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ACT EU multi-stakeholder platform annual meeting

Annual meeting report

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Contents

Executive summary

Collaboration and innovation continue to underpin efforts to strengthen the European clinical trials ecosystem under the Accelerating Clinical Trials in the European Union (ACT EU) initiative. The multi-stakeholder platform (MSP) plays a central role in this work by providing a structured forum for dialogue and cooperation among regulators, ethics committees, patients, industry, academia, healthcare professionals and funders. This work reflects a shared commitment across the network to advancing a coherent, efficient and innovation-driven clinical trial environment in Europe.

The MSP has contributed to tangible progress in regulatory consistency, efficiency and transparency. Key developments include work on recommendations that address issues identified during clinical trial assessments, improved Clinical Trial Information System (CTIS) handbook and the establishment of dedicated focus groups. Parallel efforts continued to strengthen the coordinating role of the reporting Member State (RMS) and improve the management of requests for information, supporting more predictable and harmonised implementation of the Clinical Trials Regulation and the use of the Clinical Trials Information System.

A central theme of the MSP annual meeting was innovation, reflecting the recognition that scientific and technological advances in clinical trials must be accompanied by regulatory and operational evolution. The meeting highlighted the importance of integrating patient experience data across the clinical trial and medicine lifecycles using transparent and validated methodologies. Emphasis was also placed on the need to move from consultation of patients to meaningful co-creation, where patients are research partners and their input becomes an integral part of evidence generation. Early involvement, capacity building and harmonised approaches were identified as essential to achieving sustainable, transparent and representative patient participation in clinical trials.

The convergence of innovative trial methodologies and evolving biotechnology was also addressed. Adaptive, platform and model-informed trial designs were recognised as valuable tools to enhance efficiency and evidence generation. Their broader adoption depends on robust data standards, interoperable infrastructure and early, coordinated dialogue between regulators, ethics committees and health technology assessment bodies. Operational fragmentation across Member States remains a barrier to consistent implementation and equitable access. This underscores the need for greater coordination, harmonisation and sustained collaboration to embed innovation within routine healthcare systems.

Digitalisation and artificial intelligence are increasingly shaping the design, conduct and evaluation of clinical trials. The European Health Data Space was identified as a key opportunity to facilitate patient-mediated data sharing, improve recruitment and support decentralised and hybrid trial models. At the same time, the meeting highlighted the need for clear guidance aligning the General Data Protection Regulation, the Medical Device Regulation and the AI Act, along with strengthened data governance, cybersecurity preparedness and sustained investment in digital infrastructure and site capacity. Trust, transparency and human oversight were consistently emphasised as prerequisites for responsible adoption.

Ethical oversight remained a cross-cutting theme. Participants emphasised the importance of proportionate and consistent ethics review processes that support innovation while safeguarding participant protection. They also highlighted the need for broader expertise, clearer coordination across Member States and robust frameworks for decentralised and digital trials. In parallel, the

meeting identified the importance of informed consent evolving into a continuous, participant-centred process, supported by accessible digital tools but grounded in human interaction.

Overall, Europe's clinical research environment is characterised by complexity and diversity, and sustained collaboration is essential to enhance competitiveness, foster innovation and ensure timely patient access to research. These considerations will inform follow-up actions and contribute to the refinement of ACT EU priorities and future workplans.

Introduction

Marianne Lunzer (AEGS), Denis Lacombe (EORTC), Emer Cooke (EMA), Sandra Gallina (European Commission), Nils Falk Bjerregaard (DKMA)

Collaboration and innovation remain fundamental to strengthening the European clinical trial landscape. This is recognised through the work of the multi-stakeholder platform (MSP), which continues to play a pivotal role under the Accelerating Clinical Trials in the European Union (ACT EU) initiative. By bringing together representatives of industry, academia, patients, healthcare professionals and funders, along with regulators and ethics committee representatives, the MSP provides a structured forum for dialogue and cooperation, ensuring that clinical research in the EU evolves in a coherent, harmonised and innovation-driven manner.

Through regular exchanges and shared planning, the MSP has helped align priorities across the network, ensuring that the updated ACT EU workplan for 2025–2026 reflects stakeholder expectations, operational realities and long-term objectives. This ongoing collaboration illustrates the joint commitment to transforming how clinical trials are conducted in Europe and to create a more effective, flexible and patient-centred environment for research.

Over the past year, tangible progress has been achieved in several key areas. Important milestones in improving regulatory consistency and efficiency include recommendations on auxiliary medicinal products in clinical trials, recommendations on frequent issues identified during the trial assessment and the establishment of dedicated focus groups. Parallel efforts are under way to strengthen the coordinating role of reporting Member States and to optimise the management of requests for information. These initiatives directly contribute to greater transparency, predictability and harmonisation across the EU regulatory system.

