

MSP AG September 2026

Workshops status update

Update on upcoming workshops on AI in clinical trials and evidence generation

September 2026

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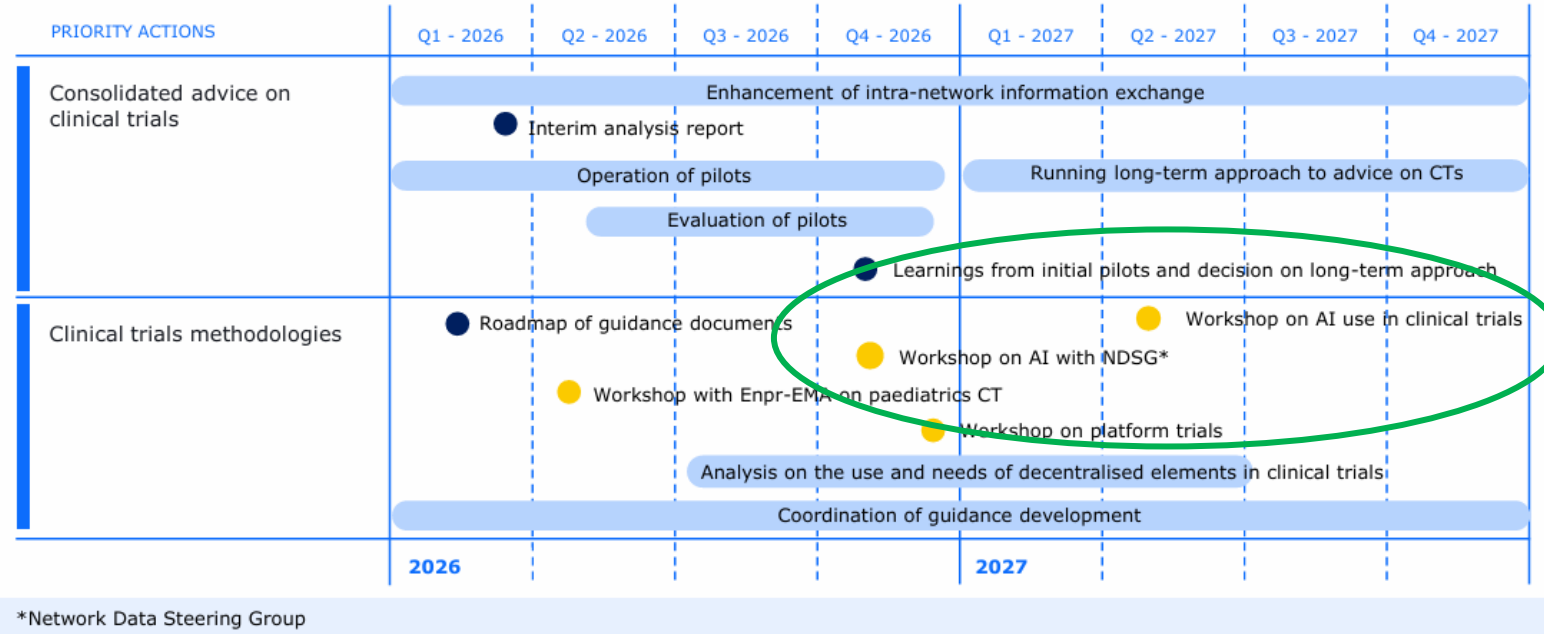
ACT EU workplan

2026 - 2027

ACT EU workplan

- NDSG AI and data forum
- Workshop on AI in clinical trials [working title]

Design and conduct of excellent clinical trials



NDSG AI and data forum

- [HMA / EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations](#), 12th + 13th of November
- Objectives:
 - Showcase state-of-the-art AI and data applications across the medicines' lifecycle,
 - Discuss the evolving EU regulatory landscape for data and AI,
 - Hear from stakeholders on data foundations, governance, quality, and interoperability across the Network
 - Strengthen stakeholder collaboration to accelerate the adoption of trustworthy AI
 - Input to the NDSG workplan in alignment with the Network Strategy to 2028
- Sessions on:
 - Navigating AI in medicines regulation: regulation, guidance and regulatory engagement
 - AI in clinical trials: practical applications and future guidance needs – **topic proposals received**

Workshop on AI in clinical trials [working title]

- Planning to be started November 2026, informed by discussion at NDSG AI & data forum
- Target date: Q2 2027
- Focus:
 - AI in clinical trials and as part of the evidence generation
 - Brings together Clinical Trial Authorisation and Marketing Authorisation perspectives
 - Deep-dive into multiple use cases from commercial and non-commercial sponsors
 - Support to the development of regulatory guidance
- Call for contributions will be shared, likely early 2027
- Topic proposals received for the NDSG AI & data forum will be considered, too

Workshop on Multiplicity in Confirmatory Clinical Trials: From Two-Arm to Platform Trials

MWP-led 27 November

Collignon Olivier

Workshop on Multiplicity in Confirmatory Clinical Trials: From Two-Arm to Platform Trials

- ACT-EU / MWP workshop planned on the 27th of November 2026
 - Scientific Committee from MWP, CHMP, SAWP, EMA
- Primary objective of the workshop is to support finalisation of GL on Multiplicity and RP on Confirmatory Platform Trials
 - Platform Trials are to be discussed specifically through the lens of multiplicity
- Workshop targeting methodologists but clear opportunity for MSP to collaborate
 - ENPR-EMA already engaged – currently waiting for potential examples in scope

Objective for today's discussion - call for

- Session co-chairs / panellists
- examples of platform trials with multiplicity issues

[3.1. Agenda for Workshop on multiplicity and platform trials.docx](#)



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Any questions?

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