Accelerating Clinical Trials in the EU (ACT EU)

Revised workplan 2025-2026

MSP Advisory Group meeting, 12 March 2025

Presented by Laura Pioppo
ACT EU Programme Manager
European Medicines Agency

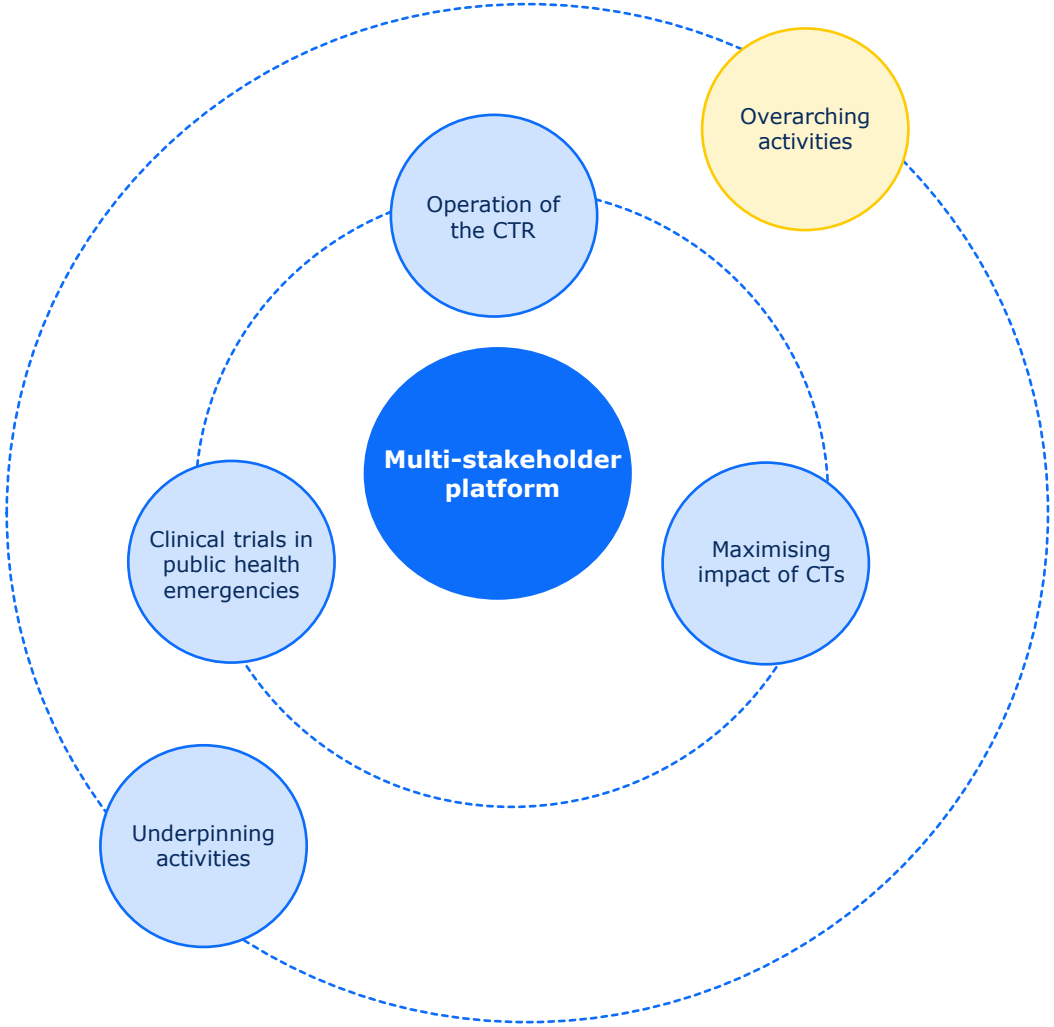
ACT EU partners

- 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 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

ACT EU workplan 2025-2026: CTR implementation

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

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 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

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

CTR implementation

- Regular Weekly meetings (EMA/European Commission/MSs)
- Review of the points raised documented in a masterlist of issues
- Discuss proposed solutions, timelines and responsible bodies
- Dedicated presentation on better preparation of the RFI and strengthening the role of RMS will follow

Pilots on scientific and regulatory advice

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

- 5 applications received:
  - 2 completed
  - 1 ongoing (FUP advice, Cardiovascular DE Coordinator, ART discussion on 6 March)
  - 2 under validation

Pre-CTA

- 14 procedures received:
  - 11 completed
  - 2 rejected in validation
  - 1 Ongoing

