Lessons-learned workshop on Clinical Trials in Public Health Emergencies

9 June 2023, EMA, Amsterdam

Hybrid meeting - WebEx/Room 1D

Background and objectives

The late public health emergencies have urged stakeholders to adapt and facilitate the generation of clinical research. To ensure preparedness for potential public health emergencies (PHEs), it is imperative to establish efficient and harmonized mechanisms to generate clinical data rapidly. The purpose of this workshop is to evaluate the knowledge gained from COVID-19 and Monkeypox emergencies related to setting up and conducting clinical trials (CTs).

By bringing together experts in CTs and regulatory bodies, the workshop should result in concrete action items to streamline processes, ensure synergies and avoid duplication of work within the network.

The aims of the workshop are to:

- Review current processes for CTs during emergencies
- Explore actions that could expedite approval process of multinational EU trials
- Define a framework for a more integrated framework for clinical trials during and in preparation of emergencies with the aim of fostering larger multinational clinical trial

Lessons-learned workshop on Clinical Trials in PHEs

Chaired by Marco Cavaleri (EMA) and Sandra Gallina (European Commission, DG SANTE)

9 June 2023, 09h30-17h30 (CET)

09:30 Joining and technical checks

10:00 Welcome and opening speech

Welcome and introduction **20'**
Emer Cooke (ED EMA)
Sandra Gallina (European Commission, DG SANTE)
Björn Eriksson (HMA)

Outline of the day and objectives **5'**
Marco Cavaleri (EMA)

10:25 Session 1: Process and regulatory approval of large, multinational clinical trials in the EU during emergencies

Chair: Peter Arlett (EMA) and Sylvain Giraud (European Commission, DG SANTE)

10:25 **Setting the scene on the current regulatory framework** **10'**
Isabelle Clamou (European Commission, DG SANTE)

10:35 **Role of the Member State National Competent Authority, Ethics Committee, CT-CURE and ACT EU** **25'**
Greet Musch (FAMHP, BE), Kaate Vanmolkot (CCMO, NL) and Sébastien Vanhiesbecq (Clinical Trial College, BE)
- *Coordination between MSCs*
- *Role of the RMS*
- *Possibilities for expedition*
- *Opportunities offered by ACT EU*
- *Optimization*

11:00 **Role of EMA-ETF** **10'**
Manuela Mura (EMA)

11:10 **Past-Experience: MOSAIC, EU-RESPONSE and STRIVE** **45'**
Piero Olliaro (University of Oxford) 20'
Inge Christoffer Olsen (Oslo University Hospital) and Yazdan Yazdanpanah (ANRS) 15'

	Jens Lundgren (Rigshospitalet, University of Copenhagen)	10’
11:55	***Coffee break***	**15’**
12:10	**Discussion on the cases presented and possible way forward** *All*	**50’**
13:00	***Lunch***	**45’**
13:45	**Session 2: Framework for funding clinical research during emergencies in the EU** *Chair: Marco Cavaleri (EMA) and Peter Piot (Special Advisor to EC President)*	
13:45	**Current efforts for clinical research in preparedness and during emergencies in the EU** *Irene Norstedt (European Commission, DG RTD)* *Laurent Muschel (European Commission, HERA)* *Pandemic Preparedness Partnership – Hervé Raoul (ANRS)*	**30’**
14:15	**Coordination of trials - the TCB** *Victoria Simensen and John-Arne Rottingen (NIPH and Norwegian GOV)*	**10’**
14:25	**JAAM** *Jacques Demotes (ECRIN)*	**10’**
14:35	**Experience from clinical trials/studies** MPOX – *Liem Binh Luong (AP - Hôpitaux de Paris)* VACCELERATE – *Oliver Cornely (University of Cologne)* MPOX EPOXI – *Miquel Ekkelenkamp (Utrecht Medical Center)*	**30’** 10’ 10’ 10’
15:05	**European partnership on clinical trials initiative** *Herman Goossens (BE presidency)*	**10’**
15:15	**Discussion on actions to strengthen the current EU framework** *All* Governance framework Product prioritization Funding options	**75’**
16:30	***Coffee break***	**15’**
16:45	**Session 3: Consolidation of actions** *Chair: Marco Cavaleri (EMA) and Peter Piot (Special Advisor to EC President)*	**30’**
17:15	**Closing remarks**	

Wrap up: take-home messages and next steps **15'**

Sandra Gallina (European Commission, DG SANTE), Marco Cavaleri (EMA) and Peter Piot (Special Advisor to EC President)

17:30 End of meeting