Accelerating Clinical Trials in the EU (ACT EU)

Revised workplan 2025-2026

PCWP-HCPWP meeting, 1 April 2025

Presented by Laura Pioppo
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European Medicines Agency

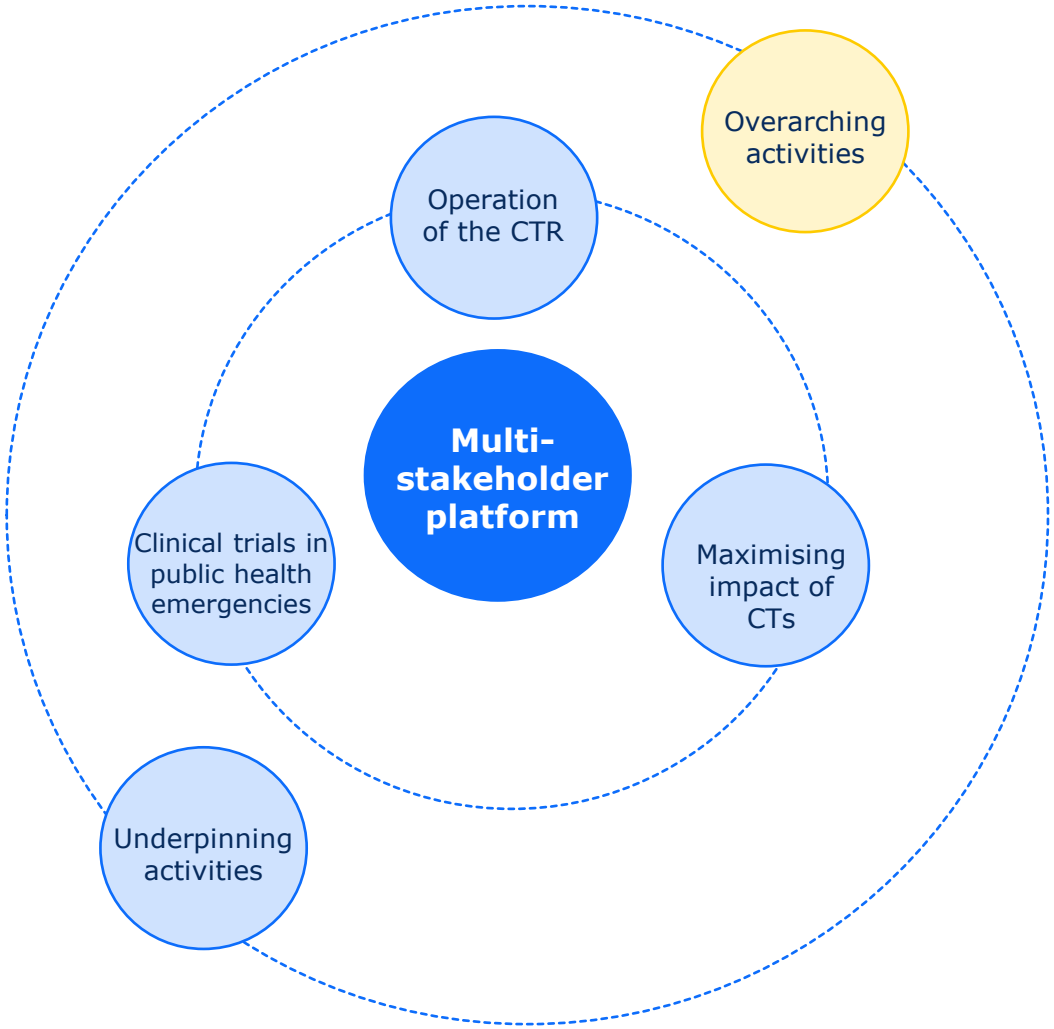
ACT EU partners

- A joint initiative by the European Commission, Heads of Medicines Agencies and EMA
- Established in 2022
- Building on the momentum of the implementation of the Clinical Trials Regulation (CTR)

“Our vision is to have **better, faster and optimised** clinical trials in the EU, creating a favourable environment for clinical research.”

