Meeting highlights – ACT EU Multi-stakeholder Platform Advisory Group

20 March 2026, 09:30-13:30 (CEST), Teams meeting

Co-Chairs: Catherine Paugam-Burtz (Regulatory co-chair), Denis Lacombe (Stakeholder co-chair)

1. Opening of the meeting

The meeting opened with the introduction of the new regulatory co-chair, Catherine Paugam-Burtz, Director General of National agency for the safety of medicine and health products, France (ANSM), following the selection process outlined in the mandate.

The new regulatory co-chair introduced herself and acknowledged the contributions of her predecessor. The outgoing regulatory co-chair, Maria Lamas, delivered farewell remarks, reflecting on the collaborative nature of the group and value of bringing together regulatory, clinical, sponsor and patient perspectives. She highlighted the constructive engagement of stakeholders and the openness of the regulatory network to feedback, noting that discussions within the group have contributed to ongoing developments, including elements reflected in the Biotech Act.

Both co-chairs and the secretariat expressed appreciation for the outgoing co-chair's leadership and contributions, as well as for the continued engagement of all members.

The co-chairs proceeded to inform the group about changes in the composition of the MSP AG

2. ACT EU update

ACT EU objectives and workplan 2026-2027

The presentation provided an update on ACT EU key performance indicators (KPIs) and the revision of programme objectives, building on MSP AG discussions from March and September 2025.

The programme is underpinned by two KPIs, with quarterly publication on ACT EU website of aggregated and monthly data to support trend monitoring and inform actions with partners. The revised objectives and workplan reflect recent legislative, strategic, and operational developments, as well as stakeholder input. Proposed additions include activities on AI in clinical trials, implementation of the Biotech Act, improved data usability, and enhanced communication.

Publication of the revised workplan and related materials is expected in Q2 2026.

Updates were also provided on progress across selected ACT EU priority actions.

Under the Clinical trials data analytics priority action, key achievements include the delivery of Trial map in March 2025 and improvements to its functionality, taking into account stakeholder feedback. Further enhancements to Trial map are planned for 2026, alongside upcoming publications on research priorities and clinical trial trends (building on the ACT EU Clinical trials analytic workshop), and the establishment of a network of experts to support data analysis.

For the Support for clinical trials in public health emergencies (PHE) priority action, progress includes the establishment of a collaboration process between PHE Ethics Advisory Group and the Emergency task force (ETF) in providing scientific advice, contributing to more streamlined clinical trial applications. Planned activities include a public consultation on a draft guidance document outlining the conduct of clinical trials during public health emergencies (open until 30 April), as well as the finalisation of a simplified submission package, expected in Q2 2026.

Updates were also provided on focus groups (FG).

- The FG on resign of CTIS and CTR training materials contributed to the review of the published sponsor master handbook and CTIS Sponsor Frequently Asked Questions (FAQ)
- The FG on risk-based approaches (RBA) was established in September 2025 and is currently exploring how best to reflect stakeholder input and examples in the revision of the existing guidance document.
- The FG on training needs for Academia and SMEs is working towards a sustainable training framework for academia and SMEs, including mapping existing training opportunities and signposting these via the ACT EU website.

Finally, participants were informed of upcoming stakeholder engagement activities, including a webinar on contractual agreements (14 April 2026), public consultation on a draft guidance document outlining the conduct of clinical trials during public health emergencies (30 April 2026) and workshop on paediatric clinical trials with EnprEMA (12 May 2026).

During the discussion MSP AG members provided feedback on improving Clinical Trials Information System (CTIS) data export functionality to support better use of clinical trial data. Additionally, MSP AG members welcomed new priorities on data use and digitalisation, with emphasis on incorporating stakeholder needs and exploring broader involvement in data analytics initiatives.

Next steps / Action points

- The ACT EU will explore the possibility of expanding FG on RBA membership (e.g. pharmacist), with follow-up once the group resumes.
- The ACT EU will, taking into account stakeholder input and priorities, explore appropriate approaches to data analysis and potential improvements to data export functionalities from CTIS.

3. Experience and learnings from ACT EU consolidated advice pilots in clinical trials

Consolidated advice pilots in clinical trials (status update)

The group was updated on the ACT EU consolidated advice pilots – Scientific Advice Working Party-Clinical Trials Coordination Group (SAWP/CTCG) pilot and pre-clinical trial application (pre-CTA) pilot, focusing on applicants feedback collected through two separate surveys and corresponding interim analyses.

The interim analyses indicate overall positive feedback across both pilots.

The interim analysis indicates overall positive feedback across both pilots (see presentation for details). Key recommendations from participants include positioning the SAWP/CTCG pilot as a standard scientific advice option, ensuring alignment between the proposed Reporting Member State (RMS) and the Member State leading the pilot assessment, providing upfront clarity on participating Member States, and involving ethics committees where relevant (slide 5). For the pre-CTA pilot, participants highlighted the importance of RMS participation in the advice, and the benefit of enabling early clarification of specific issues ahead of CTA submission (slide 9).

