Accelerating Clinical Trials in the EU (ACT EU)

General update on ACT EU

PCWP-HCPWP meeting, 18 November 2025

Presented by Laura Pioppo
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European Medicines Agency

ACT EU partners

- A joint initiative by the European Commission, Heads of Medicines Agencies and EMA
- Established in 2022 with a vision to have better, faster and smarter clinical trials in the EU
- Building on the momentum of the implementation of the Clinical Trials Regulation (CTR)

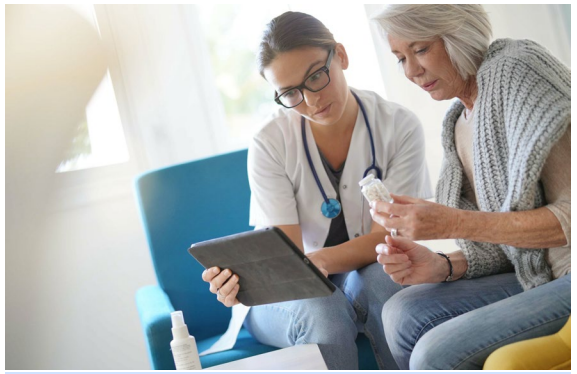
Background: Monitoring CT environment

- **Aim:** monitor the clinical trial environment to render the EU a favourable environment for clinical research
- **Three** overarching benefits identified, two KPIs to be measured against targets, news announcement

Increased attractiveness of the EU

KPI 1: Number of authorised multinational clinical trials

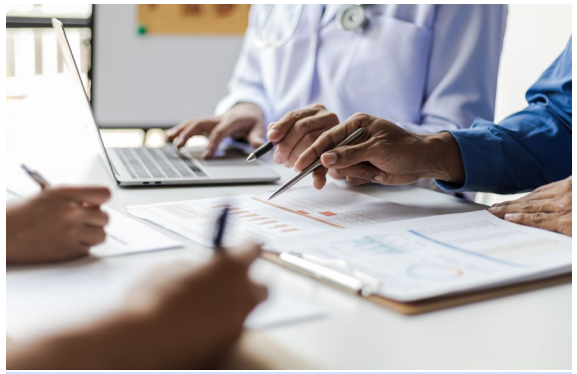
Target : 500 additional clinical trials in the EU in 5 years



Faster access to treatment

KPI 2: Recruitment of patients at the first MSC ≤200 calendar days after CTA submission

