Meeting highlights – ACT EU Multi-stakeholder Platform Advisory Group

18 September 2025, 09:30-13:30 (CEST), Webex

Co-Chairs: Maria Jesús Lamas (Regulatory co-chair), Denis Lacombe (Stakeholder co-chair)

1. Opening of the meeting

The co-chairs welcomed participants to the Multi-stakeholder Platform Advisory Group (MSP AG) meeting and briefly outlined the agenda, which focused on key policy initiatives, industry proposals, and regulatory updates relevant to the EU clinical trials landscape, including the core dossier proposal, the reduction of clinical trial review timelines, cross-border clinical trials and EU clinical trial metrics.

Further, the membership updates were briefly presented.

Links to presentations and meeting agenda.

2. Cross-border Clinical Trials

2.1 Cross-border clinical trials and arrangements to take part in a trial abroad

The presentation highlighted three main challenges facing cross-border clinical trials in Europe: liability insurance conditions, import and delivery of investigational and authorised medicinal products (IMP/AMP), and patient recruitment. Current insurance coverage is limited to the host country, leaving gaps when patients return home, while a lack of harmonisation on IMP/AMP delivery creates operational barriers. A proposal was made for the ACT EU to organise a multi-stakeholder workshop focused on improving recruitment, including through matchmaking and reducing barriers to cross-border participation. Enhancing the CTIS clinical trial map and database by including a "cross-border readiness" feature was also suggested to increase transparency on trials open to cross-border patients.

Q&A session

The discussion focused on challenges and opportunities for cross-border clinical trial participation. While some suggested prioritising rare and life-threatening diseases, others stressed access should not be restricted, as neighbouring countries may be more accessible than domestic sites. The patient community voiced strong support for addressing cross-border access more broadly, underlining that access should not depend on where patients live.

Key barriers identified included gaps in liability insurance, with current policies limited to the trial country and the European Health Insurance Card not applying to clinical trials. In addition, some countries require direct negotiations with insurers in their own jurisdiction, adding complexity and

delays. The need for EU-level harmonisation to ensure clarity and consistent patient protection were underscored.
Participants also highlighted the lack of harmonisation across Member States in IMP/AMP import and delivery, stressing the need for EU guidance to provide more consistent rules for sponsors/sites and avoid delays and inequities. Recruitment was highlighted as a central challenge, with barriers such as matchmaking and cross-border cooperation. An ACT EU-organised workshop to address these issues was well received, and EU-level support was considered valuable.
Further concerns were raised about the ability of very ill patients and those with disabilities to travel for trials, highlighting the need to consider accessibility and patient well-being. At the same time, it was noted that some patients may be willing to travel despite health challenges, emphasising the importance of providing flexible options rather than one-size-fits-all solutions. During the discussion, it was noted that a form of classification of clinical trials could be useful, distinguishing between those that naturally call for cross-border participation, such as trials requiring access to sites with specialised technologies, and more conventional clinical trials that should ideally be available to patients within their own countries. The discussion also underlined that clinical trials should be integrated within broader cross-border healthcare systems, requiring stronger collaboration with healthcare providers to ensure continuity of care and patient well-being. Enhancing the Clinical Trials Information System (CTIS) trial map to indicate sites ready for cross-border patients was seen as a promising and transparent tool to support trial planning.

Next Steps / Action points

- The ACT EU programme will consider the proposal for a potential multi-stakeholder workshop to discuss options for improving recruitment, including through matchmaking and reducing barriers to cross-border participation in Europe.
- The potential addition of a "cross-border readiness" field in the CTIS trial map will be further explored.

3. CTR/CTA optimisation

3.1 Core Dossier: opportunities for increasing efficiency and future proofing the CT ecosystem in Europe

The presentation introduced the concept of a core dossier model as a shift from a trial-by-trial approach to a product-based approach. The proposed core dossier would consolidate key documents, such as the Investigator's Brochure (IB) and the Investigational Medicinal Product Dossier (IMPD), into a continuously updated single reference to support multiple trials. This would reduce duplication, improve efficiency, and embed reliance on prior assessments throughout a product's lifecycle. It was emphasised that the focus of this presentation was on the conceptual framework rather than on technical solutions, with a request for stakeholder feedback on potential enablers, barriers, and benefits. Initial analysis indicated that the CTR does not prevent the implementation of this model, though practical implementation challenges remain.