The pilots have been extended through 2026 to allow for further experience and continued feedback collection. Sponsors are encouraged to apply to support broader participation and ongoing evaluation.
Overall, the pilots are considered a useful mechanism to support more efficient, coordinated, and predictable clinical trial processes in the EU.

Pre-CTA and SAWP-CTCG pilots

The presentation provided an industry perspective on the advice pilots, confirming that both are meeting their objectives and adding value (see slides for details). Feedback on the pre-CTA pilot was largely positive, with only some concerns regarding consistent involvement of the Reporting Member State and potential downstream impact (see slide 4). Similarly, the SAWP/CTCG pilot was viewed as efficient and beneficial for coordinated input and clearer regulatory expectations, with some need for further clarification on roles, information sharing, and impact on subsequent procedures (see slide 4).
Suggested improvements focus on enhancing transparency, clarifying roles and participation, expanding scope and flexibility, and strengthening alignment across Member States, alongside broader stakeholder involvement where relevant (see slide 5).
Overall, industry expressed the view that the pilots are delivering tangible benefits and should, with targeted refinements, evolve into a permanent offering. Continued participation, broader engagement across Member States, and adequate resourcing were highlighted as important considerations for future development.

Q&A session

The discussion explored practical aspects of the pilots' implementation and potential future evolution. Participants noted the importance of gaining broader experience across a wider range of Member States and reflected on whether increased transparency regarding participation could support a more balanced distribution of applications.
The discussion also touched on stakeholder involvement, including the potential role of ethics committees and, where relevant, patients. While the added value of broader engagement was acknowledged, it was noted that integrating such elements within existing procedural timelines may be challenging and could require consideration of complementary approaches outside the formal procedures.
Resource considerations were highlighted, particularly in the context of a potential transition to a permanent offering. While the pre-CTA pilot was considered manageable, the SWAP/CTCG pilot was noted to be more resource-intensive, and further network assessment will be needed to ensure sustainability and scalability.
Participants also raised broader reflections on the landscape of scientific advice offerings, noting that the range of available pathways, while valuable, may present complexity for sponsors. Suggestions included improving clarity through enhanced guidance or signposting, and potentially exploring more streamlined access points, while recognising the need to balance this with operational feasibility.
Finally, it was acknowledged that the pilots remain in a learning phase, and continued experience, alongside ongoing feedback, will be important to further assess their impact and inform next steps

4. Topic on patient involvement in clinical trial design and conduct

Overview of patients' priorities

The presentation provided an overview of 12 priorities identified by patient representatives, reflecting a shared ambition to strengthen patient-centred approaches within the European clinical trial framework. The priorities aim to support the development of clinical trials that are more relevant to patients and better aligned with their needs.
A key priority highlighted was the systematic involvement of patients in clinical trial design and conduct, in line with existing guidance. While the importance of patient involvement is broadly

recognised, further work is needed to operationalise this in practice and ensure it is implemented consistently.
The importance of patient-reported outcomes and patient preference studies was also emphasised, with a view to better capturing quality of life and patient experience. The recent EMA reflection paper on patient experience data (PED) was welcomed as a positive development. However, it was noted that further methodological work and clearer guidance may be needed to support the broader use of such data in regulatory decision-making.
Additional priorities included advancing new methods and endpoints that better reflect patient-relevant outcomes and addressing practical aspects such as cross-border participation in clinical trials, where current processes remain complex and could benefit from further clarification and coordination.
Further areas of focus included strengthening paediatric patient involvement, exploring the use of artificial intelligence to facilitate patient identification and participation in trials, and supporting the uptake of innovative trial designs, particularly those that may enhance patient involvement.
The need to improve the informed consent process was also highlighted, with a view to making it more understandable and meaningful for patients. In addition, expanding the capacity of clinical trial sites, particularly those not yet engaged in research, was identified as an important enabler to improve patient access to trials.
Finally, priorities related to increasing awareness of clinical trials within patient communities and improving inclusiveness, including for older and underrepresented populations, were emphasised. Ongoing initiatives in this area, such as projects aimed at identifying barriers to participation and improving diversity in trials, were noted as important building blocks for future work.
Overall, the presentation highlighted a broad set of interconnected priorities, with a common objective of ensuring that clinical trials in Europe are more patient-centred, inclusive, and fit for purpose.

