



# Multi-stakeholder platform 2025 activity

## PCWP/HCPWP annual meeting

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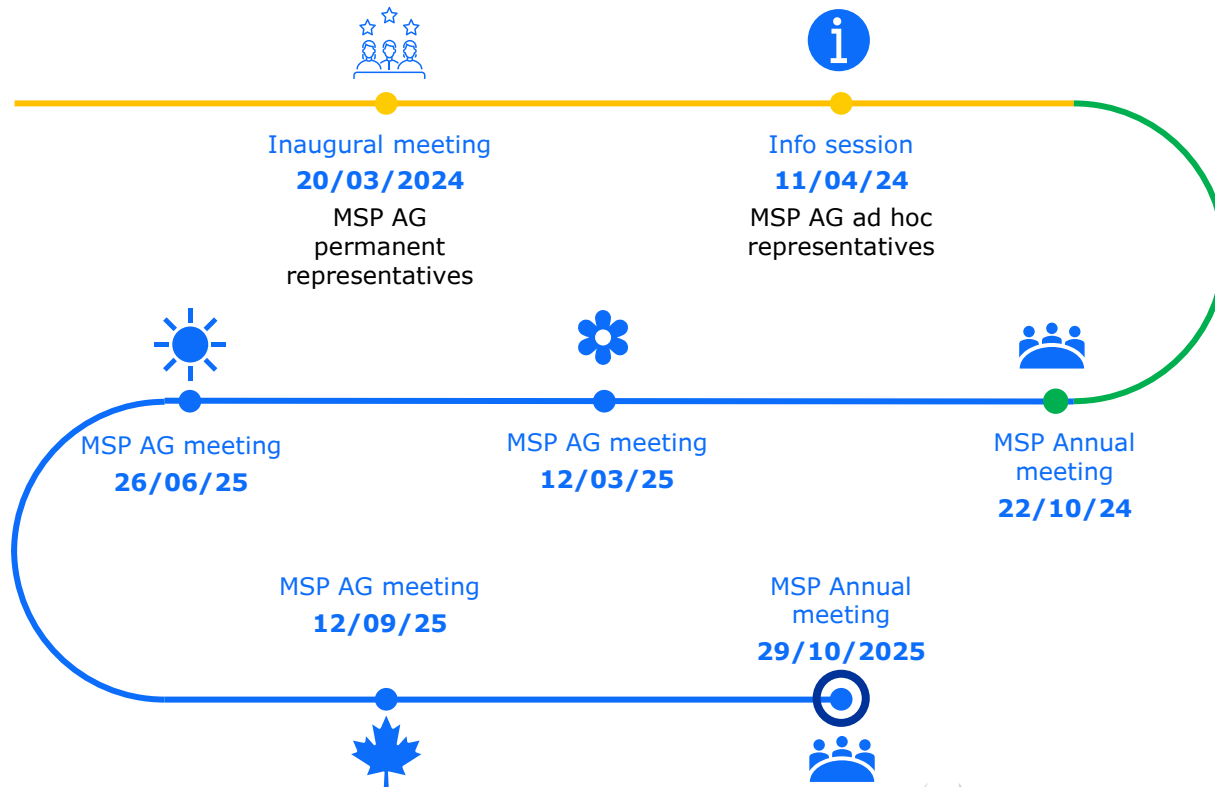
# MSP objective and timeline



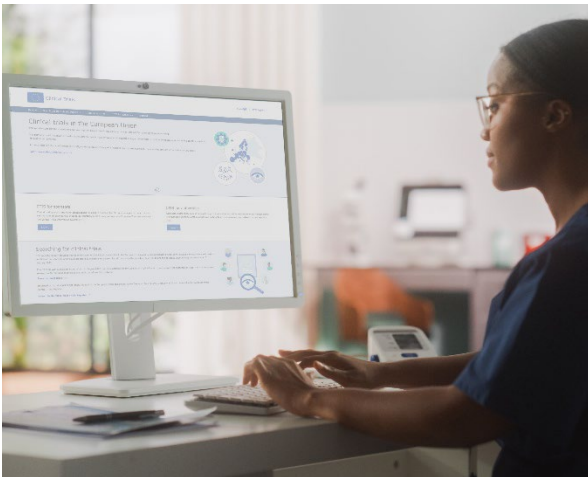
ENGAGE ALL STAKEHOLDERS TO PROACTIVELY DELIVER INCLUSIVE PATIENT-ORIENTED MEDICINES DEVELOPMENT AND DELIVERY ACROSS POPULATIONS BY ESTABLISHING A MULTI-STAKEHOLDER PLATFORM

