations. (Populations in Which the Change Reached the Accepted Level of Statistical Significance - $p < /- .05$ - are marked by an asterisk*.) (P=Present; A=Absent)

Rank No.	Population	Percentage of change	N.
24	Leonhard Mixed Incomplete Depression	54.1	3
25	DSM MDE, Single Episode Severe	53.7	4
26	Kielholz Endogenous Depression*	52.6	18
27	Kraepelin Depressive State*	51.7	37
28	RDC DMDD, Prim., Ret., Incap., Def. Endogenous	51.4	11
29	Leonhard Mixed Depression*	47.9	21
30	Kraepelin Melancholia Gravis	47.8	2
31	RDC DMDD, Recur., Prim., Incap., Def. Endogenous*	47.2	17
32	Leonhard Mixed Complete Depression*	46.8	18
32	Vienna Endogenomorphic-Depressive Axial Syn.*	46.8	31
34	Kraepelin Melancholia Simplex*	46.6	35
35	Kielholz Endogenous (Etiological) Depression*	45.6	35
36	Klein Endogenomorphic Depression*	44.9	36
37	Foulds Neurotic Depression*	43.7	42
37	RDC Definite Major Depressive Disorder*	43.7	42
39	Hamilton Retarded Depression*	43.0	35
39	Mendels Definite Endogenous Depression	43.0	35
41	Robins primary Affect. (Depressive) Disorder*	42.8	41
42	Composite Endogenous Depression*	42.6	24
43	Schneider Vital Depression*	42.5	43
44	ICD-10 Severe Depressive Episode*	41.3	25
45	ICD-10 Depressive Episode*	41.2	44
45	Lewis Melancholia*	41.2	44
45	Kiloh Endogenous Depression*	41.2	44
45	Mendels Endogenous Depression*	41.2	44
45	Paykel Group 4A/Psychotic Depression*	41.2	44
45	CATEGO Class R/Retarded Depression*	41.2	44
45	St. Louis Definite Primary Depression*	41.2	44
45	DSM-III-R major Depressive Episode*	41.2	44
45	Taylor Endogenous Depression*	41.2	44
45	Pollitt Psychological Type S Depression*	41.2	44
55	Mendels Probable Endogenous Depression*	41.1	6
56	ICD-10 Recurrent Severe Depressive Episode*	41.0	19
57	Pilowsky Class B/Endogenous Depression*	40.2	43
58	Winokur Depressive Spectrum Disease	40.0	8
59	Lewis Definite Melancholia*	39.9	40
60	Overall Type A/Anxious Depression*	39.2	10
61	Kielholz Endogenous Periodic Depression*	38.1	17
62	Raskin Type 3/Endogenous Depression*	37.8	40

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Table 37 (continue)

Rank Order of Responsiveness - With Consideration of Number of Patients Included in Sample - in Terms of Percentages Change in Total Scores of HAMD from Day 0 to Day 42 in Diagnosis-Based Populations. (Populations in Which the Change Reached the Accepted Level of Statistical Significance - $p = < /- .05$ - are marked by an asterisk*.) (P=Present; A=Absent)

Rank No.	Population	Percentage of change	N.
63	Leonhard Definite Pure Melancholia*	35.4	18
64	Composite Endogenous Depressive Illness	35.2	5
65	RDC DMDD, Prim. Ret., Incap., Def. Endog., Agit.	34.6	6
66	DSM-III-R MDE, Single Epis., Severe, Melancholia*	34.4	19
67	Leonhard Pure Melancholia*	33.2	19
68	Leonhard Non-participatory Pure Depression	31.3	2
69	DSM-III-R MDE, Recur., Sev., Melancholic, Chr.	28.8	5
70	Winokur Sporadic Depression*	28.5	15
71	Leonhard Pure Depression	28.4	3
72	Kielholz Psychogenic (Etiological) Depression	24.2	9
73	Hamilton Agitated Depression	24.1	7
74	Leonhard Self-torturing Pure Depression	22.9	1
74	Composite Depressive Illness Chronic vital	22.9	1
76	Mendels Possible Endogenous Depression	20.9	3
77	RDC DMDD, Prim., Ret., Incap., Def. Endog., Sit.	18.6	6
78	Kielholz Psychogenic Reactive Depression	13.8	7
78	Composite Reactive Depressive Disorder	13.8	7
80	Composite Endogenous Depressive State	6.9	5
81	Schneider Reactive Depression	-7.1	1
82	Klein Acute Dysphoria	-7.9	1
83	Klein Chronic Neurotic Dysphoria	-8.1	3
84	Leonhard Probable Pure Melancholia	-8.8	1
84	RDC Probable Major Depr. Disorder	-8.8	1
84	RDC PMDD, Rec., Prim., Incap., Def. Endogenous	-8.8	1
84	DSM-III-R MDE, Recurrent, Moderate, Melancholic	-8.8	1
88	Foulds Dysthmic Depression	-11.8	1
89	RDC DMDD, Prim., Incap., Def. Endog., Sit., Agit.	-12.2	1
90	Overall Type B/Hostile Depression	-18.5	2
91	Foulds Psychotic Depression	-21.2	1
92	Composite Endog. Depressive Ill. Pure Chr. Atyp.*	-22.1	2
93	DSM-III-R MDE, Recurrent, Moderate, Chronic	-24.2	1
93	Composite Vital Depressive Ill. Pure Chr. Atyp.	-24.2	1

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Comparative Responsiveness of Diagnosis-Based Populations to Treatment

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Responsiveness of diagnosis-based populations in the RBX (Table 38) and PBO (Table 39) groups was examined by measuring the actual and percentile changes (with level of statistical - t-test - significance) in HAMD total scores from Day 0 to Day 42; and differential responsiveness was explored by comparing the level of statistical significance between the two treatment groups in each diagnosis-based population (Table 40). Of the 93 diagnosis-based populations, in 58 therapeutic responsiveness was greater (as measured by the level of statistical significance of the change from Day 0 to Day 42) in the RBX than in the PBO-treated group; in 27 diagnosis-based populations responsiveness in the two treatment groups was equal (in no case the sample size was greater than 1 per cell); and in the eight diagnosis-based populations responsiveness was greater in the PBO-treated than in the RBX-treated group (in no case the sample size was greater than 5 per cell).

Table 38

Responsiveness to RBX in Diagnosis-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test).

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Kraepelin Depressive State	20	36.75	11.55	25.20	68.6	p=.000
Kraepelin Melancholia Gravis	2	34.50	18.00	16.50	47.8	p=.303
Kraepelin Melancholia Simplex	18	37.00	10.83	26.17	70.7	p=.000
Schneider Vital Depression	22	36.86	11.27	25.59	69.4	p=.000
Leonhard Pure Melancholia	10	36.60	11.40	25.20	68.9	p=.000
Leonhard Pure Melancholia Def.	10	36.60	11.40	25.20	68.9	p=.000
Leonhard Pure Depression	2	34.50	16.00	18.50	53.6	p=.329
Leonhard Self-torturing Pure Depression	1	35.00	27.00	8.00	22.9	N/A
Leonhard Non-participatory Pure Depression	1	34.00	5.00	29.00	85.3	N/A
Leonhard Mixed Depression	9	37.89	10.78	27.11	71.5	p=.000
Leonhard Mixed Depr. Complete	8	37.25	11.38	25.87	69.4	p=.001
Leonhard Mixed Depr. Incomplete	1	43.00	6.00	37.00	86.0	N/A
Vienna Endogenomorphic-Depressive Axial Syndrome	16	37.88	9.00	28.88	76.2	p=.000
ICD-10 Depressive Episode	22	36.86	11.27	25.59	69.4	p=.000
ICD-10 Depressive Episode Severe	13	37.62	7.92	29.70	78.9	p=.000
ICD-10 Depr. Epis. Recurrent Severe	9	35.78	16.11	19.67	55.0	p=.008
Lewis Melancholia	22	36.86	11.27	25.59	69.4	p=.000
Lewis Melancholia Definite	20	37.10	11.90	25.20	67.9	p=.000
Lewis Melancholia Probable	2	34.50	5.00	29.50	85.5	p=.011
Hamilton Retarded Depression	18	36.78	12.06	25.72	67.2	p=.000
Hamilton Agitated Depression	2	40.00	5.00	35.00	87.5	p=.036
Kiloh Endogenous Depression	22	36.86	11.27	25.29	69.4	p=.000
Pilowsky Class A/Neurotic Depr.	1	35.00	5.00	30.00	85.7	N/A

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Table 38 (continue)

Responsiveness to RBX in Diagnosis-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test).

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Pilowsky Class B/Endog. Depr.	21	36.95	11.57	25.38	68.7	p=.000
Mendels Endogenous Depression	22	36.86	11.27	25.59	69.4	p=.000
Mendels Endog. Depr. Definite	19	36.68	12.26	24.42	66.6	p=.000
Mendels Endog. Depr. Probable	2	40.00	5.00	35.00	87.5	p=.036
Mendels Endog. Depr. Possible	1	34.00	5.00	29.00	85.3	N/A
Foulds Neurotic Depression	22	36.86	11.27	25.59	69.4	p=.000
Overall Type A/Anxious Depr.	4	39.50	7.75	31.75	80.4	p=.000
Overall Type B/Hostile Depr.	1	31.00	39.00	-8.00	-25.8	N/A
Overall Type C/Retarded Depr.	13	37.00	9.69	27.31	73.8	p=.000
Paykel Group 4A/Psychotic Depr.	22	36.86	11.27	25.59	69.4	p=.000
Raskin Type 1/Agitated Depr.	1	34.00	5.00	29.00	85.3	N/A
Raskin Type 2/Neurotic Depr.	1	38.00	5.00	33.00	86.8	N/A
Raskin Type 3/Endogenous Depr.	20	36.95	11.90	25.05	67.8	p=.000
CATEGO Class R/Retarded Depr.	22	36.86	11.27	25.59	69.4	p=.000
Robins Primary Affective (Depressive) Disorder	21	37.00	11.57	25.43	68.7	p=.000
St. Louis Definite Primary Depr.	22	36.86	11.27	25.59	69.4	p=.000
Winokur Pure Depression	14	36.79	10.00	26.79	72.8	p=.000
Winokur Sporadic Depression	4	37.50	11.25	26.25	70.0	p=.023
Winokur Depr. Spectrum Disease	4	36.50	15.75	20.75	56.8	p=.097
RDC Major Depr. Disorder Definite	22	36.86	11.27	25.59	69.4	p=.000
RDC, DMDD, Primary, Retarded, Incap., Definite Endogenous	7	37.71	7.86	29.85	79.2	p=.000
RDC, DMDD, Primary, Ret., Incap., Def. Endogen., Situational	2	38.00	8.50	29.52	77.6	p=.054
RDC, DMDD, Primary, Ret., Incap., Def. Endogen., Agitated	3	38.33	8.67	29.66	77.4	p=.032
RDC, DMDD, Primary, Ret., Incap., Probable Endogenous	1	34.00	5.00	29.00	85.3	N/A
RDC, DMDD, Rec. Prim., Incap., Definite Endogenous	9	35.78	16.11	19.67	55.0	p=.008
DSM-III-R Major Depr. Episode	22	36.86	11.27	25.59	69.4	p=.000
DSM-III-R MDE, Sing., Epis., Sev.	2	35.50	8.00	27.50	77.5	p=.035
DSM-III-R MDE, Sing., Epis., Sev. Melancholic	9	38.78	8.56	30.22	77.9	p=.000
DSM-III-R MDE, Sing., Epis., Sev. Melancholic, Chronic	2	34.50	5.00	29.50	85.5	p=.075

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Table 38 (continue)

Responsiveness to RBX in Diagnosis-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test).

