4th National Meeting on Clinical Research & Biomedical Innovation

Ensure faster and better clinical trials in the EU – ACT EU

Marianne Lunzer (CTCG) - 14 May 2025

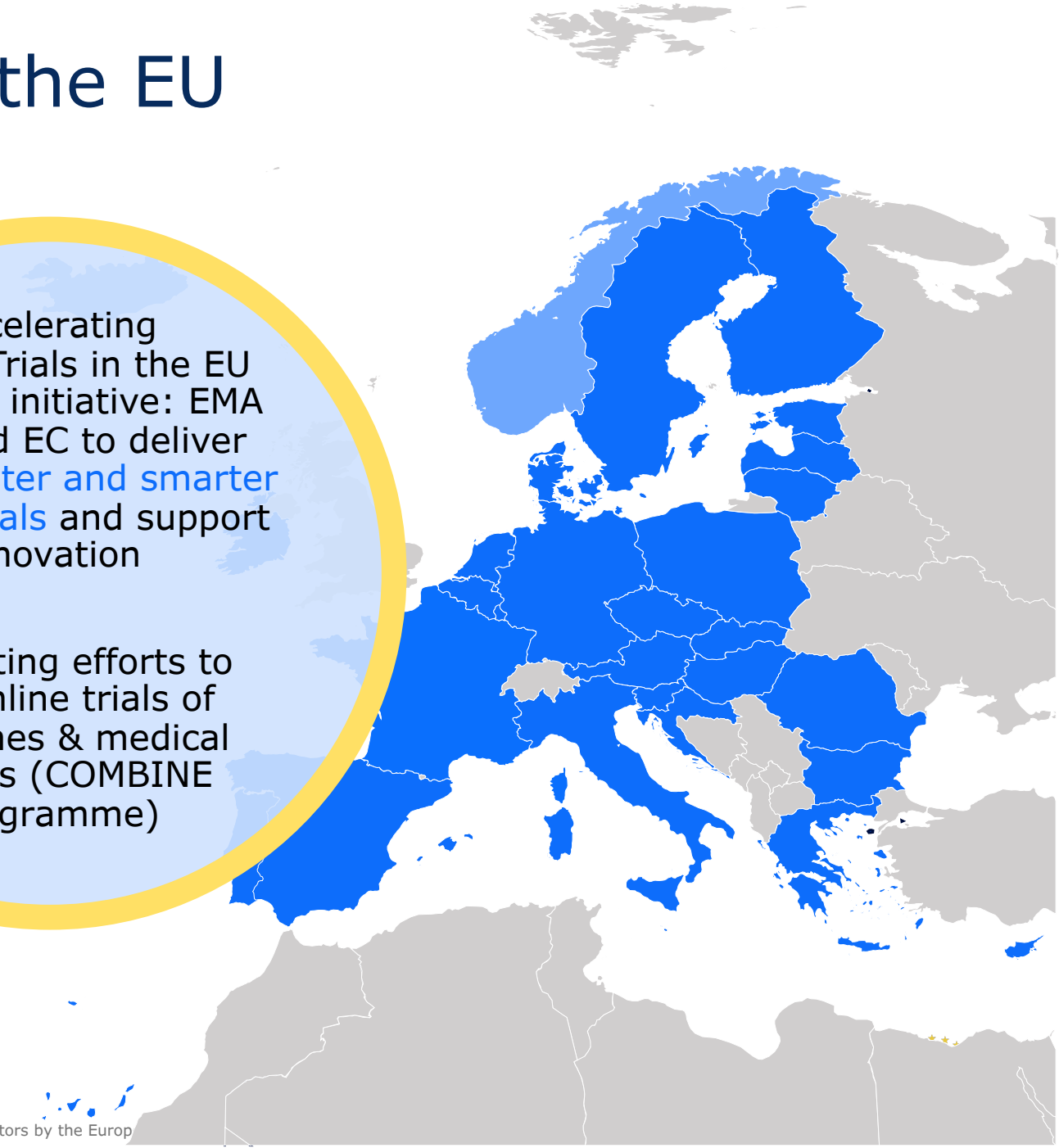
Supporting clinical trials in the EU

Supporting the implementation of the Clinical Trials Regulation and further harmonisation (CTR Collaborate)

Maintaining and improving the Clinical Trials Information System (CTIS), the IT tool of the CTR