The 2025 annual meeting placed innovation at the centre of discussion, reflecting the shared recognition that science and regulation must evolve in tandem. As new technologies redefine research design, regulatory frameworks must adapt to ensure timely access to innovation. The launch of the EU clinical trials map, now accessible in all official EU and EEA languages, marks an important step in improving public transparency and patient engagement. Similarly, the updated recommendations on clinical trials with decentralised elements demonstrate a continuous effort to align guidance with emerging digital tools and new methodologies.

At the same time, participants recognised that Europe’s clinical research ecosystem remains complex and fragmented. Sustaining competitiveness requires ongoing collaboration to overcome national divergences, promote regulatory convergence and foster an environment conducive to investment, innovation and scientific excellence. The forthcoming Biotech Act provides a strategic opportunity to strengthen Europe’s capacity for innovation, attract high-value research and reinforce its position as a global leader in biomedical development.

A focus on results and accountability has become a defining feature of ACT EU’s progress. The introduction of targets and key performance indicators (KPIs) to monitor the EU clinical trials environment represents a major step towards evidence-based policy evaluation. The ambition is to have 500 additional multinational trials authorised by 2030 and for two-thirds of trials to start recruitment within 200 days of application submission.

Timeliness remains central to Europe’s attractiveness as a research hub. Each additional week of delay in clinical trial authorisation or site activation translates into tangible costs, affecting both competitiveness and patient access to innovation. Efforts to reduce these timelines could

significantly enhance the EU's appeal for global research investment and ensure that opportunities are more evenly distributed across Member States.

Collectively, these achievements and commitments reaffirm a shared direction: to ensure that regulation actively enables scientific progress, that collaboration drives efficiency and that clinical research in Europe continues to deliver innovation, quality and tangible benefits for patients. The discussions and outcomes of the 2025 MSP annual meeting underscore this vision of a strong, united and forward-looking European clinical trials landscape that is built on trust, transparency and shared responsibility.

Keynote

European Federation of Pharmaceutical Industries and Associations (EFPIA)

Innovation and collaboration remain the cornerstones of progress in healthcare and clinical research. This was powerfully illustrated in the keynote address, which drew a parallel between the ocean and the healthcare ecosystem: two vast, interconnected systems that thrive on balance, interdependence and resilience. Just as the ocean sustains life through continuous exchange and adaptation, the healthcare ecosystem depends on coordinated effort and shared responsibility to maintain equilibrium in an era of rapid transformation. This transformation is increasingly being shaped by AI, which is no longer a future aspiration but an integral component of modern healthcare and clinical research.

AI technologies are already reshaping how data are interpreted, decisions are made and evidence is generated. Across Europe, hospitals and research institutions are adopting digital tools that assist clinicians in identifying drug interactions, summarising treatment histories and detecting disease patterns invisible to the human eye. Virtual assistants now support patient follow ups, improve adherence and reduce the administrative burden on healthcare professionals. In research and development, AI is being applied to protocol design, patient identification, site selection and the generation of synthetic and real-world data, with AI-qualified statistical methodologies demonstrating potential to optimise study design and accelerate access to reliable evidence. These developments underline the shift from experimental use to mainstream integration of AI across the research and healthcare continuum.

Europe is uniquely positioned to lead this transformation through the creation of a cohesive digital and data framework. The European Health Data Space (EHDS), supported by the General Data Protection Regulation (GDPR) and the forthcoming EU AI Act, provides the foundation for secure, trustworthy and innovation-friendly data sharing. However, to ensure coherence and continued public trust, regulatory frameworks must evolve in step with technological progress.

While the opportunities presented by AI are considerable, the address emphasised that ethical integrity, quality assurance and scientific validation must remain central to its adoption. A clear distinction should be made between human-controlled and autonomous systems, and AI tools must be transparent, traceable and rigorously tested before integration into clinical or regulatory decision making. AI's value depends on the quality and interoperability of underlying data, making robust governance and data provenance essential. Advances in natural language processing enable insights from unstructured information, yet human expertise must remain central to interpretation and decision-making. Ultimately, AI should enhance, not replace, human expertise and clinical reasoning.

AI is expected to play an increasingly important role across the clinical trial lifecycle, supporting decentralised and hybrid trial models, digital twins and predictive analytics that can improve trial efficiency, inclusiveness and data reliability. Yet, technological progress must advance hand in hand with operational excellence. Streamlining regulatory timelines remains one of the most effective ways to strengthen Europe's competitiveness and ensure timely access to innovation for patients.