Q&A Session

Participants generally supported the concept of a core dossier model as a way to streamline submissions, reduce duplication, and improve efficiency, but raised concerns on practical implementation aspects, particularly the administrative burden of keeping trial sites information up to date. Additional considerations on eventual responsibilities for the core dossiers were flagged, especially when trial-specific information should supplement the dossier and how deviations should be handled.
International experience, including the FDA's use of a similar model, demonstrated feasibility, but protocol-specific requirements would still need to be addressed alongside the core dossier. Safeguards were deemed essential to ensure accuracy and reliability.

The discussion stressed the importance of distinguishing what is possible under the current Clinical Trials Regulation (CTR) and CTIS framework from what may need longer-term legislative changes. No major legal barriers were identified, but CTIS functionality was seen as a limitation. A pilot within CTIS was proposed to test feasibility and gather evidence. The European Commission noted that the CTR and CTIS already support cross-referencing (e.g., IMPD-Q), with current policy developments like the Biotech Act aligned with this approach. Furthermore, stakeholders were strongly encouraged to share their views through the ongoing impact assessment surveys that have been launched by the European Commission in the context of the upcoming Biotech Act.
Participants confirmed that a modification to a single core quality dossier could apply across linked trials, though practical and legal details would need clarification under the Biotech Act or CTR annexes.
Overall, strong support was expressed for the model's alignment with EU priorities and its potential efficiency gains, but expectations must be managed. The Commission confirmed its role at this stage is primarily to listen and gather input while the regulatory and operational analysis is completed.

Next Steps / Action points
Stakeholders were invited to share via the ongoing European Commission impact assessment survey their perspective and suggestions on the above topic.

3.2 Reducing review timelines to 60 days: enhancing competitiveness through faster CTA approval
The presentation introduced industry's proposal to reduce clinical trial review timelines from the current 106 days stipulated in the CTR to 60 days to boost Europe's competitiveness. National pilots show feasibility of this proposal, with no legislative change needed. Proposed measures to reduce assessment timelines include removing holiday pauses, strengthening reliance on the Reporting Member State (RMS), and harmonising Member State requirements, with key actions focusing on streamlining procedures, addressing operational inefficiencies, and adopting best practices already applied in some Member States.

Q&A session
Participants noted that Europe's timelines often cause delays in trial initiation and recruitment. A differentiated approach between simple and complex trials was suggested, while emphasising that faster timelines must not compromise patient safety and data quality.
Stakeholders discussed scaling up good national practices, noting that some Member States already managed to implement shorter timelines through efficient coordination and better resource management. Industry stressed that faster, more predictable reviews would boost Europe's competitiveness for multinational trials. Recruitment competition was flagged as a key challenge, with delays in authorisation reducing time for patient enrolment and limiting access. Inefficiencies in authorising substantial modifications were also seen as barriers to timely trial adjustments, patient safety and the expansion of recruitment.
The proposal was recognised as timely in the context of the Biotech Act, with stakeholders encouraged to provide concrete evidence and proposals through the ongoing European Commission impact assessment surveys.
Regulators underlined the importance of strengthening the role of the RMS while noting that any acceleration must be carefully planned to support multinational collaboration. The Commission acknowledged that long timelines place Europe at a competitive disadvantage for multinational trials and confirmed ongoing work through the CTIS Simplification Taskforce to identify where efficiencies could be introduced. At the same time, it was noted that structural and resource constraints may limit how far timelines can realistically be shortened.
Stakeholders welcomed the support shown and called for piloting the 60-day model, though concerns were raised about Member States' capacity to manage increased trial volumes. It was

agreed that Advisory Group feedback will inform the Commission's Biotech Act policy work, with piloting and targeted efficiency measures to be further explored.

4. ACT EU training curriculum

5.1 Proposals on content for ACT EU clinical trials curriculum

The presentation highlighted the need for a sustainable, multi-level training curriculum to support academic clinical trials, extending beyond investigators to include all staff involved in a clinical trial. Existing national and EU initiatives were noted, though many face sustainability issues after funding ends. ACT EU was proposed to integrate these resources into an agile curriculum covering regulatory, scientific, operational, and technical aspects. The new ACT EU focus group on clinical trials training was suggested as the forum to align priorities, avoid duplication, and incorporate stakeholder feedback to ensure the curriculum meets practical needs.