Framework for shared patients' input

In this presentation a more detailed proposal on how to operationalise patient involvement in clinical trial design and conduct, in line with the recommendations of ICH E8 (R1), was presented. While various approaches are already in place, such as sponsor-led advisory boards, these were noted to be variable in scope and not yet systematically applied. It was also highlighted that patient involvement remains limited in certain areas, including paediatric research.
The concept of Community Advisory Boards (CABs) was presented as an established model at EU level for structured patient engagement which could serve as the starting point for a pilot initiative under the auspices of the EMA (see slide 5).
Overall, the presentation highlighted a potential pathway to move from ad hoc patient involvement towards a more structured and scalable approach, while recognising the need for further discussion and piloting.

Q&A session

The discussion reflected interest in advancing patient involvement and improving how patient input is captured and used across clinical research.
One point raised was the potential value of creating a centralised mechanism to collect and share patient insights, to reduce duplication of efforts and support sponsors in better understanding patient needs. In response, it was acknowledged that there are already some ongoing regulatory initiatives and that certain elements of patient input could potentially be made more accessible, while respecting confidentiality constraints. Further exploration of such approaches, including through existing structures, was considered worthwhile.
It was confirmed that the patient priorities outlined in the letter will be discussed by the ACT EU Steering Group, including in the context of workplan revision and prioritisation. It was also noted that, while multiple initiatives are already ongoing in this area, there may be opportunities for the

ACT EU programme to focus on specific areas where it can add value or provide additional momentum, including more structured approaches to patient input.
The Regulatory co-chair noted interest in further progressing this topic, including exploring practical implementation aspects such as coordination between EU and national levels, as well as potential improvements to current approaches for gathering and using patient input.
The discussion highlighted a constructive and supportive environment, with recognition of ongoing efforts and openness to further developing structured and scalable approaches to patient involvement, including through dedicated discussion to further reflect the proposal.

5. Accelerating the contracting process

EU model template for "Clinical site agreements" between sponsors and clinical sites

The European Clinical Research Infrastructure Network (ECRIN) has developed an EU model template for clinical site agreements under the ERA4Health project to support harmonisation in multinational clinical trials (see slides for details).
The initiative addresses delays caused by differing national contractual requirements by providing a standardised framework applicable across Member States. It focuses on core, non-controversial clauses, while accommodating country-specific elements through structured appendices.
Designed to reduce negotiation time and improve legal clarity, the template aims to facilitate faster trial start-up, particularly for academic sponsors. It will be published shortly and tested in a pilot phase, with further refinements based on practical use.
Overall, it offers a pragmatic, consensus-based approach to streamline contractual processes while respecting national requirements.

Q&A session

The discussion reflected interest in initiatives aimed at improving contractual processes for clinical trials, which remain a key challenge in trial start-up, with timelines in some cases extending over several months. Recent progress at national level in Germany was highlighted, including the introduction of standardised and legally binding contract clauses, which are expected to support reduced contracting timelines. The value of further harmonisation and alignment of processes across countries was acknowledged, with supporting evidence from a survey conducted by EFIPA and EUCROF identifying contract and budget negotiations as the primary bottleneck in trial start-up.
It was confirmed that the template is currently being tested in a multinational trial and that outcomes will be shared once available.

6. Clinical research in Europe

Recommendations by the Coalition for Reducing Bureaucracy in Clinical Trials

Representatives of the coalition presented recommendations to reduce administrative burden in Europe.
Key challenges were identified in three areas: inconsistent implementation of the Clinical Trials Regulation, increasing administrative complexity, and a disconnect between regulation and real-world clinical research (see slide 4). These issues may affect trial efficiency, innovation, and investigators' ability to focus on safety.
The recommendations propose pragmatic, risk-based improvements, including regulatory harmonisation, streamlined safety reporting, and more patient-centred informed consent. A revised consent template, developed with patient input, was highlighted as a key output. The package calls for collaborative action to support a more efficient and balanced clinical trial environment.

eConsent Initiative

The presentation provided an overview of European Forum for Good Clinical Practice (EFGCP) work to support the implementation of e-consent in clinical trials. Practical recommendations covering operational, regulatory, and documentation aspects, including how e-consent should be reflected in protocols, submissions, and study plans were outlined. These tools are publicly available and have

already been referenced in related guidance. A key output is a "fit-for-purpose" framework to support tailored implementation, based on defining study-specific benefits, assessing challenges, selecting appropriate solutions, and evaluating outcomes through defined metrics. Survey results highlighted variability in expectations, particularly regarding signature requirements depending on context (e.g. on-site vs remote), while also showing some alignment across regions. The presentation emphasised that there is no one-size-fits-all approach and that implementation should be adapted to the study context. It also highlighted the need to streamline and better integrate the consent development process, which remains complex and resource-intensive, particularly when transitioning to digital solutions.

Q&A session

Following the presentation on the recommendations to reduce bureaucracy in clinical trials, participants highlighted that existing flexibilities, particularly in risk-proportionate safety reporting, are not always fully utilised in practice, with protocols not consistently reflecting available options to reduce administrative burden. The importance of increasing awareness of how regulatory requirements are applied in real-world settings and the role of sponsors and other stakeholders in supporting more proportionate approaches was noted, alongside ongoing work on related guidance.

