



ACT EU update at CDDF

Presented by Laura Pioppo and Marianne Lunzer



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

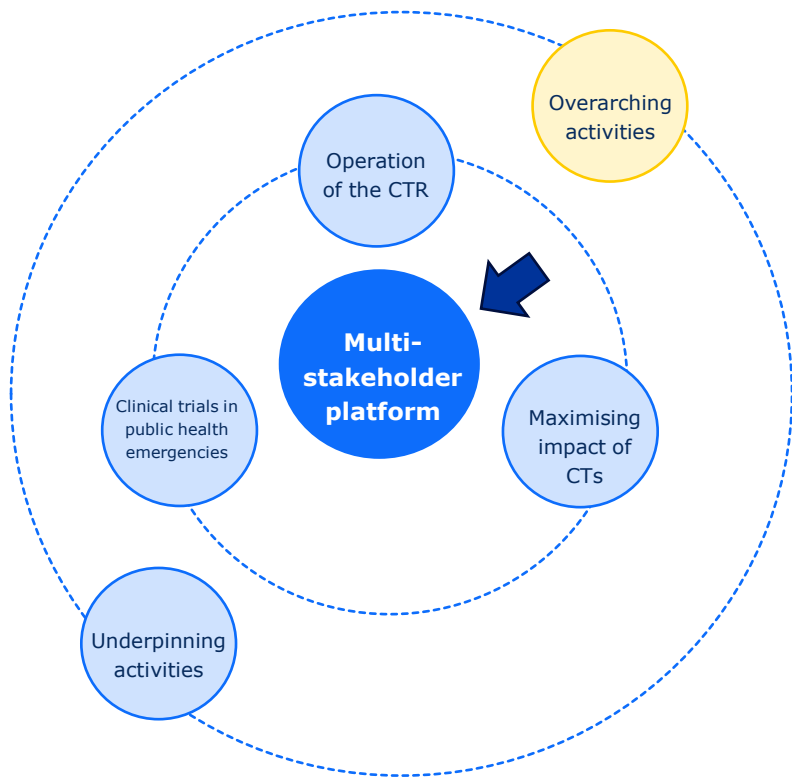


Impactful clinical trials

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)

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
- Publication of most frequently asked 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:

- 3 webinars occurred (IE, AT and BE) and 1 planned (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, training material available on the [event page](#)
- Communication on ICH E6(R3) principles, Annexes 1 via the newsletter and the ACT EU webpage: [Good clinical practice modernisation](#)

Upcoming:

- Finalisation of Annex 2
- Training and change management activities with focus on academia
- Workshop on ICH E6(R3) implementation planned for late 2026



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



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



Clinical Trials

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

🏠 Search clinical trials and reports > Search for clinical trials

Σε αυτή τη σελίδα μπορείτε να αναζητήσετε δοκιμές και να εμφανίσετε τα αποτελέσματα σε έναν χάρτη. Αν θέλετε να αναζητήσετε δοκιμές χρησιμοποιώντας κείμενο με προηγμένα κριτήρια αναζήτησης, μπορείτε να το κάνετε [εδώ](#).

Πώς να χρησιμοποιήσετε τον χάρτη (κάντε κλικ για εμφάνιση)

Σύνολο μελετών 9966
Σύνολο κέντρων 8197

Αναζήτηση μελετών

Ιατρική πάθηση

π.χ. εμβόλια, διαβήτης



☐ Εμφάνιση μόνο μελετών που επιλέγονται συμμετέχοντες

Χώρα

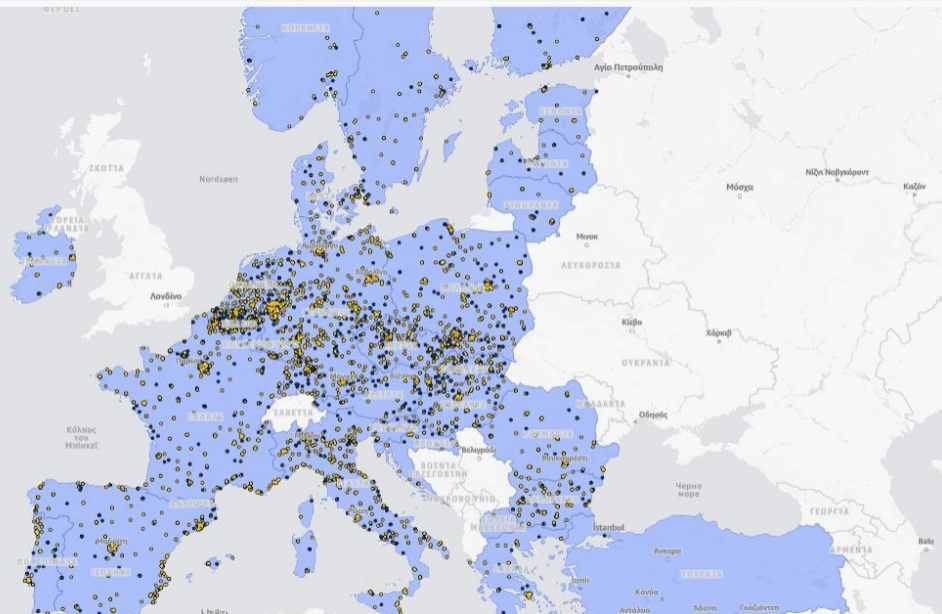
Επιλέξτε χώρα

Προβολή τοποθεσιών ανά

Χώρα

Κάντε κλικ σε ένα κέντρο μελέτης για λεπτομέρειες

Επιλέγονται
● συμμετέχοντες αυτή τη στιγμή
● Δεν επιλέγονται συμμετέχοντες



- **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)
- 31 applications received since the launch of the initiative
- Positive feedback from applicants, consideration on whether to move to permanent offerings

