8 North Darfur State Ministry of Health. Report on the current health situation in El Fasher. El Fasher: El Fasher Specialized Hospital for Obstetrics and Gynaecology, Curative Medicine Office; Oct 13, 2025.
9 Yale School of Public Health Humanitarian Research Lab. Systematic arson attacks mark next phase of mass atrocities in El-Fasher. October, 2025. https://files-profile.medicine.yale.edu/documents/319dd62a-d4d2-454b-8205-47214168dcf5 (accessed Oct 22, 2025).

Centralised ethics review of clinical trials in a public health emergency in the EU

The COVID-19 pandemic caused major excess mortality worldwide. Although many innovations originated in the EU, pivotal vaccine, diagnostic, and therapeutic trials largely occurred outside the EU. Unlike the more centralised approaches in the USA and UK, the EU's fragmented clinical trial system—particularly the complex trial application (CTA) and approval processes across 27 member states and European Economic Area countries—slowed research response.

The Accelerating Clinical Trials in the EU (ACT EU) programme was launched in 2022 by the European Commission, European Medicines Agency, and the Heads of Medicines Agencies.[1] One priority is improving flexibility and speed in multinational trials during public health emergencies. One proposal is the creation of a European Central Ethics Committee (ECEC); however, there are advantages and disadvantages.

An ECEC could provide an optional, unified EU ethics review pathway for CTAs in public health emergencies, offering a faster and more coordinated framework. By streamlining and simplifying the process, the EU's large network of advanced clinical sites could be mobilised more efficiently, boosting European and global competitiveness. Importantly, participation would remain optional for member states, preserving national authority. Existing initiatives, such as MedEthicsEU, which seeks to enhance collaboration among ethics committees, could serve as the foundation for the ECEC.[2] During 'peacetime' the ECEC could support preparedness by conducting dry runs and rapid review exercises. The ECEC could also drive the harmonisation of ethical standards and operational simplifications, aligning with ACT EU's recommendations for streamlined CTAs during public health emergencies.

However, considerable challenges remain. Establishing an ECEC would require changes to EU law and member states would need to accept some pooling of sovereignty over CTA decisions during emergencies. Legal issues related to cross-border authority—including insurance, trial participant reimbursement, investigator qualifications, and site approvals—would need careful resolution.

Despite these obstacles, strengthening EU coordination is essential and a balanced discussion on the value of an ECEC for public health emergencies is necessary. Only by exploring new ways to join our forces within the EU and the European Economic Area in view of a threat will we find the right path towards a better response to future emergencies. Clinical trials remain at the core of public health response during emergencies, and time is essential.

WEB is a board member of MedEthicsEU and the Association of Medical Ethics committees in Germany. JMD is a board member of the Committee for the Protection of Persons in the South Mediterranean and the National Commission for Research Involving the Human Person. MA is the Vice-chair of the Clinical Trials Coordination Group and Co-chair of MedEthicsEU. All other authors declare no competing interests. This Correspondence reflects the personal opinions of contributors involved in different functions within ACT EU's priority action on public health emergencies and does not represent the official positions of their institutions or ACT EU.

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1 EU. Accelerating Clinical Trials in the EU. 2025. https://accelerating-clinical-trials.europa.eu/index_en (accessed Oct 9, 2025).
2 EU. Clinical trials–MedEthicsEU–group of national representatives of medical research ethics committees. 2025. https://health.ec.europa.eu/medicinal-products/clinical-trials/medethicseu_en (accessed Oct 8, 2025).

Research integrity is undoubtedly in crisis

Richard Horton's view that there is not a research integrity crisis[1] contradicts the initiation of the *Lancet* Commission on Research Integrity, which states "There is clearly a crisis in research integrity that needs urgent action."[2] This divergence might be because Horton focuses on researcher misconduct, a relatively small contributor to compromised publication integrity, when other explanations are more commonly at play. This misstep shifts focus from the question most important to the scientific community and the public—is the research reliable—to the less important secondary one—why is it unreliable? Focusing primarily on the reliability of research will improve the consistency and timeliness of resolution of concerns about publication integrity.[3] Although Horton suggests that publisher responses to integrity concerns are not too slow, the published record universally contradicts this claim, and reports they are also opaque, incomplete, and inconsistent.[4]

Trust as a foundation of science is an admirable notion, but it must be earned. In the face of rapidly increasing numbers of unreliable publications, and unreliable systems for preventing, detecting, and correcting them, a trust-based system is neither safe nor sensible. Readers of a publication, be they editors, peer reviewers, scientists, clinicians, or members of the public, should ask themselves whether the paper meets criteria for reliability. That is not cynical, but pragmatic.