In the discussion on the eConsent Initiative, variability in expectations and approaches among stakeholders, including ethics committees and sponsors, was highlighted as an area where further alignment could support more consistent implementation.

7. Legislative and non-legislative development update

Update on Biotech Act

An update was provided on the Biotech Act, including proposed amendments to the Clinical Trials Regulation aimed at improving the efficiency and attractiveness of the EU clinical trial landscape. Key measures include streamlined authorisation procedures, alongside a stronger risk-based approach. The proposal also introduces provisions to support innovation, including AI use, decentralised trial elements, e-consent, and direct-to-patient supply. Further amendments focus on harmonisation and simplification, such as EU-wide templates, a single assessment procedure for combined studies, and a harmonised legal basis for data processing under General Data Protection Regulation (GDPR).

Update on FAST-EU (Facilitating and Accelerating Strategic Trials) initiative

An overview was provided of the FAST-EU pilot, launched to improve the attractiveness of Europe for clinical trials, accelerate patient access to innovative treatments, and strengthen the EU as a hub for clinical research, while maintaining scientific standards and patient protection. The initiative builds on collaboration between national competent authorities and ethics committees, to streamline processes within the existing regulatory framework. Key features include a 70-day procedure timeline, fixed timelines, and adapted document allocation to support more efficient assessments. Broad participation across Member States was highlighted, with most countries already involved and efforts ongoing to expand participation further. Strong interest from sponsors was noted, with applications exceeding available capacity. Selection of pilot procedures is therefore managed pragmatically, considering both scientific and operational considerations, as well as available resources. Initial experience from the first rounds shows progress in implementation, including increased flexibility in submission processes and expanded capacity beyond initial expectations. The pilot is expected to provide practical insights to inform future improvements to clinical trial processes in the EU.

Update on Clinical Research Investment Plan

An update was provided on the development of the Clinical Research Investment Plan under the European Life Sciences Strategy, aimed at strengthening Europe's competitiveness in clinical research. The initiative responds to the current fragmentation of the clinical research landscape and

is aligned with broader EU objectives, including ACT EU priorities. The plan is a non-regulatory initiative structured around two main pillars: facilitating funding for multinational clinical trials and strengthening European research infrastructures. It is intended to complement ongoing regulatory efforts, including the Biotech Act. Stakeholder consultations highlighted key needs, including more flexible and coordinated funding models, improved access to research infrastructures, and stronger support for SMEs and academic sponsors. There was also interest in exploring a potential single-entry point to connect sponsors with trial sites and infrastructures, as well as the use of AI and digital tools to support trial design and conduct. Overall, the plan aims to improve the efficiency and attractiveness of the EU clinical research ecosystem and support faster patient access to innovative treatments.

Q&A session

The discussion focused on the implementation and implications of the proposed CTR amendments under the Biotech Act, particularly regarding the strengthened risk-based approach. It was noted that the introduction of the "minimum intervention" trial category provides an opportunity to further operationalise risk-based methodologies, including in areas such as safety reporting and monitoring. Participants highlighted the value of ongoing work under ACT EU in supporting practical implementation and alignment across stakeholders. Continued exchange with MedEthicsEU was welcomed. Positive feedback was expressed on the overall direction of the proposals, with recognition that stakeholder input over recent years is reflected in the amendments. Clarifications were also sought on related initiatives, including templates, potential future stakeholder consultation and change management practices, with follow-up to be provided separately. The strong interest from sponsors in EU initiatives, including pilot activities, was acknowledged as a positive signal for the attractiveness of the European clinical trial landscape. It was clarified that the Biotech Act introduces targeted amendments to the existing Clinical Trials Regulation, building on its foundations while addressing areas for further simplification, coordination, and efficiency.

8. Launch of call for Stakeholder Co-chair

Public call for Stakeholder Co-chair

Following the expiry of the current stakeholder co-chair's mandate, the MSP AG Secretariat has launched a call for expression of interest, in line with the procedure outlined in 3.2.1. of MSP AG mandate and Annex 4. The stakeholder co-chair shall be selected from the non-commercial representatives (permanent and alternate) of the MSP AG.

Interested candidates are invited to submit their application, including a CV outlining relevant experience and a short statement of motivation, to the MSP AG Secretariat by 13 May 2026. The appointment of the new stakeholder co-chair is expected in June 2026.

9. Closing remarks

The co-chairs thanked participants and speakers for their active engagement and insightful discussions. Progress achieved to date, particularly over the past year, was acknowledged, reflecting strong collective efforts to improve the clinical trial ecosystem. At the same time, it was recognised that this remains ongoing work requiring continued adaptation to evolving scientific and regulatory landscapes.