7 September 2026

EMA/174448/2026

Agenda – ACT EU Multi-stakeholder Platform Advisory Group

17 September 2026, 09:30-13:30 (CEST), Teams meeting

Co-chair: Catherine Paugam-Burtz (Regulatory co-chair) and François Houÿez (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. Patient involvement in clinical trial design and conduct			
09:35 – 09:45	10’	Building patient engagement across clinical research	Donato Bonifazi (TEDDY)
09:45 – 09:55	10’	Update on patients’ panels	Virginie Hivert (EURORDIS)
09:55 – 10:15	20’	Q&A	All
3. Multistakeholders workshops update			
10:15 – 10:25	10’	AI in Clinical Trials: practical applications and future guidance needs o Session at the NDSG data forum (12/13 Nov) o AI workshop planned Q2 2027	Florian Lasch (EMA)
10:25 – 10:35	10’	Workshop on multiplicity and platform trials (27 Nov)	Olivier Collignon (EMA)
10:35 – 10:45	10’	Q&A	All
Coffee break 15’			

4. ACT EU – Clinical Trials in Public Health Emergency (PHE)			
11:00 – 11:30	30’	Priority action on clinical trials in public health emergencies (PHE) • Track 2 CTA simplified package (15’)	Ann Marie Janson Lang (MPA), Maria Elena Mendez Garcia (Ethics Committee, Spain)
		• Track 3 Guidance document on the conduct of clinical trials (15’)	Nele Steens (FAGG) Sarah ‘Tkindt (FAGG)
11:30 – 11:45	15’	Q&A	All
5. From commitment to action: advancing clinical trial transparency			
11:45- 12:00	15’	Monitoring submission of clinical trial results in CTIS	Marianne Lunzer (CTCG)
12:00- 12:10	10’	Q&A	All
6. Legislative and non-legislative update			
12:10 – 12:30	20’	Update from the European Commission	EC *(TBC verbal or written update)*
7. MSP organisation updates			
12:30 – 12:40	10’	Update on MSP AG EU Survey and MSP AG call for nominations	Laura Pioppo (EMA)
12:40 – 12:50	10’	Update on MSP annual meeting	Ana Zanoletty (EMA)
8. Pre-read			
○ Update on MSP AG focus groups: • Risk based approaches in clinical trials • Training needs for academia and SME • Sponsors serious breaches notifications ○ Update on activities to speed up patient recruitment – progress on contractual agreements ○ Reminder on public consultation on recommendations on cross-border access to paediatric clinical trials ○ Other updates (MedEthicsEU) ○ Women’s Health Workshop update			
12:50 – 13:20	30’	Q&A on pre-read and (non)-legislative update	All
9. 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*

***Timing is indicative and might be subject to changes*