

A brighter future for clinical trials in the EU

ACT EU multi-stakeholder platform annual meeting
Industry associations view

22 October 2024



A brighter future for clinical trials in the EU



Bringing innovative medicines to EU patients.

- Improvement of review process coordination
- CTIS to become more flexible (platform to serve the purpose rather than us serving the platform)
- Overcome fragmentation between different regulations

- Use novel methodologies, Master Protocols, decentralized elements, digital health technologies, endpoints used in the real world, patient experience data
- Consider patient journey, enhance cooperation with patients' organisations
- Improve access to clinical trials (e.g., enable cross-border access), increase flexibility and diversity.

Maintain same proportional efficacy & safety standards across all trials/stakeholders

Thinking ahead



Declaration of Helsinki*:

Clinical trials are regulated in order to protect the **life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research participants**

CTR 536/2014**:

In a clinical trial the **rights, safety, dignity and well-being of subjects** should be **protected** and the **data generated should be reliable and robust**. The **interests of the subjects** should always **take priority** over all other interests.

- **Risk-based approach and trust:** Could documentation already reviewed and accepted by regulators and EC in previous CTAs be trusted and fully relied upon (reduce review duplication)?
- Could it make sense to establish a **life-cycle dossier approach**?
- Could there be **other models to facilitate CTs in rare diseases and pediatric populations** to benefit patients in all EU Members States?
- Is there any opportunity to establish one **single entry point / one committee for all clinical research**?
- **Review on impact of CTR acc. to Article 97 & potential revision** leading to a less prescriptive and more adaptable regulation (long-term)

*<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

**<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536>