ACT EU partners

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

Towards our vision: ACT EU workplan 2025-2026

- Revision driven by stakeholder feedback collected via:
  - MSP advisory group
  - Sponsor survey on implementation of the Clinical Trials Regulation (CTR) by Clinical Trials Advisory Group (CTAG)
  - CTR Collaborate (CTCG)
- Significant overlap in the feedback collected via the different channels
- CTR implementation remains the **top** priority

*RFI: Request for information, RMS: Reporting Member State
**LICT: Low intervention clinical trials

ACT EU workplan 2025-2026: CTR implementation

- Working with the ACT EU regulatory partners to jointly address main issues on CTR implementation
- Tracking the performance of the European clinical trials environment though regular reporting (quarterly)
- Re-organising existing training material and guidance documents on CTR/CTIS, to facilitate access to users and update content
- Organising dedicated workshops, in liaison with the multistakeholder platform (MSP) advisory group, to address issues raised by stakeholders

Network initiatives on CTR implementation

Issue reported	Responsible bodies
Preparation of requests for information (RFI)	CTCG (CTR Collaborate), MedEthicsEU (part II of CTA), CTAG
Strengthening the role of the reporting Member States (RMS)	CTAG, CTCG, NCA and Ethics Committees
Harmonisation on CTA part II requirements	CTAG, MedEthicsEU, CTCG
Use of common templates in CTA	MedEthicsEU, CTAG
Translation aspects (CTA documents/RFI)	MedEthicsEU, CTAG, CTCG
Risk based approach and Low Interventional Clinical Trials	CTAG, CTCG, MedEthicsEU
Patients' involvement in clinical trials	CTCG
Interplay CTR/IVDR/MDR	COMBINE Programme - Combined studies - European Commission
CTIS functionalities	CTIS Programme - Clinical trials in human medicines | European Medicines Agency (EMA)
Additional relevant initiatives	
Strengthening funding mechanisms	European Commission

Revision of CTR / CTIS training materials

- Included in the endorsed ACT EU workplan 2025-2026
- First phase focused on training materials for sponsors
- Process and next steps:

Set up of the external stakeholder focus group – Kick off meeting on 4 March 2025

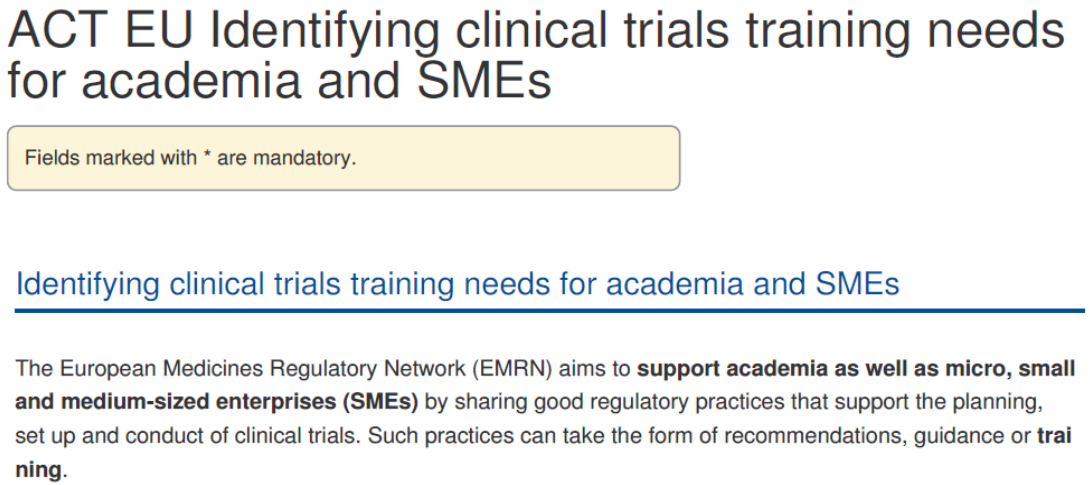
Stakeholder focus group performs an **intermediate review and validation** of the sponsor-facing content in April 2025

