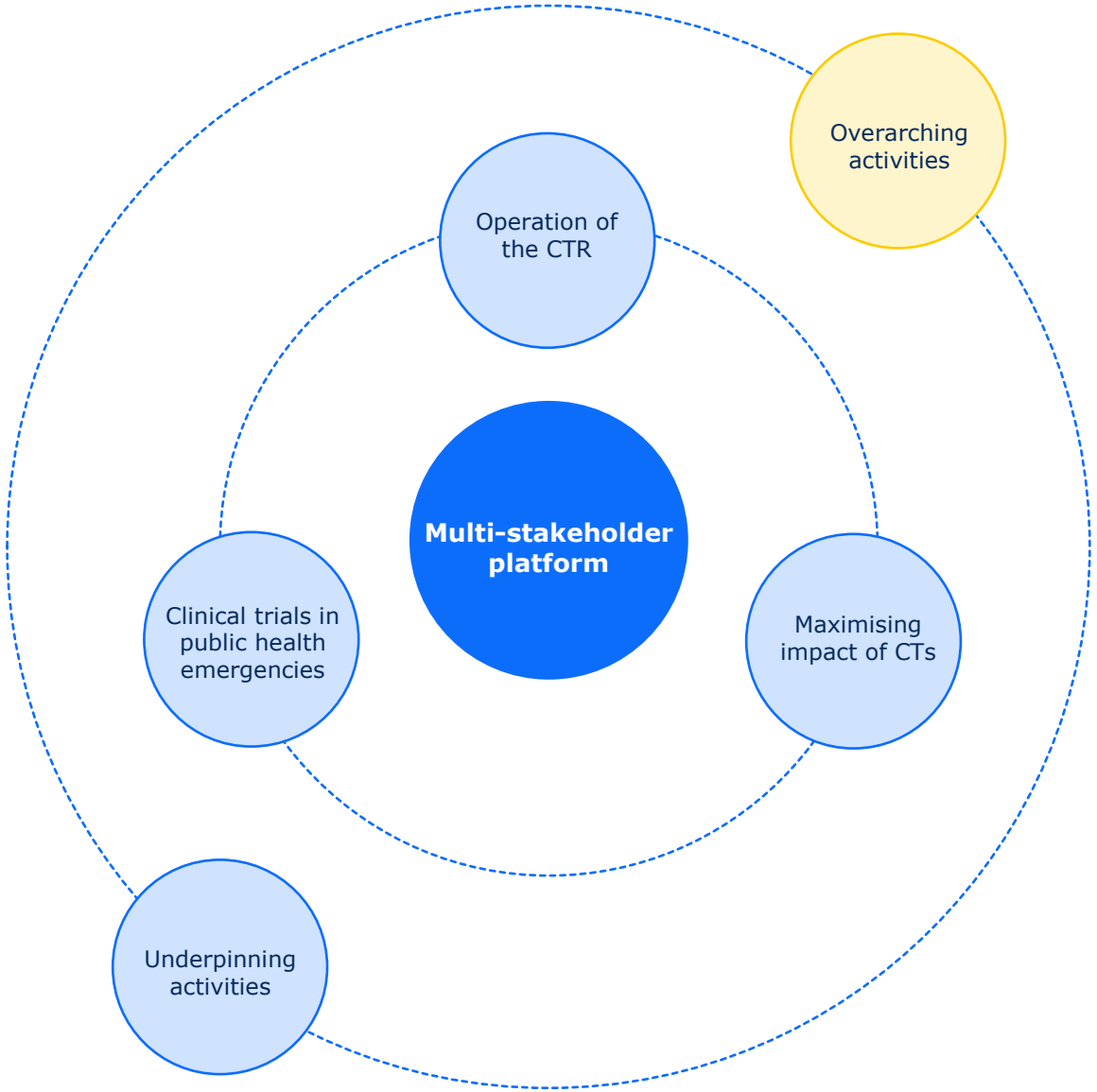
ACT EU MSP AG

Pre-read 18 September 2025

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

Overarching activities

ACT EU Governance and Multi-stakeholder Platform

Delivered in 2025:

- Regular meetings of the ACT EU Steering Group
- Quarterly meetings of the MSP Advisory Group, with agendas, presentations and meeting highlights published on the ACT EU website

Upcoming:

- Annual MSP public event on 29 October
- ACT EU workplan update in January 2026

MSP Advisory Group meetings

For information on upcoming and past meetings of the MSP AG, including meeting materials, see below.

