



Update on the Multi-stakeholder platform

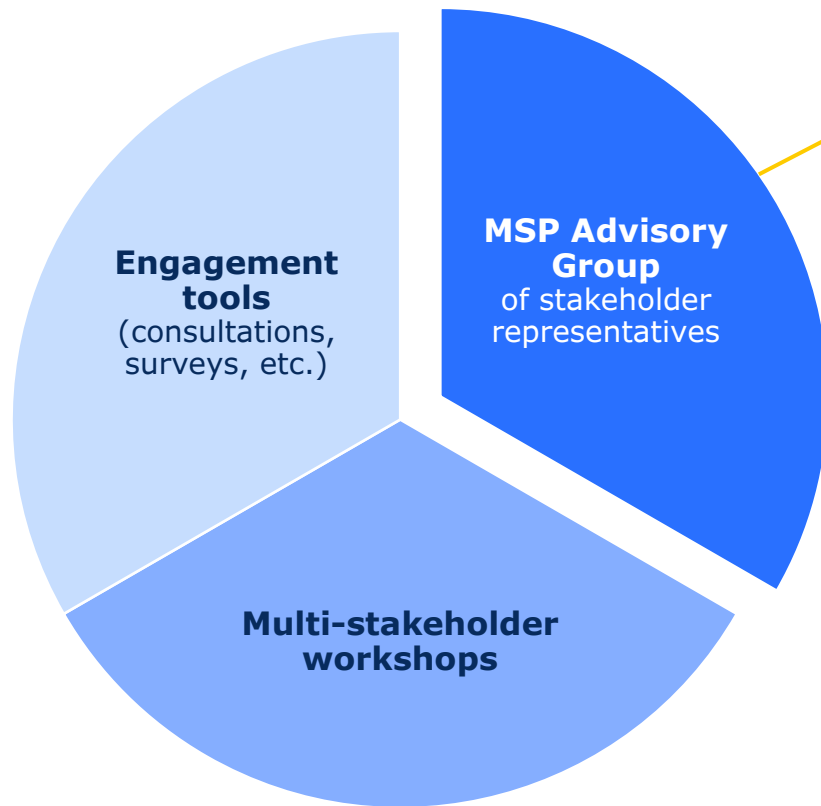
PCWP-HCPWP meeting
1 April 2025

Presented by Ana Zanoletty
Head of Clinical Trials Transformation Workstream
European Medicines Agency



Multi-stakeholder platform (MSP)

What is the MSP?



MSP advisory group

- 1 **Regulator Co-chair** rotated within ACT EU
- 1 **Stakeholder Co-chair** selected amongst MSP AG non-commercial representatives and agreed by ACT EU Steering Group
- **20 permanent stakeholder representatives** appointed via public call for expression of interest from:
 - patients/consumers' organisations
 - healthcare professionals' organisations
 - academia and funders
 - industry EU trade organisations
- 2 Ethics Committee representatives
- *Ad hoc* participation of other experts (HTA, ACT EU Priority Actions, payers, international authorities) - **New ad hoc member: European University Hospital Alliance**

What is the MSP advisory group involved in?



Collection of problematic Requests for Information (RFIs)



Creation of focus group for the redesign of CTIS training & support material



Ad hoc consultation on [Recommendations on the use of Auxiliary Medicinal Products in Clinical Trials](#)



Consultation on how to monitor the EU clinical trials environment

MSP advisory group meeting 12 March 2025

Key topics discussed

- Revised ACT EU workplan
- Developing metrics to monitor the EU clinical trials environment – asking for their input
- How the Network is working to address issues reported by stakeholders with CTR implementation
- Results of the survey of SME* and academia training needs
- Update from ICH E6 R3 multi-stakeholder workshop on Good Clinical Practice, 19-20 February

* SME – small and medium-sized enterprises



MSP advisory group upcoming meetings

- Thursday, 26 June 2025, online
- Thursday, 18 September 20225, online
- Wednesday, 29 October 2025, on-site at EMA

More info: [Multi-stakeholder platform \(ACT EU website\)](#)

Full composition: [MSP Advisory Group members \(ACT EU website\)](#)



Thank you

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