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
DSM-III-R MDE, Recurrent, Sev. Melancholic.	6	35.83	11.67	24.16	67.4	p=.010
DSM-III-R MDE, Recurrent, Sev. Melancholic, Chronic	3	35.67	25.00	10.67	29.9	p=.456
Taylor Endogenous Depression	22	36.86	11.27	25.59	69.4	p=.000
Klein Endogenomorphic Depr.	18	37.56	9.56	28.00	74.5	p=.000
Klein Chr. Neurotic Dysphoria	2	33.00	33.00	0.00	0.0	p=1.000
Pollitt Physiolo. Type S Depr.	22	36.86	11.27	25.59	69.4	p=.000
Kielholz Endog. (Etiol) Depr.	20	36.75	11.55	25.20	68.6	p=.000
Kielholz Endog. Periodic Depr.	9	35.78	16.11	19.67	55.0	p=.008
Kielholz Endogenous Depression	11	37.55	7.82	29.73	79.2	p=.000
Kielholz Psychog. (Etiol) Depr.	2	38.00	8.50	29.50	77.6	p=.054
Kielholz Psychog. Reactive Depr.	2	38.00	8.50	29.50	77.6	p=.054
Composite Reactive Depr. Disorder	2	38.00	8.50	29.50	77.6	p=.054
Composite Vital Depression	6	37.00	8.33	28.67	77.5	p=.001
Composite Vital Depressive State	1	38.00	6.00	32.00	84.2	N/A
Composite Vital Depr. State Pure	2	38.50	5.50	33.00	85.7	p=.077
Composite Vital Depr. State Pure Chronic Atypical	1	37.00	4.00	33.00	89.2	N/A
Composite Vital Depr. III. Pure	1	35.00	5.00	30.00	85.7	N/A
Composite Vital Depr. III. Chr.	1	35.00	27.00	8.00	22.9	N/A
Composite Endogenous Depression	14	36.64	12.71	23.93	65.3	p=.000
Composite Endog. Depressive State	1	39.00	9.00	30.00	23.1	N/A
Composite Endog. Depr. State Pure	5	38.00	10.00	28.00	73.7	p=.000
Composite End. Depr. St. Chr. Atyp.	1	32.00	6.00	26.00	81.13	N/A
Composite Endog. Depressive Illness	2	36.00	22.00	14.00	38.9	p=.596
Composite Endog. Depr. III. Pure	3	36.00	7.00	29.00	80.6	p=.006
Composite Endog. Depr. III. Chronic Atypical	1	41.00	9.00	32.00	78.03	N/A
Composite Endog. Depr. III. Pure Chronic Atypical	1	31.00	39.00	-8.00	25.83	N/A

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Table 39

Responsiveness to PBO in Diagnosis-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test).

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Kraepelin Depressive State	17	34.47	27.82	6.65	19.3	p=.072
Kraepelin Melancholia Simplex	17	34.47	27.82	6.65	19.3	p=.072
Schneider Reactive Depression	1	42.00	45.00	-3.00	-7.1	N/A
Schneider Vital Depression	21	35.00	30.52	4.48	12.8	p=.145
Leonhard Pure Melancholia	9	34.89	37.78	-2.89	-8.3	p=.257
Leonhard Pure Melancholia Def.	8	35.00	37.88	-2.88	-8.2	p=.319
Leonhard Pure Melancholia Prob.	1	34.00	37.00	-3.00	-8.8	N/A
Leonhard Pure Depression	1	33.00	41.00	-8.00	-24.2	N/A
Leonhard Non-participatory Pure Depression	1	33.00	41.00	-8.00	-24.2	N/A
Leonhard Mixed Depression	12	35.83	25.42	10.41	29.1	p=.028
Leonhard Mixed Depr. Complete	10	36.20	26.00	10.20	28.2	p=.071
Leonhard Mixed Depr. Incomplete	2	34.00	22.50	11.50	33.8	p=.083
Vienna Endogenomorphic-Depressive Axial Syndrome	15	35.60	30.80	4.80	13.5	p=.193
ICD-10 Depressive Episode	22	35.32	31.18	4.14	11.7	p=.159
ICD-10 Depressive Episode Severe	12	35.83	36.33	-0.50	-1.4	p=.869
ICD-10 Depr. Epis. Recurrent Severe	10	34.70	25.00	9.70	28.0	p=.070
Lewis Melancholia	22	35.32	31.18	4.14	11.7	p=.159
Lewis Melancholia Definite	20	35.65	31.80	3.85	10.8	p=.220
Lewis Melancholia Probable	2	32.00	25.00	7.00	21.9	p=.611
Hamilton Retarded Depression	17	35.53	29.65	5.88	16.5	p=.110
Hamilton Agitated Depression	5	34.60	36.40	-1.80	-5.2	p=.605
Kiloh Endogenous Depression	22	35.32	31.18	4.14	11.7	p=.159
Pilowsky Class B/Endog. Depr.	22	35.32	31.18	4.14	11.7	p=.159
Mendels Endogenous Depression	22	35.32	31.18	4.14	11.7	p=.159
Mendels Endog. Depr. Definite	16	35.88	30.75	5.13	14.3	p=.180
Mendels Endog. Depr. Probable	4	31.75	28.00	3.75	11.8	p=.568
Mendels Endog. Depr. Possible	2	38.00	41.00	-3.00	-7.9	p=.000
Foulds Neurotic Depression	20	35.50	30.40	5.10	14.4	p=.109
Foulds Psychotic Depression	1	33.00	40.00	-7.00	-21.2	N/A
Foulds Dysthymic Depression	1	34.00	38.00	-4.00	-11.8	N/A
Overall Type A/Anxious Depr.	6	35.33	32.33	3.00	8.5	p=.595
Overall Type B/Hostile Depr.	1	34.00	38.00	-4.00	-11.8	N/A
Overall Type C/Retarded Depr.	9	35.89	26.44	9.45	26.3	p=.107
Paykel Group 4A/Psychotic Depr.	22	35.32	31.18	4.14	11.7	p=.159

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Table 39 (continue)

Responsiveness to PBO in Diagnosis-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test).

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Raskin Type 2/Neurotic Depr.	1	30.00	13.00	17.00	56.7	N/A
Raskin Type 3/Endogenous Depr.	20	35.70	33.30	2.40	6.7	p=.404
CATEGO Class R/Retarded Depr.	22	35.32	31.18	4.14	11.7	p=.159
Robins Primary Affective (Depressive) Disorder	21	35.50	30.40	5.10	14.4	p=.109
St. Louis Definite Primary Depr.	22	35.32	31.18	4.14	11.7	p=.159
Winokur Pure Depression	7	35.00	33.57	1.43	4.1	p=.797
Winokur Sporadic Depression	11	35.72	31.18	4.54	12.7	p=.263
Winokur Depr. Spectrum Disease	4	34.75	27.00	7.75	22.3	p=.416
RDC Major Depr. Disorder Definite	20	35.50	30.45	5.05	14.2	p=.114
RDC, DMDD, Primary, Retarded, Incap., Definite Endogenous	4	34.25	26.75	7.50	21.9	p=.406
RDC, DMDD, Primary, Ret., Incap., Def. Endogen., Situational	4	37.50	41.75	-4.25	-11.3	p=.011
RDC, DMDD, Primary, Ret., Incap., Def. Endogen., Agitated	3	34.00	38.67	-4.67	-13.7	p=.184
RDC, DMDD, Prim., Incap., Definite Endog., Situat., Agitat.	1	41.00	46.00	-5.00	-12.2	N/A
RDC, DMDD, Rec., Prim., Incap., Definite Endogenous	8	35.00	21.63	13.37	38.2	p=.034
RDC Maj. Depr. Disorder Probable	1	34.00	37.00	-3.00	-8.8	N/A
RDC, PMDD, Rec., Prim., Incap., Definite Endogenous	1	34.00	37.00	-3.00	-8.8	N/A
DSM-III-R Major Depr. Episode	22	35.32	31.18	4.14	11.7	p=.159
DSM-III-R, MDE, Single Epis., Sev.	2	38.00	26.00	12.00	31.6	p=.570
DSM-III-R, MDE, Single Epis., Sev., Melancholic	10	35.40	38.40	-3.00	-8.5	p=.148
DSM-III-R, MDE, Recurrent, Sev.	1	30.00	13.00	17.00	56.7	N/A
DSM-III-R MDE, Recurrent, Sev. Melancholic.	5	36.00	21.60	14.40	40.00	p=.087
DSM-III-R MDE, Recurrent, Sev. Melancholic, Chronic	2	35.00	25.50	9.50	27.1	p=.667
DSM-III-R MDE, Recurrent, Moderate, Melancholic	1	34.00	37.00	-3.00	-8.8	N/A
DSM-III-R MDE, Recurrent, Sev. Moderate, Chronic	1	33.00	41.00	-8.00	-24.2	N/A

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Table 39 (continue)

Responsiveness to PBO in Diagnosis-Based Populations as Measured by Changes in the Total Scores of the HAMD from Day 0 to Day 42, with Level of Statistical Significance (t-test).

Population	N (100%)	Means		Change		Level of Significance
		Before	After	Actual	%	
Taylor Endogenous Depression	22	35.32	31.18	4.14	11.7	p=.159
Klein Endogenomorphic Depr.	18	35.67	30.78	4.89	13.7	p=.154
Klein Chr. Neurotic Dysphoria	1	33.00	41.00	-8.00	-24.2	N/A
Klein Acute Dysphoria	1	38.00	41.00	-3.00	-7.9	N/A
Pollitt Physiolo. Type S Depr.	22	35.32	31.18	4.17	11.7	p=.159
Kielholz Endog. (Etiol) Depr.	15	34.87	30.20	4.67	13.4	p=.214
Kielholz Endog. Periodic Depr.	8	35.50	28.75	6.75	19.0	p=.248
Kielholz Endogenous Depression	7	34.14	31.86	2.28	6.7	p=.658
Kielholz Psychog. (Etiol) Depr.	7	36.29	33.29	3.00	8.3	p=.562
Kielholz Psychog. Reactive Depr.	5	38.20	42.60	-4.40	-11.5	p=.002
Kielholz Psychog. Neurotic Depr.	2	31.50	10.00	21.50	68.3	p=.131
Composite Reactive Depr. Disorder	5	38.20	42.60	-4.40	-11.5	p=.002
Composite Depressive Illness	1	30.00	13.00	17.00	56.7	N/A
Composite Vital Depression	5	33.60	20.00	13.60	40.5	p=.100
Composite Vital Depressive State	2	36.00	16.00	20.00	55.6	p=.214
Composite Vital Depr. III. Pure	1	30.00	20.00	10.00	33.3	N/A
Composite Vital Depr. III. Chronic Atypical	1	33.00	7.00	23.00	21.2	N/A
Composite Vital Depr. III. Pure Chronic Atypical	1	33.00	41.00	-8.00	-24.2	N/A
Composite Endogenous Depression	10	35.50	32.00	3.50	9.9	p=.000
Composite Endog. Depressive State	4	34.00	38.50	-4.50	-13.2	p=.032
Composite Endog. Depr. State Pure	1	31.00	37.00	-6.00	-19.4	N/A
Composite Endog. Depressive Illness	3	36.67	24.67	12.00	32.7	p=.270
Composite Endog. Depr. III. Pure	1	41.00	11.00	30.00	73.2	N/A
Composite Endog. Depr. III. Pure Chronic Atypical	1	37.00	44.00	-7.00	-18.93	N/A

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Table 40

Level of Statistical Significance of the Change in HAMD Total Scores from Day 0 to Day 42 on the 93 Diagnosis-Based Populations with RBX-and PBO Separately. Populations With Statistically Significant ($p < .05$) Changes Only With RBX are Marked with an Asterisk (*) and Only with PBO are Marked with a plus (+).