Scientific advice from SAWP-CTCG

For developers of medicines



What advice is offered?

Scientific advice on suitability of clinical trial design to support marketing authorisation application (MAA) and/or clinical trial applications (CTA)



Who is providing the advice?

Scientific Advice Working Party ([SAWP](#)) and the Clinical Trials Coordination Group ([CTCG](#))



How much does it cost?

Standard fees for scientific advice by SAWP apply



How long does it take?

Standard timelines for scientific advice by SAWP apply



How to apply?

Via the [IRIS platform](#), justifying why joint advice from SAWP-CTCG is requested

Pre-CTA advice from CTCG

Technical, regulatory advice on clinical trials



What advice is offered?

Technical, regulatory advice before the submission of a clinical trial application (CTA) in CTIS



Who is providing the advice?

The Clinical Trials Coordination Group ([CTCG](#)) of clinical trial experts from all EU Member States



How much does it cost?

Lead Member State raises a single fee based on the reduced scope of the advice



How long does it take?

Short timeline, advice provided within 30 days



How to apply?

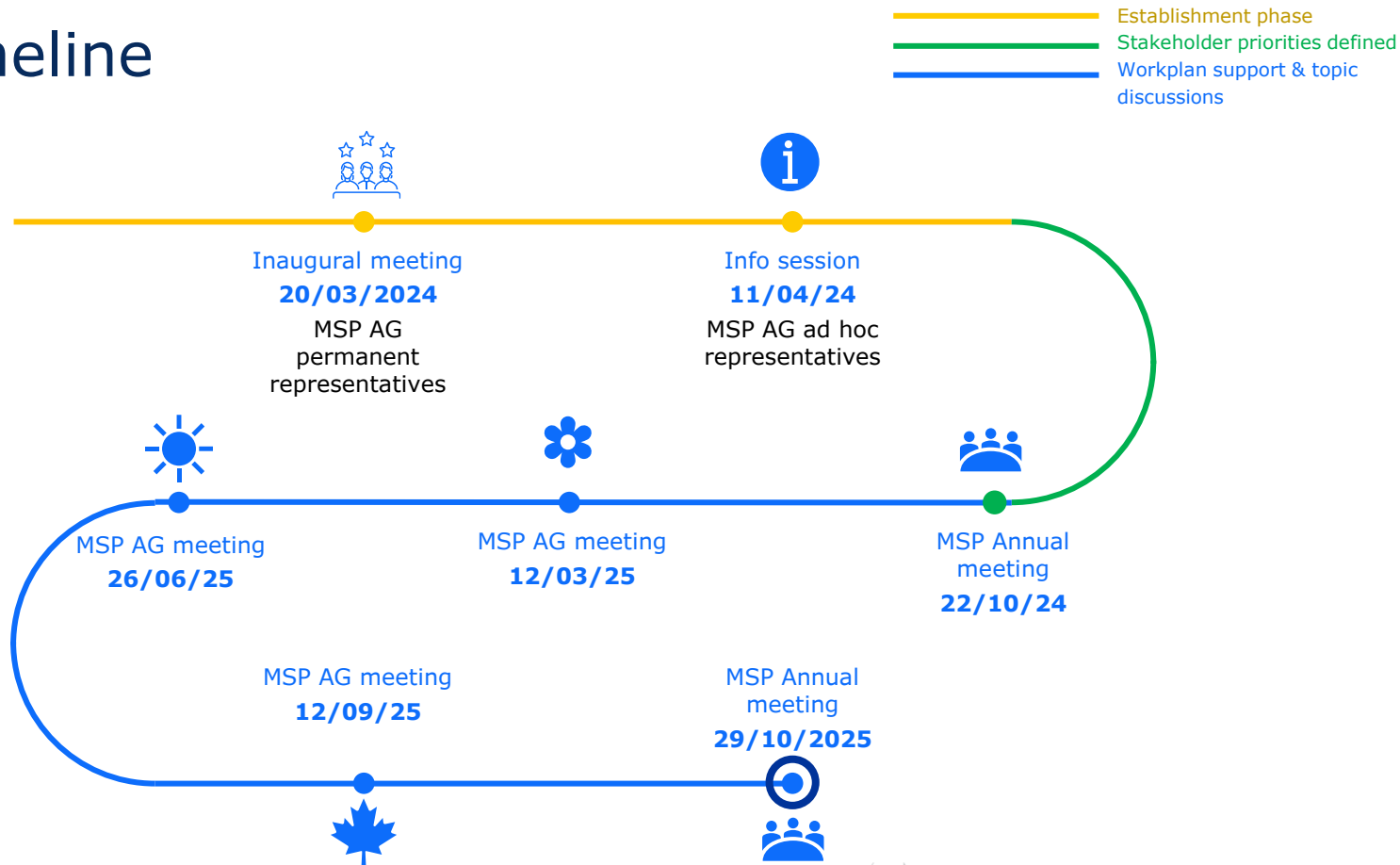
Fill out the [application form](#) and submit via email to snsa@fagg-afmps.be