Q&A session

Participants welcomed the initiative, emphasising sustainability and better integration of existing training resources. Fragmentation and the short-lived nature of project-based programmes were highlighted as key challenges, with mapping and signposting seen as a valuable first step. Concerns were raised about the burden of training for each trial, leading to calls for a structured curriculum that distinguishes between generic and trial-specific content. Stronger generic training was suggested to streamline protocol-specific training and reduce duplication while ensuring quality and consistency.

Training was seen as essential for all trial team members, including study nurses, pharmacists, clinical research associates and other healthcare professionals, to build a competent workforce. Participants highlighted the challenge of high staff turnover in public research organisations, which often leads to repeated retraining. High-quality training opportunities were also considered important for attracting and retaining staff. It was underlined that training should equip both assessors and investigators for future innovations, with adaptable courses addressing new scientific and digital skill needs. Participants supported integrating risk-based and pragmatic approaches, as well as multinational trial and portfolio management, to build capacity and career pathways.

Alignment with international initiatives like WHO's work to accelerate access to training for the research workforce was encouraged to avoid duplication. In addition, the proposed agile, multi-level structure was welcomed as a way to tailor training to staff roles. Coordination with regulatory training and inclusion of operational and technical aspects, such as quality management and project oversight, were also seen as priorities.

The absence of SME representation in the ACT EU clinical trials training focus group was noted, with their input considered essential. The focus group will lead the mapping and integration of existing initiatives and gather further stakeholder input to refine the curriculum, ensuring it remains responsive to evolving needs such as innovation, digitalisation, and proportionality.

Next steps/ Action points:

Launch a call for SME representatives (e.g., EUCOPE or EuropaBio) and healthcare professional representatives to join the ACT EU focus group on clinical trials, with deadline of 6 October to express interest.

5. Ensuring Regulatory Agility for Clinical Trials During Public Health Crises

5.1 PA11 Regulatory flexibility for CTs during Public health emergency

The presentation addressed regulatory flexibility for clinical trials during public health emergencies, presenting the new guidance, which is being drafted, drawing on lessons from the COVID-19 pandemic as well as existing regulations. The guidance will expand beyond pandemic situations to cover other crisis scenarios, such as natural disasters, and aims to provide a framework for adapting

clinical trials in emergencies. Key reference points include the CTR and ICH guidelines E6(R3) and E8(R1), which support risk-proportionate approaches and a focus on critical-to-quality factors.

Q&A session

Participants reflected on lessons from COVID-19, stressing the need for preparedness in future crises. A key priority was clarifying when and how regulatory flexibilities can be applied, supported by practical examples for sponsors and investigators. While crisis-specific flexibilities are essential, some MSP AG members suggested that certain principles could also be applied in routine settings, fostering a preparedness mindset across the system. Safeguards must remain in place to protect patients and ensure data integrity. Operational challenges were noted, including harmonisation across Member States, logistical barriers, and oversight when conventional monitoring is disrupted. The importance of consultation with stakeholders, particularly sponsors, ethics committees, and regulators, was emphasised to ensure the guidance is both practical and implementable.

Ongoing EU and international initiatives were highlighted as important for global coordination, with investigator groups and academia leading efforts, and industry engagement considered vital to avoid misalignment. It was confirmed that stakeholders will be consulted once the draft guidance is ready, while sponsors were encouraged to share if they already include crisis preparedness in their trial design and to identify the main challenges, they face in applying regulatory flexibility. The guidance will be refined based on this input, aiming to balance flexibility with quality and patient safety. Post-meeting note: A dedicated email was circulated to the MSP AG representatives on 29 September, with a deadline for responses set for 13 October.

6. Clinical trials related legislative developments

6.1 Update on policy development at the EU level

The update on policy and legislative developments highlighted the Pharmaceutical Legislation reform, the Biotech Act, and ACT EU's role in modernising the CTR. Alignment with ICH guidelines, work on decentralised trials, crisis preparedness, and patient access were noted. The importance of synergies with EU digitalisation, data governance, and the European Health Data Space was underlined, as these will directly shape how clinical trial data are generated, shared, and assessed, supporting Europe's competitiveness in clinical research.

