EMA/156463/2025

Agenda – ACT EU Multi-stakeholder Platform Advisory Group

18 September 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		*Joining and technical checks*	
1. Opening of the meeting			
09:30 - 09:35	5’	Opening remarks	Co-chair
2. Cross-border Clinical Trials			
09:35 – 09:55	20’	Cross-border clinical trials and arrangements to take part in a trial abroad	François Houyez (EURORIDS); Ingrid Klingmann (EFGCP)
09:55 – 10:10	15’	Q&A	ALL
3. CTR / CTA optimisation			
10:10 – 10:30	20’	Core Dossier: opportunities for increasing efficiency and future proofing the CT ecosystem in Europe	Martin O’Kane (EFPIA)
10:30 – 10:45	15’	Q&A	ALL
10:45 – 11:05	20’	Reducing review timelines to 60 days: enhancing competitiveness through faster CTA approval	Blanca Garcia Ochoa (EuropaBio)
11:05 – 11:20	15’	Q&A	ALL
Coffee break (20’)			

4. ACT EU training curriculum			
11:40 – 11:50	10’	Proposals on content for ACT EU Clinical trials curriculum	Amelie Michon (ECRIN)
11:50 – 12:05	15’	Q&A	ALL
5. Ensuring Regulatory Agility for Clinical Trials During Public Health Crises			
12:05 – 12:15	10’	PA11 Regulatory flexibility for CTs during Public health emergency	Marco Cavaleri (EMA), Giacomo Capone (EMA)
12:15 - 12:25	10’	Q&A	ALL
6. Clinical trials related legislative developments			
12:25 – 12:35	10’	Update on policy development at the EU level	Edit Szepessy (EC)
12:35 – 12:45	10’	Q&A	ALL
7. Clinical trials metrics			
12:45 – 12:55	10’	Update on EU clinical trials metrics	Laura Pioppo (EMA)
8. Pre-read			
• Update on the Focus Group on Risk-based approaches • Update on all ongoing actions identified last year, including RMS, RFI and AxMP • Update on the outcomes of Paediatric workshop • Update on patient involvement project • Update on ACT EU progress			see pre-read
12:55 – 13:15	20’	Q&A	ALL
9. A.O.B.			
13:15 – 13:20	5’	A.O.B.	ALL
10. Closing remarks			
13:20 – 13:30	10’	Closing remarks	Co-chairs

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