Accelerating Clinical Trials in the EU (ACT EU)

ACT EU Multistakeholder kick-off meeting
22-23 June 2023

Presented by Monique Al

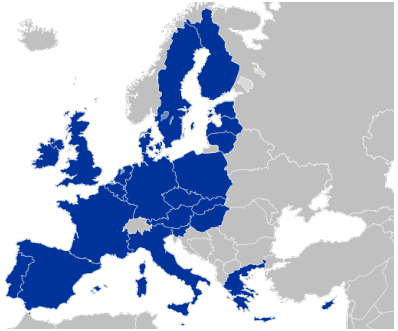
In this presentation

- Background on the programme
- Key outputs from 2022
- 2023 planning
- Multi-stakeholder platform
- Key messages

Evolution of EU clinical trials regulation

Pre 2004: No harmonisation

National rules, different processes in each Member State.
Resulted in **delays** and **complications**



Clinical Trials Directive
(EU 2001/20/EC)

Some harmonisation, but **national systems & processes varied**

Entered into application 1 May 2004

Clinical Trials Regulation
(No.536/2014)

Full harmonisation, collaborative assessment of **multinational trials**, single EU portal & database (CTIS)

Applies as of **31 January 2022**

The European clinical trials environment

Problem statement

- Absence of EU impactful multi-state trials
  - Non-commercial trials (40%) primarily mono-national (1.2 average MS/trial)
- Split responsibilities across multiple actors, with multiple initiatives across network
- EU seen as less friendly for clinical research

ACT EU vision

- Transform EU clinical trials environment for Europe to flourish as a global focus for clinical research
- Through excellent scientific advice and optimised regulatory oversight enable the conduct of large impactful clinical trials in the EU that deliver decisional evidence
- Improve health of European patients through faster access to innovative medicines and optimised use on the market.

New tools and methods

Decentralised and complex trials

Modern regulatory supervision

Digitisation and future-proof guidance

Accelerating Clinical Trials in the EU (ACT EU)

ACT EU is business change initiative to **transform the EU clinical research environment** in support of medical innovation and better patient outcomes.

- **Builds on the momentum** of the Clinical Trials Regulation and CTIS
- **Driven by** the Network Strategy to 2025 and the EU Pharmaceutical Strategy
- Launched 13 January 2022
- 10 priority actions with a focus on:
  - **enabling clinical trials** (in particular multinational trials)
  - **innovative trial methods**
  - **GCP modernisation**
  - **engaging all stakeholders**
- Read the press release and paper

ACT EU priority actions

PA 1	Map existing initiatives and develop a governance rationalisation strategy (aligning different expert groups and working parties in the EMRN and ethics infrastructure).
PA 2	Successful and timely implementation of the CTR and its implementing acts: • develop KPIs and dashboard to track performance of the European clinical trials environment; • including the promotion of larger, multinational trials specifically in the academic setting.
PA 3	Establish a multi-stakeholder platform, including patients, after stakeholder analysis
PA 4	Implementing the GCP modernisation informed by the development of guidance at ICH
PA 5	Analyse data about clinical trials leveraging academic, non-profit, European, and international initiatives, improving the impact of policymaking and funding on research outputs to support evidence-based decision making
PA 6	Plan and launch a targeted communication campaign to engage all enablers (including data protection experts, academia, SMEs, funders, HTA bodies, healthcare professionals)
PA 7	Reinforce the coordination between scientific advice on CT approval and CT design and link to the methodologies working party domain
PA 8	Develop and publish key methodologies guidance e.g. on AI/ML impacted CTs, complex trials, decentralised CTs and IVDR/CTR interface (to strengthen links between innovation and scientific advice fora)
PA 9	Successfully establish CT safety monitoring and bridge to the EU4Health Joint Action and start its integration into a pre- and post-marketing safety monitoring framework
PA 10	Deliver a clinical trials training curriculum including modules on drug development and regulatory science with links to universities and SMEs (serving as an educational 'ecosystem')

Programs within the different Priority Actions

Example: PA02 - successful implementation of CTR

- **Key Performance indicators**
- **Survey on the implementation of CTR (sponsors CTIS)**
- **Non-commercial trial support**
- **Transparency rules**
- **Transition clinical trials**

ACT EU is delivering: Key outputs in 2022

Complex clinical trials Q&A

23 May 2022
EMA/298712/2022

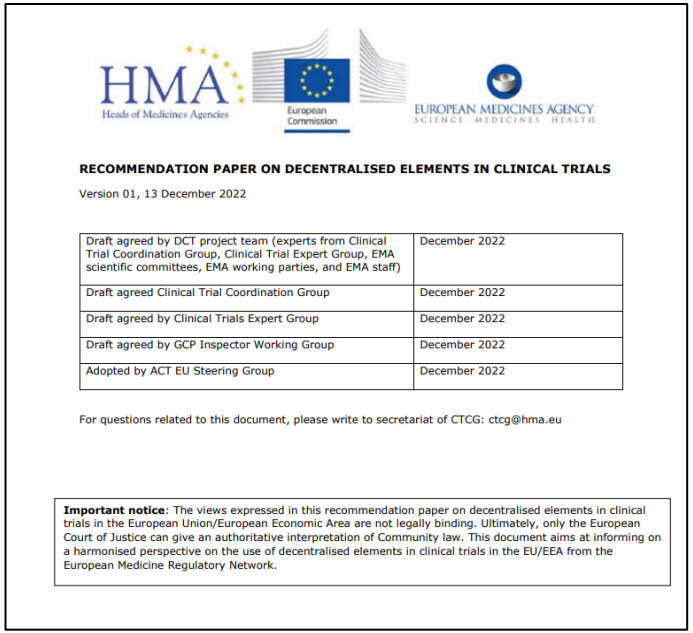
Complex clinical trials – Questions and answers
Version 2022-05-23

