EMA/253131/2024

Agenda – ACT EU Multi-stakeholder Platform Advisory Group

04 July 2024, 09:30-17:00 (CEST), Webex

Co-Chairs: Maria Jesús Lamas (MSP AG regulatory co-chair), Denis Lacombe (MSP AG stakeholder co-chair)

Time	Topics	Speakers
09:20	*Joining and technical checks*	
09:30	Opening of the meeting and outline of the day	Maria Lamas Denis Lacombe
1. Session 1: ACT EU overview and discussion		
09:35	1.1. Presentation of ACT EU workplan and deliverables • Overview of the programme structure and workplan • Update on PA 1 on mapping and governance • PA 2 CTR implementation and workstreams within the PA	Laura Pioppo
10:00	• Update on PA 2.1 support to non-commercial sponsors	Giacomo Capone Lene Grejs Petersen
10:15	➢ Discussion	All
10:30	• Proposal for EU level funding to support academic sponsors conduct multi-national clinical trials	Ana Zanoletty
10:40	➢ Discussion	All
10:45	• Update on: PA 3 - Establishment of a multi-stakeholder platform PA 4 - GCP modernisation PA 5 - CT data analytics	Laura Pioppo
10:55	*Coffee break*	

Time	Topics	Speakers
11:10	1.1. Presentation of ACT EU workplan and deliverables – continued • Update on: PA 6 - Communication campaigns PA 8 – CT methodologies (outputs of methodology workshops and the coordination process between MWP/CTCG/HTAs)	Laura Pioppo
11:20	• PA 7 on consolidated pilots for SAWP/CTCG and pre-CTA	Marianne Lunzer Massimiliano Sarra
11:35	➢ Discussion	All
11:50	• PA 10 - training curriculum (gap analysis for academia and SME)	Theo Framke Monique Al
12:05	➢ Discussion	All
12:20	• Update on: PA 9 - Safety PA 11 - CT in public health emergencies	Laura Pioppo
12:30	*Lunch break*	
2. Session 2: Stakeholder presentation on critical use-cases		
13:30	2.1. <u>CTA review process and CTR implementation</u> • VACCINES EUROPE: Enhancing and Harmonizing Regulatory Process for Clinical Trials	Megan Heath
13:40	• EORTC: Low-intervention clinical trials	Stéphanie Kromar
13:50	• EFPIA: CTA review process and CTR implementation	Lada Leyens
14:00	➢ Discussion	All
14:20	2.2. <u>CTA and Scientific advice mechanisms</u> • KWF: Limited scientific advice for academic developers	Delphi Coppens
14:30	➢ Discussion	All
14:40	2.3. <u>Ensure EU ecosystem is set up for future methodological innovations</u> • EURODIS: Challenges and possible options when designing a Platform Trial	François Houÿez

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14:50	• TEDDY: Innovative Study Designs in Paediatrics: Limited Practical Implementation - operational issues related to the practical implementation of innovative study designs	Donato Bonifazi
15:00	➢ Discussion	All
15:15	*Coffee break*	
15:30	2.4. Access to medicines for EU patients and sharing academic specific challenges • UMC Utrecht: Challenges in performing multi-country Investigator Initiated Trials in EU	Mira Gerta Petra Zuidgeest
15:40	➢ Discussion	All
15:50	2.5. Patient engagement in clinical trials • eYPAGnet: Paediatric patients' involvement in the drug development	Begonya Nafria Escalera
16:00	➢ Discussion	All
16:10	2.6. Other topics • CDDF: Enabling CTIS Public Data Use	Fergus Sweeney
16:20	➢ Discussion	All
3. Session 3: Consolidation discussion, summarising and closing		
16:30	3.1. Consolidation discussion, summarising and closing • Closing remarks	Maria Lamas Denis Lacombe
16:55	• Actions • Next steps	Ana Zanoletty