



## Executive summary of ACT EU annual matrix meeting

The annual ACT EU matrix meeting, with representatives of the EU Member States, European Commission and EMA, was organised in Copenhagen on 1 October 2025, under the auspices of the Danish Presidency of the Council of European Union.

The aim of the meeting was to present two [Key Performance Indicators](#) (KPIs) designed to support broader efforts to enhance the attractiveness of clinical research in the EU and accelerate patients' access to treatment through clinical trials. The long-term objective is that, within five years, the EU will see an additional 500 authorised multinational trials and that 66% of trials will recruit their first patient within 200 days of application submission.

### Overview of ACT EU programme status delivery

An update on the [ACT EU programme](#) was provided, presenting progress on deliverables and highlighting how the priority actions directly address key issues raised by stakeholders.

The discussion stressed the importance of maintaining the EU's global competitiveness compared to other global regions, by shortening assessment timelines and reducing delays. The significance of methodological elements in clinical trials was highlighted, particularly decentralised elements. Finally, the importance of increasing patients' awareness of clinical trial opportunities was emphasised.

### Updates from the European Commission on Biotech Act and Strategy for European Life Sciences

The preparatory work for the Biotech Act amending the Clinical Trials Regulation (CTR) represents an important step to reinvigorate the European clinical trial environment. Stakeholders contributed through targeted surveys on the policy options under consideration, and the proposal has also been presented to the EU regulatory network through various fora for further discussion and input.

Furthermore, the [European Life Science Strategy](#) has been developed to strengthen competitiveness and maintain global leadership, structured around three main pillars: optimising the research and innovation ecosystem, ensuring smooth and rapid market access, and boosting trust in and uptake of life science innovation.

### Activities in place to address operational aspects of CTR implementation

An update of the EU4Health work programme was provided. From the perspective of national competent authorities, enhancing the European Union's attractiveness for clinical research was seen as closely linked to the need for greater unity and the avoidance of fragmentation across Member States. Lastly, from the standpoint of ethics committees', the discussion emphasised the importance of robust governance structures, noting in some instances, the benefits of a central ethics committee at national level.

## Break out session on CTR implementation

The plenary was invited to discuss two questions focusing on how to best achieve the targets related to attractiveness and fast access to treatment. Feedback highlighted the need to further simplify, centralise and harmonise clinical trial application processes, as well as to strengthen governance arrangements for ethics committees and support training and capacity building for assessors. Participants also highlighted the importance of scientific and regulatory advice, improved collaboration and communication between clinical centres, and the need for measures to facilitate greater participation of academic sponsors in multinational clinical trials.

## Clinical trials data analytics

An analysis conducted on the landscape of clinical trials in Europe looked at the at the number of clinical trials pre and post Covid-19, with less trials conducted by non-commercial sponsors compared to commercial sponsors. In addition, the development of a dashboard for the European medicines regulatory network to monitor the KPIs and their associated targets and sub-metrics was presented. Training on the use of the dashboard under development, and a network of Member State analytics experts will be built.

On separate note, it was highlighted that the [Trial Map](#) is available now in all EU/EEA languages.

## Pilots for consolidated advice on clinical trials

Updates were provided on the [SAWP-CTCG and pre-CTA pilots](#) launched in June 2024, noting that both have received positive feedback from applicants and assessors. In particular, participants highlighted the value of early dialogue, improved alignment across Member States, and strengthened collaboration during the clinical trial development process. An interim report covering the first 10 SAWP/CTCG applications and 15 pre-CTA applications is planned for publication in 2026, supporting ongoing reflections on the next steps for these pilot initiatives.

## Training needs for academia and micro, small and medium sized enterprises (SMEs)

Training needs of academia and SMEs were identified through a survey completed in early 2025. The resulting [report](#) outlines key training needs, potential gaps, challenges and proposed solutions. Next steps include creating a centralised mapping and signposting of existing training. During the discussion, participants stressed the need to improve access to trainings in a digestible format to reduce regulatory and administrative burden for academic sponsors, who can perceive these as a limitation to conduct research.

## What is needed to meet the targets on attractiveness and speed

Participants were invited to reflect on concrete actions to support the growth of clinical trials in the EU. They highlighted that the EU remains a strong environment for clinical research, with substantial expertise already embedded in practice. Key recommendations include defining a clear strategy, prioritising pilot initiatives and acting quickly to accelerate trial authorisation, patient recruitment, and the development of new therapies, while ensuring that European patients gain timely access to innovative treatments.

The meeting underscored participants' motivation to drive impactful changes in the EU clinical trials environment, highlighting the current state of play, the objectives to be achieved by 2030 and the urgency to act now based on a well-defined strategy.