Population	Reboxetine		Placebo		Comp.
	N	L.S.	N	L.S.	
Kraepelin in Depressive State*	20	p=.000	17	p=.072	R>P
Kraepelin in Melancholia Gravis	2	p=.303	0	N/A	R>P
Kraepelin in Melancholia Simplex*	18	p=.000	17	p=.072	R>P
Schneider in Reactive Depression	0	N/A	1	N/A	R=P
Schneider in Vital Depression*	22	p=.000	21	p=.145	R>P
Leonhard Pure Melancholia*	10	p=.000	9	p=.257	R>P
Leonhard Pure Melancholia Definite*	10	p=.000	8	p=.319	P>R
Leonhard Pure Melancholia Probable	0	N/A	1	N/A	R=P
Leonhard Pure Depression	2	p=.329	0	N/A	R>P
Leonhard Self-torturing Pure Depression	1	N/A	0	N/A	R=P
Leonhard Non-participatory Pure Depression	1	N/A	1	N/A	R=P
Leonhard Mixed Depression	9	p=.000	12	p=.028	R>P
Leonhard Mixed Depression Complete*	8	p=.001	10	p=.071	R>P
Leonhard Mixed Depression Incomplete	1	N/A	2	p=.083	P>R
Vienna Endogenomorphic Depr. Axial Syndrome*	16	p=.000	15	p=.193	R>P
ICD-10 Depressive Episode*	22	p=.000	22	.159	R>P
ICD-10 Depressive Episode Severe*	13	p=.000	12	p=.869	R>P
ICD-10 Depressive Episode Recurrent Severe*	9	p=.000	10	p=.070	R>P
Lewis Melancholia*	22	p=.000	22	p=.159	R>P
Lewis Melancholia Definite*	20	p=.000	20	p=.220	R>P
Lewis Melancholia Probable*	2	p=.011	2	p=.611	R>P
Hamilton Retarded Depression*	18	p=.000	17	p=.110	R>P
Hamilton Agitated Depression*	2	p=.036	5	p=.605	R>P
Kiloh Endogenous Depression*	22	p=.000	22	p=.159	R>P
Pilowsky Class A/ Neurotic Depression	1	N/A	0	N/A	R=P
Pilowsky Class B/ Endogenous Depression*	21	p=.000	22	p=.159	R>P
Mendels Endogenous Depression*	22	p=.000	22	p=.159	R>P
Mendels Endogenous Depression Definite*	19	p=.000	16	p=.180	R>P
Mendels Endogenous Depression Probable*	2	p=.036	4	p=.568	R>P
Mendels Endogenous Depression Possible	1	N/A	2	p=.000	P>R
Foulds Neurotic Depression*	22	p=.000	20	p=.109	R>P
Foulds Psychotic Depression	0	N/A	1	N/A	R=P
Foulds Dysthymic Depression	0	N/A	1	N/A	R=P
Overall Type A/Anxious Depression*	4	p=.000	6	p=.595	R>P

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Table 40 (continue)

Level of Statistical Significance of the Change in HAMD Total Scores from Day 0 to Day 42 on the 93 Diagnosis-Based Populations with RBX-and PBO Separately. Populations With Statistically Significant ($p < .05$) Changes Only With RBX are Marked with an Asterisk (*) and Only with PBO are Marked with a plus (+).

Population	Reboxetine		Placebo		Comp.
	N	L.S.	N	L.S.	
Overall Type B/Hostile Depression	1	N/A	1	N/A	R=P
Overall Type C/Retarded Depression*	13	p=.000	9	p=.107	R>P
Paykel Group 4A/Psychotic Depression*	22	p=.000	22	p=.159	R>P
Raskin Type 1/Agitated Depression	1	N/A	0	N/A	R=P
Raskin Type 2/Neurotic Depression	1	N/A	1	N/A	R=P
Raskin Type 3/Endogenous Depression	20	p=.000	20	p=.404	R>P
CATEGO Class R/Retarded Depression*	22	p=.000	22	p=.159	R>P
Robins Primary Affective Depressive Disorder*	21	p=.000	20	p=.109	R>P
St. Louis Definite Primary Depression*	22	p=.000	22	p=.159	R>P
Winokur Pure Depression*	14	p=.000	7	p=.797	R>P
Winokur Sporadic Depression*	4	p=.023	11	p=.263	R>P
Winokur Depressive Spectrum disease	4	p=.097	4	p=.416	R>P
RDC Definite Major Depressive Disorder*	22	p=.000	20	p=.114	R>P
RDC DMDD Prim.,Ret., Incap.,Def. Endogenous*	7	p=.000	4	p=.406	R>P
RDC DMDD Prim.,Ret., Incap.,Def. Endog.,Sit +	2	p=.054	4	p=.011	P>R
RDC DMDD Prim.,Ret., Incap.,Def. Endog.,Agit*	3	p=.032	3	p=.184	R>P
RDC DMDD Prim., Incap.,Def. Endog., Sit., Agit	0	N/A	1	N/A	R=P
RDC DMDD Prim., Ret., Incap. Prob. Endogenous	1	N/A	0	N/A	R=P
RDC DMDD Rec., Prim., Incap., Def. Endogenous	9	p=.008	8	p=.034	R>P
RDC Probable Major Depressive Disorder	0	N/A	1	N/A	R=P
RDC PMDD Rec., Prim., Incap., Def. Endog.	0	N/A	1	N/A	R=P
DSM-III-R Major Depressive Episode*	22	p=.000	22	p=.159	R>P
DSM-III-R MDE, Single Episode, Severe*	2	p=.035	2	p=.570	R>P
DSM-III-R MDE, Single Epis., Sev., Melancholic*	9	p=.000	10	p=.148	R>P
DSM-III-R MDE, Sing. Epis., Sev., Mel., Chronic	2	p=.075	0	N/A	R>P
DSM-III-R MDE, Recurrent, Severe	0	N/A	1	N/A	R=P
DSM-III-R MDE, Rec., Sev., Melancholic*	6	p=.010	5	p=.087	R>P
DSM-III-R MDE, Rec., Sev., Mel., Chronic	3	p=.456	2	p=.667	R>P
DSM-III-R MDE, Rec., Moderate, Melancholic	0	N/A	1	N/A	R=P
DSM-III-R MDE, Rec., Moderate, Chronic	0	N/A	1	N/A	R=P
Taylor Endogenous Depression*	22	p=.000	22	p=.159	R>P
Klein Endogenomorphic Depression*	18	p=.000	18	p=.154	R>P
Klein Chronic Neurotic Dysphoria	2	p=1.000	1	N/A	R>P

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Table 40 (continue)

Level of Statistical Significance of the Change in HAMD Total Scores from Day 0 to Day 42 on the 93 Diagnosis-Based Populations with RBX-and PBO Separately. Populations With Statistically Significant ($p < .05$) Changes Only With RBX are Marked with an Asterisk (*) and Only with PBO are Marked with a plus (+).

Population	Reboxetine		Placebo		Comp.
	N	L.S.	N	L.S.	
Klein Acute Dysphoria	0	N/A	1	N/A	R=P
Pollitt Physiological Type S Depression*	22	p=.000	22	p=.159	R>P
Kielholz Endogenous (Etiologic) Depression*	20	p=.000	15	p=.214	R>P
Kielholz Endogenous Periodic Depression*	9	p=.008	8	p=.248	R>P
Kielholz Endogenous Depression*	11	p=.000	7	p=.658	R>P
Kielholz Psychogenic (Etiologic) Depression	2	p=.054	7	p=.562	R>P
Kielholz Psychogenic Reactive Depression	2	p=.054	5	p=.002	P>R
Kielholz Psychogenic Neurotic Depression	0	N/A	2	p=.131	P>R
Composite Reactive Depressive Disorder	2	p=.054	5	p=.002	P>R
Composite Depressive Illness	0	N/A	1	N/A	R=P
Composite Vital Depression*	6	p=.001	5	p=.100	R>P
Composite Vital Depressive State	1	N/A	2	p=.214	P>R
Composite Vital Depressive State Pure	2	p=.077	1	N/A	R>P
Composite Vital Depr. St. Pure Chronic Atypical	1	N/A	0	N/A	R=P
Composite Vital Depressive Illness Pure	1	N/A	0	N/A	R=P
Composite Vital Depressive Illness Chronic	1	N/A	0	N/A	R=P
Composite Vital Depressive Illness Chr. Atyp.	0	N/A	1	N/A	R=P
Composite Vital Depressive Ill. Pure Chr. Atyp.	0	N/A	1	N/A	R=P
Composite Endogenous Depression*	14	p=.000	10	p=.452	R>P
Composite Endogenous Depressive State	1	N/A	4	p=.073	P>R
Composite Endogenous Depressive State Pure*	5	p=.000	1	N/A	R>P
Composite Endogenous Depressive St. Chr. Atyp.	1	N/A	0	N/A	R=P
Composite Endogenous Depressive Illness	2	p=.596	3	p=.270	P>R
Composite Endogenous Depressive Illness Pure*	3	p=.006	1	N/A	R>P
Composite Endogenous Depressive Ill. Chr. Atyp.	1	N/A	0	N/A	R=P
Composite Endogenous Depressive Ill. Pure Chr. Atyp.	1	N/A	1	N/A	R=P

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Differential Responsiveness to Treatment in Selected Diagnosis-Based Populations

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Differential responsiveness to RBX and PBO treatment was examined by employing analyses of covariance in 39 of the 93 diagnosis-based populations which included at least five patients in each treatment cell. As a result, as shown in Table 41, it was found that in 33 of the 39 diagnosis-based populations RBX treatment was statistically significantly superior to PBO treatment, whereas in six diagnosis-based populations it was equal; among the latter, in no case the sample size was greater than 10 per cell. In no diagnosis-based population was PBO superior to RBX treatment.

Table 41
Differential Responsiveness to Treatment in the Two Treatment Groups Based on Changed in Mean HAMD Total Scores From Day 0 to Day 42 (With Level of Statistical Significance).

Population	Reboxetine			Placebo			Level of Signif.	Group
	Day 0 Mean	Day 42 Mean	N	Day 0 Mean	Day 42 Mean	N		
Kraepelin Depressive State	36.86	11.27	20	35.32	31.18	17	p=.002	RBX
Kraepelin Melancholia simplex	37.00	10.83	18	34.47	27.82	17	p=.002	RBX
Schneider Vital Depression	36.86	11.27	22	35.00	30.52	21	p=.000	RBX
Leonhard Pure Melancholia	36.60	11.40	10	34.89	37.78	9	p=.000	RBX
Leonhard Pure Melancholia Definite	36.60	11.40	10	35.00	37.86	8	p=.000	RBX
Leonhard Mixed Depression	37.89	10.78	9	35.83	25.42	12	p=.029	RBX
Leonhard Mixed Depr. Complete	37.25	11.38	8	36.20	26.00	10	p=.058	---
Vienna Endog.-Depr. Axial syndrome	37.88	9.00	16	35.60	30.80	15	p=.000	RBX
ICD-10 Depressive Episode	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
ICD-10 Depressive Episode Severe	37.62	7.92	13	35.83	36.33	12	p=.000	RBX
ICD-10 Depr.Epis. Recurrent Severe	35.78	16.11	9	34.70	25.00	10	p=.273	---
Lewis Melancholia	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
Lewis Melancholia Definite	37.10	11.90	20	35.65	31.80	20	p=.000	RBX
Hamilton Retarded Depression	36.78	12.06	18	35.53	29.65	17	p=.001	RBX
Kiloh Endogenous Depression	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
Pilowsky Class B/Endogenous Depression	36.95	11.57	21	35.32	31.18	22	p=.000	RBX
Mendels Endogenous Depression	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
Mendels Endogenous Depression Definite	36.68	12.26	19	35.88	30.75	16	p=.000	RBX
Foulds Neurotic Depression	36.86	11.27	22	35.50	30.40	20	p=.000	RBX
Overall Type C/Retarded Depression	37.00	9.69	13	35.89	26.44	9	p=.004	RBX
Paykel Group 4A/Psychotic Depression	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
Raskin Type 3/Endogenous Depr.	36.95	11.90	20	35.70	33.20	20	p=.000	RBX
CATEGO Class R/Retarded Depression	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
Robin Primary Aff. Depr. Disorder	37.00	11.57	21	35.50	30.40	20	p=.000	RBX
St. Louis Definite Primary Depr.	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
Winokur Pure Depression	36.79	10.00	14	35.00	33.57	7	p=.000	RBX
RDC Major Depression Disorder Definite	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
RDC MDED, Rec., Prim., Incap. Def. End	35.78	16.11	9	35.00	21.63	8	p=.515	---
DSM-III-R major Depr. Episode	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
DSM-III-R Sing. Epis. Sev. Melanch.	38.78	8.56	9	35.40	38.40	10	p=.000	RBX
DSM-III-R Recurrent Sev. Melanch.	35.83	11.67	6	36.00	21.60	5	p=.214	---
Taylor Endogenous Depression	36.86	11.27	22	35.83	31.18	22	p=.000	RBX
Klein Endogenomorphic Depression	37.56	9.56	18	35.67	30.78	18	p=.000	RBX
Pollitt Physiological Type S Depr.	36.86	11.27	22	35.83	31.18	22	p=.000	RBX

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Inclusiveness of Classification

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Table 44
Rank Order of "Narrowness" of the 25 Classifications.

