



EMA/3965/2026

Agenda – ACT EU Multi-stakeholder Platform Advisory Group

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

Time		Topics	Speakers
09:15		<i>Joining and technical checks</i>	
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 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) Jane Moseley (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'	Framework for shared patient input in a specific indication across products	Speaker TBC
10:50 – 11:00	10'	Q&A	ALL
5. Accelerating the contracting process			
11:00 – 11:10	10'	EU model template for "Clinical site agreements" between sponsors and clinical sites	Mihaela Matei (ECRIN)
11:10 – 11:20	10'	Q&A	ALL

Time	Topics	Speakers
Coffee break (15')		
6. Clinical research in Europe		
11:35 – 11:45	10'	Recommendations by the Coalition for Reducing Bureaucracy in Clinical Trials
11:45 – 11:55	10'	eConsent Initiative
11:55 – 12:10	15'	Q&A
7. Legislative and non-legislative development update		
12:10 – 12:20	10'	Update on Biotech Act
12:20 – 12:30	10'	Update on FAST-EU (Facilitating and Accelerating Strategic Clinical Trials) initiative
12:30 – 12:45	15'	Q&A
12:45 – 12:55	10'	Update on Clinical Research Investment Plan
12:55 – 13:05	10'	Q&A
8. Launch of call for Stakeholder Co-chair		
13:05 – 13:15	10'	Public call for Stakeholder Co-chair
13:15 – 13:20	5'	Q&A
9. Closing remarks		
13:20 – 13:30	10'	Closing remarks
Pre-read		
<ul style="list-style-type: none"> • <u>Recommendations by the Coalition for Reducing Bureaucracy in Clinical Trials</u> • Update on MedEthicsEU and CTR Collaborate • Revised ACT EU workplan for 2026-2027 		

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