The keynote concluded with a clear message of collective responsibility and partnership. Realising the full potential of AI in healthcare and clinical research will require sustained collaboration among regulators, researchers, clinicians, industry and patients. Innovation must remain ethical, transparent and centred on patient benefit. Through shared understanding,

trust-based governance and continued dialogue, Europe can lead in harnessing AI as a force for good, strengthening resilience, inclusiveness and excellence across its healthcare and research systems.

Session 1

Innovation in patient-oriented research

Moderators: Begoña Nafria (eYPAGnet) and Juan Garcia Burgos (EMA)

Key messages

- Patient experience data (PED) are relevant in making medicine development more relevant and responsive to real patient needs.
- PED should be integrated across the medicine's lifecycle through transparent and validated methodologies.
- Innovation in clinical trials requires a cultural shift, from consultation to genuine co-creation, with patients seen as experts with lived experience who work alongside regulators and clinicians in a collaborative model.
- Early involvement, capacity building and harmonised frameworks are essential for sustainable and meaningful participation.
- Inclusion, transparency and representativeness must guide the collection, publication and use of patient-generated evidence.

Summary of presentations and panel discussion

Update on EMA's work on patient experience data

Integrating patient experience data (PED) into the medicine development and regulatory lifecycle remains a key priority for the European Medicines Regulatory Network (EMRN). PED are essential to ensuring that medicines are developed and assessed in ways that truly reflect real patient needs, preferences and lived experiences.

This initiative supports developers, researchers and patient organisations in adopting structured and transparent approaches to collecting, analysing and using PED from early development through to post marketing.

A key milestone is the recent publication of a reflection paper clarifying the regulator's position on the potential value of PED. The paper:

- provides a framework of principles and avenues for developers to liaise with EMA on how to systematically embed PED throughout the medicine's lifecycle.
- provides guidance on how qualitative and quantitative data, such as patient-reported outcomes, preference studies and structured engagement exercises, can complement traditional evidence in the benefit–risk assessment.
- emphasises validated, reproducible methodologies to ensure the credibility and representativeness of patient-derived information.

In parallel, the European Medicines Agency (EMA) promotes early dialogue between sponsors, patient organisations and regulators through scientific advice and qualification procedures, supporting alignment on methodological plans and data strategies. This engagement aims to foster mutual understanding and ensure that patient perspectives are considered from the earliest stages of product development.

Additional priorities include integrating PED into regulatory documentation, promoting transparent reporting and disseminating results in accessible formats for patients.

The overarching principle is that patient input should not be treated as a separate evidence stream but as an integral part of the scientific continuum that informs regulatory evaluation.

The continuous evolution of PED initiatives demonstrates the commitment of the regulatory network to embed patient perspectives across all phases of medicines development and to ensure that evidence generation remains both scientifically rigorous and responsive to patient realities. By systematically integrating PED in clinical trial design and fostering meaningful involvement of patients, the EMRN seeks to create a more responsive and inclusive research ecosystem.

Involving patients in clinical trial design — where can we innovate?

Patient involvement in trial design must move beyond consultation to genuine co-creation. This requires not only technological innovation, but innovation in how research is conceived and conducted. It requires a cultural shift to move beyond reactive approaches that only engage patients after diagnosis and instead take on proactive strategies that leverage community-driven solutions and improve health literacy.

Early and systematic engagement is key. This means involving patients from the outset in the design of clinical trial protocols, such as endpoint definition, recruitment strategies and outcome measures that reflect real-world priorities. Such collaboration improves patient-centric design, acceptability and feasibility, enhances recruitment and retention and ensures that clinical research outcomes are more relevant to patients. However, this input is often missing from regulatory documentation, which limits its impact.

To make patient involvement meaningful, organisations and regulators must remove barriers and recognise patients as experts with lived experience, working alongside clinicians and regulators as equal partners in a collaborative model. This requires investment in training and capacity building, for both patients and researchers, as well as harmonised guidelines and sustainable funding that enable patient organisations to contribute effectively. Importantly, participation must be genuine and consistent across trials, not siloed or tokenistic.

Ensuring patient input is inclusive and representative is a critical challenge. For example, under-represented groups such as minors need tailored frameworks for participation. In addition, transparent publication of patient-generated evidence will strengthen trust and visibility. Initiatives such as the development of a WHO guidance to promote equitable access of underrepresented populations to clinical trials (for interventions they could benefit from) and the GCTF members' initiative (Global Clinical Trials Forum - a WHO managed network) on defining outcome measures for effective participants engagement in clinical trials, aim to set clear patient-driven standards for patient-investigator-sponsor interactions throughout the lifecycle. These initiatives reinforce accountability and consistency across the clinical research process.

