ACT EU: summary of recent workshops and establishment of the Multistakeholder Platform Advisory Groups

28 February 2024

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European Medicines Agency

Overview of the regulatory landscape

- Two years since the launch of ACT EU
- Two years since the implementation of CTR and use of CTIS
- Several international collaborations (ICH, ICMRA, bilateral collaboration EMA/CTTI and EMA/WHO, etc..)
- EU Health Data Space
- Interplay CTR/IVDR/MDR
- Opportunity to combine clinical trials data with Real world evidence data
- Creation of an EU ethics platform
- AI

Clinical Trials Coordination Group (CTCG) - ethics collaboration

Aims to optimise alignment between NCAs and ethics bodies, ensuring harmonisation and seamless cooperation for safe, high-quality trials

Survey to map landscape of part I assessment NCA/ethics

Lists of **issues** and **proposed solutions** to optimise work procedures

Joined (NCA and ethics) **update of best practices**

Implementation of best practices via CTCG roundtables/ workshops to harmonise and collaborate

Communication with NCA/ethics/sponsors

MedEthicsEU

Initiative from Ethics committees in cooperation with European Commission

Position of ethics committees in assessment of clinical trials changed with CTR:

- only one MS decision integrating conclusions from NCA and Ethic Committees
- CTR timelines for assessment
- mandatory use of a Clinical Trial Information System (CTIS).

Need for increased alignment between the research ethics committee system of the different MSs in the EU.

The EU Ethics Group will aim to:

- strengthen cooperation between EU ethics committees
- facilitate exchange of experience
- align best practices and provide training.
- integrate ethics in European Medicines Regulatory Network (EMRN)

ACT EU Priority actions 2023-2026

ACT EU is delivering benefits to clinical trial stakeholders across key areas:

Mapping & governance

Implementation of the Clinical Trials Regulation

Multinational clinical trials by non-commercial sponsors

Multi-stakeholder platform

Good clinical practice modernisation

Clinical trials analytics

Scientific advice

Clinical Trials methodologies

Clinical trials safety

Clinical trials training curriculum

Clinical trials in public health emergencies

Action plan to support non-commercial sponsors

- Mapping existing initiative at national/EU level (*signposting*)
- Optimisation of regulatory helpdesk, leveraging national initiatives
- CTR/CTIS support (*handholding*) for large multinational clinical trials, including support for transitional trials from CTD to CTR
- Advice for large multinational clinical trials
- Involvement of academia in the MSP AG
- Communication campaign, workshops and trainings

Resulting in:

- Higher number of non-commercial multinational clinical trial;
- Non-commercial clinical trials generating **high quality scientific evidence**
- **Benefit for EU citizen's health** through optimized therapies and access to innovative medicines

Clinical trial analytics workshop

Held on 25 and 26 January 2024

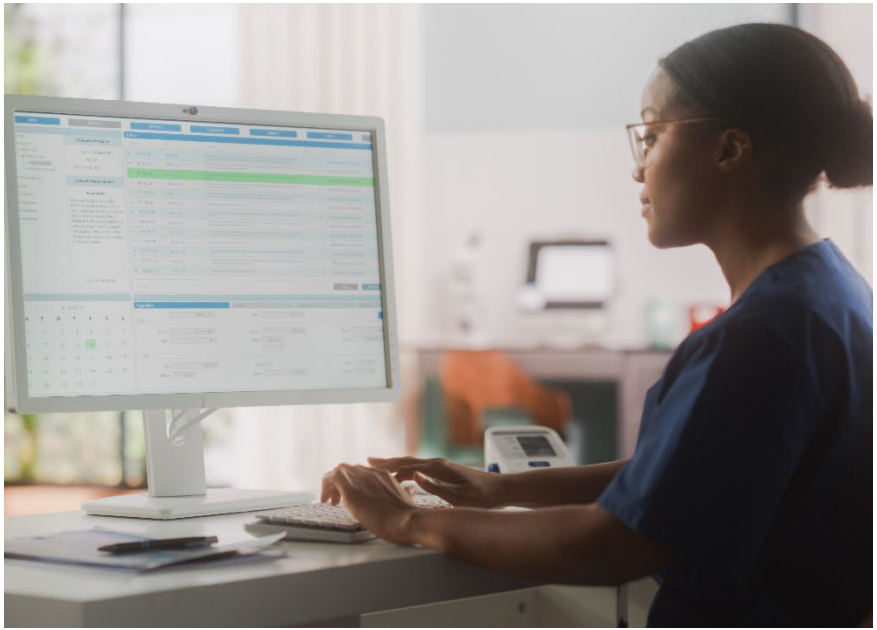
Over 80 F2F participants, around 140 online

Key takeaways

- Desire for improved access to more detailed & up-to-date CT data
- Importance to have patients actively involved
- Identify the right data sources
- Standardisation can play a crucial role

Next steps

- Publication of video recording & presentations on event page
- Workshop report publication March 2024



Consolidated scientific advice pilots

SAWP-CTCG

- One single point for scientific aspects on clinical development.
- Mechanism to discuss topics of common interest for CTCG/SAWP, also likely to impact on trial/program design for MAA.
- Identifying and understanding positions/challenging rationales, higher chances for harmonised position from the different perspectives.