EMA reviews and analyses feedback to identify key themes and actionable improvements

Finalisation of the sponsor handbook in May 2025

Academia & SMEs consultation

- **Survey** targeting academic stakeholders and SMEs involved in the development of medicines for human use launched to gain insight in their clinical trial training needs
- Responses were collected from 14 January to 11 February 2025
- **375 responses** received on:
  - Importance and adequacy of training on clinical, non-clinical and quality areas
  - Accessibility of training (challenges, preferred format)



ACT EU Identifying clinical trials training needs for academia and SMEs

Fields marked with * are mandatory.

Identifying clinical trials training needs for academia and SMEs

The European Medicines Regulatory Network (EMRN) aims to **support academia as well as micro, small and medium-sized enterprises (SMEs)** by sharing good regulatory practices that support the planning, set up and conduct of clinical trials. Such practices can take the form of recommendations, guidance or **trai ning**.

Pilots on scientific and regulatory advice

- ACT EU launched **two pilots on consolidated advice** on 10 June 2024
- 20 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

Consolidated advice achievements

SAWP-CTCG

- 6 applications received:
  - 3 completed
  - 2 ongoing
  - 1 under validation

Pre-CTA

- 14 procedures received:
  - 12 completed
  - 2 rejected in validation

Early feedback from applicants

- Opportunity to identify issues ahead of submission of clinical trial applications
- Harmonisation of scientific and regulatory expectations
- Greater consistency and streamlined process for multinational trials
- Cuts down the number of issues raised during clinical trial applications
- Simple and smooth procedures to obtain the advice
- Positive feedback on communication with EMA

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"

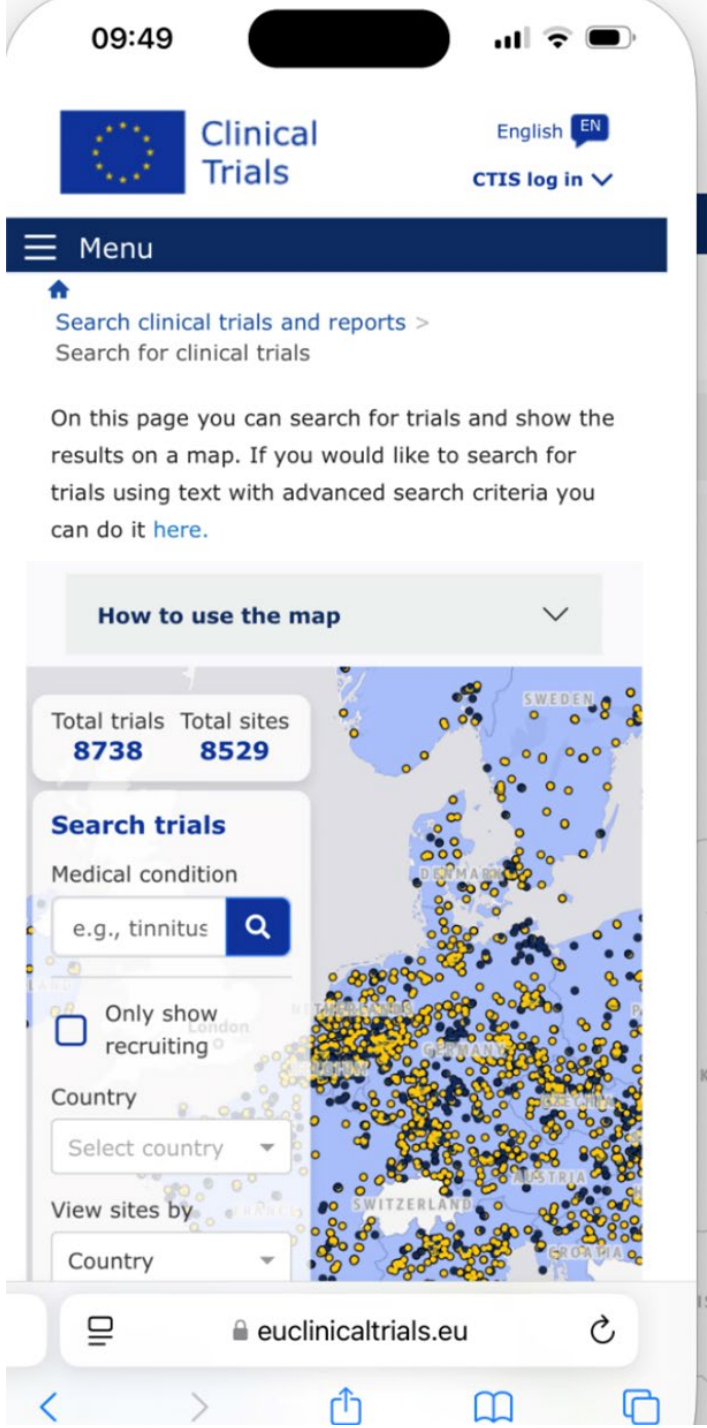
- Launched on 3 March 2025 on CTIS public website
- Public webinar on how to use the Trial Map on 7 March; recording soon to be available on the event page
- We want your feedback to inform future versions of the map