Accelerating Clinical Trials in the EU (ACT EU) initiative: EMA HMA and EC to deliver better, faster and smarter clinical trials and support innovation

Supporting efforts to streamline trials of medicines & medical devices (COMBINE programme)



Clinical trials: the EU landscape

More information on the ACT EU website: [Mapping & governance]

European Commission | EMA | HMA Heads of Medicines Agencies

Implementing and monitoring impact of the CTR

√ Surveys, KPI reports

A voice for stakeholders

√ Multi-stakeholder platform (MSP) & MSP Advisory Group established

√ Workshops on key topics

Increased transparency of clinical trials

√ Simplified CTIS transparency rules

√ More user-friendly public portal

Consolidated advice for clinical trials

√ Pilots for scientific and regulatory advice

Support for non-commercial sponsors

√ Mapping of existing national initiatives

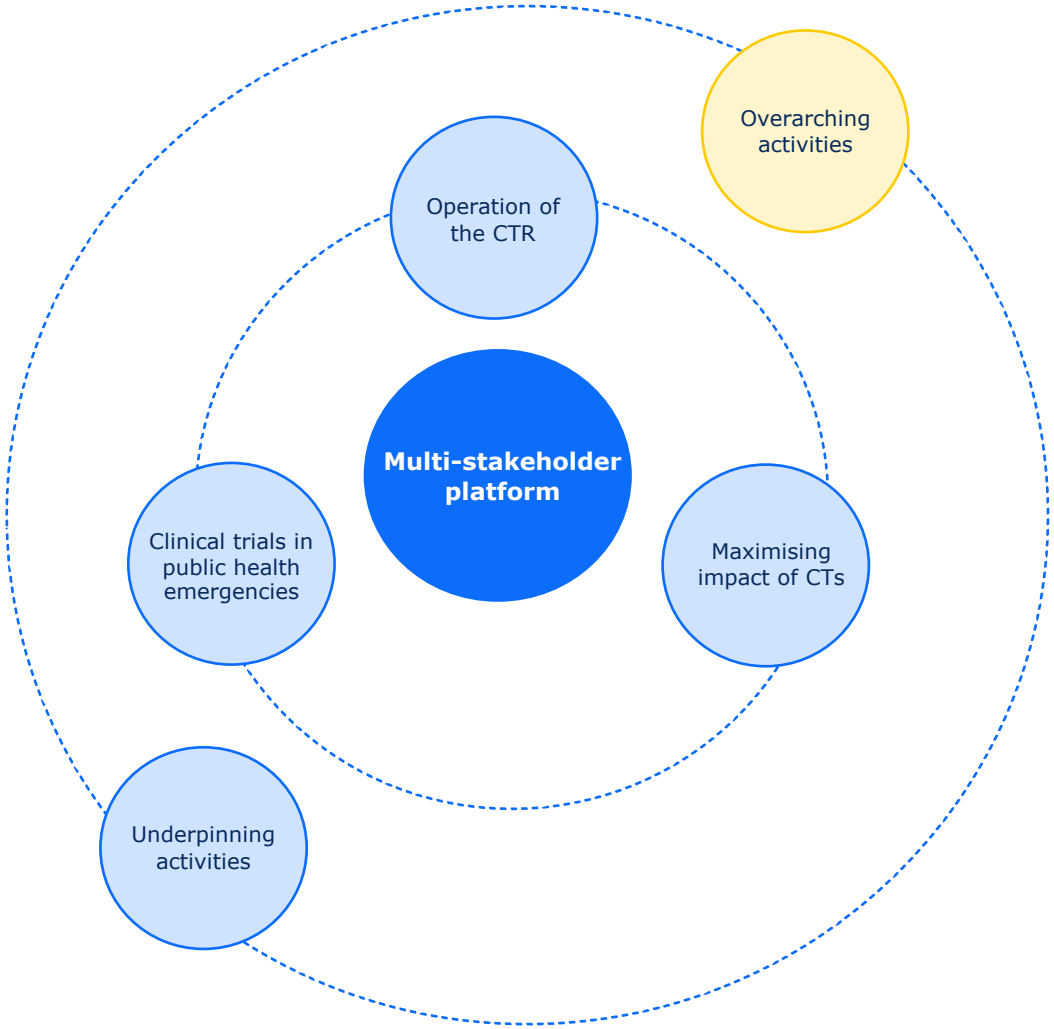
√ First steps in creating regulatory helpdesk

