ACT EU multi-stakeholder platform kick off workshop

22-23 June 2023

Virtual meeting / EMA, Amsterdam, Room 1D Auditorium

The success of clinical trials relies on a multitude of stakeholders and therefore regular dialogue between all parties can help to identify and advance clinical trial methods, technology and science, as well as remove roadblocks. To advance this, the EC-HMA-EMA initiative, Accelerating Clinical Trials in the EU (ACT EU), foresees the establishment of a multi-stakeholder platform (MSP) as one of its priority actions.

Through a series of workshops in 2023 and 2024, an EU multi-stakeholder platform on clinical trials will be established to advance discussions and joint action on priority topics.

The first workshop aims at:

- Understanding stakeholders' perspectives on how to transform the EU environment for clinical trials.
- Present and discuss the feedback obtained during the MSP public consultation.
- Initiate discussion on priority areas identified during the MSP public consultation.
- Present and discuss a proposed model for the establishment of the MSP on ACT EU.

This workshop is open to all stakeholders.

ACT EU multi-stakeholder platform kick off workshop

Day 1 – 22 June 2023, 13:00 – 18:35 (CEST)

Co-chairs: Peter Arlett (EMA) and Björn Eriksson (HMA)

12:30 Joining and technical checks

13:00 Welcome and opening speech

Opening remarks from EMA Executive Director **5'**
Emer Cooke (EMA)

Opening remarks from the European Commission **5'**
Sandra Gallina (EC)

Opening remarks from Heads of Medicines Agencies **5'**
Björn Eriksson (HMA)

13:15 Session 1: Setting the scene

Moderators: Peter Arlett (EMA) and Björn Eriksson (HMA)

ACT EU initiative **15'**
Monique Al (HMA/CCMO)

Outcome of public stakeholder consultation on ACT EU multi-stakeholder platform **10'**
Giacomo Capone *(EMA)*

Panel and audience discussion **70'**

14:50 Coffee break

15:15 Session 2: Discussion on priority areas

Moderators: Stan van Belkum (HMA/CCMO) and Harald Mische (EC)

Clinical trial regulation (CTR) implementation update **15'**

Christophe Didion (EC)

Member States support to the CTR implementation **15'**
Marianne Lunzer (HMA/CTCG)

	Panel and audience discussion	**25'**
	The role of ethics committees in clinical trials *Helle Christiansen (Danish Centre for Ethics)*	**15'**
	Panel and audience discussion	**45'**

17:10 Coffee break

17:35 Session 2: Discussion on priority areas

Moderators: Stan van Belkum (HMA/CCMO) and Harald Mische (EC)

	Transparency of clinical trials *Laura Pioppo, EMA*	**10'**
	Panel and audience discussion	**45'**

18:30 Conclusions and wrap up of day 1

	Wrap up *Peter Arlett (EMA), Björn Eriksson (HMA) and Harald Mische (EC)*	**5'**

ACT EU multi-stakeholder platform kick off workshop

Day 2 – 23 June 2023, 08:30 – 13:40 (CEST)

Co-chairs: Peter Arlett (EMA) and Björn Eriksson (HMA)

08:30 Joining and technical checks

09:00 Welcome and opening speech

Outline of the day **5'**

Co-chairs: Peter Arlett (EMA) and Björn Eriksson (HMA)

09:05 Session 3: Discussion on priority areas

Moderators: Paolo Foggi (HMA/SAWP) and Marianne Lunzer (HMA/CTCG)

Supporting non-commercial clinical trials **15'**

Elke Stahl (HMA/CTCG)

Panel and audience discussion **45'**

Reinforcing coordination between scientific advice and CT approval **20'**

Jane Moseley (EMA), Laurence O'dwyer (HMA/EU-IN) and Sandra Petraglia (HMA/CTCG)

Panel and audience discussion **40'**

Optimising the EU infrastructure for methodology guidance **15'**

Ditte Zerlang Andersen (HMA) and Florian Lasch (EMA)

Clinical trials in situations of public health emergency **10'**

Marco Cavaleri (EMA)

11:30 Coffee break

12:10 Session 4: Building a multi-stakeholder platform for Europe

Moderators: Melanie Carr (EMA), Maria Lamas (HMA)

Opportunities from a European CT multi-stakeholder platform **15'**
Gunilla Andrew-Nielsen (HMA)

Panel and audience discussion **60'**

13:25 Closing remarks

Wrap up **15'**
Björn Eriksson (HMA), Sylvain Giraud (EC) and Peter Arlett (EMA)

13:40 Networking lunch