Target : 66% of clinical trials recruiting within expected timeframe



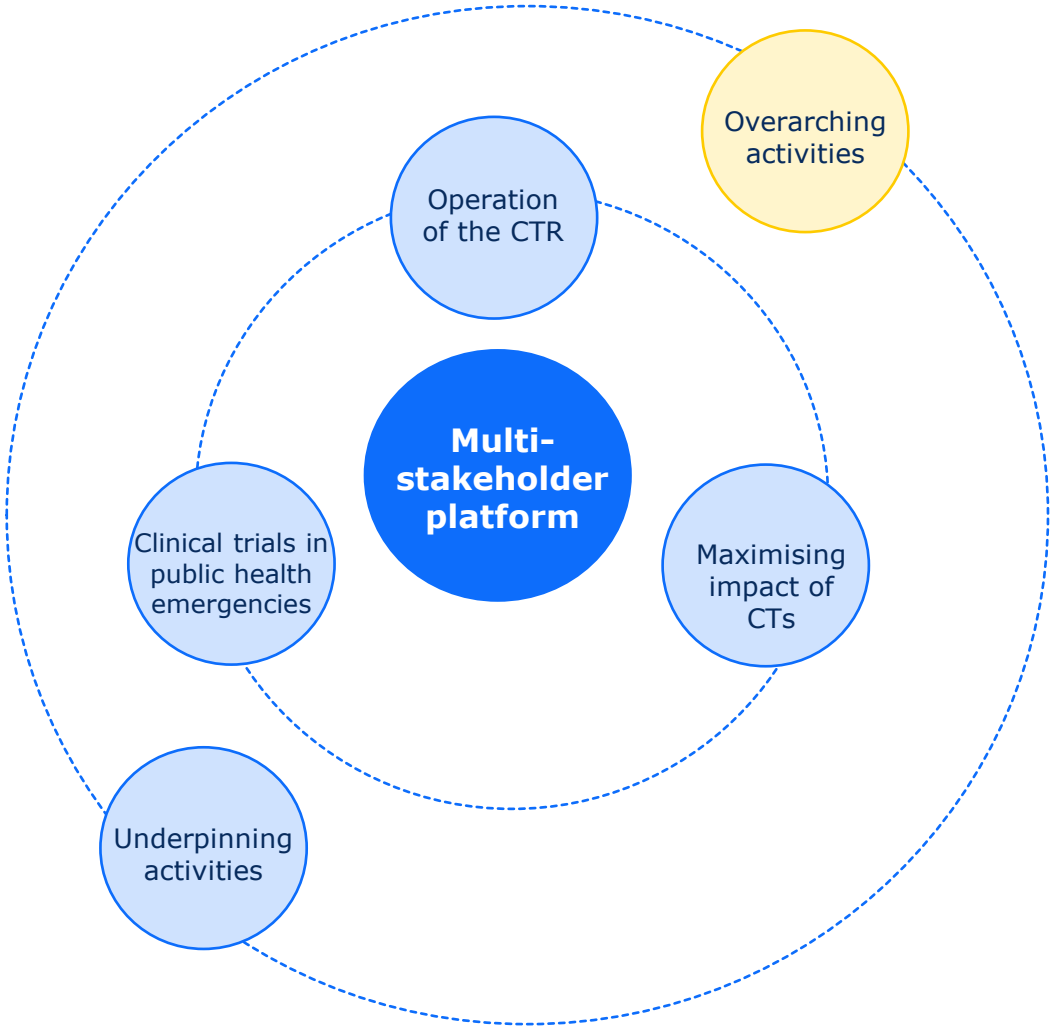
Impactful clinical trials

With input from **MSP AG:** composite approach, no single KPI but several sub-metrics measured regularly (using CTIS data) and periodically (e.g. qualitative study)

- KPIs to be published on ACT EU website and new metrics to complement already existing reports (updated on quarterly basis)

MSC – Member State concerned

ACT EU focus 2025-2026



Overarching activities:

- ACT EU Governance
- Multi-stakeholder Platform

Operation of the Clinical Trials Regulation:

- Implementation of Clinical Trials Regulation
- Support for non-commercial sponsors
- Clinical trial 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

Implementation of the Clinical Trials Regulation

Delivered in 2025:

- Quarterly reports to monitor the performance of the EU clinical trials environment published on the ACT EU website
- Publication of the 3-year analysis report for CTIS data during transition period
- Redesigned CTIS training material for sponsors, with publication of a master handbook for sponsors
- Publication of mostly frequently raised requests for information (RFI) part I and part II

Upcoming:

- Publication of sponsor FAQ on CTIS in Q4 2025
- Workshop on contractual agreements in Q1 2026
- Risk based approaches workshop (F2F) in Q1 2026

Support for non-commercial sponsors

Delivered in 2025:

- 2 webinars occurred (IE and AT) and 2 planned (BE and FR) on fostering clinical research by non-commercial sponsors
- Continued tailored technical assistance on CTIS functionalities and regulatory requirements provided under regulatory helpdesk, 6-month report analysis recently published
- Map of national support initiatives kept up-to-date on ACT EU website
- Other stakeholders' initiatives: signposting (example waivers for scientific advice)

Upcoming:

- Continue hosting ACT EU webinars for academic sponsors
- Continue support through the regulatory helpdesk
- Workshop on fostering clinical research by non-commercial sponsors planned for 2026

Good clinical practice modernisation

Delivered in 2025:

- Workshop on ICH E6(R3) principles and Annex 1 held on 19-20 February followed by 2,000 participants from 50 countries, with video recording, agenda and presentations published on the event page
- Workshop report published on ACT EU website
- Communication on ICH E6(R3) principles, Annexes 1 via the newsletter (February 2025, April 2025, July 2025, November 2025) and the ACT EU webpage: Good clinical practice modernisation

Upcoming:

- Finalisation of Annex 2
- Implementing the changes in EU guidance documents referring to ICH E6(R3)
- Workshop on ICH E6(R3) implementation planned for late 2026
- Training and change management activities with focus on academia

Clinical trials methodologies

Delivered in 2025:

- Signposting of existing guidance on clinical trial methodologies on ACT EU website
- **Coordination between CTCG, MWP and HTA** on methodology guidance established and ongoing
- Workshop on Bayesian statistics on 17 June 2025, with the video recording, agenda, presentations published on the event page
- Workshop for assessors of paediatric trials on 14-15 July 2025, report published
- Workshop on external controls on 3 November 2025, recording to be published on event page
- Updated recommendation paper on clinical trials with decentralised elements

Upcoming:

- Roadmap/overview of guidance documents on clinical trials under development
- Workshop with Enpr-EMA planned for 2026
- Workshop on platform trials planned for 2026

CTCG- clinical trials coordination group, MWP- methodology working party, HTA – health technology assessment