Main features of the Trial Map

- User-friendly search for clinical trials:
  - By medical condition, title, and MedDRA* terms
  - With suggestion system “did you mean …” in case of no hits
  - Search and suggestion system make use of **Consumer Health Vocabulary**, allowing for searches in **lay language**
- Search by geographic area and trial status (e.g., recruiting)
- Count sites per region
- Detailed site view with contact details for investigators and a link to the full trial information on the CTIS public portal

Currently the map only supports searches in English - more EU languages to be available in the future.

*Medical Dictionary for Regulatory Activities



Key benefits of the Trial Map

Empowers patients and healthcare professionals:

- Provides easy **access to information** about clinical trials operating in their area
- Gives an overview of site distributions to **support advocacy efforts** regarding clinical trial access
- Improves **access to trials** by making it easy to find the contact information for each clinical trial site
- Increases **findability of trials** by allowing for medical condition searches in lay language (through the Consumer Health Vocabulary)

Monitoring the EU clinical trials environment

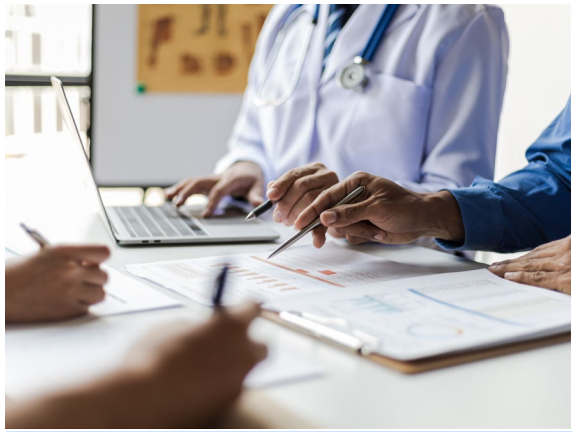
Metrics under development to monitor how ACT EU and relevant initiatives contribute towards **3 overarching benefits** of rendering the EU a favourable environment for clinical research:

Increased attractiveness of the EU

A favourable region for conducting clinical trials, with clear regulatory requirements & smooth collaboration between sponsors and Member States

Faster access to treatment

Incl. fast treatment access to patients at the time of the clinical trial & also in the post marketing phase, when applicable



Impactful clinical trials

Having the best treatment options, supporting innovations and new methodologies

European Commission | EMA | HMA Heads of Medicines Agencies

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