Finally, reducing the burden of trial-by-trial involvement and creating mechanisms for shared patient input across therapeutic areas and indications can prevent duplication and ensure continuity. By systematically embedding patient perspectives in clinical trial design and fostering genuine collaboration, we can build a research ecosystem that is responsive, inclusive and aligned with patient needs.

Session 2

The convergence of innovative methodology and evolving biotechnology

Moderators: Lada Leyens (EFPIA) and Isabelle Clamou (European Commission)

Key messages

- Innovative clinical trial designs are most effective when supported by robust data standards, sound modelling approaches and early coordinated dialogue between regulators and health technology assessment (HTA) bodies.
- Patient trust in innovative trial design requires proof of value, timely training, resources for meaningful input and structured dialogue between patients, sponsors and regulators.
- Fragmentation of approval pathways for advanced therapy medicinal products (ATMPs) creates duplication and delay; coordinated, single-entry mechanisms could accelerate timelines and enhance predictability.
- Operational fragmentation across Member States remains a barrier to consistent implementation, equitable access and data comparability, underscoring the need for harmonised procedures and streamlined contracting frameworks.
- Strengthened collaboration, shared data infrastructure and stable, long-term platform-trial frameworks are essential to sustaining innovation and embedding research in routine healthcare systems, and will also help build long-term, "learning health system" capacity across Europe.
- ACT EU can facilitate progress by supporting a harmonised approach at national level, promoting harmonised contracting templates, publishing methodological playbooks and piloting combined reviews for complex products and designs.

Summary of key presentations and panel discussion

Concrete examples of trials approved with innovative design

Innovation in clinical trial design is transforming how evidence is generated and assessed across Europe. Advances in adaptive, platform and multi-arm multi-stage (MAMS) designs should be viewed as an evolution of established practice rather than a disruption. The objective is to enhance efficiency, inclusiveness and scientific robustness, while maintaining the reliability of evidence supporting regulatory and clinical decision-making.

Adaptive, platform and MAMS designs enable simultaneous evaluation of multiple interventions, flexible recruitment strategies and early termination based on futility or success. These approaches have proven to be particularly effective in well-resourced therapeutic areas such as oncology and infectious diseases, where collaborative networks provide shared infrastructure, harmonised governance and coordinated data systems. However, replicating such models in rare or paediatric diseases remains challenging due to limited populations, resource constraints and disparities in methodological expertise across Member States.

Operational innovations, such as shared controls and collaborative trial platforms, and methodological advances, including n-of-1 trials, digital twins and model-based evidence synthesis, could increase efficiency and personalise research. Their value depends on clear standards for data quality, validation and regulatory credibility. Methodological innovation therefore needs robust statistical frameworks and should be supported by interoperable data systems capable of generating reproducible, high-quality results.

Other innovative trial designs include model-based and synthetic-control approaches, which require access to harmonised, longitudinal data sources, such as disease registries and electronic health records. However, without consistent data provenance and shared analytical standards, the regulatory relevance of these tools remains limited. Furthermore, alignment in the interpretation of data protection frameworks, including GDPR, would help ensure consistency in cross-border data use. In summary, strong data governance, harmonised frameworks and sustainable infrastructure are necessary to ensure that real-world and model-derived evidence meet scientific and regulatory requirements.

Beyond methodology, system-level alignment is essential.

Operational fragmentation across Member States continues to delay implementation and compromise data comparability. This is reflected in divergent national approaches to aspects such as direct-to-patient shipping, e-consent and home-nursing procedures.

In addition, variation in the interpretation of decentralised trial requirements can result in multiple parallel national processes, effectively multiplying administrative workload. As a result, sponsors must adapt a single protocol multiple times, increasing administrative burden and delaying trial initiation. Strengthening coordination among national authorities and promoting harmonised operational standards are therefore critical to establishing a more predictable and equitable trial landscape.

To achieve a sustainable infrastructure, research should be embedded within the healthcare delivery system through permanent EU-wide platforms. Such "learning health system" models would allow continuous participants recruitment, facilitate registry-based and embedded randomised trials and better connect clinical evidence with real-world outcomes. To support the maturation of these platforms and move beyond short-term, project-based financing, long-term, multi-year funding mechanisms are required.

Patient trust and collaboration are integral to achieving these changes. However, trust cannot be achieved through communication alone. Moreover, while patients have access to excellent training programmes, these often lag behind the pace of innovation, making it difficult to stay aligned with evolving methodologies. Meaningful involvement also requires time and resources for protocol reviews, an area where patient organisations may face capacity challenges. Furthermore, there is currently no mechanism for consulting patient organisations during the clinical trial assessment, limiting opportunities for early dialogue between patients, sponsors and regulators. Structured engagement channels would strengthen trust, improve trial relevance, and ensure that patient perspectives inform regulatory decisions.