SYSTEM OF CLASSIFICATION	N	%
Vienna	13	29.5
Overall	10	22.7
Kraepelin	7	15.9
Klein	4	9.1
Robins	3	6.8
Hamilton	2	4.5
Leonhard	1	2.3
Raskin	1	2.3
RDC	1	2.3
Composite	1	2.3
Schneider	0	0.0
ICD-10	0	0.0
Lewis	0	0.0
Kiloh	0	0.0
Pilowsky	0	0.0
Mendels	0	0.0
Foulds	0	0.0
Paykel	0	0.0
CATEGO	0	0.0
St. Louis	0	0.0
Winokur	0	0.0
DSM-III-R	0	0.0
Taylor	0	0.0
Rollitt	0	0.0
Kielholz	0	0.0

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PART FOUR:
CORRESPONDENCE BETWEEN
SEVERITY SCORES

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Correspondence between the mean CODE-DD severity score, the mean total score of the 20-item ZUNG and the Severity of Illness (SI) component of the Clinical Global Impressions (GCI) at Day 0 was tested on the 44 patients in the total populations. As shown in Table 45, it was found that the correlation (.0532) between the CODE-DD severity score (mean: 32.75, s.d.: 2.878) and HAMD total score (mean: 36.09; s.d.: 3.340) at pretreatment was $p=.732$; the correlation (.0615) between the CODE-DD severity score and ZUNG total score (mean: 67.36; s.d.: 3.417) at pretreatment was $p=.692$; and the correlation (.0969) between the CODE-DD severity score and CGI-SI (mean: 5.59; s.d.: .542) at pretreatment was $p=.532$. It was noted that none of these correlations reached the acceptable level of statistical significance ($p < .05$).

Correspondence between the mean total scores of HAMD and ZUNG and mean severity scores of the CGI at pre-treatment was also tested. As shown in Table 46, there were significant ($p=.005$ and $p=.023$) correlations between mean total scores of the HAMD and ZUNG and between total score of the HAMD and CGI-SI. The correlation between the ZUNG and the CGI-SI did not reach the acceptable level of statistical significance ($p < .05$).

Table 45

Correspondence Between Mean CODE-DD Severity Score and Mean HAMD Total Score, Mean ZUNG Total Score and Mean CGI-SI in the Total Population at Day 0

Variable	N	Mean	Std. Dev.	Corr.	Level of Significance
CODE-DD Severity Score	44	32.750	2.8783	-	--
HAMD Total Score	44	36.090	3.3398	.0532	$p=.732$
ZUNG Total Score	44	67.360	3.4174	.0615	$p=.692$
CGI-SI	44	5.591	.5421	.0969	$p=.532$

Table 46

Correspondence Between Mean HAMD Total Scores and Mean ZUNG Total Scores; Between Mean HAMD Total Scores and mean CGI-SI; and Between Mean ZUNG Total Scores and Mean CGI-SI in the Total Population at Day 0

Instruments	Correlation	Level of Significance
HAMD and ZUNG	.4127	$P=.005$
HAMD and CGI-SI	.3421	$p=.023$
ZUNG and CGI-SI	.1700	$p=.270$

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PART FIVE:

ROW DATA LISTINGS

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CODE-DD VARIABLES I

Listing	Variable	(1=Absent 2=Present)
1	Acute Onset	
2	Subacute Onset	
3	Prolonged Duration	
4	First Episode	
5	Seasonal Pattern	
6	Responsiveness to Somatic Treatment in Past	
7	Full Recovery in Past	
8	Continuous Presence in Past	
9	Manic/Hypomanic Episode in Past	
10	Precipitating Factor	
11	Temporal Connection with Precipitating Factor	
12	Medical Non-Psychiatric Illness	
13	Temporal Connection with Medical Non-Psychiatric Illness	
14	Medical Psychiatric Illness	
15	Temporal Connection with Medical Psychiatric Illness	
16	Treatment with Mood Depressant Medications	
17	Temporal Connection with treatment with Mood Depressant Medications	
18	Early Onset	
19	Anxiety	
20	Phobias	
21	Anxious Mood	
22	Depressed Mood	
23	Unmotivated Depressed Mood	

LISTING NUMBERS:

Pat. No.	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	0	1	2	3	
81	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	
82	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	2	2
83	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	2	2	
84	1	2	1	1	1	2	2	1	1	1	1	1	1	1	1	1	1	1	2	2	2	2	2	
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94	2	1	1	2	1	1	1	1	1	2	2	1	1	1	1	1	1	1	2	2	2	2	1	
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CODE-DD VARIABLES II

Listing Number	Variable	(1 = Absent 2 = Present)
24	Displeasure	
25	Dysphoria	
26	Unmotivated Dysphoria	
27	Constricted Affect	
28	Anhedonia	
29	Lack of Interest	
30	Apathetic Indifference	
31	Feeling of Loss of Feeling	
32	Reactive Mood Changes	
33	Depressive Evaluations	
34	Hopelessness	
35	Loss of Desire to Live	
36	Suicidal Tendencies	
37	Felt Loss of Vitality	
38	Asthenia	
39	Disturbance of Vital Balance	
40	Worse in the Morning	
41	Diurnal Variation	
42	Lack of Drive	
43	Disturbance of Concentration	
44	Indecisiveness	
45	Abulia	
46	Feeling of Inadequacy	

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LISTING NUMBERS:

Pat. No.	2	2	2	2	2	2	3	3	3	3	3	3	3	3	3	3	4	4	4	4	4	4	4	4
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Number of cases read = 44

Number of cases listed = 44

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CODE-DD VARIABLES III

Listing Number	Variable	(1=Absent 2=Present)
47	Irritability	
48	Hostility	
49	Feeling of Guilt	
50	Self-Incrimination	
51	Feeling of Impoverishment	
52	Hypochondriasis	
53	Vegetative manifestations	
54	Bodily Misperceptions	
55	Corporeization	
56	Decreased Appetite	
57	Excessive Appetite	
58	Decreased Sex Drive	
59	Early Insomnia	
60	Middle Insomnia	
61	Late Insomnia	
62	Hypersomnia	
63	Rumination	
64	Obsessive Thoughts	
65	Constricted thinking	
66	Derealization	
67	Depersonalisation	
68	Hallucinations	
69	Suspiciousness	

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CODE-DD VARIABLES IV

Listing Number	Variable	(1 = Absent 2 = Present)
70	Ideas of Reference	
71	Delusions	
72	Thought Broadcasting	
73	Thought Withdrawal	
74	Thought Insertion	
75	Other Feelings of Alien Influence	
76	Inhibited Thinking	
77	Time Still	
78	Impairment of Social Adaptation	
79	Impairment of Social Adaptation in Past	
80	Excessive Alcohol Consumption	
81	Genetically Pure	
82	Genetically on Spectrum	
83	Retarded Thinking	
84	Complaintiveness	
85	Driven Complaintiveness	
86	Motor Retardation	
87	Motor Restlessness	
88	Histrionics	
89	Negativism	
90	Parakinesis	
91	Parathymia	
92	Incoherence	
93	Tangential Thinking	
94	Mood Congruent Psychotic Symptoms	

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LISTING NUMBERS:

Pat. No.	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4	8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3	9 4
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99	1	1	1	1	1	1	1	1	1	1	2	1	1	2	1	2	2	1	2	1	1	1	1	1	1
100	1	1	1	1	1	1	1	1	1	1	2	1	1	2	1	2	2	2	1	1	1	1	1	1	1
121	1	1	1	1	1	1	1	1	1	2	2	1	1	1	1	1	1	1	2	1	1	1	1	1	1
122	1	1	1	1	1	1	1	1	1	2	2	1	1	2	1	2	2	2	2	1	1	1	1	1	1
123	1	1	1	1	1	1	1	1	1	1	2	2	1	1	2	2	1	1	2	1	1	1	1	1	1
124	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	2	1	1	2	1	1	1	1	1	1
125	1	1	1	1	1	1	1	1	1	1	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1
126	1	1	1	1	1	1	1	1	1	1	2	2	1	1	1	1	2	1	2	1	1	1	1	1	1
127	2	1	1	1	1	1	1	1	1	2	2	1	1	1	1	1	2	1	2	1	1	1	1	1	1
128	1	1	1	1	1	1	1	1	1	2	2	1	1	2	1	2	2	2	2	1	1	1	1	1	1
129	1	1	1	1	1	1	1	1	1	2	2	1	1	1	1	2	2	1	1	2	1	1	1	1	1
130	1	1	1	1	1	1	1	1	1	2	2	2	1	2	1	1	2	1	2	1	1	1	1	1	1
131	1	1	1	1	1	1	1	1	1	2	2	1	1	1	2	2	2	1	2	1	1	1	1	1	1
133	1	1	1	1	1	1	1	1	1	2	2	1	1	1	1	2	1	1	1	2	1	1	1	1	1
141	1	1	1	1	1	1	1	1	1	2	2	2	1	2	1	1	2	2	1	1	2	1	1	1	1
142	1	1	1	1	1	1	1	1	1	2	2	2	1	2	1	2	2	2	2	1	1	1	1	1	1
143	1	1	1	1	1	1	1	1	1	2	2	1	1	2	2	2	2	2	1	1	1	1	1	1	1
144	1	1	1	1	1	1	1	1	1	2	2	1	1	1	1	2	1	1	2	1	1	1	1	1	1
145	2	1	1	1	1	1	1	1	1	2	2	1	1	2	1	2	2	2	2	1	2	1	1	1	1
146	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	2	1	1	2	1	2	1	1	1	1
147	1	1	1	1	1	1	1	1	1	2	2	1	1	2	1	2	2	2	2	1	1	1	1	1	1
148	1	1	1	1	1	1	1	1	1	2	2	1	1	1	2	2	1	1	2	1	1	1	1	1	1
149	1	1	1	1	1	1	1	1	1	2	2	1	1	2	1	2	2	1	2	1	1	1	1	1	1
150	1	1	1	1	1	1	1	1	1	2	2	2	1	1	2	1	2	2	1	2	1	1	1	1	1
151	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	2	2	2	2	1	1	1	1	1	1
153	1	1	1	1	1	1	1	1	1	2	2	1	1	2	1	2	2	2	1	2	1	1	1	1	1