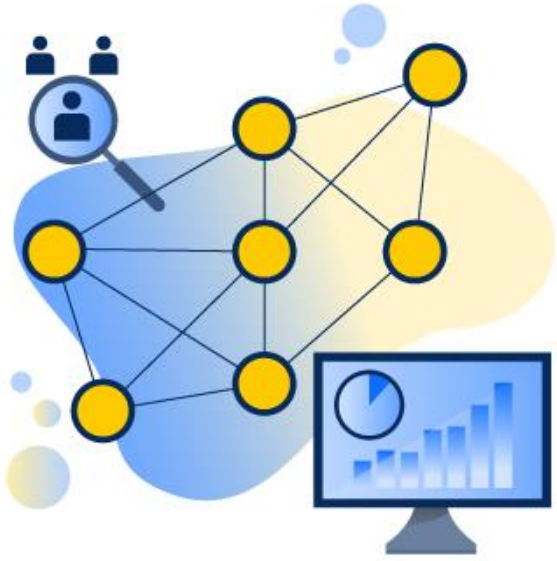
Early feedback from applicants

- 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
- 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
- ✓ Accessible from CTIS public website : https://euclinicaltrials.eu/search-for-clinical-trials/trial-map/?lang=en
- ✓ Trial Map based on CTIS public data, focus on patients and healthcare professionals
- ✓ Searches for medical conditions also in lay terms, recruiting status, symptoms via Thesaurus, etc.
- ✓ Initial release in English; future functionalities will be considered for development
- ✓ Recording of the 7th March available in the dedicated event page
- ✓ Covered by media, recent article published

Clinical Trials

About | Search for trials | CTIS for sponsors | CTIS for authorities | Support

Search clinical trials and reports > Search for clinical trials

On this page you can search for trials and show the results on a map. If you would like to search for trials using text with advanced search criteria you

How to use the map (click to show)

