

ACT EU multi-stakeholder platform annual meeting agenda

29 October 2025, 09:30 – 17:00 (CET/CEST)

Virtual meeting/ EMA, Amsterdam

Innovation is reshaping the future of clinical trials in Europe—driving better, faster, and smarter research that is more inclusive and responsive to patient and societal needs. This year's annual ACT EU Multistakeholder Platform meeting offers an in-depth exploration of the strategic importance of innovation in strengthening Europe's clinical trials ecosystem.

Across four thematic sessions— patient-oriented research, AI and digitalisation, methodological and biotechnology advances, and ethics and regulatory preparedness—we will explore how innovation can improve trial design, execution, and impact. The programme features insights from patient, healthcare professional, industry and academic representatives, regulators and global experts, showcasing real-world use cases and highlighting opportunities to enhance inclusiveness, ethical integrity, and readiness for emerging technologies.

The multi-stakeholder platform (MSP) annual meeting aims to:

- Support alignment of innovation efforts in clinical trials with the EMAN to 2028 strategy and ACT EU priorities
- Showcase domain-specific innovations and their potential to improve trial outcomes and patient impact.

- Facilitate multistakeholder dialogue to identify good practices and strengthen collaboration across sectors.
- Explore regulatory and ethical readiness across domains and identify where further enablers are needed to support inclusive and responsible innovation.

This workshop is open to all stakeholders through the broadcast link.

Broadcast link available at the event webpage: [ACT EU multi-stakeholder platform annual meeting | European Medicines Agency \(EMA\)](#)

ACT EU multi-stakeholder platform annual meeting agenda

Chaired by Maria Jesús Lamas Díaz (HMA/AEMPS) and Denis Lacombe (EORTC)

09:00 Joining and technical checks

09:30 Welcome and opening remarks

Co-chairs welcome and opening of the meeting <i>Maria Jesús Lamas Díaz and Denis Lacombe</i>	5 min
Opening remarks <i>Emer Cooke (EMA)</i>	5 min
Opening remarks <i>Sandra Gallina (European Commission)</i>	5 min
Opening remarks <i>Nils Bjerregaard (HMA/DKMA)</i>	5 min

09:50 Keynote address

Keynote address	20 min
Q&A session	10 min

10:20 Session 1: Innovation in patient-oriented research

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

Update on EMA's work on patient experience data	15 min
Involvement of patients in clinical trial design	15 min
Panel and audience discussion	45 min

11:35 Coffee break

11:55 Session 2: The convergence of innovative methodology and evolving biotechnology

Moderators: Lada Leyens (EFPIA) and Marianne Lunzer (CTCG)

Concrete examples of trials approved with innovative design 15 min

ATMPs - transformative therapies **15 min**

Panel and audience discussion	45 min
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13:10 Lunch

14:00 Session 3: Innovation in AI and digitalisation

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

Digital Innovation in the healthcare setting **15 min**

Data-Driven Healthcare: Patient finding and datasets 15 min

Panel and audience discussion	45 min
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15:15 Session 4: Innovation in Ethics

Moderators: Tarec El-Galaly (EMA) and European Commission (TBC)

Safeguarding participants while driving innovation **15 min**

Building better consent models for innovative trials	15 min
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Panel and audience discussion	45 min
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16:30 **Closing remarks**

Wrap up **15 min**