Training

√ Training needs for CT assessors published

√ Analysis of training needs for regulators, academia & SMEs started

ACT EU focus 2025-2026



Overarching activities:

- ACT EU governance
- Multi-stakeholder Platform

Operation of the Clinical Trials Regulation:

- Implementation of the Clinical Trials Regulation
- Support for non-commercial sponsors
- Clinical trials safety

Maximising impact of clinical trials – design and conduct of excellent clinical trials:

- Good clinical practice modernisation
- Consolidated advice on clinical trials
- Clinical trials methodologies

Underpinning activities:

- Communication
- Clinical trials analytics
- Clinical trials training

Support to non-commercial sponsors

Objectives

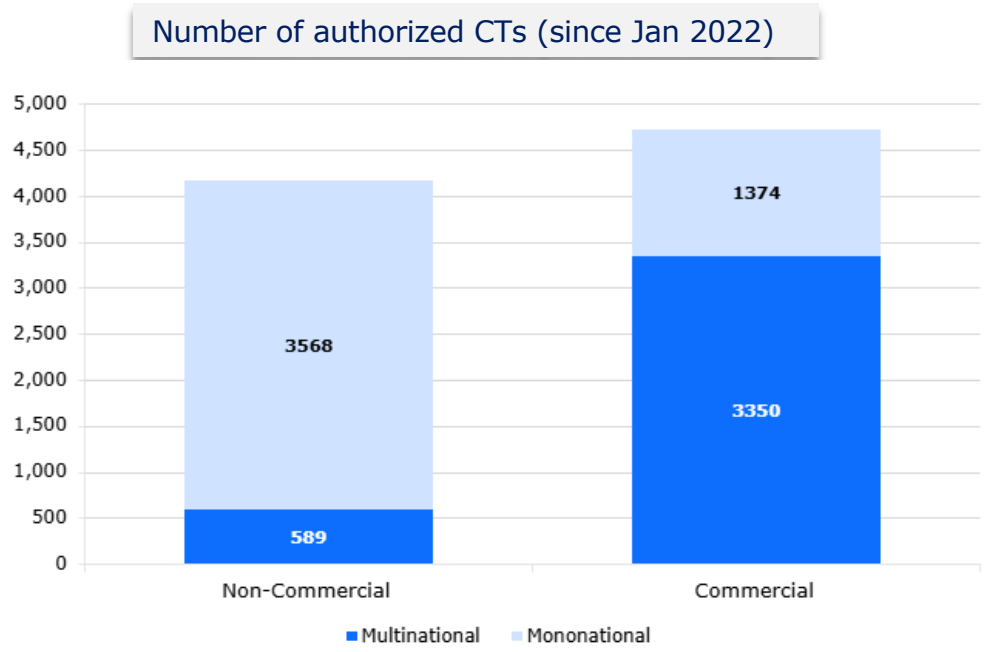
- More multinational clinical trials by non-commercial sponsors
- Clinical trials by non-commercial sponsors generating **high quality scientific evidence**
- **Benefit for EU citizen's health** through optimised therapies and access to innovative medicines

Action plan in progress

- A live **interactive map** of national initiatives on the ACT EU website (*signposting*), with input from NCAs, that is kept updated
- Optimisation of regulatory helpdesk offering CTR-CTIS support; around 1170 tickets addressed since mid-October 2024
- Involvement of academia in the MSP Advisory Group

European Commission | EMA | HMA Heads of Medicines Agencies

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



The programme intends to propose pragmatic and harmonised solutions to support non-commercial sponsors setting up and conducting clinical trials across the European Union / European Economic Area.

European Commission | EMA | HMA Heads of Medicines Agencies

Pilots on scientific and regulatory advice

- ACT EU launched **two pilots on consolidated advice on 10 June 2024**
- 21 applications received so far

Pilot I: Scientific Advice Working Party (SAWP)-Clinical Trials Coordination Group (CTCG)

Pilot II: Pre-CTA (clinical trial application) advice

Webinars for applicants (recorded) and for assessors

Published guidance documents on ACT EU website

Up-to-date mapped information on current voluntary advice procedures available from EU regulators

Lists: Member States participating in ACT EU pilots on consolidated advice

How do the pilots contribute to optimised CTs in the EU?

