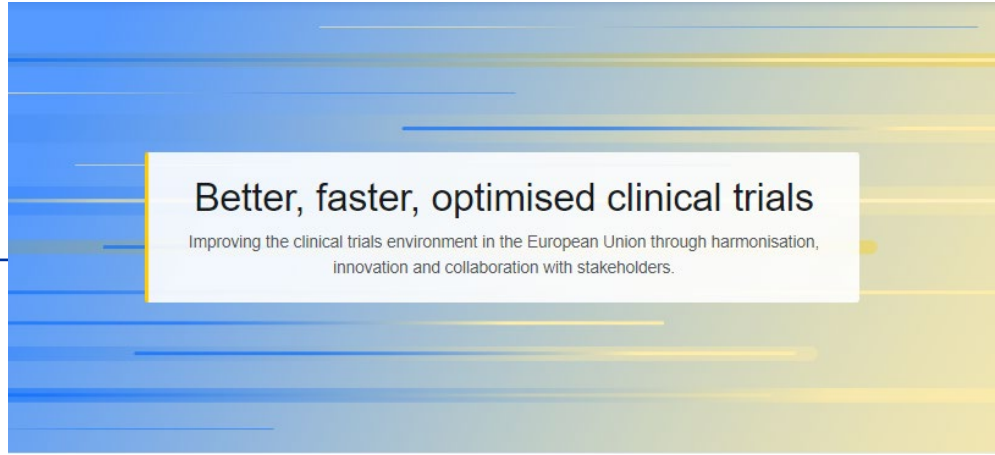
Multi-stakeholder platform meeting



Accelerating clinical trials in the EU (ACT EU) initiative

PCWP/HCPWP Meeting with all eligible organisations

Ana Zanoletty (EMA) and Denis Lacombe (EORTC)

How stakeholders are involved

Multi-stakeholder platform (MSP)

Multi-stakeholder workshops

Engagement tools
(consultations, surveys…)

+

MSP Advisory Group
Stakeholder representatives

Patients, industry, HCP, academia, funders, ethics committees, providing:

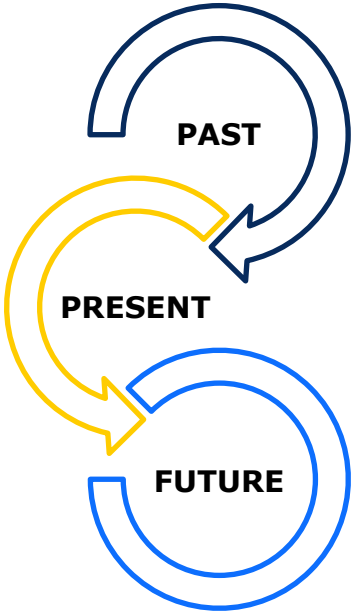
- strategic advice
- steer on engagement of stakeholders

Key objectives

- Accelerate change and innovation in EU clinical trials
- Build trust and understanding between stakeholders to drive change
- Enable and support capacity building and training
- Ensure timely transparency

Agenda of the 2024 MSP Annual Meeting

Session 1	Review of ACT EU's achievements and impact
Session 2	Discussion of current clinical trial landscape and stakeholders' needs
Session 3	Looking to the future to visualise what the success looks like for stakeholders



Review of ACT EU's achievements and impact

ACT EU is delivering benefits to clinical trial stakeholders across key areas, joint initiative of EMA, European Commission and Member States, through HMA:

Mapping & governance

Implementation of the Clinical Trials Regulation

Support for non-commercial sponsors

Multi-stakeholder platform

Good clinical practice modernisation

Clinical trials analytics

Consolidated advice on clinical trials

Clinical trials methodologies

Clinical trials safety

Clinical trials training curriculum

Clinical trials in public health emergencies

Review of ACT EU's achievements and impact

Increasing quality of applications and harmonisation

- Consolidated advice

Faster access to relevant information

- New CTIS transparency rules

Listening to stakeholders

- MSP Advisory group feedback

MSP Advisory group feedback

- ! CTR implementation, with several working groups already involved

  CTCG/CTAG/MedEthicsEU/Collaborate

  - Operational aspects (e.g., RFI/RMS/templates/national requirements/translations)
  - Technical aspects CTIS related (e.g., workflow, timelines, substantial modifications/IMPD)
- ! Funding infrastructure/funding scheme
- ! Clinical Trials on medical devices

- Low interventional trials and undertaking a risk-based approach
- Support to non-commercial sponsors/academia, particularly for CTIS and review ICH E6 (R3)
- Closer collaboration on paediatric trials including (CTCG/PDCO) for example about PIP, and more focus on paediatric population (patients' involvement but also on methodological aspects)
- Ethics Committees' involvement in the pilots on consolidated advice on clinical trials

MSP Advisory group feedback

- Methodologies and innovative trial designs:
  - Digital health
  - Pragmatic trials RWE/D
  - Complex trials
  - Clinical trials with decentralised elements
- Embedding clinical trials in normal clinical practice
- Cross border trials, patients' engagement and diversity in clinical trials
- More focus on ATMP, e.g., cell therapies/ gene therapies trial design and support to innovation

Current landscape

- Implementation of the Clinical Trials Regulation - what do the numbers tell us?
  - Stable submissions of new clinical trial applications
  - Increasing submissions of trial applications transitioning to the Regulation from the previous legislative framework (Clinical Trials Directive)
  - Timelines for new and resubmitted trial applications remain high

- A decreased share of global trials taking place in the EU, compared to the US & China
- Clinical research and health remain a key part of the European Commission's agenda

ACT EU partners

Collaboration between NCAs and Ethic Committees

- CTR Collaborate

Addressing CTR/IVDR/MDR interface challenges

- COMBINE

Strengthening collaboration between the MRECs across Member States

- MedEthicsEU

Member State work to increase harmonisation

- Clinical Trials Coordination & Advisory Group

Challenges faced by stakeholders

Stakeholders highlighted the following challenges that should be addressed to increase the EU's attractiveness for clinical research:

Lack of true harmonisation and need for reduced administrative burdens across Member States with streamlined timelines for assessment of trials

Lack of funding and capacity to address rare diseases and therapeutic advancements

Lack of patient involvement throughout the clinical trial lifecycle

The future of clinical trials in the EU

Several priorities emerged as common among stakeholders:

- Effective implementation of the CTR, addressing complexities related to the interface of CTR with other regulations
- Support for investigator-led trials and academic research
- Encouraging meaningful, patient-centered trials, especially for minorities and unmet medical needs
- Facilitating innovative, collaborative trial designs
- Supporting training, including for patients
- Promoting research in primary care, and utilizing technology and real-world data

Vision for success

Streamlined, pragmatic and inclusive clinical trials to address core challenges and strengthen the EU's clinical trial landscape

Key take-aways from the meeting

- Achievements of ACT EU and linked initiatives recognised as having a **positive impact** on clinical trial environment
- Challenges remain, with the need for "true harmonisation", resource alignment, simplification, legislative interplay between CTR/MDR/IVDR*
- A clear **sense of urgency** to address reported stakeholder priorities
- The **key to success**:
  - increase trials availability, accessibility and diversity
  - innovate methodology approaches
  - reduce unnecessary burdens
  - adjust on operational aspects to achieve harmonisation
  - continue with **stakeholder engagement**

*Clinical Trial Regulation/Medical Device Regulation/In vitro Diagnostic Regulation

What's next for clinical trials in the EU

- Keeping an **open dialogue** with stakeholders via the multi-stakeholder platform, considering enhancements where needed
- Incorporating key priorities and stakeholder needs into the ACT EU workplan and other relevant initiatives to identify **tangible solutions**

Meeting report and recording will be published on the event page.

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