Accelerating Clinical Trials in the EU (ACT EU)

Transforming clinical trials in Europe

PCWP/HCPWP 2 March

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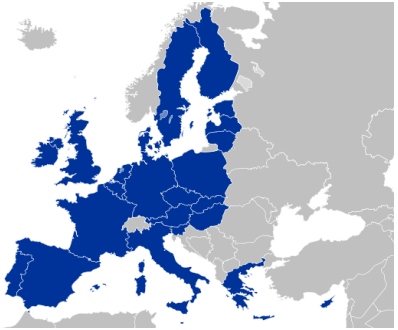
Clinical trials in the EU now

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

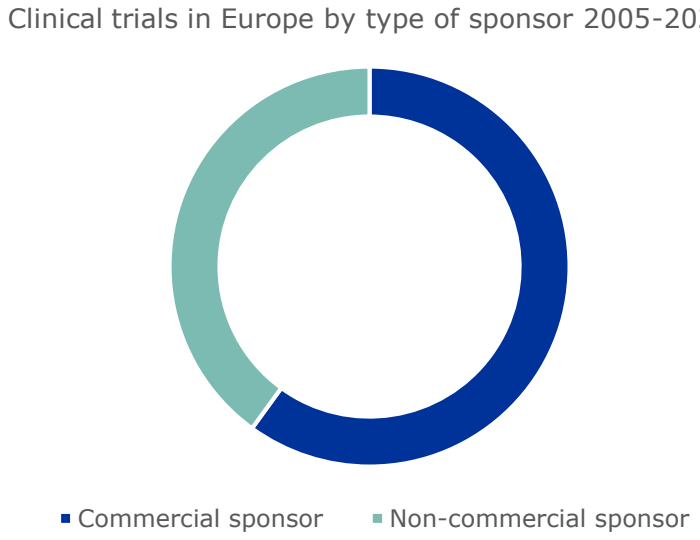
Clinical Trials Regulation
(No.536/2014)

