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EU4Health CT Cure

Emergency preparedness through platform trials in EU-EEA

– training for clinical trial application assessors from Medical Research Ethics Committees and National Competent Authorities –

Background and objectives

CT-CURE is an EU4Health joint action of Member States funded by the European Union that aims to establish a network of Medical Research Ethics Committees (MREC), and National Competent Authorities (NCAs) that gain experience on conducting expedited assessment of clinical trial applications on COVID-19 therapeutics.

The CT-CURE vision and rationale is an accelerated, harmonised regulatory review of clinical trials to facilitate rapid generation of clinical data on novel therapeutic strategies in public health emergencies.

In order to increase emergency preparedness in EU/EEA this training focusses on the regulatory review of large platform trial applications bringing assessors from both Medical Research Ethics Committees (MREC) Ethics Committees and National Competent Authorities together. The training is open to all Member States in EU/EEA and part of the Training Work Package 7 for CT-CURE.

Aims and learning objectives

The overall aim of the training program is to increase the capacity and readiness of MREC and NCAs in the EU-EEA to review and approve platform trials for pandemic preparedness and response.

- **Plenary setting:** To understand the rationale, design and methodology of platform trials, identify key regulatory and ethical issues and challenges adopting a harmonized and proportionate approach for the expedited review process in EU/EEA Member States of clinical trial applications in public health emergencies.
- **Break-out session setting:** Discussion sharing experiences and reviewing public health emergency case studies among assessors from EU MREC and NCAs with the aim to propose additional steps to expedite and harmonise reviews while ensuring regulatory scientific and ethical excellence.

Target audience

The training program is intended for clinical trial application assessors from MREC and CAs in the EU-EEA, who are involved in the review and approval of clinical trials. We aim for a balanced representation of MREC and NCAs from different countries, both members and non-members to CT-CURE.

Program

DAY 1 Plenary and Break-out sessions (September 5, 2024)

13.00 Introduction - Nele Steens, FAMHP, BE

13.10 Best practices on expedited assessment of COVID-19 therapeutic trials in CT-CURE - Ann Marie Janson Lang, Swedish MPA, SE

13.35 Platform trials during the COVID-19 pandemic:
- Overview of complex clinical trials including platform trials - Olga Kholmanskikh, FAMHP, BE
- Methodological aspects of platform trials - Benjamin Hofner, PEI, DE
- Operational aspects including trial oversight management - Monique Al, CCMO, NL

14.40 Coffee break

15.10 Planning and conduct of public health emergency platform trials – practical experience from the academic sponsor perspective - Inge Christoffer Olsen, Dept. of Research Support for Clinical Trials, Oslo University Hospital, NO

15.30 Plenary introduction of Break-out sessions Day 1 - Olga Kholmanskikh - FAMHP, BE

15.45 Parallel Break-out sessions Day 1:
- *Sharing lessons learned for emergency preparedness based on case studies*
- *Initial application assessment– topics of interest include: blinding, choice of control groups, how to adapt for 'standard-of-care developed during PHE', scientific rationale in complex design*
- *Substantial Modification application assessment – topics of interest include scientific rationale of subprotocols/substudies, clarification on situations when there is a need for a separate trial application, additional aspects on methodology and trial oversight management*

17.30 End of Day 1 – Network dinner

DAY 2 Plenary and Break-out sessions September 6

9.00 Summary of the plenary sessions Day 1 - Nele Steens, FAMHP, BE

9.05 Feedback and proposals from Break-out sessions Day 1

9.55 Practical tips on how to work within and outside the Clinical Trials Information System (CTIS) when assessing multinational platform trials with expedited timelines- Ann Marie Janson Lang, Swedish MPA, SE

10.25 Plenary introduction of Break-out sessions Day 2 - Monique Al, CCMO, NL

10.35 Coffee break

11.05 Parallel Break-out sessions Day 2:
- *Safety, rights and well-being of trial participants during the trial life cycle – topics of interest include how to maintain oversight of the trial participants' safety*
- *Informed consent process and information to participants*
- *Transparency of trials and results - topics of interest include how to define end of trial, publication of interim results*

12.05 Feedback and proposals from Break-out sessions Day 2

12.55 Concluding remarks - Nele Steens, FAMHP, BE

13.00 End of Day 2