MSP objective and timeline

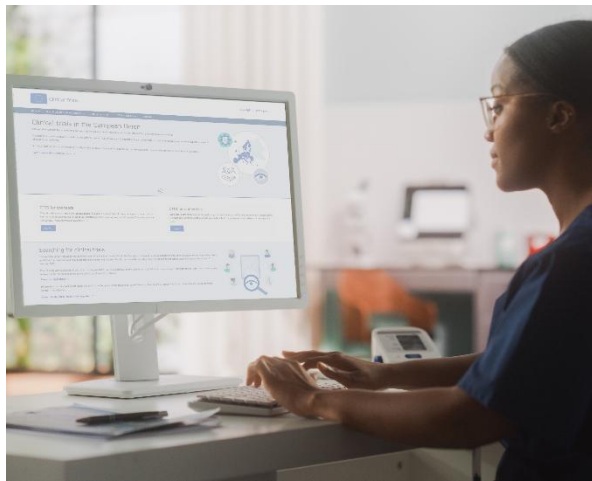


ENGAGE ALL STAKEHOLDERS TO
PROACTIVELY DELIVER INCLUSIVE
PATIENT-ORIENTED MEDICINES
DEVELOPMENT AND DELIVERY
ACROSS POPULATIONS BY
ESTABLISHING A MULTI-
STAKEHOLDER PLATFORM

MSP timeline



MSP AG 2025 activity



Risk proportionate approaches

MSP AG focus group to integrate stakeholders' views into the revision of the 2017 Recommendation paper on risk proportionate approaches in clinical trials

Re-design of CTIS training materials and Trial Map

MSP AG focus group fully involved in delivery of the re-designed [CTIS Sponsor Handbook](#)



Auxiliary Medicinal Products (AxMP)

MSP AG feedback on classification IMP*/AxMP for background treatment as standard of care, registration in CTIS and safety reporting issues



CTR optimisation

Proposals on reducing review timelines and core dossier relevant to Biotech Act discussions



Improvement of RFIs

Input provided for RFIs that have been perceived as problematic. In turn [Recommendation paper on frequent issues identified guides sponsors on avoidable RFIs](#)



Monitoring the EU clinical trials environment

Feedback on new key performance indicators for the EU clinical trials environment

[New targets for clinical trials in Europe | European Medicines Agency \(EMA\)](#)



ACT EU workshop programme committee members

ICH E6 R3

MSP Annual meeting

Upcoming: 2026 Enpr-EMA-ACT EU
workshop on paediatric clinical trials



SME and academia training needs

Creation of MSP AG focus group to
support ACT EU priority action on
training



Other topics discussed

CTCG Patient involvement project

Public Health Emergencies and the
Emergency Taskforce (ETF)

Cross-border clinical trials

Innovative designs and co-
partnership models

MSP Annual meeting debrief

- Hybrid & broadcast; EMA premises
- MSP AG permanent and ad hoc organisations onsite
- Co-chaired by Marianne Lunzer and Denis Lacombe, with opening remarks from EMA, EC, HMA
- Connecting to EMANS 2028 innovation theme
- Keynote on how AI innovation can help shape clinical trials and healthcare systems
- > 510 followed meeting
 - 175 online / 66 people in the meeting room F2F / 275 people following broadcast
- [ACT EU multi-stakeholder platform annual meeting | European Medicines Agency \(EMA\)](#)





Main takeaways

- Innovation in science and tech is outpacing regulation—collaboration is needed to align regulation with scientific progress.
- The EU must maintain leadership in clinical research by improving regulatory environments and embracing biotech innovation.
- AI is transforming healthcare but must be ethically trained and validated
- Capture patient input over time and include it in core regulatory dossiers
- Optimise the respective role of RWD in relation to CTs
- Innovative trial designs are available; mindset shift to mainstream their use
- “Ethics by design” and privacy by design (e.g., EHRs, e-consent) are key.
- Biotech act is a vital opportunity to create a more favourable environment for biotech/innovation
- The ACT EU workplan 2026/2027 should reflect stakeholder expectations.

Continuing the dialogue



The multi-stakeholder platform is fully embedded in ACT EU



Key input to shape the delivery of the programme and continue defining priorities



Strong patient and healthcare professional voices are crucial

Open dialogue between stakeholders, regulators and ethics remains at the core of ACT EU

Thank you