# MSP timeline

- Establishment phase
- Stakeholder priorities defined
- Workplan support & topic discussions



# MSP AG 2025 activity



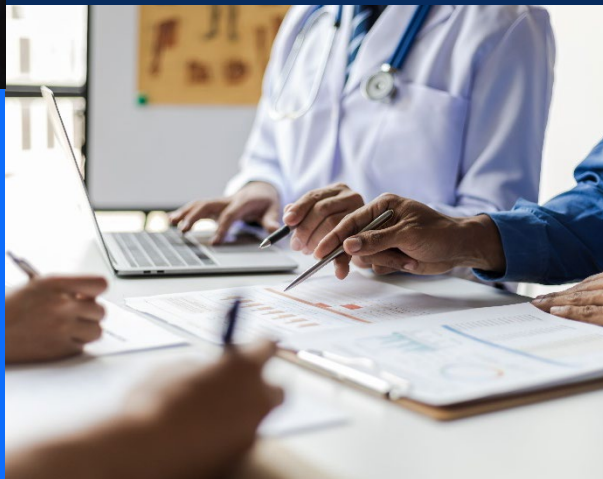
## Risk proportionate approaches

Creation of MSP AG focus group to integrate stakeholder views into the revision of the 2017 Recommendation paper on risk proportionate approaches in clinical trials



## Re-design of CTIS training materials and TrialMap

MSP AG focus group fully involved in delivery of the re-designed [CTIS Sponsor Handbook](#)



## Auxiliary Medicinal Products (AxMP)

MSP AG feedback on classification IMP\*/AxMP for background treatment as standard of care, registration in CTIS and safety reporting issues [1bf35e45-134c-4f2e-9c68-0e8537eef867\\_en](#)



## CTR optimisation

Proposals on reducing review timelines to 60 days and core dossier relevant to Biotech Act discussions



## Improvement of RFIs

Input provided for [Recommendation paper on frequent issues identified](#)



## Monitoring the EU clinical trials environment

Feedback on new key performance indicators for the EU clinical trials environment

[New targets for clinical trials in Europe | European Medicines Agency \(EMA\)](#)



## ACT EU workshop programme committee members

ICH E6 R3

MSP Annual meeting

Upcoming: 2026 Enpr-EMA-ACT EU workshop on paediatric clinical trials



## SME and academia training needs

Creation of MSP AG focus group to support ACT EU priority action on training



## Other topics discussed

CTCG Patient involvement project

Public Health Emergencies and the Emergency Taskforce (ETF)

Cross-border clinical trials

Innovative designs and co-partnership models

# The patient perspective

# MSP Annual meeting

# MSP Annual meeting debrief

- Hybrid & broadcast; EMA premises
- MSP AG permanent and ad hoc organisations onsite
- Co-chaired by Marianne Lunzer and Denis Lacombe, with opening remarks from EMA, EC, HMA
- Connecting to EMANS 2028 innovation theme
- Keynote on how AI innovation can help shape clinical trials and healthcare systems
- > 510 followed meeting
  - 175 online / 66 people in the meeting room F2F / 275 people following broadcast
- [ACT EU multi-stakeholder platform annual meeting | European Medicines Agency \(EMA\)](#)





# Opening session

- Emer Cooke, Sandra Gallina, Nils Bjerregaard
- The ACT EU workplan should reflect stakeholder expectations.
- Achievements like the auxiliary guideline, Q&A, and focus groups show progress, but work remains.
- Innovation in science and tech is outpacing regulation—collaboration is needed to align regulation with scientific progress.
- Strengthening clinical trials across the EU is essential, including decentralised trials and multilingual trial maps.
- The EU must maintain leadership in clinical research by improving regulatory environments and embracing biotech innovation.
- KPIs show progress (e.g., more multinational CTs, faster patient recruitment), but further improvements are needed.
- Biotech act is a vital opportunity to create a more favourable environment for biotech/innovation

# Keynote

- AI is transforming healthcare but must be ethically trained and validated.
- AI is already used in drug discovery, personalised medicine, and clinical decision-making.
- EMA is interested in understanding stakeholder use of AI.
- The future of healthcare includes AI-generated evidence, virtual assistants, and enhanced patient engagement.
- Stakeholders must reflect on their roles in this transformation.
- Collaboration is key to building next-gen healthcare systems.
- Q&A highlighted the need for:
  - Differentiating human made vs non-human made AI / Validating AI across sectors / Addressing poor data quality / Creating frameworks for AI adoption / Balancing AI with human aspects in clinical trials