Map of all trial sites in the public portal

Total trials 8738 | Total sites 8529

Search trials

Medical condition

e.g., tinnitus, diabetes

Only show recruiting

Country

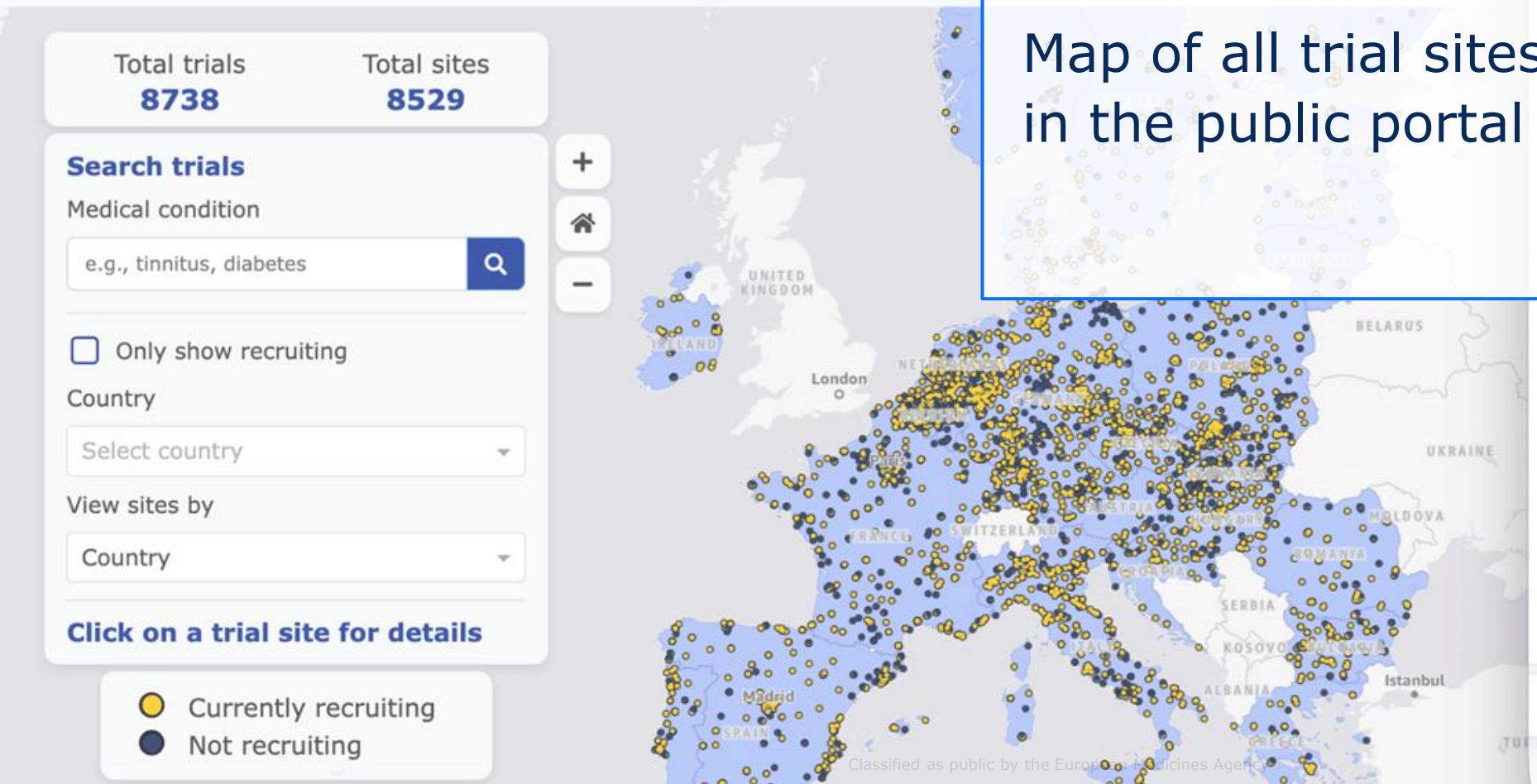
Select country

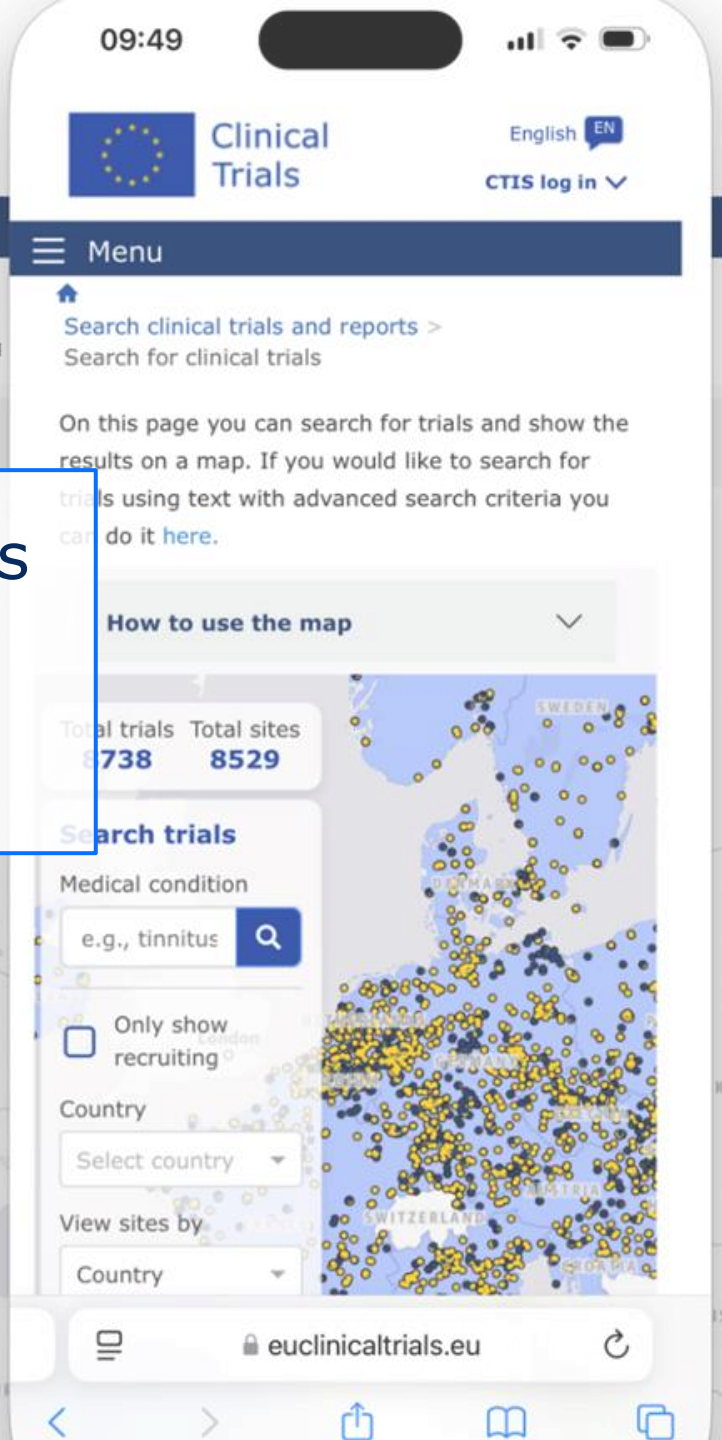
View sites by

Country

Click on a trial site for details

Currently recruiting
Not recruiting





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