Draft agreed by experts from EMA scientific committees, working parties and staff	May 2022
Draft agreed by Clinical Trials Coordination Group	May 2022
Draft agreed by Clinical Trials Expert Group	May 2022
Adopted by ACT EU Steering Group	23 May 2022

Keywords	Clinical trial; complex clinical trial; clinical trial authorisation application; marketing authorisation application; trial design; trial analysis; Clinical Trials Regulation; master protocol; platform trial; biomarker; adaptive design; modifications; Bayes; control data; transparency

Q2 2022 Complex clinical trials Q&A

Recommendation paper DCT



RECOMMENDATION PAPER ON DECENTRALISED ELEMENTS IN CLINICAL TRIALS

Version 01, 13 December 2022

Draft agreed by DCT project team (experts from Clinical Trial Coordination Group, Clinical Trial Expert Group, EMA scientific committees, EMA working parties, and EMA staff)	December 2022
Draft agreed Clinical Trial Coordination Group	December 2022
Draft agreed by Clinical Trials Expert Group	December 2022
Draft agreed by GCP Inspector Working Group	December 2022
Adopted by ACT EU Steering Group	December 2022

For questions related to this document, please write to secretariat of CTCG: ctcg@hma.eu

Important notice: The views expressed in this recommendation paper on decentralised elements in clinical trials in the European Union/European Economic Area are not legally binding. Ultimately, only the European Court of Justice can give an authoritative interpretation of Community law. This document aims at informing on a harmonised perspective on the use of decentralised elements in clinical trials in the EU/EEA from the European Medicine Regulatory Network.

Q4 2022 EU DCT recommendation paper

ACT EU 2023 focus

- Reinforced focus on successful **implementation of the Clinical Trials Regulation**, including use of Clinical Trials Information System (CTIS): change management including stakeholder engagement, surveys, training, communication
- Launch a scheme to **support academic sponsors** conducting large multi-national clinical trials
- **Creation of the Multi-stakeholder platform**
  - A sustainable platform that enables all stakeholders to collaborate for better clinical trials
  - Kick-off meeting: **22-23 June 2023**
- **Revise workplan** informed by learnings and Network needs and priorities (CTR)

ACT EU keeps delivering

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ACT EU multi-stakeholder platform kick-off workshop

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Date: 22/06/2023 to 23/06/2023

Location: European Medicines Agency and online, day 1: 13:00 - 18:00, day 2: 09:00 - 13:00, Amsterdam time (CEST)

Event summary

Accelerating Clinical Trials in the EU (ACT EU) Priority Action 3 aims to establish a platform where all stakeholders involved in designing, regulating, performing and participating in clinical trials can, through regular dialogue, identify relevant scientific, methodological and technological advances to develop the clinical trials environment in the EU.

Through a series of workshops to be held in 2023 and 2024, an EU multi-stakeholder platform on clinical trials will be established to advance discussions on priority topics by efficiently incorporating the views, needs and concerns of all parties involved in the process.

ACT EU objectives

1	Optimise the EU environment for clinical research in Europe by: **a) Strengthening leadership and coordination** on clinical trial authorisation and execution. **b) Optimising ethical oversight** and further integrate ethics committees into the clinical trial and medicines regulatory lifecycle. c) Supporting the **conduct of large-scale multinational clinical trials** **d) Reducing administrative burden and increasing efficiency**.
2	**Strengthening clinical trials** for unmet medical needs, rare diseases, and vaccines and therapeutics for public health crises, ensuring support for HTA bodies as well as for academic and SME sponsors.
3	**Heighten the impact of European clinical trials** through excellent and coordinated **scientific advice** as a complement to trial authorisation and to support marketing authorisation.
4	**Engage all stakeholders** to proactively deliver inclusive patient-oriented medicines development and delivery across populations.
5	**Ensure a clear and unified European position** on clinical trials in strategic matters at the international level.
6	**Build capacity** in all aspects of drug development and regulatory science through, amongst others, research collaboration and training with academia.

ACT EU for all of us

PATIENTS

HEALTH CARE PROFESSIONALS

CROs

HMA

HTA BODIES

INDUSTRY

SPONSORS

INSPECTORATES

EMA

ETHICS COMMITTEES

EUROPEAN COMMISSION

SME

CONSUMERS

REGULATORS

TRIAL PARTICIPANTS

INVESTIGATORS

PAYERS

SERVICE PROVIDERS

RESEARCH FUNDERS

ACADEMICS

NATIONAL COMPETENT AUTHORITIES

Bigger, better, faster clinical trials: guiding principles

- Acknowledge the problems we face
- Guided by patients
- Plan and re-plan
- Travel together
- Harness the resources we need (people, data, technology, knowledge)
- Global perspective with EU as leader
- Remain focused on benefits

ACT EU: Key messages

- ACT EU is the EU initiative to **modernise** and **invigorate** clinical trials in Europe
- ACT EU brings a **change management** focus that complements and supports implementation of the Clinical Trials Regulation
- Binds EC/HMA/EMA to deliver for EU **innovation** and **better medicines** for patients
- **Steady progress** in 2022 including on communications, training, decentralised and complex trials and supporting the CTR
- Focus in 2023: supporting **CTR**, **academic CTs** and the **multi-stakeholder platform**

Any questions?

Further information on ACT EU

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Newsletters | European Medicines Agency (europa.eu)

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