

22 April 2026

Submission of comments on **Guidance on the conduct of clinical trials during public health emergencies** EMA/44884/2026

Name of organisation or individual*	Line from* (line Nr or 0 for general comment)	Line to* (line Nr or 0 for general comment)	Section number	Comment and rationale (to go to next line within the same cell use Alt + Enter)	Proposed changes / recommendation (if applicable - to be used if you want to propose specific text changes)
Institute for Quality and Efficiency in Health Care (IQWiG)	0	0		<p>With this draft, the European Medicines Agency is making an important contribution to the rapid yet scientifically sound generation of evidence in times of crisis. The IQWiG also expressly welcomes the clear recommendation to use platform trials and master protocols. Experience with, for example, the RECOVERY trial — an adaptive, multi-arm, randomised, open-label study launched in the UK to evaluate potential COVID-19 treatments — demonstrates that such study designs were able to rapidly provide robust evidence during the COVID-19 pandemic, thereby substantially supporting decision-making processes within healthcare systems.</p> <p>Nevertheless, it should be noted that the DARWIN EU infrastructure, established by the EMA and building on the European Health Data Space (EHDS), currently focuses exclusively on non-interventional real-world data analyses. The EHDS and DARWIN EU can therefore only serve as resources to support analyses of routine care. Up to now, the opportunity has been missed to design the framework so that it also supports interventional, randomised trials for comparative benefit assessment of medicines. Building on and in line with the Accelerating Clinical Trials in the EU (ACT EU) initiative, DARWIN EU should therefore be further developed and expanded. This would make it possible to draw more quickly on already established infrastructures during future public health emergencies, thereby improving the speed and quality of evidence generation. In line with the present guidance, this would help ensure robust public health decisions, even in future emergencies.</p>	