Number of cases read = 44
 Number of cases listed = 44

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124 CTN: 20124/ADE 091

CODE-DD DEMOGRAPHIC VARIABLES I

Listing Number	Variable
1	Treatment Group 1=RBX 2=PBO
2	Marital Status 1=Married/Common Law 2= Divorced/Separated 3=Widow(er) 4=Single
3	First marriage? 0=Yes 1=No
4	Times Married
5	Highest Grade Completed 1=Completed H.S. 2=Completed College
6	Presently Working? 0=Yes 1=No
7	Current Employment . =None
8	Length of Previous Employment-Years
9	Length of Previous Employment-Months
10	Length of Time Unemployment-Years
11	Length of Time Unemployment-Months
12	Previous Occupation 1=Fireman 2=Skill Worker 3=Professional 4=Housewife 5=Secretary 6=Student
13	Prior Hospitalisation? 0=Yes 1=No
14	Number of Time Hospitalised
15	Age at First Hospitalisation
16	Prior doctor's visit? 0=Yes 1=No
17	Age at First doctor's Visit

LISTING ITEMS:

Pat. No.	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7
81	1	1	0	1	1	1	.	6	.	.	2	2	1	.	.	0	34
82	2	1	0	1	2	1	.	2	.	.	2	3	1	.	.	0	33
83	2	4	.	.	1	1	1	6	1	.	.	1	.
84	1	4	.	.	1	1	.	6	.	.	1	3	1	.	.	0	27
85	2	2	1	2	2	1	.	20	.	.	1	3	1	.	.	0	40
86	1	1	0	1	2	1	.	8	.	.	3	3	1	.	.	0	38
87	2	1	0	1	1	1	.	4	.	.	3	3	1	.	.	0	27
88	2	1	0	1	2	1	.	6	.	.	2	3	1	.	.	0	32
89	1	1	1	2	2	1	.	15	.	.	3	3	1	.	.	1	.
90	1	4	.	.	1	1	6	1	.	.	0	24
91	1	4	.	.	2	1	1	5	1	.	.	1	.
92	1	1	0	.	1	1	3	3	1	.	.	0	30
93	2	1	0	.	1	1	.	.	.	1	.	3	0	2	40	0	40
94	2	4	.	.	1	1	6	3	1	.	.	1	.
95	1	1	1	2	2	1	1	3	1	.	.	1	.
96	2	3	.	1	1	1	.	.	.	5	.	3	1	.	.	0	42

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124 CTN: 20124/ADE 091

CODE-DD DEMOGRAPHIC VARIABLES II

Listing Number	Variable		
1	Current Age		
2	Presently Being Treated for Depression	0=Yes	1=NO
3	Presently Being Treated with Medication	0=Yes	1=NO
4	Present Medication is Antidepressant	0=Yes	1=No
5	Treated in the Past with Medication	0=Yes	1=No
6	Treated in the Past with ECT	0=Yes	1=No
7	Surgical Intervention	0=Yes	1=No
8	Hysterectomy/Tubal Ligation	0=Yes	1=No
9	Patient's Sex	0=Female	1=Male
10	Childbearing Potential	0=Yes	1=No
11	Patient's Status	1=Inpatient	2=Outpatient
12	Omega Sign Present	0=Yes	1=No
13	Veraguth's Folds Present	0=Yes	1=No
14	Patient is Tearful	0=Yes	1=No

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124 CTN: 20124/ADE 091

LISTING ITEMS:

Pat. No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14
81	34	0	0	1	1	1	0	1	1	1	1	1	1	0
82	33	0	0	1	1	1	1	1	1	1	1	1	1	1
83	20	0	0	1	1	1	0	1	1	1	1	0	1	0
84	33	0	0	1	0	1	0	0	1	1	1	0	0	1
85	47	0	0	1	0	1	0	1	1	1	1	1	1	0
86	38	0	0	1	1	1	1	1	1	1	1	1	0	1
87	27	0	0	1	1	1	.	1	1	1	1	1	1	1
88	37	0	0	1	0	1	1	1	1	1	1	1	1	1
89	49	0	0	1	1	1	1	1	1	1	1	1	1	1
90	24	0	0	1	1	1	0	1	1	1	1	1	1	1
91	37	0	0	1	1	1	0	1	0	1	1	1	1	1
92	43	0	0	1	0	1	0	0	0	1	1	1	0	1
93	51	0	0	1	0	1	0	1	0	1	1	1	1	1
94	29	0	0	1	1	1	1	1	0	0	1	1	1	1
95	48	0	0	1	1	1	0	1	0	1	1	0	1	1
96	55	0	0	1	0	1	0	0	0	1	1	1	1	1
97	30	0	0	1	1	1	1	1	0	0	1	1	1	1
98	26	0	0	1	1	1	1	1	0	0	1	1	1	0
99	18	0	0	1	1	1	1	1	0	0	1	1	1	1
100	34	0	0	1	0	1	0	1	0	0	1	1	1	0

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124

CTN: 20124/ADE 091

CODE-DD DIAGNOSTIC VARIABLES

Listing Letters	Variable
A Kraepelin	1=Psychiatric Disorder 5=Melancholia Gravis 6=Melancholia Simplex
B Schneider	2=Reactive Depression 3=Vital Depression
C Leonhard	1=Psychiatric Disorder 3=Definite Pure Melancholia 4=Probable Pure Melancholia 8= Self-torturing (Pure) Depression 9=Non-participatory (Pure) Depression 10=Mixed (Complete) Depression 10=Mixed (Incomplete) Depression
D Vienna	1=Psychiatric Disorder 3=Endogenomorphic-Depressive Axial Syndrome
E ICD-10	1=Psychiatric Disorder 3=Severe Depressive Episode 4=Recurrent Severe Depressive Episode
F Lewis	4=Probable Melancholia 5=Definite Melancholia
G Hamilton	2=Retarded Depression 3= Psychiatric Disorder 4=Agitated Depression
H Kiloh	2=Endogenous Depression
I Pilosky	2=Class B/ Endogenous Depression
J Mendels	3=Possible Endogenous Depression 4=Probable Endogenous Depression 5=Definite Endogenous Depression
K Foulds	3=Psychotic Depression 4=Neurotic Depression 5=Dysthymic Depression
L Overall	2=Psychiatric Disorder 3=Type B/Hostile Depression 4=Type C/Retarded Depression 5=Type A/Anxious Depression
M Paykel	3=Group 4A/Psychotic Depression
N Raskin	2=Type 3/Endogenous Depression 3=Type 2/Neurotic Depression 5=Psychiatric Disorder 6=Type 1/Agitated Depression
O CATEGO	4=Class R/Retarded Depression
P Robins	2=Psychiatric Disorder 4=Primary Affective (Depressive) Disorder
Q St. Louis	4=Definite Primary Depression
R Winokur	4=Pure Depression 5=Depressive Spectrum Disease 6=Sporadic Depression

Pharmacia CNS

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124

CTN: 20124/ADE 091

LISTING LETTERS:

Pat. No.	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
81	5	3	3	3	4	5	2	2	2	5	4	4	3	2	4	4	4	4
82	6	3	3	3	3	5	4	2	2	5	4	5	3	2	4	4	4	5
83	6	3	11	3	3	5	2	2	2	5	4	4	3	2	4	4	4	6
84	6	3	10	3	4	5	2	2	2	5	4	4	3	2	4	4	4	4
85	6	3	10	1	4	5	2	2	2	5	3	4	3	2	4	4	4	6
86	1	3	3	3	3	5	2	2	2	5	4	4	3	2	4	4	4	4
87	1	3	10	1	3	5	4	2	2	5	4	5	3	2	4	4	4	6
88	6	3	3	3	4	5	2	2	2	5	4	4	3	2	4	4	4	6
89	6	3	10	3	3	5	2	2	2	5	4	5	3	2	4	4	4	4
90	1	3	10	3	3	5	2	2	2	5	4	4	3	2	4	4	4	6
91	6	3	11	3	3	5	4	2	2	4	4	5	3	2	4	4	4	4
92	6	3	3	3	4	5	2	2	2	5	4	4	3	2	4	4	4	5
93	6	3	10	3	4	5	2	2	2	5	4	4	3	2	4	4	4	6
94	1	2	10	3	3	5	2	2	2	3	4	2	3	2	4	4	4	5
95	6	3	10	1	3	5	4	2	2	4	4	2	3	2	4	4	4	4
96	6	3	10	3	4	5	2	2	2	5	4	4	3	2	4	4	4	4
97	6	3	9	1	3	4	3	2	2	3	4	2	3	6	4	2	4	4
98	6	3	3	3	3	5	2	2	2	5	4	4	3	2	4	4	4	4
99	1	3	10	1	3	5	2	2	2	5	4	5	3	2	4	4	4	4
100	6	3	3	3	4	5	2	2	2	5	4	2	3	2	4	4	4	4
121	5	3	8	3	4	5	2	2	2	5	4	2	3	2	4	4	4	6
122	6	3	3	3	3	5	2	2	2	5	4	4	3	2	4	4	4	4
123	6	3	10	1	4	4	2	2	2	4	4	2	3	3	4	4	4	5
124	6	3	4	3	4	4	2	2	2	3	4	2	3	2	4	2	4	6
125	6	3	1	3	4	4	2	2	3	5	4	5	3	2	4	4	4	4
126	6	3	10	1	3	5	2	2	2	5	4	4	3	2	4	4	4	6
127	6	3	10	3	3	5	2	2	2	5	4	4	3	2	4	4	4	6
128	6	3	3	3	4	5	2	2	2	5	4	4	3	2	4	4	4	4
129	6	3	3	3	3	5	4	2	2	5	4	5	3	2	4	4	4	6
130	6	3	9	3	4	5	2	2	2	4	4	2	3	2	4	2	4	4
131	6	3	3	1	4	5	2	2	2	5	4	4	3	2	4	4	4	5
133	6	3	3	1	3	5	4	2	2	5	4	2	3	2	4	4	4	6
141	6	3	11	3	4	5	4	2	2	4	4	5	3	2	4	4	4	4
142	1	3	3	1	3	5	2	2	2	5	4	4	3	2	4	4	4	4
143	6	3	3	3	3	5	2	2	2	5	4	5	3	2	4	4	4	5
144	6	3	10	3	4	5	2	2	2	5	4	4	3	3	4	4	4	6
145	6	3	10	1	3	5	2	2	2	5	4	4	3	2	4	4	4	4
146	6	3	10	3	3	5	2	2	2	4	5	3	3	2	4	4	4	6
147	6	3	3	3	3	5	2	2	2	5	4	4	3	2	4	4	4	4
148	6	3	3	1	3	5	2	2	2	5	4	4	3	2	4	4	4	5
149	6	3	10	1	4	5	2	2	2	5	4	3	3	2	4	4	4	4
150	6	3	10	3	4	5	2	2	2	5	4	5	3	5	4	4	4	5
151	1	3	3	3	3	5	2	2	2	5	4	4	3	2	4	4	4	6
153	6	3	3	3	3	5	3	2	2	5	4	2	3	2	4	4	4	4

Number of Cases Read = 44

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124 CTN: 20124/ADE 091

Number of Cases Listed = 44

CODE-DD DIAGNOSTIC VARIABLES

Listing Letters	Variable
S	RDC 1=Psychiatric Disorder 3=Probable Major Depressive Disorder 4=Definite Major Depressive Disorder
a	Situational
b	Secondary
c	Primary
d	Recurrent
e	Psychotic
f	Agitated
g	Retarded
h	Incapacitating
i	Probable Endogenous
j	Definite Endogenous
K	Simple
l	With Significant anxiety
T	DSM-III-R 1=Psychiatric Disorder 3&5= major Depression DSM-III-R Subtypes 0= Absent 1= Present
a	Single episode
b	Recurrent Seasonal Pattern
c	Recurrent
d	Mild
e	Moderate
f	Severe
g	With Mood Congruent Psychotic Symptoms
h	With Mood Incongruent Psychotic Symptoms
i	Melancholic
j	Chronic
k	Double Depression

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124 CTN: 20124/ADE 091

CODE-DD DIAGNOSTIC VARIABLES (cont.)