The use of innovative designs must also be accompanied by mechanisms that facilitate transparency and knowledge sharing. For example, by making platform and adaptive trials easily searchable and traceable within CTIS, successful methodologies could be identified and replicated. Such an approach would foster continuous learning and broader uptake across the EU. Collectively, these actions support the alignment of methodological innovation with coordinated national implementation, data readiness and stable infrastructures to deliver faster, more inclusive and higher-quality clinical research across Europe.

ATMP innovation in the current EU clinical trials landscape: a case study

Advanced therapy medicinal product (ATMP) trials exemplify both the opportunities and challenges associated with high-technology, first-in-human research within the EU. A case study on the development of a gene-insertion platform using a viral vector combined with a CRISPR-based editing component illustrates the systemic issues faced by developers of complex products.

ATMP development currently requires multiple, unaligned approval pathways, including a clinical trial application via CTIS, genetically modified organism (GMO) authorisation at national level, and, for companion diagnostics, a performance study application under the In Vitro Diagnostic Regulation (IVDR). Early regulatory dialogue and scientific advice have proven valuable in lowering the risk associated with development and in aligning expectations. However, procedural fragmentation and different national requirements continue to create inconsistencies in how regulations are interpreted and consequently extend timelines.

This fragmentation leads to redundant reviews and different start-up times across Member States. Differences in how GMO and IVDR provisions are applied add further complexity and unpredictability. To address this, stakeholders discussed establishing a single-entry coordination mechanism, to align the review and authorisation of clinical trial application, GMO and IVDR components. Such an approach could streamline processes, improve predictability and enhance Europe's competitiveness in advanced therapy research.

From a methodological perspective, developers face uncertainty about evidence requirements for small-population and adaptive designs, as well as the use of external or historical controls. Early joint scientific advice involving regulators, HTA bodies and ethics committees could clarify expectations, promote methodological consistency and ensure that innovative designs remain both scientifically sound and relevant.

Equally critical are data quality and interoperability. High-quality registries, curated metadata and standardised outcome definitions are required to support model-informed evidence generation and the integration of real-world data in regulatory evaluation. Investment in shared data standards and certification mechanisms would help build trust in digital-twin and synthetic-control approaches.

Operational and administrative processes remain a major source of delay, with multi-agency reviews and complex contracting often exceeding the duration of scientific assessment. Establishing harmonised model contracts, standard templates and indicative timelines across Member States would serve as a practical short-term measure to enhance efficiency and predictability.

Europe's capacity to maintain global leadership in advanced therapy innovation depends not only on scientific excellence, but also on simplifying and aligning regulatory processes, strengthening data infrastructure and enhancing operational efficiency through platform technology frameworks for clinical trials. A coordinated, transparent and data-driven framework, supported by long-term infrastructure, harmonised procedures and sustained collaboration, will be key to ensuring that scientific progress translates effectively into patient benefit.

Session 3

Innovation in AI and digitalisation

Moderators: Amélie Michon (ECRIN) and Peter Arlett (EMA)

Key messages

- Building sustainable site and hospital capacity is essential to enable efficient, high-quality research.
- Clear guidance aligning GDPR, Medical Device Regulation (MDR) and the AI Act is needed to ensure responsible use of AI within good clinical practice frameworks.
- Stronger data quality and interoperability are crucial for trustworthy use of AI and enabling seamless cross-border research.
- The European Health Data Space (EHDS) is a key opportunity to facilitate patient-mediated data sharing, accelerate recruitment and promote inclusive participation in clinical trials.
- Long-term digital transformation requires a resilient infrastructure, cybersecurity preparedness and sustained investment in "warm base" platforms that integrate research into routine care.
- Technology alone will not transform clinical trials; trust, collaboration and shared responsibility will make the difference.

Summary of key presentations and panel discussion

Digital innovation in healthcare: challenges and possibilities

AI and digital tools are increasingly transforming the design, conduct and evaluation of clinical trials across Europe. These technologies offer the potential to streamline trial operations, enhance data quality and support faster, more inclusive research. However, integration of such tools into clinical and regulatory systems across the EU remains constrained by infrastructure gaps, fragmented governance and a lack of common standards.

Hospitals and research centres are showing growing interest in digital transformation, particularly in areas such as automated eligibility pre-screening, real-time monitoring, data curation and adverse event detection. Such tools can help embed continuous learning within healthcare systems and bridge the gap between clinical research and routine care. Yet, many institutions lack the necessary technical capacity to sustain these innovations and are restricted by the limited availability of dedicated trial units, data-engineering staff and sustainable funding.