CTCG pre-CTA advice

- One single point of contact for administrative aspects of the CTA
- Will be delivered via the SNSA procedure

Launch of both pilots: Q2 2024

Clinical trial methodology guidance workshop

Held on 23 November 2023 with over 110 participants

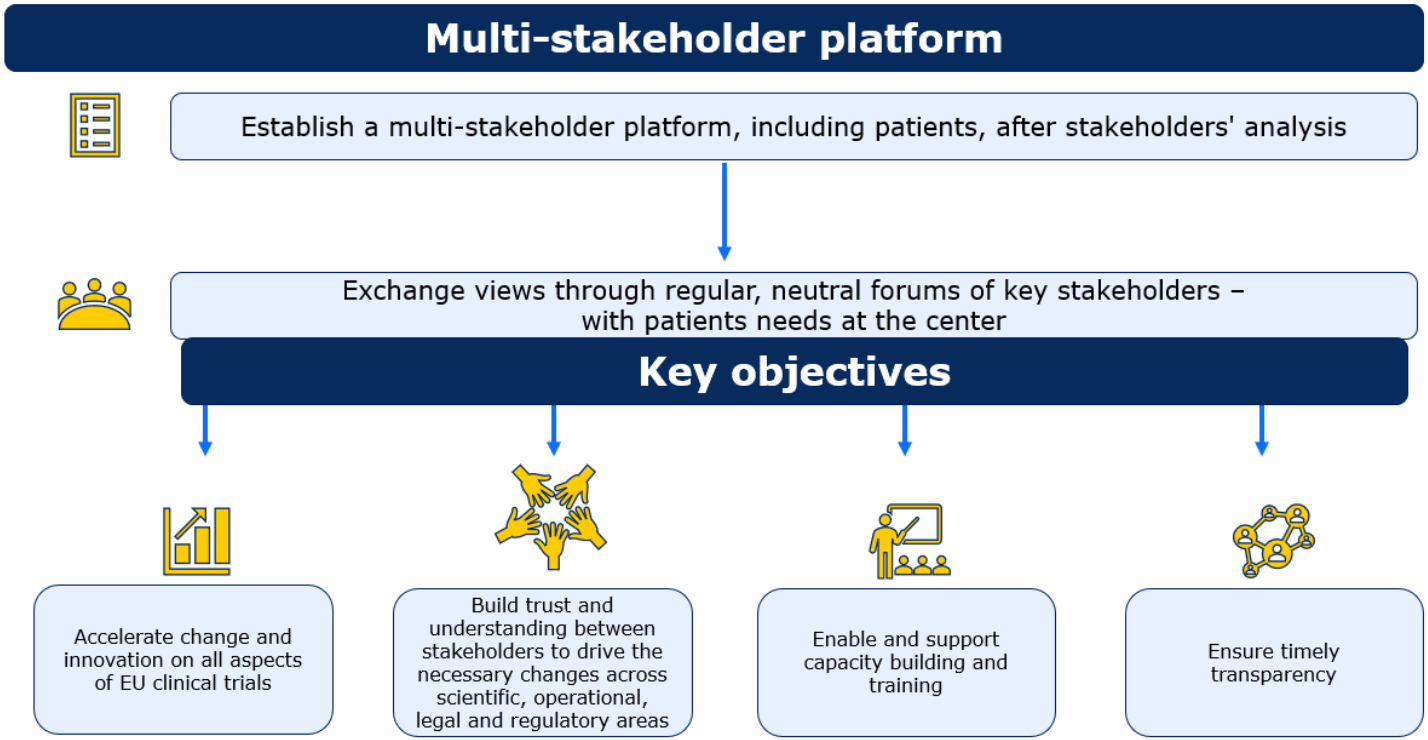
Highlights

- Stakeholders and regulators exchanged views on key methodology topics - focus on patients' needs
- Collaboration in breakout sessions to identify main challenges per topic and ways forward
- Meeting documents published on event page

Next steps

- Publication of the workshop report end-February 2024, summarising key conclusions from the discussions
- Report as input for future methodology guidance development by the network

ACT EU Multi-Stakeholder Platform



Concept paper: an EU multi-stakeholder platform for improving the EU clinical trials environment

How the Multi-stakeholder platform works

Multi-stakeholder platform

Multi-stakeholder workshops

Engagement tools

(consultations, surveys…)

MSP Advisory Group

Stakeholder representatives

providing:

- strategic advice
- steer on engagement of stakeholders

MSP Advisory Group

- 1 **Regulator Co-chair** rotated within ACT EU: Maria Lamas (AEMPS)
- 1 **Stakeholder Co-chair** selected amongst MSP AG non-commercial representatives and agreed by ACT EU Steering Group (SG)
- **Inaugural meeting** 20 March 2024, incl. launch of Stakeholder co-chair nomination process
- **Stakeholder co-chair appointment** in April 2024.

Twenty (21) permanent stakeholder representatives appointed via **public call for expression of interest**:

- from patients/consumers organisations,
- from healthcare professionals' organisations,
- from industry EU trade organisations,
- from academia and funders.

- ACT EU regulatory partners
- 2 Ethics Committee representatives
- Ad hoc participation of other experts (HTA, ACT EU Priority Actions, payers, international authorities)

More information on the ACT EU website: Multi-stakeholder platform

Looking ahead

Q1-Q2 2024

- First meeting of the MSP Advisory Group
- Launch of scientific advice pilots
- ACT EU Multi-stakeholder Platform annual meeting
- CTIS workshop on best practices for transitioning trials to CTR

Q3-Q4 2024

- ACT EU multi-stakeholder workshop on methodology guidance in CTs
- ACT EU multi-stakeholder workshop on ICH E6 R3
- ACT EU Annual matrix meeting

Any questions?

Further information

ACT EU website
Clinical trials in human medicines | European Medicines Agency (europa.eu)

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