# Patient involvement in Clinical Trials

- Redesign medicines lifecycle to place patients at center of research and care
- Early and consistent patient involvement is crucial but not yet standard
- Integrate PED throughout the medicine lifecycle
- Drive cultural change to treat patients as equal experts
- Focus on patient-centered innovation, replacing irrelevant data with meaningful insights
- Capture patient input over time and include it in core regulatory dossiers
- Social media and spontaneous data collection platforms offer new opportunities
- Ensure dissemination of results to patients in accessible formats
- Invest in capacity building and measure impact
- Include patients in governance
- Transparency and co-creation are key for meaningful change
- Challenges include representativeness of patient voices / regulatory and funding barriers / recruiting patient advocates / collecting input from children/minors

# Methodologies (biotech)

- Potential for platform technologies to streamline CT processes and reduce workload; call for permanent platform trial infrastructure
- Importance of early scientific advice to align with regulatory requirements and de-risk applications
- Assess the value of synthetic control arms into future clinical trials to improve efficiency and reduce patient burden
- Optimise the respective role of RWD and CT real-world data into RCTs
- Importance of learning healthcare systems, research in care and access to patient in real life to CT
- Harmonise contracts across Europe and simplify processes
- DCT requirements at national level transform 1 CT -> 5/6 CTs
- Harmonising GDPR interpretations
- Address operational challenges in global trials caused by fragmented regulations
- Innovative trial designs are available; mindset shift to mainstream their use.
- Integration of research into routine health systems key to sustainability and scalability

# AI and digitalisation

- Legislative barriers (GDPR, AI Act) complicate AI use but also present opportunities.
- Key challenges:
  - Lack of AI validation frameworks / Generational gaps in tech adoption / Data fragmentation and quality issues.
- Opportunities:
  - Assessment of eligibility and AI to support learning health care systems, research into care.
  - Central AI validation platforms / Federated data infrastructure / Training and public-private partnerships.
- European Health Data Space (EHDS) aims to improve data sharing.
- Regulators should create standards and support SMEs/startups in AI compliance.
- Building trust in AI among HCPs is essential.

# Ethics in Clinical Trials

- Ethical reflection must remain central to innovation
- More regulation doesn't always mean better patient protection—simplification is needed.
- Develop a framework for better value for ethics reviews, possibly through optimised working process addressing regulatory compliance and ethics reflections.
- Innovation and agility in ethics review to embrace new types of designs.
- “Ethics by design” and privacy by design (e.g., EHRs, e-consent) are key.
- Public engagement is crucial to build trust in data use.
- More expertise is needed to keep pace with legislative advances.
- Industry seeks dialogue with MedEthics EU.

# Looking to the future

# Continuing the dialogue



The multi-stakeholder platform is fully embedded in ACT EU



Key input to shape the delivery of the programme and continue defining priorities



Strong patient and healthcare professional voices are crucial

**Open dialogue between stakeholders, regulators and ethics remains at the core of ACT EU**

# Patient/consumer and HCP representation

## [Multi-stakeholder platform - Accelerating Clinical Trials in the EU](#)

Patients/ Consumers

Cancer Patients Europe

Patients/ Consumers

European AIDS Treatment Group (EATG)

Patients/ Consumers

European Patients' Forum (EPF)

Patients/ Consumers

European Young Person's Advisory Groups Network (eYPAGnet)

Patients/ Consumers

Rare Diseases Europe (Eurordis)

Healthcare professionals

European Academy of Neurology (EAN)

Healthcare professionals

European Haematology Association (EHA)

Healthcare professionals

European Society of Oncology Pharmacy (ESOP)

Healthcare professionals

European Society of Cardiology (ESC)

**Check the website and reach out to your representative to raise topics!**

# 2026 meeting dates

## 2026

Multi-stakeholder platform Advisory Group (MSP AG)	Friday, 20 March 2026	Online – Webex meeting
Multi-stakeholder platform Advisory Group (MSP AG)	Thursday, 18 June 2026	Online – Webex meeting
Multi-stakeholder platform Advisory Group (MSP AG)	Thursday, 17 September 2026	Online – Webex meeting
Multi-stakeholder platform annual meeting (MSP)	Thursday, 22 October 2026	European Medicines Agency, Amsterdam, the Netherlands

# Thank you