Clinical trials analytics

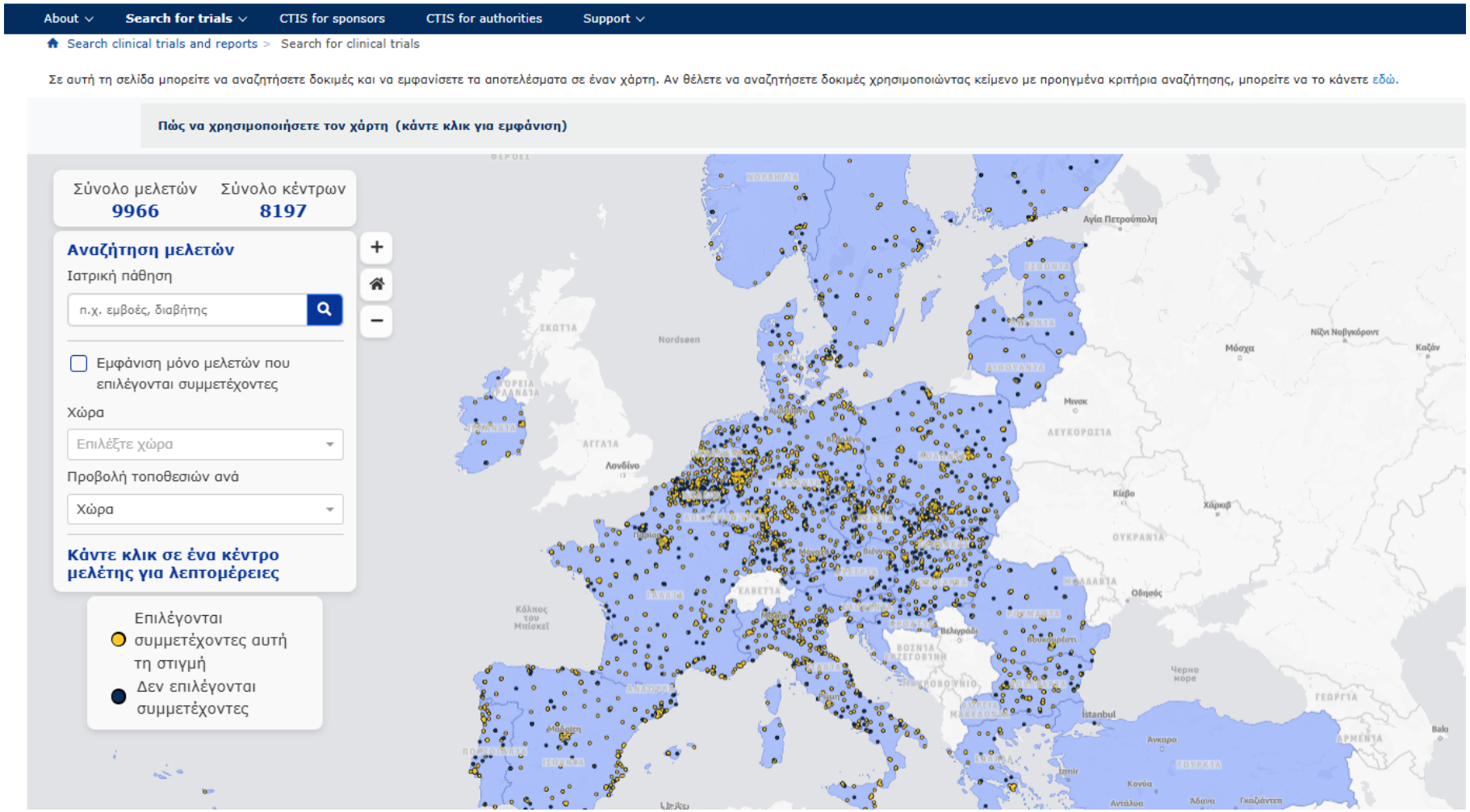
Delivered in 2025:

- Launch of Trial Map on 3 March 2025; dedicated demo and materials available on the event page
- Launch of Trial Map in all the EU/EEA official languages on 29 October 2025

Upcoming:

- Publication of paper on clinical trials analytics following 2024 workshop (report)
- Publication of paper on clinical trials trend based on info in EU CTR and CTIS
- Building a network of experts (EMA/MSs/EC) looking at analysis of CT data
- Future releases of the Trial Map with more features

Trial Map



[Search for clinical trials – CTIS website]

- **Trial Map** developed to empower patients and healthcare professionals
- Integrated with CTIS public portal
- Easy access to information on clinical trials by geographical region and disease area

Additional activities

Training needs for academia and SME:

- Survey conducted in Q1 2025
- Feedback from academia and SME analysed and reflected in a published report
- Next steps include mapping and signposting of existing offerings and collaboration with WHO

Pilots on consolidated advice in clinical trials:

- Initiative to facilitate dialogue between sponsors and regulators
- Focus on scientific (SAWP/CTCG) and regulatory aspects of the CTA (pre-CTA CTCG led)
- 28 applications received since the launch of the initiative
- Positive feedback from applicants, consideration on whether to move to permanent offerings

CTA – clinical trial application, SAWP – scientific advice working party

How to stay informed

[Subscribe](#) to the CT Highlights newsletter and CTIS Newsflash

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Thank you

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