MSP Advisory Group - 26 June 2025

MSP Advisory Group - 12 March 2025

- Agenda
- Meeting highlights
- Presentation - Monitoring the EU clinical trials environment - J. van Wyk (EMA)
- Presentation - Revised ACT EU workplan - L. Pioppo (EMA)
- Presentation - Update on EMA Emergency Task Force (ETF) - M. Mura (EMA)
- Presentation - Preparation of request for information and strengthening the role of RMS - C. Temple (CTCG)
- Presentation - COMBINE programme progress report - I. Clamou (EC)
- Presentation - Re-design of CTIS supporting materials - R. Spulber (EMA)
- Presentation - Overview of 2025 events - O. Ademi (EMA)
- Presentation - Survey on SME and academia training needs - E.Psarelli (EMA)
- Presentation - Overview of ICH E6 R3 renovation - P. Twomey (EMA)

How is the MSP Advisory Group driving progress in clinical trials?

Consultations on dedicated topics:

- The revision of the *recommendation paper on the use of* ***Auxiliary Medicinal Products in clinical trials*** *(nearly final)*
- The revision of *the recommendation paper on* ***risk proportionate approached (RBA) in clinical trials*** *(early draft),* in preparation for a dedicated workshop in early 2026 and the establishment of a dedicated focus group on RBA
- Examples of problematic **Requests for Information (RFIs)** raised during the assessment circulated to MSs, including MedEthicsEU, and provided as input for CTR Collaborate workshop in May 2025
- A focus group reviewed and validated content of the **redesigned Handbook for CTIS sponsors**, published in July 2025 to simplify and improve accessibility of information for sponsors
- A focus group being created to discuss training needs for academia and SME

Operation of the Clinical Trials Regulation

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
- Redesigned CTIS training material for sponsors, with publication of a master handbook
- Working with ACT EU regulatory partners to address issues raised by stakeholders (RFI/RMS)

Upcoming:

- Publication on 22 September of the 3-year analysis report
- LinkedIn live on KPIs on 24 September
- Workshop on contractual agreements planned for Q4 2025
- Publication of sponsor FAQ on CTIS, incl. clarifications on CSR & policy 0070, planned for Q4 2025

9 July 2025
EMA/186412/2021
Clinical Trials Transformation

Sponsor handbook

Clinical Trial Information System (CTIS) user guidance on the sponsor's workspace

Version 6.0

Redesigned CTIS sponsor handbook

- Published on 9 July 2025, with a dedicated CTIS bitesize talk to introduce the handbook to users
- Aligned with stakeholder feedback received via the focus group established under the MSP AG
- Consolidates hundreds of training documents into a single streamlined document
- Includes a clickable table of contents, step-by-step guides and embedded video tutorial
- Saves time and empowers users with clearer, more actionable guidance

Support for non-commercial sponsors

Delivered in 2025:

- 2 webinars occurred (IE and AT) and 1 planned (BE) with academic networks in EU Member States
- Continued tailored technical assistance on CTIS functionalities and regulatory requirements provided under regulatory helpdesk , 6-month report analysis soon to be published
- Map of national support initiatives kept up-to-date on ACT EU website

Upcoming:

- Continue hosting webinars for academic sponsors
- Workshop on fostering clinical research by NCS in 2026

