



EMA/138451/2025

Agenda – ACT EU Multi-stakeholder Platform Advisory Group

26 June 2025, 09:30-13:30 (CEST), Webex

Co-Chair: Maria Jesús Lamas (Regulatory co-chair) and Denis Lacombe (Stakeholder co-chair)

Time		Topics	Speakers
09:15		<i>Joining and technical checks</i>	
1. Opening of the meeting			
09:30 – 09:35	5'	Opening remarks	Co-chair
2. Risk – based approaches in clinical trials 09:35 – 11:00 (85')			
09:35 – 09:45	10'	Presentation on LICT/ flexible safety reporting	Tarec Christoffer El-Galaly (EHA)
09:45 – 09:55	10'	Presentation on OECD framework	Jacques Demotes (ECRIN)
09:55 – 10:05	10'	Update on revision of the March 2024 Recommendation paper on the use of Auxiliary Medicinal Products in Clinical Trials	Monique AI (CTCG)
10:05 – 11:00	55'	Discussion on risk-based approaches	ALL
3. Update on Public Health Emergencies (PHEs) 11:00 – 11:40 (40')			
11:00 – 11:10	10'	Update from Emergency Task Force	Manuela Mura (EMA)
11:10 – 11:25	15'	Update from ACT EU Priority Action on Clinical Trials in PHEs	Marco Cavaleri (EMA), Monique AI (CTCG), Isabelle Clamou (European Commission)
11:25 – 11:40	15'	Q&A	ALL
Coffee break 11:40 – 12:00 (20')			

4. Update on stakeholder initiatives/proposals 12:00 – 12:30 (30')			
12:00 – 12:15	15'	Pilot programmes for innovative designs and co-partnership models	Donato Bonifazi (TEDDY)
12:15 – 12:30	15'	Q&A	ALL
5. Updates from ACT EU and partners 12:30 – 13:20 (50')			
		<ul style="list-style-type: none"> • ACT EU workplan • Monitoring of the clinical trials environment • CTR Collaborate • COMBINE programme • MedEthicsEU • WHO Global action plan/resolution 75.8 activity • Lancet series – Clinical Trials in Global Health 2025 	see pre-read
12:30 – 12:35	5'	Update on upcoming ACT EU workshop on external controls	Ina Rondak (EMA)
12:35 – 12:45	10'	Update on policy development at the EU level	Isabelle Clamou (European Commission)
12:45 – 12:55	10'	Update on patient involvement project	Marianne Lunzer, Monique Al (CTCG)
12:55 – 13:20	25'	Q&A	ALL
6. A.O.B.			
7. Closing remarks 13:20 – 13:30 (10')			
13:20 -13:30	10'	Closing remarks	Co-chair

** Meeting highlights will be published approximately 5 weeks after the meeting on the ACT EU website.*