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

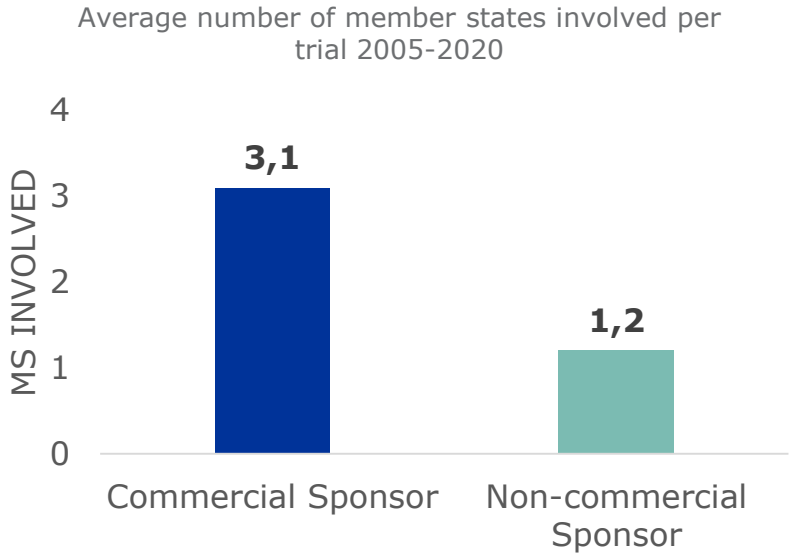
Applies as of **31 January 2022**

The climate for clinical trials in the EU

40% of clinical trials are non-commercial



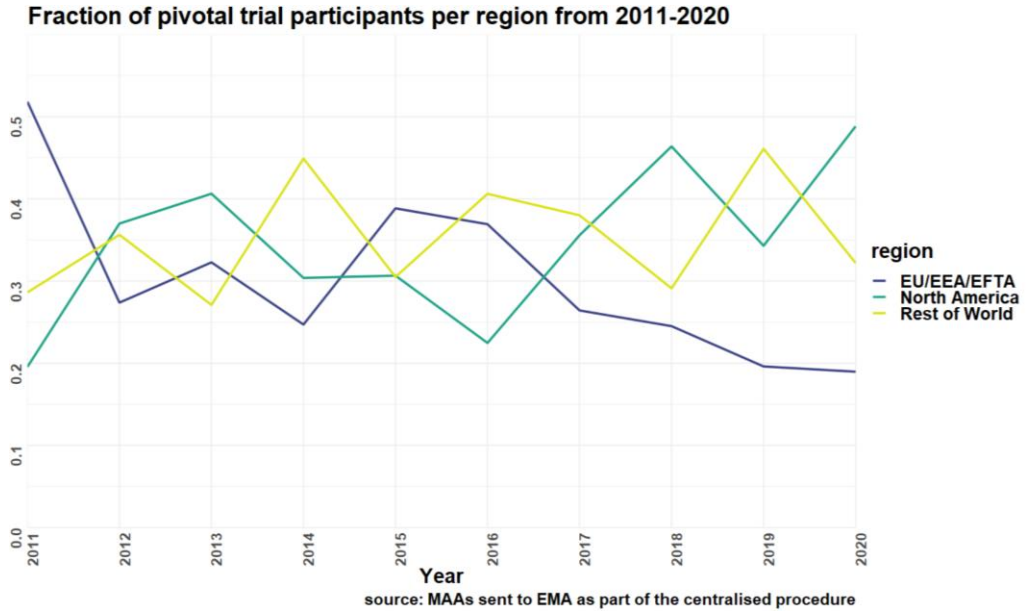
Non-commercial CTs are predominantly mono-national



The fraction of EEA trial participants is trending downwards

European trial participants in centralised procedure MAAs:

- Constituted only **19%** in 2020
- Has been **trending downwards** since 2015



- *Vaccines & therapeutics*
- *UK included as Rest of World*

Strengthening clinical trials in the EU

Three pillars of the Clinical Trials Regulation

Harmonisation

Harmonised clinical trial processes

- Collaborative assessment
- Reduced administrative burden
- Enabling multinational trials

Transparency

Increased transparency of clinical trials data

- Empowering patients & HCPs to find recruiting trials
- Enabling research

Safety

Enhanced safety procedures

- Single submission process for sponsors
- Increased cooperation for MS

The CTR and Clinical Trials Information System (CTIS)

CTIS is the business tool of the Clinical Trials Regulation.

CTIS **harmonises the submission, assessment and supervision of clinical trials** in the EU/EEA.

Public health

Facilitates multinational trials to address key health issues, increase transparency & enables patient enrolment

Research and innovation

Enables collaboration and access to clinical research data.

Global hub for clinical trials

Ensures the EU/EEA remains an attractive clinical research hub globally.

Accelerating Clinical Trials in the EU (ACT EU)

ACT EU is an 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
- Read the press release and paper

ACT EU objectives

Support the conduct of **large, multinational trials** with specific support for:

- SME, academia and Health Technology Assessment bodies (HTAs)
- Trials which address unmet needs, rare diseases & medicines for public health crises

Facilitate **coordinated scientific advice** to support trial authorisation, marketing authorisation & the medicine lifecycle

Ensure **a unified European approach** for trial processes and strategic matters at the international level

Engage all stakeholders to deliver inclusive patient-oriented medicines development and delivery across populations

ACT EU Priority actions for 2022-2023

Governance & Integration

1. Develop a **governance rationalisation strategy** (aligning different expert groups and working parties)

7. Reinforce the **coordination** between **scientific advice on CT approval and CT design** and link to the methodologies working party domain.

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.

Engagement

3. Establish a **multi-stakeholder platform**, including patients, after stakeholder analysis.

6. Plan and launch a targeted **communication campaign** to engage all enablers.

10. Deliver a clinical trials **training curriculum** on drug development and regulatory science with links to SMEs & academia.

Methods & Practice

4. Implementing the **GCP modernisation** informed by the development of guidance at ICH.

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).

Impact

2. The successful and timely **implementation of the CTR** and its implementing acts.

- **KPIs** to track performance of the European CT environment.
- **Promote larger, multinational trials** specifically in academia

5. **Analyse data about clinical trials** leveraging academic, non-profit, European, and international initiatives, improving the impact of policymaking and funding to support evidence-based decision making.

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Other important initiatives to strengthen clinical trials

- EMA Emergency Task Force (**ETF**) mandate strengthened for CT support
- Safety implementing regulation 31 January 2022 + EU4Health Joint Action on **safety monitoring**
- Joint Action on expedited **COVID-19 assessment**

What this means for PCWP-HCPWP

- For PCWP-HCPWP, the Clinical Trials Regulation, CTIS and ACT EU will:
  - support bigger and **better CTs**;
  - drive **innovation** in CT methods;
  - generate data about clinical trials to better understand and **address health needs**; and
  - provide an **opportunity to engage** through the multi-stakeholder platform

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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