ACT EU and GCP modernisation

ICH E6 R3 workshop

19 February 2025

Presented by Peter Arlett

Head of Data Analytics and Methods Taskforce

European Medicines Agency

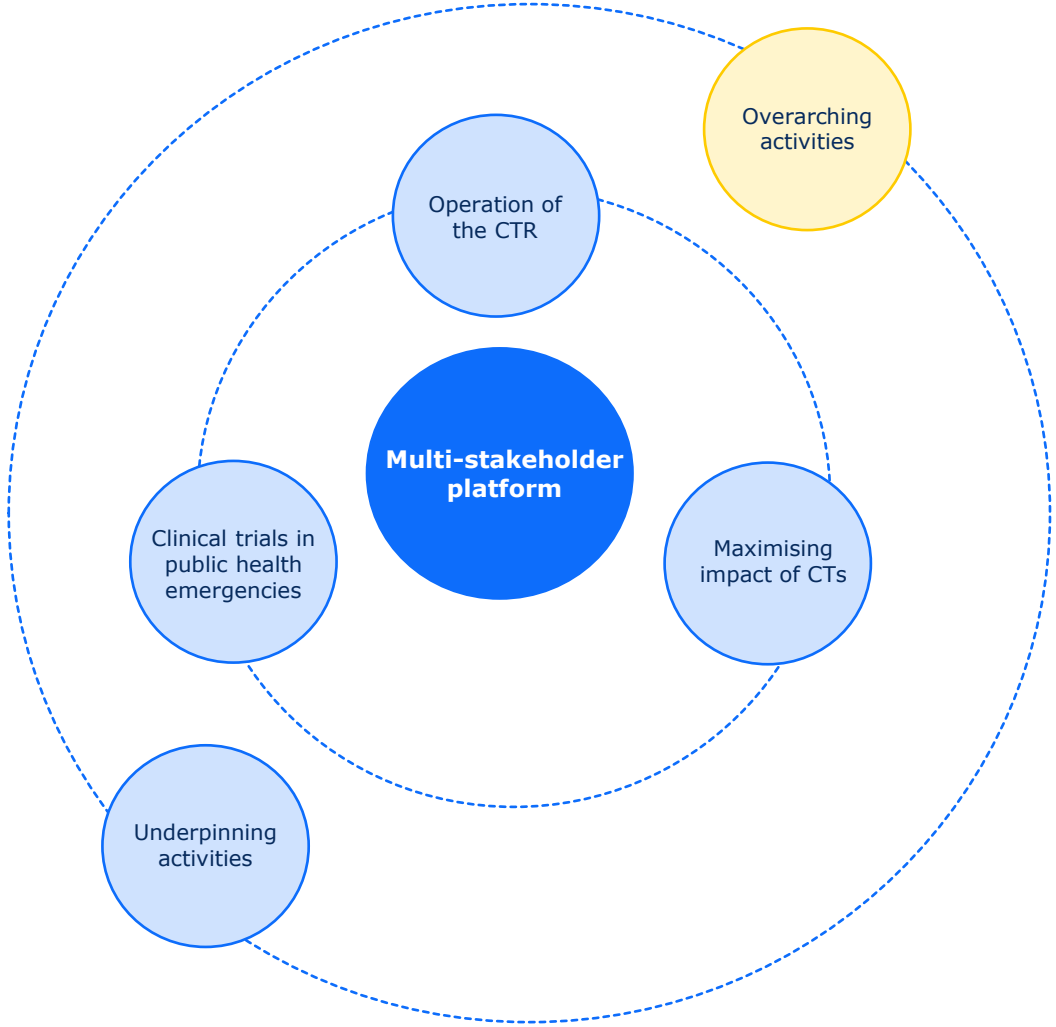
ACT EU partners

- A joint initiative by the European Commission, Heads of Medicines Agencies and EMA
- Established in 2022
- Building on the momentum of the implementation of the Clinical Trials Regulation (CTR)

Our vision is to have **better, faster and optimised** clinical trials in the EU, creating a favourable environment for clinical research.

ACT EU partners

ACT EU focus for 2025-2026



Overarching activities:

- ACT EU governance
- Multi-stakeholder Platform

Operation of the Clinical Trials Regulation:

- Implementation of the Clinical Trials Regulation
- Support for non-commercial sponsors
- Clinical trials safety

Maximising impact of clinical trials – design and conduct of excellent clinical trials:

- Good clinical practice modernisation
- Consolidated advice on clinical trials
- Clinical trials methodologies

Underpinning activities:

- Communication
- Clinical trials analytics
- Clinical trials training

ACT EU support to GCP modernisation

Multi-stakeholder workshop
13/07/2023
During public consultation of ICH E6 R3 principles & annex I, to support stakeholders in providing feedback

Multi-stakeholder workshop
19-20/02/2025
Following publication of ICH E6 R3 principles and annex, to support implementation

Updating EU guidelines
2025
Updating relevant EU guidelines impacted by the change

Additional support
2025
Communication & trainings to support implementation

What we aim to achieve with this workshop

- Present an overview of major changes in the ICH E6(R3) guideline
- Highlight key concepts for adapting GCP to recent developments in trial design, organisation and technology
- Enable discussion with stakeholders on the guideline's implementation
- Provide a brief update on the draft ICH E6(R3) annex II

Thank you

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