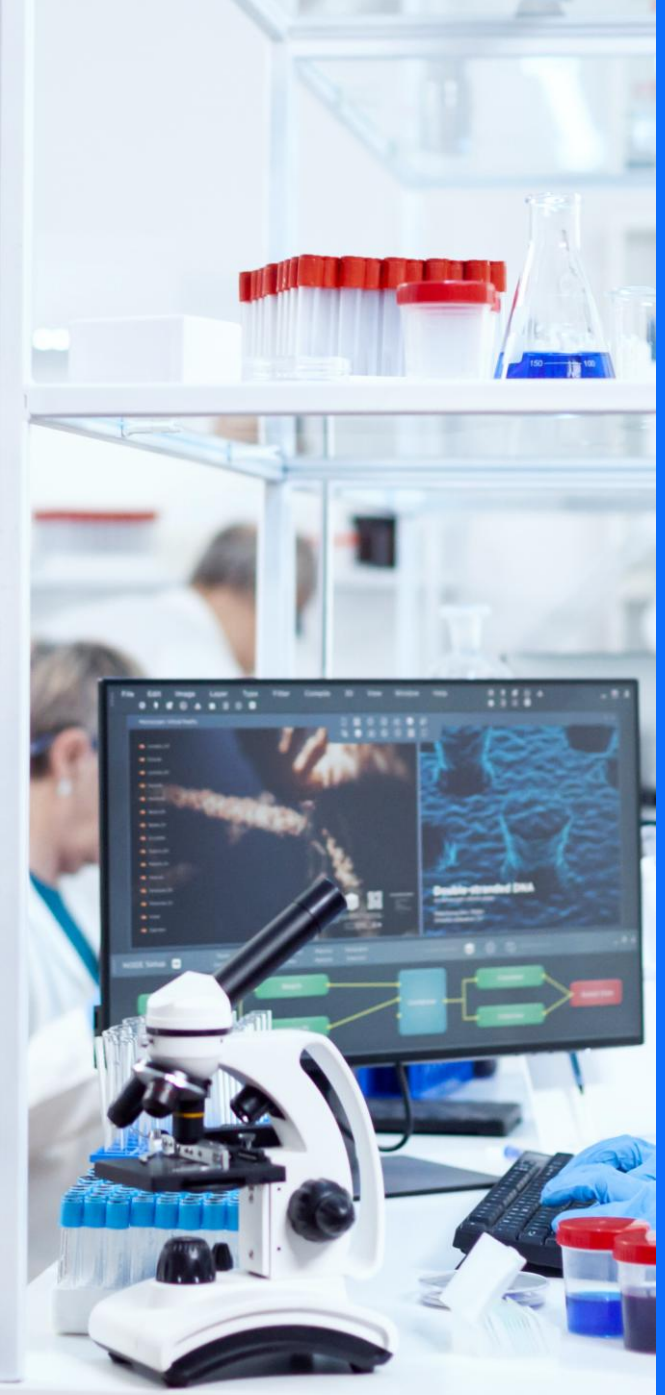
Safety in clinical trials

Delivered in 2025:

- SAFE CT meeting hosted in April 2025 (training for safety assessors)
- Safety assessors round table organised on monthly basis
- Exchange with PRAC on regular basis
- Development on safety features in CTIS (*managed by CTIS programme*)

Upcoming:

- Launch of new CTIS safety module early 2026 (*managed by CTIS programme*)
- SAFE CT meeting planned for 2026



Design and conduct of excellent clinical trials

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) and the ACT EU webpage: Good clinical practice modernisation

Upcoming:

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

Consolidated advice on clinical trials

Delivered in 2025:

- Consolidated pilots on SAWP/CTCG interaction and pre-CTA (CTCG)
- 27 applications received and assessed, 11 for SAWP-CTCG, 16 for pre-CTA
- Feedback provided by the applicants
- Feedback provided by Member States

Upcoming:

- Evaluation of pilots and publication of learnings
- Consider next steps for the pilots

Clinical trials methodologies

Delivered in 2025:

- Signposting of existing guidance on clinical trial methodologies on ACT EU website
- Workshop on Bayesian statistics on 17 June 2025, with the video recording, agenda, presentations published on the event page
- Internal workshop for assessors of paediatric CTs on 14-15 July 2025, report soon to be published
- Best practice on guidance development finalised and distributed within the EU regulatory network

Upcoming:

- Roadmap/Overview on CTs guidance documents under development
- Workshop on external controls on 3rd November
- Workshop with Enpr-EMA planned for 2026
- Workshop on platform trials planned for 2026

Clinical trials in public health emergencies

Clinical trials in public health emergencies

Delivered in 2025:

- PHE ethics advisory group established under the MSP
- PHE ethics advisory group joined EMA's Emergency Task Force in providing input during scientific advice procedures

Upcoming:

- Publication of a simplified CTA package
- Public consultation of a guidance on conduct of clinical trials in PHE