Q&A session

Participants welcomed the policy update and underlined the need for transparency and predictability in ongoing reforms. The potential impact of the Biotech Act on clinical trial submissions and timelines was discussed, with emphasis on the importance of continuous dialogue. ACT EU was recognised as central in aligning implementation with legislative changes and ensuring CTR/CTIS readiness. Stakeholders stressed the value of integrating ICH guidance on risk-proportionate approaches, pragmatic designs, and digital elements, while avoiding duplication with international efforts. Concerns were raised about ensuring that legislative changes do not overburden sponsors, investigators, or Member States with additional administrative requirements. Instead, participants stressed that reforms should deliver simplification, harmonisation, and improved efficiency, while maintaining patient safety and scientific integrity.

Next steps include continued stakeholder engagement in legislative processes, close alignment of ACT EU activities with evolving frameworks, monitoring ICH updates, and continuous update on cross-cutting digital initiatives such as the European Health Data Space.

7. Clinical trials metrics

7.1 Update on EU clinical trials metrics

An update was provided on clinical trial metrics and key performance indicators (KPIs), aimed at monitoring the attractiveness, efficiency, and impact of the EU clinical trial ecosystem. Two core KPIs were outlined: the number of authorised multinational trials and the number of clinical trials with first patient recruited within 200 calendar days of CTA submission. The overall impact of clinical trials on public health and research innovation will also be monitored although no dedicated KPI has been set for this parameter due to its multidimensional nature. These will serve as the reference for tracking Europe's performance, supported by sub-metrics under development and a forthcoming three-year analysis report.

Q&A session

Participants welcomed the introduction of KPIs and encouraged expanding them to capture innovation and decentralised trial elements, ensuring Europe's leadership in modern trial design is reflected. It was clarified that the initial focus will remain on agreed KPIs to establish a baseline, with additional measures to be integrated over time and targets reviewed regularly to adjust accordingly and remain ambitious. It is believed that Europe is the first region to adopt such metrics, and stakeholders valued the transparency, stressing their importance for future dialogue. Continued feedback and engagement in upcoming communication activities, including the live LinkedIn update on 24 September, were encouraged.

Further input was invited on possible additional parameters to include in CTIS, as adjustments can still be made while the system is being updated to reflect the agreed KPIs. CTIS was praised as a valuable information source and a strong foundation for evidence-based discussions on EU clinical trial performance.

Next steps/Actions:

MSP AG members are invited to provide proposals for additional fields to be included in CTIS to facilitate the search for specific types of clinical trials, such as complex and/or decentralised trials. Please submit any suggestions to the MSP AG Secretariat (msp-agsecretariat@ema.europa.eu) by close of business on 31 October 2025.

Post meeting note: More information on the clinical trial metrics can be found at the three-year report, the news announcement, and the LinkedIn Live session.

8. Pre-read

No formal presentation was provided. Participants were reminded that all supporting documents and updates, including focus group work, ongoing actions, workshop outcomes, patient involvement, and overall ACT EU progress, were shared in advance and were available on the ACT EU website.

Q&A session

Participants requested further insight into the timeline of ongoing initiatives.

Updates were provided, noting that the AxMP document was in its final stages and expected to be endorsed and published soon. Work on RFI Part I and II was close to completion, with both sets of questions to be consolidated into a single document. The role of the RMS continued to be discussed in CTCG, with efforts focused on strengthening trust and ensuring more consistent practices. Stakeholders also asked about harmonisation of requirements, and it was explained that assessors are working towards identifying critical considerations only, to avoid unnecessary requests or deletions. An update was also provided on the risk-based approaches drafting group, which had launched in the summer, and which will work in collaboration with the MSP AG focus group. The focus group will meet on a monthly basis and provide further detailed examples and input to inform the revision of the 2017 Recommendation paper on risk proportionate approaches.

A.O.B.
Participants were informed that, from 2026 both permanent and alternate representatives of the MSP AG will be invited to attend all MSP AG meetings. The revised 2026 meeting dates were announced as 20 March and 18 June and have been published online. Further, participants were encouraged to register for the upcoming ACT EU workshop on external controls, scheduled for 3 November, with details available on the EMA website and included in the chat and post-meeting package.
Closing remarks
The co-chairs closed the meeting by thanking participants for their contributions and engagement. Actions arising will be followed up as needed. Next meeting is on 20 March 2026 (virtual) and deadline for topic submissions is 18 January 2026.