Regulatory complexity compounds these challenges. Overlapping requirements from the GDPR, Medical Device Regulation (MDR) and the AI Act create uncertainty around classification, accountability and documentation. Clear guidance is essential to build confidence and accelerate adoption of these regulations. At the same time, Europe's strong emphasis on risk management, while vital for patient safety, may unintentionally slow innovation. It is therefore critical that the EU strikes the right balance between safeguarding data and the application of AI. AI should serve patients and, as such, it should be developed and deployed as assistive tools that reinforce human expertise. Hospitals need practical guidance, standard operating procedures and collaboration frameworks to integrate AI responsibly and effectively. Building

digital literacy across all professional groups is critical, alongside investment in education and change management.

Access to data and infrastructure varies widely across Europe. This is often due to institutional resistance and complex governance processes, rather than technological challenges. Another major barrier remains data integration between hospitals and academia, which limits scalability. Regulators play a key role in supporting harmonisation and interoperability by issuing guidance, recommendations and best practices.

Finally, the resilience of the digital health ecosystem is also important. As systems become increasingly interconnected, cybersecurity risks threaten both hospital operations and ongoing trials. A coordinated European approach to digital infrastructure and cybersecurity is therefore essential to safeguard patient safety and ensure research continuity.

Opportunities for the European Health Data Space to change clinical trial recruitment

The European Health Data Space (EHDS) represents a pivotal opportunity to transform trial recruitment, participation and monitoring. Today, recruitment across Member States often relies on manual chart reviews and fragmented communication channels, leading to inefficiencies and limiting access to eligible patients. The EHDS aims to replace these manual processes with standards-based, patient-mediated data sharing that enables secure, real-time access to key health information.

When fully implemented, the EHDS will allow patients to authorise the sharing of priority health data categories, including laboratory results, imaging, diagnostic reports and medication histories, directly with researchers and sponsors. This has the potential to accelerate pre-screening, enhance eligibility assessment and support decentralised or hybrid trial models. Integration of electronic health records (EHRs), electronic case report forms (eCRFs) and wearables into interoperable architectures will further enhance efficiency and inclusion, extending participation beyond major urban centres and academic sites.

To achieve this vision, harmonisation and data quality are paramount. For example, the effective use of digital tools and AI depends on consistent metadata, common vocabularies and well-defined interoperability standards. However, at present, data exchange across the EU is hampered by fragmented data systems and inconsistent coding practices. Further alignment in the interpretation of data protection frameworks, including the GDPR, will be essential to ensure consistency in cross-border data use and to facilitate efficient multinational trial conduct.

Pragmatic guidance for AI validation and lifecycle management specific to clinical research will also be critical. For example, establishing clear expectations for algorithmic transparency, explainability and performance monitoring will support regulatory predictability and inspection readiness. In addition, targeted guidance for small to medium-sized enterprises and emerging developers can help accelerate innovation while ensuring compliance with the AI Act and broader EU data governance requirements.

Embedding fairness, privacy and inclusiveness in AI design principles will be key to broadening research participation for underrepresented groups and remote populations. Federated data architectures that protect patient identity while enabling secure, multi-country analyses can help reconcile the goals of innovation and data protection. Consistent ethical frameworks and model contracts across jurisdictions will further support transparency and trust in data sharing for research.

Ensuring long-term sustainability will require a shift from isolated pilot projects to permanent, large-scale digital infrastructures that are research ready and embedded within healthcare systems. Multi-year investment in "warm base" (permanent, always-on digital infrastructures that link healthcare and research) platforms integrating clinical care, routine data capture and research operations will enable continuous learning, reuse of algorithms and more efficient coordination between public and private research initiatives across Europe. These infrastructures will constitute the foundation of a resilient, inclusive and digitally empowered European clinical research ecosystem, where innovation, trust and patient benefit remain central.

Session 4

Innovation in ethics

Moderators: Monique Al (CCMO/MedEthicsEU/CTCG) and Tarec El-Galaly (DK-MREC/EMA)

Key messages

- Consistently applied guidance can build mutual understanding and trust between ethics committees and sponsors.
- Ethics review should support innovation while upholding ethical reflection and participant protection, with proportionate, two-stage models separating administrative checks from substantive ethical assessment.
- Ethics committees need broader multidisciplinary expertise in data science, AI, usability and privacy, alongside full access to trial documentation to ensure contextual evaluation.
- Decentralised and digital trials require clear allocation of responsibilities, robust data-handling procedures and inclusive participation options for those less familiar with technology.
- Europe's cultural pluralism should be seen as a strength. Coordination across Member States should focus on sharing best practices and promoting consistency, while respecting national ethics frameworks and avoiding rigid centralisation.
- Informed consent should become a continuous, participant-centred process, supported by accessible digital tools that enhance understanding and trust without replacing human interaction.