Early dialogue between sponsors and regulators

Well-designed CT

Harmonised opinions

Rapid and smooth approval of CT applications

Data integrity

Decision making

Accelerating patient access to medicines

Consolidated advice achievements: 21 applications received

SAWP-CTCG

7 procedures:

- 4 successfully concluded
- 2 ongoing
- 1 under validation

Pre-CTA

14 procedures:

- 12 successfully concluded
- 2 rejected at the validation phase

Early feedback from applicants

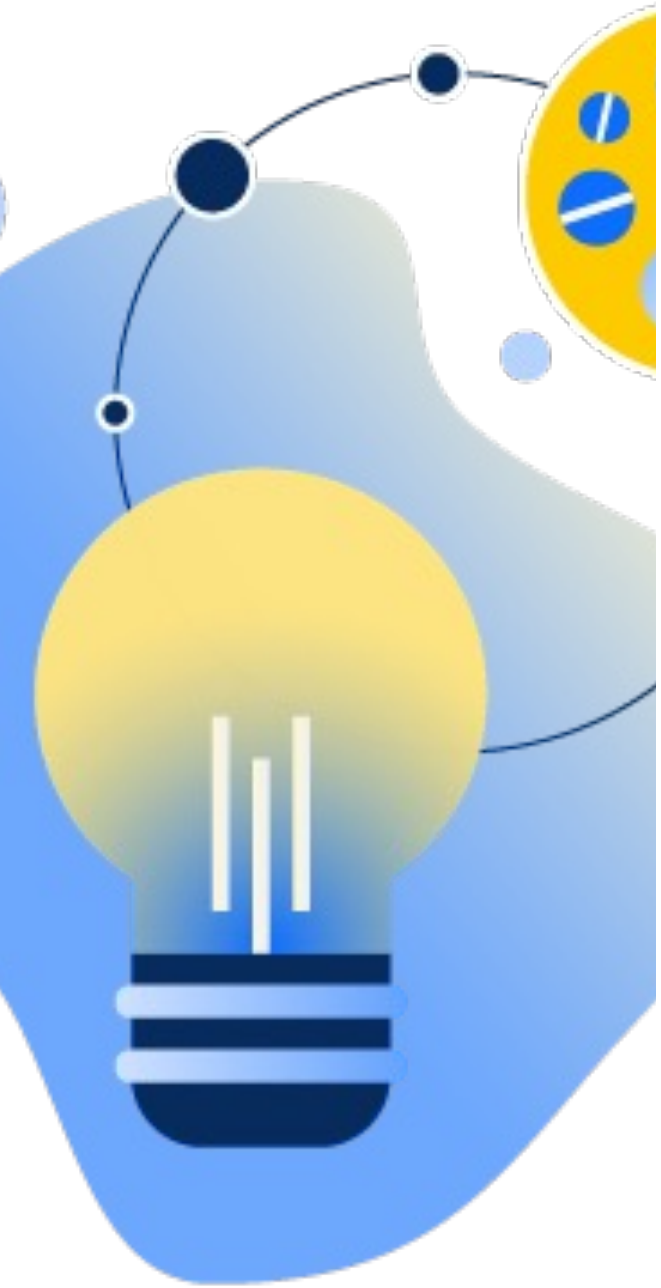
- ✓ Opportunity to identify issues ahead of CTA submission
- ✓ Harmonisation of scientific and regulatory expectations
- ✓ Greater consistency and streamlining the process for multinational trials
- ✓ Cut down the number of issues raised during the CTA
- ✓ Simple and smooth procedures to obtain the advice

Data Analytics – Trial Map

- Created based on stakeholder feedback from the ACT EU workshop on data analytics held in January 2024:

"…a simple, patient oriented, dashboard available in CTIS, that patients, their carers or their healthcare professionals, can use to locate potentially suitable trials for the patient, should be set up by EMA"

- Launched on 3 March 2025 on CTIS public website
- Public webinar on how to use the Trial Map on 7 March; recording soon to be available on the event page
- We need your feedback to inform future versions of the map



Conclusions

- Regulators across EU/EEA collaborate actively to invigorate the Clinical Trials ecosystem
- Dedicated support is provided to non-commercial sponsors (to support multi-national applications)
- Advice pilots have been launched to streamline individual procedures and to inform regulators on topics for future guidance
- Increased transparency of Clinical Trials in EU/EEA for researchers and patients
- The success of all activities is monitored by predefined criteria

Thank you

Muito obrigado pela vossa atenção.

marianne.lunzer@ages.at