EMA/553576/2024

Agenda – ACT EU Multi-stakeholder Platform Advisory Group

12 March 2025, 09:30-13:30 (CEST), Webex

Co-Chairs: Maria Jesús Lamas (Regulatory co-chair), Denis Lacombe (Stakeholder co-chair)

Time		Topics	Speakers
09:15		*Joining and technical checks*	
1. Opening of the meeting			
09:30 – 09:35	5’	Opening remarks	Co-chairs
2. Revised ACT EU workplan			
09:35 – 09:55	20’	Monitoring the EU clinical trials environment	Jacobus van Wyk (EMA)
09:55 – 10:10	15’	Q&A	ALL
10:10 – 10:30	20’	Presenting revised ACT EU workplan	Laura Pioppo (EMA)
10:30 – 10:40	10’	Update on Emergency Task Force (ETF)	Manuela Mura (EMA)
10:40 – 11:00	20’	Q&A	ALL
Coffee break (10’)			
3. Network initiatives and activities to address critical and major issues reported by stakeholders regarding CTR implementation			
11:10 – 11:30	20’	Preparation of request for information and strengthening the role of RMS	Claire Temple (CTCG)
11:30 – 12:00	30’	Q&A	ALL
12:00 – 12:10	10’	COMBINE programme progress report - Interaction between regulations (IVDR/MDR/CTR)	Isabelle Clamou (European Commission)
12:10 – 12:25	15’	Re-design of CTIS supporting materials and overview of 2025 events	Roxana Spulber (EMA) Ornela Ademi (EMA)
12:25 – 12:40	15’	Q&A	ALL

Time		Topics	Speakers
4. Survey on SME and academia training needs			
12:40 -12:55	15’	Presentation of survey results	Eftychia-Eirini Psarelli (EMA)
12:55 -13:05	10’	Q&A	ALL
5. Good clinical practice ICH E6 R3 - risk proportionate approaches to clinical trials			
13:05 – 13:15	10’	Update following 19-20 February ACT EU multi-stakeholder workshop	Peter Twomey (EMA)
13:15 - 13:25	10’	Q&A	ALL
6. Closing remarks			
13:25 - 13:30	5’	Closing remarks	Co-chairs