Listing Letters	Variable
U	Taylor 5=Endogenous Depression
V	Klein 2=Psychiatric Disorder 3=Endogenomorphic Depression 4= Acute Dysphoria 5=Chronic Neurotic Dysphoria
W	Pollitt 2=Physiological Type S Depression
X	Kielholz 3=Psychogenic Reactive Depression 4= Psychogenic Neurotic Depression 6=Endogenous Periodic Depression 7=Endogenous Depression
Y	Composite 1=Psychiatric Disorder 5=Reactive Depressive Disorder 9=Vital Depressive State 12=Vital Depressive State Pure 30= Vital Depressive State Pure Chronic Atypical 31=Depressive Illness 34=Vital Depressive Illness Pure 39=Vital Depressive Illness Chronic 51=Vital Depressive Illness Chronic Atypical 54=Vital Depressive Illness Pure Chronic Atypical 55=Endogenous Depressive State 56=Endogenous Depressive State Pure 61=Endogenous Depressive State Chronic Atypical 63=Endogenous Depressive Illness 64=Endogenous Depressive Illness Pure 69=Endogenous Depressive Illness Chronic Atypical 70= Endogenous Depressive Illness Pure Chronic Atypical

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124

CTN: 20124/ADE 091

LISTING LETTERS:

Pat. No.	U	V	W	X	Y
81	5	3	2	6	64
82	5	3	2	7	55
83	5	3	2	7	9
84	5	3	2	6	64
85	5	3	2	6	1
86	5	3	2	3	5
87	5	3	2	3	5
88	5	3	2	6	63
89	5	3	2	7	56
90	5	3	2	3	5
91	5	3	2	7	12
92	5	3	2	6	69
93	5	3	2	6	63
94	5	3	2	3	5
95	5	3	2	7	30
96	5	3	2	6	64
97	5	2	2	7	12
98	5	3	2	7	56
99	5	4	2	3	5
100	5	3	2	6	70
121	5	5	2	6	39
122	5	3	2	7	56
123	5	2	2	4	31
124	5	2	2	6	63
125	5	2	2	6	36
126	5	3	2	7	9
127	5	3	2	7	9
128	5	3	2	6	64
129	5	3	2	7	55
130	5	5	2	6	54
131	5	3	2	6	63
133	5	3	2	7	55
141	5	3	2	6	36
142	5	3	2	3	5
143	5	3	2	7	55
144	5	3	2	6	63
145	5	3	2	7	56
146	5	3	2	7	55
147	5	3	2	7	56
148	5	3	2	7	61
149	5	5	2	6	70
150	5	3	2	4	51
151	5	3	2	3	5
153	5	3	2	7	56

Number of cases read= 44

Number of cases listed= 44

Pharmacia CNS

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124

CTN: 20124/ADE 091

HAMD Variables

Legend to HAMD		
Patient	Number	
ITEMS		
		(Score Range)
1	Depressed Mood	0-4
2	Feelings of guilt	0-4
3	Suicide	0-4
4	Early Insomnia	0-2
5	Middle Insomnia	0-2
6	Late Insomnia	0-2
7	Work and Activities	0-4
8	Retardation	0-4
9	Agitation	0-4
10	Psychic Anxiety	0-4
11	Somatic Anxiety	0-4
12	Somatic Symptoms - Gastrointestinal	0-2
13	Somatic Symptoms - General	0-2
14	Genital Symptoms	0-2
15	Hypochondriasis	0-4
16	Loss of Weight	0-3
17	Insight	0-2
18a	Diurnal Variation - time	0-2
18a	Diurnal Variations - severity	0-2
19	Depersonalisation and Derealization	0-4
20	Paranoid Symptoms	0-3
21	Obsessional and Compulsive Symptoms	0-2
	Total Score	0-64

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REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124

CTN: 20124/ADE 091

Baseline

Pat. No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18 _a	18 _a	19	20	21	Total Score
81	3	2	1	2	1	2	3	2	0	3	3	2	2	0	2	3	3	1	2	2	0	1	34.00
82	3	2	1	1	2	2	3	0	2	3	2	2	2	1	1	1	1	1	2	2	0	0	34.00
83	4	1	2	1	1	2	4	3	0	3	3	2	2	2	3	1	0	1	1	2	0	0	38.00
84	3	1	0	2	2	2	1	3	0	3	3	2	2	2	2	0	0	1	2	2	0	1	37.00
85	4	0	2	1	1	2	3	3	0	3	2	2	2	0	2	0	1	0	0	3	1	1	33.00
86	4	2	1	1	2	2	4	3	0	3	2	2	2	2	3	1	1	0	0	2	0	0	37.00
87	4	2	2	1	2	2	4	0	3	4	3	2	2	2	2	0	1	0	0	3	1	1	41.00
88	4	2	2	1	2	2	4	3	0	3	2	2	2	2	3	0	1	1	2	2	0	0	40.00
89	4	2	2	1	1	2	4	2	0	3	2	2	2	2	2	1	1	1	2	3	1	1	41.00
90	4	2	1	2	1	2	3	3	0	3	3	2	2	2	3	0	0	1	2	2	0	1	39.00
91	3	0	2	2	2	2	4	0	3	4	3	2	2	2	2	1	1	1	2	3	1	1	43.00
92	4	2	3	2	1	2	4	3	0	3	3	2	2	2	2	0	1	1	1	3	0	0	41.00
93	4	0	1	2	2	2	3	3	0	3	3	2	2	2	2	0	1	1	2	1	0	0	36.00
94	4	2	1	2	1	2	4	3	0	3	3	2	2	2	1	2	1	2	1	2	0	2	42.00
95	4	0	2	2	2	2	3	0	3	3	2	2	2	2	0	2	0	0	3	0	0	0	37.00
96	4	2	2	2	1	2	3	3	0	4	3	2	2	2	3	0	2	1	2	1	0	0	41.00
97	4	0	0	0	1	0	4	3	0	4	4	2	2	2	1	2	2	0	0	3	0	0	34.00
98	4	2	2	2	2	2	4	3	0	3	3	2	2	2	1	1	2	1	2	1	0	0	41.00
99	3	2	2	2	2	1	3	3	0	3	3	2	2	2	3	0	2	0	0	3	0	0	38.00
100	4	2	1	2	1	2	3	2	0	3	3	2	2	2	1	0	2	1	2	0	0	2	37.00
121	4	2	0	2	2	1	4	3	0	3	3	0	2	1	1	1	1	1	2	2	0	0	35.00
122	3	0	2	2	1	2	4	3	0	3	2	0	2	2	1	2	2	1	2	2	0	0	36.00
123	3	0	1	2	1	2	4	3	0	3	2	2	2	2	0	1	2	0	0	0	0	0	30.00
124	4	0	1	2	1	2	4	3	0	2	3	2	2	2	0	2	0	1	2	1	0	0	34.00
125	3	0	2	1	2	2	4	2	0	3	2	2	2	1	3	0	2	1	2	1	0	0	35.00
126	3	2	0	2	1	2	4	3	0	2	1	2	2	1	3	2	2	0	0	2	0	0	34.00
127	4	2	0	2	2	2	4	2	0	3	2	2	2	1	2	0	2	1	2	2	1	0	38.00
128	3	2	0	2	1	2	4	2	0	3	3	2	2	2	3	0	1	1	2	0	0	2	37.00
129	3	0	2	2	2	2	4	0	3	3	2	2	2	1	2	0	2	1	2	1	0	0	36.00
130	4	2	0	2	1	2	4	2	0	2	2	2	2	1	0	1	2	1	1	2	0	0	33.00
131	3	2	2	1	2	2	3	2	0	3	2	2	2	2	2	0	1	0	0	3	0	0	34.00
133	4	0	2	2	1	2	4	0	3	3	3	2	2	1	0	0	0	0	0	2	0	1	32.00
141	3	2	1	2	1	1	4	2	0	2	2	0	2	2	2	0	0	1	1	2	0	0	30.00
142	3	1	1	2	2	2	4	0	3	2	3	2	2	2	2	0	1	1	1	1	0	0	35.00
143	4	2	3	1	2	2	4	2	0	3	3	2	2	1	2	0	2	1	2	1	0	0	39.00
144	4	2	2	2	1	1	4	3	0	2	2	2	2	2	2	0	0	2	1	2	0	2	38.00
145	3	2	0	2	1	2	4	3	0	2	2	1	2	2	3	1	2	0	0	3	2	0	37.00
146	3	0	0	2	2	2	4	3	0	2	3	2	2	2	0	0	1	1	2	2	1	0	34.00
147	3	1	1	1	2	2	3	3	0	2	2	2	2	1	0	1	1	1	1	2	0	0	31.00
148	4	2	2	0	1	2	4	3	0	2	2	1	2	1	1	0	1	0	0	2	0	2	32.00
149	3	2	0	1	2	1	4	2	0	3	2	0	2	2	2	0	2	0	0	2	1	0	31.00
150	3	2	1	2	1	2	3	1	0	2	2	2	2	1	2	0	1	1	2	2	0	1	33.00
151	3	0	2	1	1	2	4	3	0	3	3	2	2	2	0	0	0	2	2	2	0	1	35.00
153	3	2	3	1	1	2	4	0	3	2	2	2	2	1	0	0	2	1	2	2	0	0	35.00