Summary of key presentations and panel discussion

Safeguarding participants while driving innovation

Ethical oversight plays a central role in ensuring that innovation in clinical research aligns with moral principles and upholds participant protection. Ethics committees, originally designed to provide independent, interdisciplinary evaluations, now face unprecedented challenges posed by AI-enabled methodologies, adaptive and platform trials and decentralised participation models. These developments have expanded the scope and the complexity of ethical review, often under shorter timelines and without additional resources or coordination. At the same time, committees are still adapting to the CTR, working to harmonise 27 culturally rooted ethics

systems and legal frameworks. The question is how ethics committees can continue to protect participants, and at the same time act as strategic partners to support innovation.

While in many ways Europe's cultural pluralism is a strength, there is a need for harmonisation across its different ethical review structures to accommodate accelerated review timelines. A first step would be to gain a clear understanding of the ethics structures across EU Member States. For example, an analysis of CTIS data could provide valuable insights into the kind of questions raised in different countries. This would help to identify areas of conflicting approaches, such as different interpretations of the GDPR.

Recent analyses of queries received by ethics committees across multiple Member States reveal clear patterns: most questions about Part 1 of the clinical trial application focus on statistical aspects and trial rationale, while Part 2 queries predominantly concern informed consent and participant information. Part 2 queries include decentralised procedures, digital consent, AI integration and secondary use of real-world and registry data. Although standardised templates, for example for informed consent forms, and pre-review checklists have helped reduce the administrative burden and requests for information, these measures have not necessarily benefitted the ethical reflection. Greater procedural compliance does not automatically equate to stronger participant protection; ethical oversight must remain grounded in the principles of proportionality, autonomy and justice.

To enhance both timeliness and quality, the ethics review could follow a structured, two-stage approach, where the administrative or legal validation is separate from the more substantive ethical evaluation. The first stage would verify completeness and regulatory compliance, while the second would focus on moral reasoning, participant welfare and proportionality. This differentiation would provide committees with the necessary space for reflection without delaying overall timelines, thereby ensuring that ethics remains a cornerstone of innovation rather than a bottleneck.

Decentralised and digital trial elements introduce new layers of ethical complexity. As research activities extend beyond traditional sites into homes and community settings, the responsibilities of sponsors, investigators and third-party providers must be clearly delineated to avoid accountability gaps. Equally important is the need for participation to remain accessible for individuals who cannot engage digitally. This will ensure that technology serves as a tool for inclusion rather than a barrier.

As clinical research grows increasingly complex, ethics committees require broader expertise in areas such as data science, cybersecurity, human-centred design and AI. Ethics committee access to the complete trial dossier, rather than fragmented documentation, would enable a more contextual evaluation and lead to more consistent decision-making. At the EU level, coordination should aim to facilitate knowledge-sharing, promote best practices and reduce duplication, while respecting the diversity of national ethics frameworks. Over-centralisation, however, could risk eroding the local insights that often enrich ethical deliberation.

Strengthening structured dialogue between ethics committees, regulators and stakeholders, supported by initiatives like MedEthicsEU, can foster consistency, mutual learning and a shared understanding of emerging ethical challenges across Europe.

Public dialogue and patient engagement remain essential pillars of ethical oversight. Ethics must not be reduced to a purely procedural formality; it must continue to serve as a space for reflection, empathy and societal trust. Building this trust requires transparency about data flows, clear accountability, and openness regarding the principles guiding ethical decision-making.

Challenges with informed consent in complex or novel trials

Informed consent continues to evolve as trial designs and technologies advance. Adaptive, pragmatic and platform studies challenge traditional models and require new approaches that preserve participant understanding and autonomy. In pragmatic trials comparing authorised standard-of-care treatments, the scope and timing of consent remain under discussion: broad consent at cohort entry may suffice in some contexts, while re-consent at randomisation may be needed in others. In multi-arm and platform trials, re-randomisation and interim analyses create situations where consent must be renewed as study arms open or close, ensuring that participants remain informed throughout the trial lifecycle.

External controls, registry-based comparisons and genomic sub-studies introduce additional ethical dimensions. Secondary use of data and incidental findings blur the boundary between research and care, underscoring the importance of clarity on data provenance, privacy and communication of results. Ethics committees must ensure that participants are informed not only about direct interventions but also about the use of their health data beyond the immediate study context.

