

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

27 November, 09:00 – 15:00 CET

EMA, Amsterdam / Hybrid meeting

The *ACT-EU Workshop on Multiplicity in Confirmatory Clinical Trials: From Two-Arm to Platform Trials* scheduled for 27th November 2026 at the EMA aims to address the role of multiplicity in regulatory decision-making for two-arm and platform trial designs. It will feature expert talks, use cases and moderated discussions on multiplicity issues in various settings, and will support the finalisation of the EMA Guideline on Multiplicity and the EMA Reflection Paper on Confirmatory Platform Trials.

We encourage all relevant stakeholders to attend and make the most of this opportunity. The event is open to all sponsor organisations, including pharmaceutical companies, contract research organisations, small and medium-sized enterprises (SMEs) and academic organisations. EMA cannot provide attendees certificates of attendance for this event.

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Draft Agenda

27 November, 09:00 – 15:00 CET

09:00 Joining and technical checks

09:15 Welcome and opening speech

Opening Remarks 5 min

The Role of Multiplicity in Regulatory Decision Making 10 min

09:30 Session 1: Fundamentals of the Multiplicity

Core Principles of the Multiplicity Guideline 30 min

Q&A / Panel Discussion 15 min

10:15 Coffee break

10:45 Session 2: Multiplicity Control in Confirmatory Platform trials

Multiplicity Control in Confirmatory Platform Trials and Multi-Arm Trials 30 min

Q&A / Panel Discussion 15 min

11:30	Session 3: Aligning the Multiple Testing Strategy with the Study Primary Objectives	
	Examples from Regulatory, Academia, and Industry	45 min
	Q&A / Panel Discussion	15 min
12:30	Lunch	
13:30	Session 4: Getting the Most of Clinical Trials While Managing Multiplicity	
	Examples from Regulatory, Academia, and Industry	45 min
	Q&A / Panel Discussion	30 min
14:45	Closing remarks	
	Wrap up	5 min