ACT EU Programme overview

MSP Annual meeting 22 October 2024

ACT EU Priority actions 2023-2026

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

Multinational clinical trials by 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

Mapping & governance

Map existing expert groups dealing with clinical trials considering a governance rationalisation strategy

Aligning different expert groups and working parties in the EMRN and ethics infrastructure

- Mapping of existing clinical trials governance groups published
- **CTR Collaborate initiative** established and anchored to ACT EU PA1

Implementation of the CTR

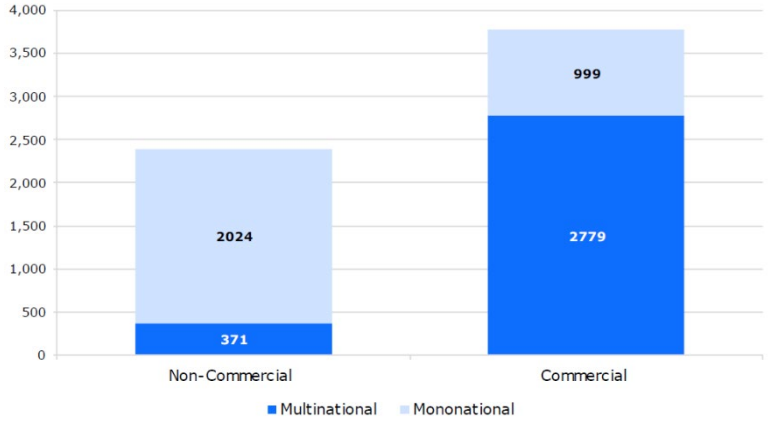
Supporting the successful and timely implementation of the Clinical Trials Regulation

1. Key performance indicators (KPI) tracking implementation of the CTR via monthly reports since May 2022.
2. Prioritising and resolving sponsor issues with CTIS/CTR implementation with regular surveys submitted to CTIS users to capture feedback on their user experience
3. Transitioning clinical trials
   - Workshops (Q1 2024), publication of key documents defining requirements to transition clinical trials on Eudralex V 10 and CTCG websites
   - Annexes available on cover letter and fees for transitional trials
   - Communication campaign
4. Transparency: revised CTIS transparency rules

Support to non-commercial sponsors

Create an action plan to help non-commercial sponsors to plan and initiate multinational CTs

Authorised clinical trials since 31 January 2022



Tailored initiatives, resulting in:

- **higher number** of non-commercial CTs conducted in more than one EU/EEA MS
- **high quality** scientific evidence generated by non-commercial clinical trials
- benefit for **EU citizen's** health through optimised therapies and access to innovative medicines

Source: *Monitoring the European clinical trials environment September 2024*

Support to non-commercial sponsors

1) Interactive map showing existing initiatives at national level (via CTCG) and other stakeholders initiatives published in June 2024:

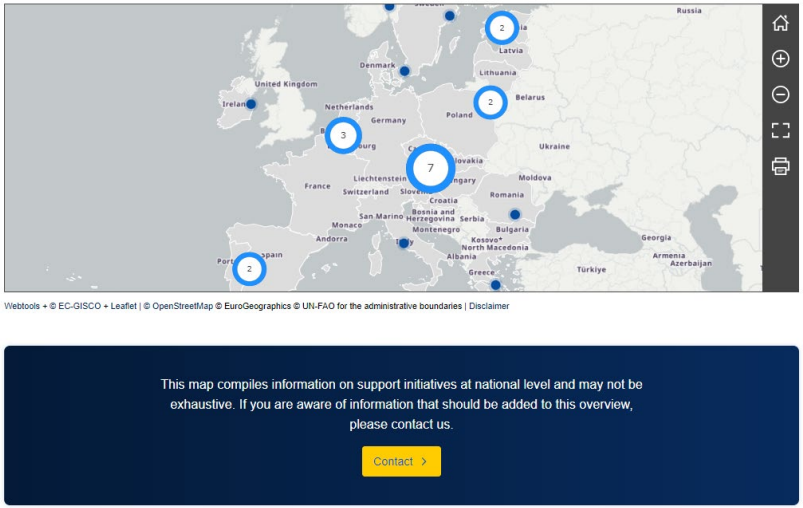
- page updated on regular basis with feedback from member states; as soon as new information becomes available;
- page populated with other initiatives (Enpr-EMA)

2) Launch of the helpdesk for non-commercial sponsors:

- dedicated support on CTR and on CTIS use with involvement of NCAs

3) Next steps:

- closer collaboration with the MSP AG to gather feedback on needs;
- organisation of training material and guidance for non-commercial sponsors.



Good Clinical Practice modernisation

Support the modernisation of good clinical practice in order to align with the increasingly diverse range of clinical trial types and data sources

- CHMP adoption of final text for principles and Annex I expected in Q4 followed by implementation in the region
- Annex II public consultation expected Q4 2024
- Broadcast workshop planned for 19 and 20 February 2025, to discuss final adopted text
- Impact analysis and change management in relation to the implementation of ICH E6(R3) and interplay with EU guidance
- Coordinate with relevant stakeholders (e.g. GCP IWG, ICH E6(R3)) Expert Working group on relevant training/communication and change management

Clinical trials data analytics

Highlighting research needs and facilitating analysis of clinical trial data

- Multi-stakeholder workshop on the needs for access to, and analysis of, data on clinical trials in January 2024 (Report)
- Ongoing development of a research priorities paper that may be put forward for EU-level funding, based on use-cases for data analytics identified during the workshop
- Possibility to link the EU-level funding to deliver the research priorities

Clinical trial methodologies

Facilitating aligned clinical trial guidance development resulting in high impact guidance documents implemented in practice

- Multi-stakeholder methodology workshop in November 2023 (Report) setting the scene for 2024 activities
- Established process in place for regular exchange between MWP, CTCG and HTA coordination group
- (Ongoing) development of a best practice document on guidance development in the European Medicines Regulatory Network

Clinical trial safety

Aims to successfully establish clinical trials safety surveillance in the European Union

- EU4Health Joint Action - SAFE CT: Capacity building, mentorship programme & assessors' training ongoing (incl. ICH E19)
- Process established for network and safety coordination – CTCG best practice finalised and implemented, sharing expertise and cases (monthly roundtable, events)
- Annual IT review: identification and re-prioritisation of CTIS functionalities for safety in collaboration with MSs and Sponsor Product Owners

Clinical trials training curriculum

A training curriculum informed by regulatory experience, with modules on drug development and regulatory science.

- Gap analysis on training needs **for regulators** started in September 2023, finalised in Q1 2024
- Summary of gap analysis report published in March 2024
- Training needs for **academia and SME** being defined, starting from STARS curriculum, consulting first regulators moving then to the interested parties (academia and non-commercial sponsors)
- Stakeholders' engagement exercise planned

CTs in public health emergencies

Aims to facilitate large and multinational clinical trials in the EU to promptly tackle public health emergencies

- Establishment of a PHE Ethics Advisory Group through MedEthicsEU in July 2024 with 14 appointed members
- First meeting of the PHE Ethics advisory group on 21 November together with ETF and the members of the PHE priority action
- Proposal for simplifications of dossier requirements for clinical trials in PHE
- Analysis of the COVID-19 guidance and existing guidance documents, adjusting to extend to PHEs

Any questions?

Further information

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