Digital consent platforms can play a constructive role in improving comprehension and engagement. By integrating multimedia explanations, adaptive language and interactive features, they can make complex information more accessible. However, such tools should never replace direct dialogue between clinical trial participants and investigators. Their purpose is to support, not substitute, human interaction. For this reason, usability, accessibility and data-security standards must guide the evaluation of e-consent systems. Further alignment in assessing their compliance with good clinical practice and legal requirements across Member States would strengthen transparency and trust.

Not all participants have equal access to technology or the digital literacy required to navigate it. Hybrid consent options, combining digital and traditional formats, will remain essential to ensure that innovation does not exacerbate disparities.

The integration of AI into participant-facing tools introduces new opportunities for personalised communication as well as new ethical and regulatory challenges. Algorithms that adapt explanations or summarise trial information must remain auditable, transparent and subject to human oversight. Ethics committees will need clear frameworks for evaluating these technologies, ensuring that fairness, explainability and data integrity are preserved.

Finally, informed consent should be viewed as a continuous process rather than a single event. Renewing consent at defined milestones, such as major protocol amendments, arm closures or genomic sub-studies, safeguards participant autonomy. Embedding this principle of "continuous consent" within regulatory guidance would align ethical reflection with the dynamic nature of modern research.

A culture of openness and dialogue will be central to maintaining trust in this evolving environment. Ethics must remain a human endeavour that is adaptable, transparent and anchored in respect for participants as partners in research.

Closing remarks

Marianne Lunzer (AGES MEA/CTCG) and Denis Lacombe (EORTC)

The meeting reflected a strong, collective commitment to advancing a coherent, efficient and innovative clinical trials ecosystem in Europe. The exchanges demonstrated the continued engagement of all stakeholders in strengthening collaboration, fostering methodological and digital innovation, and embedding patient involvement at the centre of research. The insights gathered will inform the planning of follow-up actions and future priorities under the ACT EU workplan and related initiatives.

ACT EU continues to serve as a collaborative platform bringing together regulators, ethics committees, patients, industry, healthcare professionals, academia and funders to address shared challenges and co-develop practical solutions. The meeting also reaffirmed the MSP's role as a collaborative forum to shape Europe's clinical research future, noting that innovation requires not only technology, but also trust, communication and meaningful patient partnership. Building a harmonised, inclusive and future-ready clinical research environment will depend on sustained collaboration, transparency and mutual learning across all levels of the system.

A recurring theme was the importance of a cultural shift towards collaboration and simplification. Meaningful progress depends on the collective expertise and engagement of all actors in translating principles into practice. The four thematic sessions highlighted the progress achieved and the areas requiring continued attention. The reflections gathered will guide the refinement of ACT EU priorities and the development of the workplans for the coming years.

Stakeholders were invited to continue contributing to ACT EU initiatives and upcoming consultations and to help translate the meeting's insights into practice across Member States and organisations. The discussions concluded with a shared sense of purpose and optimism, confirming that open dialogue, cooperation and trust remain the foundation for progress and for strengthening Europe's position as a global leader in high-quality, patient-centred clinical research.

Glossary

ACT EU	Accelerating Clinical Trials in the EU
AGES MEA	Austrian Agency for Health and Food Safety
ATMP	Advanced therapy medicinal products
CCMO	Central Committee on research Involving Human Subjects
CTA	Clinical trial application
CTCG	Clinical Trials Coordination Group
CTIS	Clinical Trials Information System
CTR	Clinical trials regulation
DK MREC	Danish Medical Research Ethics Committees
ECRIN	European Clinical Research Infrastructure Network
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EMRN	European medicines regulatory network
EORTC	European Organisation for Research and Treatment of Cancer
EU	European Union
EYPAGnet	European Young Patients Advisory Group Network
IVDR	In-Vitro Diagnostics Regulation
MAMS	Multi-arm multi-stage
MDR	Medical devices regulation
MSP	Multi-stakeholder platform
WHO	World Health Organization

More information

The Accelerating Clinical Trials in the EU (ACT EU) initiative aims to further develop the European Union as a competitive centre for innovative clinical research. ACT EU seeks to deliver on the clinical trial innovation recommendations of the European medicines agencies network strategy and the European Commission's Pharmaceutical strategy for Europe.

ACT EU builds on the Clinical Trials Regulation (CTR) and Clinical Trials Information System (CTIS) launched on 31 January 2022. The European Commission, EMA and Heads of Medicines Agencies launched ACT EU in January 2022 and run the initiative together, establishing a steering group in March 2022. The programme's strategy paper features priority action (PA) areas that are the basis for the ACT EU workplan.

The ACT EU workplan 2026-2027 is in the process of being revised and will be finalised in Q1 2026.

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