EMA/3965/2026

Agenda – ACT EU Multi-stakeholder Platform Advisory Group

20 March 2026, 09:30-13:30 (CEST), Teams meeting

Co-chair: Catherine Paugam-Burtz (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 - 09:45	15’	Opening remarks and introduction of new regulatory co-chair	EMA, MSP AG Secretariat Co-chairs
2. ACT EU update			
09:45 – 10:00	15’	ACT EU objectives and workplan 2026-2027	Laura Pioppo (EMA)
10:00 – 10:10	10’	Q&A	ALL
3. Experience and learnings from ACT EU consolidated pilots in clinical trials			
10:10 - 10:20	10’	Consolidated pilots in clinical trials (status update)	Massimiliano Sarra (EMA)
10:20 - 10:30	10’	Pre-CTA and SAWP-CTCG pilots	Blanca Garcia-Ochoa (EuropaBio)
10:30 - 10:40	10’	Q&A	ALL
4. Topic on patient involvement in clinical trial design and conduct			
10:40 – 10:50	10’	Overview of patients’ priorities	Claudia Louati (EPF)
10:50 – 11:00	10’	Framework for shared patients’ input	François Houÿez (EURORDIS)
11:00 – 11:10	10’	Q&A	ALL

5. Accelerating the contracting process			
11:10 – 11:20	10’	EU model template for “Clinical site agreements” between sponsors and clinical sites	Mihaela Matei (ECRIN)
11:20 – 11:30	10’	Q&A	ALL
Coffee break (15’)			
6. Clinical research in Europe			
11:45 – 11:55	10’	Recommendations by the Coalition for reducing bureaucracy in clinical trials	Robin Doeswijk (EHA)
11:55 – 12:05	10’	eConsent initiative	Hilde Vanaken (EFGCP)
12:05 – 12:20	15’	Q&A	ALL
7. Legislative and non-legislative development update			
12:20 – 12:30	10’	Update on Biotech Act	Speaker TBC
12:30 – 12:40	10’	Update on FAST-EU (Facilitating and Accelerating Strategic Clinical Trials) initiative	Marianne Lunzer (AGES – CTCG)
12:40 – 12:50	10’	Update on Clinical Research Investment Plan	Romina Escobar (EC DG RTD)
12:50 – 13:05	15’	Q&A	ALL
8. Launch of call for Stakeholder Co-chair			
13:05 – 13:15	10’	Public call for Stakeholder Co-chair	Laura Pioppo (MSP AG Secretariat)
13:15 – 13:20	5’	Q&A	ALL
9. Closing remarks			
13:20 – 13:30	10’	Closing remarks	Co-chairs
Pre-read			
• Letter to the ACT EU Governance on patients’ priorities • Recommendations by the Coalition for Reducing Bureaucracy in Clinical Trials • Update on MedEthicsEU and CTR Collaborate			

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