Number of cases read = 44

Number of cases listed = 44

Pharmacia CNS

CTN:20124/ADE 091 FINAL STUDY REPORT, ADDENDUM of January 30, 1995

FCE 20124/706 i A1

REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124 CTN: 20124/ADE 091

Final

Pat. No.																						Total Score	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18 _a	18 _a	19	20		21
81	0	0	0	1	1	0	0	0	0	1	1	1	2	0	1	0	0	0	0	0	0	1	9.00
82	4	2	2	2	2	2	4	0	4	3	3	2	2	2	2	1	0	1	2	3	0	0	43.00
83	2	1	1	1	1	2	2	1	0	2	2	1	2	1	2	0	0	1	1	2	0	0	25.00
84	0	0	0	1	1	0	0	0	0	1	1	0	2	0	1	0	0	0	0	0	0	1	8.00
85	4	1	2	2	2	2	4	3	0	3	3	2	2	2	3	0	0	0	0	3	1	1	40.00
86	1	0	0	1	0	0	1	0	0	2	1	0	2	0	1	0	0	0	0	1	0	0	10.00
87	4	2	2	2	2	2	4	0	3	4	3	2	2	2	3	0	1	1	1	3	1	1	46.00
88	2	1	0	1	1	2	2	2	0	2	2	2	2	1	2	0	0	1	1	1	0	0	25.00
89	1	0	1	0	0	0	0	0	2	1	1	2	0	1	0	0	0	0	0	0	1	1	11.00
90	0	0	0	1	1	1	0	0	0	1	1	0	0	0	1	0	0	0	0	0	0	1	7.00
91	0	0	0	1	0	0	0	0	1	1	1	0	1	0	0	0	0	0	0	0	0	1	6.00
92	0	0	0	1	1	1	0	0	0	1	1	1	2	1	0	0	0	0	0	0	0	0	9.00
93	0	0	0	1	1	1	0	0	2	2	1	2	1	1	0	0	0	0	0	0	0	0	12.00
94	4	2	2	2	2	2	4	3	0	4	3	2	2	2	2	0	2	2	3	0	2	2	45.00
95	0	0	0	0	0	1	1	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	4.00
96	1	0	0	1	0	1	1	0	0	1	1	1	1	1	1	0	0	0	0	1	0	0	11.00
97	0	0	0	0	0	0	0	0	0	1	1	1	0	1	1	0	0	0	0	0	0	0	5.00
98	0	0	0	1	0	1	0	0	0	1	1	0	2	0	0	0	0	0	0	0	0	0	6.0
99	4	2	2	2	2	2	4	3	0	4	3	2	2	2	3	0	1	0	0	3	0	0	41.00
100	4	2	2	2	2	2	3	3	0	4	3	2	2	2	2	1	1	1	2	2	0	2	44.00
121	3	1	0	1	1	3	2	0	2	2	2	2	1	1	1	1	1	1	1	1	0	0	27.00
122	0	0	0	1	1	0	1	0	0	1	1	0	0	0	1	0	0	0	0	0	0	0	6.00
123	2	0	0	1	0	1	2	1	0	1	1	2	0	1	1	0	0	0	0	0	0	0	13.00
124	4	0	2	2	2	2	4	3	0	3	3	2	2	2	1	0	1	1	2	1	0	0	37.00
125	0	0	0	1	0	0	1	0	0	1	1	0	0	0	1	0	0	0	0	0	0	0	5.00
126	0	0	0	1	0	1	1	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0	7.00
127	0	0	0	1	0	0	1	0	0	1	1	0	0	0	1	0	0	0	0	0	1	0	6.00
128	0	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	4.00
129	3	0	2	2	2	2	4	0	2	3	2	2	2	2	2	1	1	1	2	2	0	0	37.00
130	4	2	1	2	2	2	4	3	0	3	3	2	2	2	2	0	1	1	2	3	0	0	41.00
131	4	2	2	2	2	2	4	3	0	3	3	2	2	2	2	0	1	0	0	3	0	0	39.00
133	4	0	2	2	2	2	4	0	3	3	3	2	2	2	2	0	0	0	0	2	0	1	36.00
141	2	1	0	1	1	2	3	1	0	1	1	2	2	1	1	0	0	0	0	1	0	0	20.00
142	3	2	2	2	2	2	4	0	3	3	3	2	2	2	3	1	1	1	1	1	0	0	41.00
143	1	0	0	1	0	0	2	1	0	2	1	0	0	0	1	0	0	0	0	0	0	0	9.00
144	0	0	0	0	0	1	1	0	0	1	0	0	0	0	1	0	0	0	0	0	0	1	5.00
145	1	0	0	1	1	0	1	1	0	1	1	0	0	1	1	0	0	0	0	1	1	0	11.00
146	3	0	2	2	2	2	4	3	0	3	3	2	2	1	2	0	1	1	2	2	1	0	38.00
147	3	2	2	1	2	2	4	3	0	3	2	2	2	2	1	0	1	1	2	2	0	0	37.00
148	0	0	0	0	1	0	0	1	0	1	1	0	0	0	1	0	0	0	0	0	0	1	6.00
149	4	2	2	2	2	2	4	3	0	3	2	2	2	2	2	0	1	0	0	2	2	0	39.00
150	0	0	0	1	0	0	1	0	0	1	1	0	0	1	1	0	0	0	0	0	0	1	7.00
151	3	1	2	2	2	2	4	3	0	3	3	2	2	1	1	0	2	2	3	0	1	0	40.00
153	1	0	1	1	1	0	2	0	2	1	2	0	0	1	0	0	1	1	1	1	0	0	16.00

Number of cases reas = 44

Number of cases listed = 44

Pharmacia CNS

CTN:20124/ADE 091 FINAL STUDY REPORT, ADDENDUM of January 30, 1995

FCE 20124/706 i A1

REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124

CTN: 20124/ADE 091

ZUNG VARIABLES

Legend to Zung	
ITEM	Patient Number
	(Score Range 1-4)
1	I feel downheart and blue
2	Morning is when I feel the best
3	I have crying spells or feel like it
4	I have trouble sleeping at night
5	I eat as much as I used to
6	I still enjoy sex
7	I notice that I am losing weight
8	I have trouble with constipation
9	My heart beats faster than usual
10	I get tired for no reason
11	My mind is as clear as it used to be
12	I find it easy to do the things I used to do
13	I am restless and can't keep still
14	I feel hopeful about the future
15	I am more irritable than usual
16	I find it easy to make decisions
17	I feel that I am useful and needed
18	My life is pretty full
19	I feel that the others would be better off if I were dead
20	I still enjoy the things I used to do
TOTAL SCORE	
INDEX SCORE	

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Pharmacia CNS

CTN:20124/ADE 091 FINAL STUDY REPORT, ADDENDUM of January 30, 1995

FCE 20124/706 i A1

REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124 CTN: 20124/ADE 091

Baseline

Pat. No.	Items	1	2	3	4	5	6	7	8	9	0	1	1	1	1	1	1	1	1	2	Total Score	Index Score	
81	3		1	4	3	1	2	2	3	4	3	1	2	2	2	3	2	3	1	4	2	65.00	.81
82	4	1	2	3	1	2	3	2	4	2	2	1	3	1	3	1	1	1	3	2		66.00	.83
83	3	1	4	4	1	1	3	3	4	2	2	1	2	1	3	2	1	2	3	1		68.00	.85
84	4	1	4	4	1	1	3	2	3	4	1	2	3	1	3	2	1	2	3	1		71.00	.89
85	3	3	2	3	2	1	2	3	4	3	1	2	2	1	2	2	1	1	4	2		62.00	.78
86	4	3	2	3	1	1	2	3	2	4	1	2	3	2	4	1	1	2	2	1		64.00	.88
87	4	2	3	4	1	1	2	2	3	3	1	1	4	1	4	1	2	1	3	1		70.00	.88
88	4	1	3	4	2	1	2	4	3	4	2	2	3	1	3	1	1	2	4	1		70.00	.89
89	4	4	3	4	1	1	2	3	4	3	1	2	3	4	3	2	1	2	3	1		66.00	.83
90	4	1	4	3	1	1	2	3	4	4	1	1	2	1	3	1	1	1	3	2		71.00	.89
91	4	1	4	3	1	1	3	4	3	3	4	2	3	2	3	1	1	1	3	2		67.00	.90
92	4	1	4	3	4	3	4	3	4	4	1	1	4	1	3	1	1	1	4	1		72.00	.90
93	3	1	2	3	2	1	4	3	2	3	1	1	4	1	3	1	1	1	2	2		67.00	.84
94	4	2	3	4	1	1	4	3	2	3	1	1	3	1	4	1	2	2	4	1		71.00	.89
95	4	2	4	3	1	1	3	4	3	2	3	1	4	1	4	3	2	2	3	1		67.00	.84
96	4	1	4	.	1	1	2	.	.	4	1	2	2	1	4	.	.	1	.	1		67.00	.84
97	4	3	4	2	3	1	4	4	4	3	1	1	3	1	4	1	1	1	1	1		69.00	.86
98	4	1	3	4	2	1	4	3	3	4	1	2	3	1	4	2	1	1	4	1		73.00	.91
99	4	2	4	3	1	1	3	3	3	4	1	2	4	2	4	1	1	2	2	1		70.00	.88
100	4	1	3	4	1	1	3	3	3	4	1	1	2	1	4	1	1	2	3	2		71.00	.89
121	4	1	4	3	3	1	2	2	3	4	1	1	1	1	4	2	1	1	2	1		66.00	.83
122	4	1	4	4	1	2	3	1	3	4	1	2	2	1	3	1	1	2	1	1		68.00	.85
123	3	3	4	4	1	1	4	1	3	3	1	1	2	2	3	1	1	2	2	1		65.00	.81
124	4	1	4	4	1	1	3	1	2	4	1	1	2	1	4	1	1	2	2	2		68.00	.85
125	4	2	3	4	1	1	3	1	2	4	1	1	2	1	4	1	2	1	2	1		67.00	.84
126	3	2	4	4	1	1	2	2	3	4	1	1	2	1	3	2	1	1	3	1		68.00	.85
127	4	1	4	4	1	1	2	2	3	3	1	1	2	1	4	2	1	3	1	2		65.00	.81
128	4	1	4	4	1	1	1	3	3	3	2	1	3	2	3	2	1	2	1	1		65.00	.81
129	4	1	2	4	2	1	2	2	3	4	1	2	3	2	4	1	2	1	3	1		67.00	.84
130	3	1	2	3	1	2	2	3	2	2	2	1	1	2	2	1	1	3	1	2		55.00	.69
131	4	2	3	4	1	1	2	3	3	4	1	2	3	2	1	1	1	1	3	1		67.00	.84
133	3	3	2	4	1	2	2	3	3	2	2	1	4	2	4	1	2	2	3	3		61.00	.76
141	4	1	2	4	2	1	3	2	2	4	1	1	2	1	4	2	1	2	2	1		66.00	.83
142	4	2	3	4	1	1	2	3	2	4	1	2	4	4	3	1	1	1	2	2		65.00	.81
143	4	1	4	4	1	1	2	2	3	4	1	2	2	1	3	2	1	1	3	1		69.00	.86
144	4	3	4	4	1	1	2	2	3	3	1	1	2	1	4	1	1	1	3	1		69.00	.86
145	4	3	4	4	2	1	2	2	3	2	1	2	1	3	2	1	1	2	1	2		63.00	.79
146	4	1	4	4	1	1	2	2	3	4	1	2	3	1	3	1	2	2	1	1		67.00	.84
147	4	1	4	4	1	1	3	3	2	4	4	1	2	1	3	2	1	1	2	2		66.00	.85
148	4	2	3	4	1	1	2	3	3	4	1	2	2	1	4	1	2	1	3	1		69.00	.86
149	4	2	3	3	2	1	2	2	4	3	1	1	2	1	4	1	1	1	1	2		65.00	.81
150	3	1	3	4	1	1	2	3	4	3	1	1	3	1	4	1	1	1	3	2		71.00	.89
151	4	3	3	4	1	1	3	3	4	4	1	1	2	1	4	1	1	1	3	1		72.00	.90
153	4	1	4	4	1	1	2	3	3	4	1	1	4	2	3	2	1	1	4	1		73.00	.91