Underpinning activities

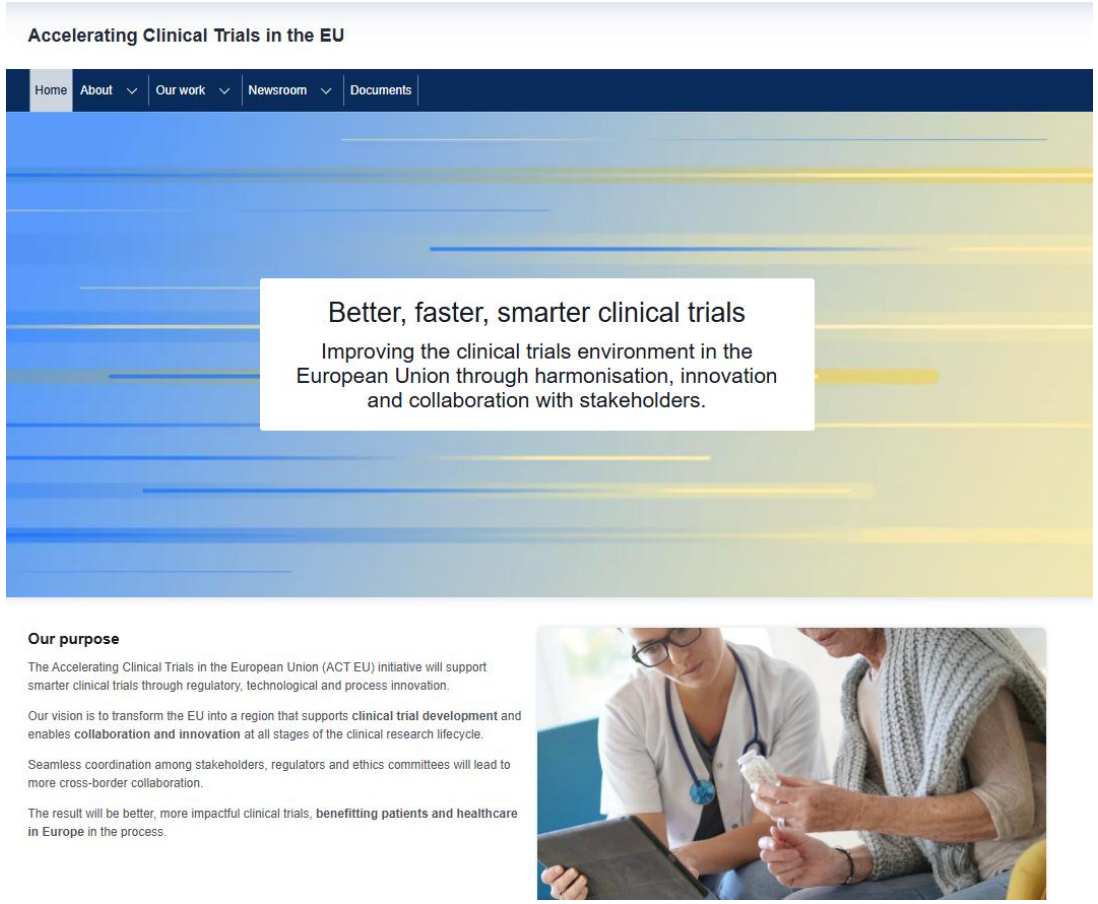
Communication

Delivered in 2025:

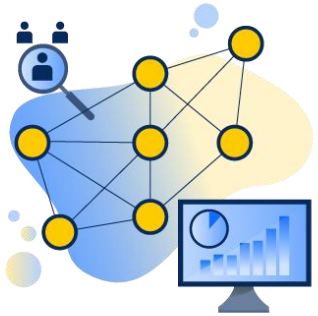
- Continuous communication support activities (promotion of milestones, newsletters, website updates)
- Maintenance of ACT EU website

Upcoming:

- Communication campaign on clinical trials



Clinical trials analytics



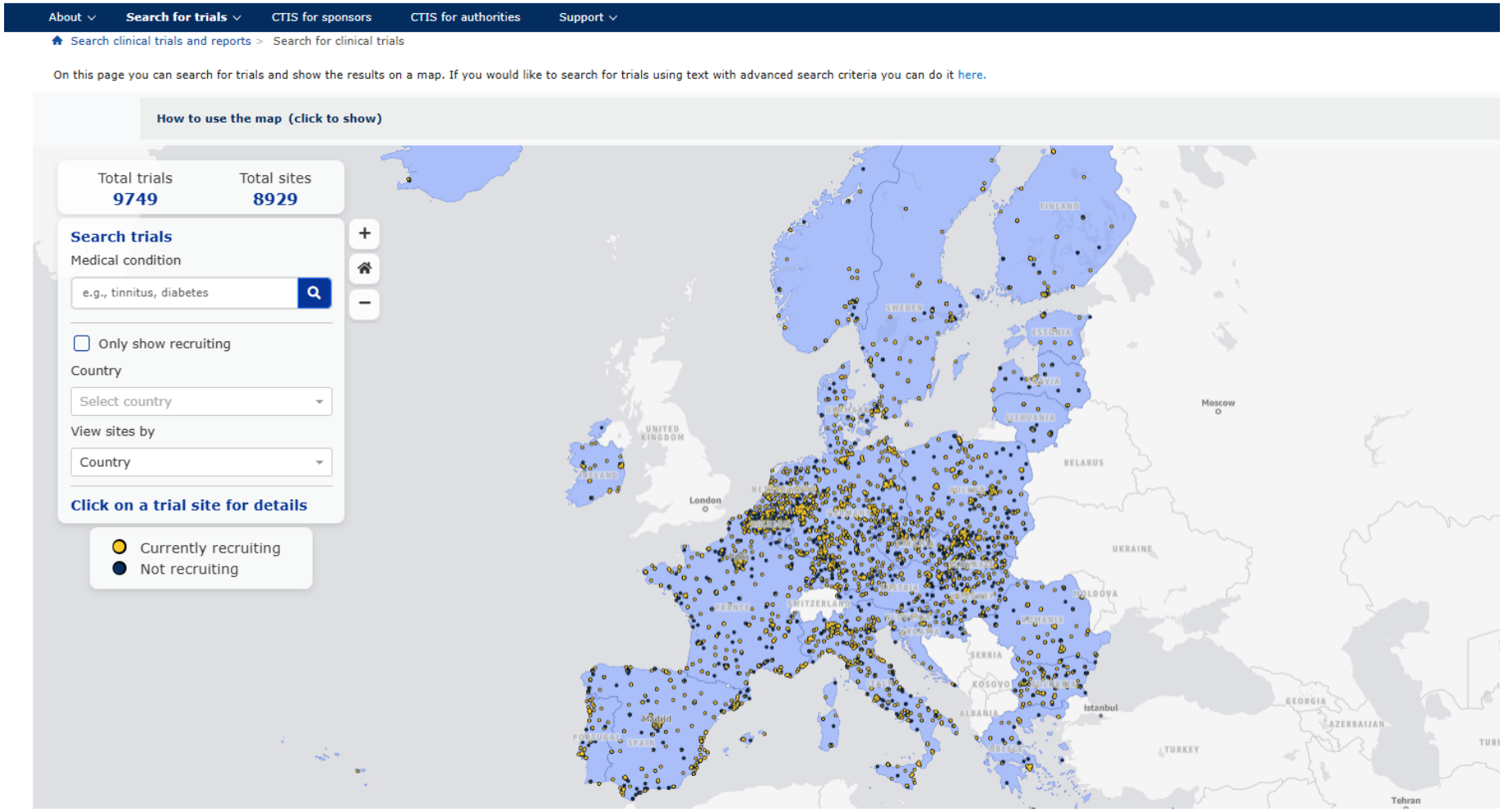
Delivered in 2025:

- Launch of Trial Map on 3 March 2025; dedicated demo & materials available on the event page
- Planned launch of network dashboards to monitor EU clinical trials, with dedicated trainings for Member States

Upcoming:

- Publication of paper on research priorities following 2024 workshop (report)
- Continued support to access and analysis of clinical trial data
- New version of the Trial Map with more features to include translations in the EU official languages

Trial Map



- **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

[Search for clinical trials – CTIS website]

Clinical trials training

Delivered in 2025:

- Survey of 400 stakeholders to identify training needs of academia & SMEs
- Report of training needs of academia & SMEs published on ACT EU website, outlining key needs, potential gaps and challenges, and suggesting ways to address them

Upcoming:

- Mapping and signposting of clinical trials trainings
- Contribute to the WHO global action plan on training
- Develop additional trainings covering the main areas identified in the report

Thank you