Number of cases read = 44
Number of cases listed = 44

Pharmacia CNS
CTN:20124/ADE 091 FINAL STUDY REPORT, ADDENDUM of January 30, 1995

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FCE 20124/706 i A1

REBOXETINE ADDENDUM TO CLINICAL STUDY REPORT 706i

FCE 20124 CTN: 20124/ADE 091

Final

Pat. No.	Items										10	11	12	13	14	15	16	17	18	19	20	Total Score	Index Score
	1	2	3	4	5	6	7	8	9														
81	1	4	1	2	3	3	1	2	3	2	3	4	2	3	1	4	4	3	1	4	34.00	.43	
82	4	1	4	4	1	1	3	2	4	4	1	1	4	1	4	2	1	1	3	1	75.00	.94	
83	3	1	2	3	3	2	1	1	2	3	3	2	2	3	3	2	3	2	2	3	48.00	.60	
84	1	4	2	2	4	3	1	1	2	2	4	4	1	3	2	4	3	3	1	4	32.00	.40	
85	4	2	4	4	1	1	1	3	4	4	1	2	1	1	4	2	1	1	4	1	70.00	.88	
86	2	3	1	2	4	4	1	3	3	3	4	2	1	3	2	3	3	2	1	3	38.00	.48	
87	4	1	4	4	1	1	3	2	4	3	1	1	4	1	4	2	1	1	3	1	74.00	.93	
88	3	2	2	3	2	1	3	2	4	3	2	3	3	4	2	3	2	2	.4	45.00	.56		
89	1	3	1	1	3	4	1	2	3	1	3	4	1	4	2	4	2	3	1	4	30.00	.38	
90	1	4	1	2	4	4	2	1	2	2	4	4	2	3	1	4	3	4	1	3	31.00	.39	
91	1	4	2	2	4	4	3	2	3	2	4	2	1	3	1	4	4	3	1	3	36.00	.45	
92	1	1	1	2	2	2	1	3	2	3	4	4	1	4	2	2	3	3	1	4	36.00	.45	
93	1	3	1	3	3	3	1	3	3	1	3	4	2	3	2	3	4	3	1	3	36.00	.45	
94	4	3	4	4	1	1	1	4	4	4	1	1	4	1	3	2	1	1	4	1	73.00	.91	
95	1	4	1	2	3	4	1	2	3	3	4	4	2	3	1	4	4	4	1	4	32.00	.40	
96	2	4	3	2	4	4	1	2	3	2	4	2	3	4	1	3	3	3	1	4	38.00	.48	
97	1	4	1	1	3	4	1	2	1	1	4	3	1	3	1	4	3	4	1	4	28.00	.35	
98	1	3	1	2	4	4	1	2	2	1	3	3	1	4	2	3	4	3	1	4	29.00	.36	
99	4	2	4	4	1	1	4	3	3	4	1	2	4	1	4	1	2	1	4	1	75.00	.94	
100	1	4	3	3	1	1	4	3	3	4	1	2	3	1	4	1	1	1	4	1	71.00	.89	
121	3	1	3	3	1	2	4	3	3	3	1	2	2	1	4	2	1	2	1	2	67.00	.84	
122	1	3	1	2	3	3	1	2	3	2	4	2	1	4	3	2	3	3	1	4	36.00	.45	
123	2	4	2	3	4	3	1	3	2	3	4	3	1	4	1	2	3	2	1	4	39.00	.49	
124	3	2	1	3	2	1	2	2	1	4	2	2	1	1	2	2	1	1	2	1	58.00	.73	
125	1	2	1	2	3	2	1	2	3	1	3	4	2	4	2	3	4	3	1	4	34.00	.43	
126	1	3	1	2	3	3	1	3	2	3	4	3	4	2	3	2	2	1	4	4	37.00	.46	
127	1	4	1	2	4	3	1	2	2	1	4	4	1	4	4	1	3	4	1	1	37.00	.46	
128	1	4	1	2	2	3	1	2	2	1	4	3	1	3	2	3	2	2	1	4	37.00	.46	
129	4	2	3	4	1	1	3	1	4	2	3	2	2	1	3	1	1	1	3	1	65.00	.81	
130	4	1	3	4	1	1	4	3	3	4	1	1	2	1	3	1	1	1	3	1	73.00	.91	
131	4	1	3	4	1	1	3	2	3	4	1	1	3	1	3	1	1	1	3	1	72.00	.90	
133	4	2	2	4	1	1	2	3	3	3	2	1	4	1	4	1	1	1	3	1	70.00	.88	
141	3	2	1	4	1	2	2	2	1	3	1	2	1	1	3	1	2	2	1	1	58.00	.73	
142	4	1	4	4	1	1	3	2	2	4	1	2	3	1	4	1	1	1	3	1	72.00	.90	
143	2	4	2	2	4	4	1	2	3	2	4	4	1	4	3	2	3	2	1	4	37.00	.46	
144	1	4	1	2	3	2	1	2	3	1	3	3	3	4	1	4	4	3	1	3	36.00	.45	
145	2	3	2	2	3	2	1	3	4	3	3	2	2	3	3	2	2	2	1	4	47.00	.59	
146	4	1	4	4	1	1	2	3	4	4	1	1	3	1	4	2	1	1	2	1	73.00	.91	
147	4	1	3	4	1	1	2	2	3	3	2	1	2	1	3	1	1	1	3	2	67.00	.84	
148	1	2	1	3	4	3	1	2	2	1	4	4	1	3	2	4	3	3	1	4	31.00	.39	
149	4	1	4	4	1	2	3	2	3	4	1	1	3	1	4	1	1	1	3	1	73.00	.81	
150	1	4	1	2	3	2	1	2	3	2	4	3	1	3	2	4	3	2	1	4	37.00	.46	
151	4	3	4	4	1	1	4	3	4	3	1	1	2	1	4	1	1	2	3	1	72.00	.90	
153	2	1	3	2	1	1	1	3	2	3	3	2	3	2	3	3	2	1	1	3	54.00	.68	

Number of cases read = 44

Number of cases listed = 44

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HAMD, ZUNG. CGI-SI AND CODE-DD SCORES

LISTING NUMBER	VARIABLE
1	HAMD Total Score - Day 0
2	HAMD Total Score - Day 42
3	ZUNG Total Score - Day 0
4	CGI-Severity -Score - Day 0
5	CODE-DD Severity Score - Day 0

LISTING NUMBERS

Pat. No.	1	2	3	4	5
81	34.00	9.00	65.00	5	38
82	34.00	43.00	66.00	5	34
83	38.00	25.00	68.00	5	31
84	37.00	8.00	71.00	6	31
85	33.00	40.00	62.00	5	36
86	37.00	10.00	64.00	6	33
87	41.00	46.00	70.00	6	31
88	40.00	25.00	70.00	5	33
89	41.00	11.00	66.00	6	34
90	39.00	7.00	71.00	6	35
91	43.00	6.00	67.00	6	34
92	41.00	9.00	72.00	6	34
93	36.00	12.00	67.00	5	33
94	42.00	45.00	71.00	6	31
95	37.00	4.00	67.00	6	33
96	41.00	11.00	67.00	6	32
97	34.00	5.00	69.00	6	30
98	41.00	6.00	73.00	6	32
99	38.00	41.00	70.00	5	34
100	37.00	44.00	71.00	6	34
121	35.00	27.00	66.00	5	29
122	36.00	13.00	65.00	5	25
124	34.00	37.00	68.00	5	26
125	35.00	5.00	67.00	6	25
126	34.00	7.00	68.00	5	30
127	38.00	6.00	65.00	6	35
128	37.00	4.00	65.00	5	34
129	36.00	37.00	67.00	6	31
130	33.00	41.00	55.00	6	29
131	34.00	39.00	67.00	6	35

LISTING NUMBERS (continue)

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Pat. No.	1	2	3	4	5
133	32.00	36.00	61.00	6	36
141	30.00	20.00	66.00	5	32
142	35.00	41.00	65.00	5	36
143	39.00	9.00	69.00	6	32
144	38.00	5.00	69.00	6	35
145	37.00	11.00	63.00	6	32
146	34.00	38.00	67.00	4	32
147	31.00	37.00	66.00	5	34
148	32.00	6.00	69.00	6	37
149	31.00	39.00	65.00	6	35
150	33.00	7.00	71.00	6	34
151	35.00	40.00	72.00	6	35
153	35.00	16.00	73.00	6	35

Number of cases read = 44

Number of cases listed = 44

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DISCUSSION

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1. CODE-DD was administered prior to commencement of treatment to all 44 patients included in the Brazilian sample of a placebo-controlled, multinational clinical trial with Reboxetine.
2. Analyses of the "introductory -- optional -- section" of CODE-DD revealed that, with the exception of 1, all patients were high school graduates including 13 patients with a university degree), and that the majority of patients (63.6%) were married.
3. It was also revealed that more than one-half of the patients have seen a physician for their depression prior to present hospitalisation, but less than one-half had prior pharmacologic treatment for depression; and only 2 of the 44 patients had prior hospitalisation for depression.
4. It was noted that more than one-half of the patients had prior surgical intervention and more than one-fifth of the females had a hysterectomy or tubal ligation.
5. It was also noted that almost one-third of the patients were tearful at the time of the diagnostic evaluation, but less than 10% displayed the Omega sign.
6. The two treatment groups were comparable in 12 of 13 personal and patient characteristics.
7. Significantly more patients in the RBX than in the PBO group had prior surgical intervention.
8. Exploration of symptoms was conducted in four steps including an analysis of symptom structure of depressive illness in the study population; an analysis of the comparability of symptom display in the two treatment groups; an analysis of responsiveness of symptom-based populations (regardless of treatment); and an analyses of comparative responsiveness of symptom-based populations.
9. In nearly one-half of the patients the depression was genetically pure and in more than fourth-fifths of the patients the depression had an acute or subacute onset.
10. Four of the 72 symptoms, i.e., depressed mood, anxiety, asthenia and impairment of social adaptation, were present in all patients; and another nine symptoms, i.e., anxious mood, depressive evaluations, lack of drive, late insomnia, disturbances of concentration, displeasure, felt loss of vitality, indecisiveness and early insomnia, were present in more than 90 percent of the patients.
11. Thirty-one symptoms were present in 75% or more of the patients and 44 symptoms were present in 50% or more.
12. The two treatment groups were comparable in all but six CODE-DD variables.
13. Patients in the RBX groups were significantly more often genetically pure and displayed bodily misperceptions, decreased appetite and time still than in the PBO group; whereas patients in the PBO group more often displayed impairment of social adaptation and early insomnia than in the RBX group.
14. Responsiveness in symptom-bases populations, as measured by the changes in total scores from Day 0 to Day 42 of the HAMD, ranged from -21.2% to +83.3% with mean responsiveness in the 15 patients with feelings of impoverishment 23.9%, and in the 15 patients with subacute onset of illness 57.2%.

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15. Presence of insidious onset, bodily misperceptions and feelings of impoverishment and/or the absence of diurnal variations had a negative effect on responsiveness to RBX.
16. While the presence of depersonalization and self-incrimination had a negative effect, the presence of precipitating factor with temporal connection and hypochondriasis had a positive effect on responsiveness to PBO.
17. In 126 of the 144 symptom-based populations therapeutic responsiveness, as measured by the level of statistical significance of the changes in the total scores of the HAMD from Day 0 to Day 42, was greater in the RBX- than in the PBO-treated group; in 11 symptom-based populations responsiveness was equal; and in seven symptom-based populations responsiveness was greater in the PBO than in the RBX group.
18. In 105 of the 144 symptom-based populations statistically significant change (improvement) was present with RBX only; and in three of the 144 symptom-based populations statistically significant change (improvement) was present with PBO only.
19. In 10 of the 25 diagnostic classifications all patients displayed one diagnostic form.
20. The two treatment groups were comparable in frequency of all but two of the 93 diagnostic forms and subforms.
21. There were significantly more patients with pure depression (in Winokur's classification) in the RBX than in the PBO group, whereas there were significantly more patients with sporadic depression in the same classification in the PBO than in the RBX group.
22. Responsiveness in the diagnosis-based populations, as measured by the changes in total scores from Day 0 to Day 42 of the HAMD, ranged from -24.2% to +89.2%, with mean responsiveness of the 15 patients with sporadic depression (Winokur) 28.5% and in the 11 patients with vital depression (Composite) 60.8%.
23. Responsiveness was placebo prone in mixed depression (Leonhard), in definite major depressive disorder, recurrent, primary, incapacitating, definite endogenous (RDC) and in reactive depressive disorder (Composite).
24. In 56 of the 93 diagnosis-based populations therapeutic responsiveness, as measured by the level of statistical significance of changes in the total scores of the HAMD from Day 0 to Day 42, was greater in the RBX- than in the PBO-treated group; in 27 diagnosis-based populations responsiveness was equal but in no case the sample size was greater than 1 per cell; and in eight diagnosis-based populations responsiveness was greater in the PBO than in the RBX group (in no case the sample size was greater than 5 per cell).
25. In 47 of the 93 diagnosis-based populations statistically significant change (improvement) was present only with RBX and in one statistically significant change (improvement) was present only with PBO.
26. In 33 of the 39 diagnosis-based populations in which at least 5 patients were included in each treatment group, treatment with RBX was significantly superior to PBO; in the remaining six diagnosis-based populations the two treatment groups were equal (among the latter in no case the sample size was greater than 10 per cell).

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27. Of the 25 diagnostic classifications, 15 accommodated 100% of the patients, whereas the remaining 10 classifications could accommodate only from 70.5 to 97.7% of the patients.
28. Correlations between CODE-DD total severity score and the severity scores of the HAMD, ZUNG and CGI-SI did not reach the accepted level of statistical significance.
29. Correlations between the HAMD total score and the ZUNG total and CGI-SI severity scores were significant
30. Correlations between the ZUNG total score and CGI-SI severity score did not reach the accepted level of statistical significance.

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