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SCIENCE MEDICINES HEALTH

2. Emergency Task Force (ETF): ETF implementation update including preparedness activities

Industry Standing Group (ISG) meeting, 21 September 2023

Presented by Marco Cavaleri, EMA

Clinical Trials in a public health emergency

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Problem statement:

- In the face of a public health emergency, need for bigger, faster and well-coordinated clinical trials in the EU and globally (focus only on Europe)

- Challenges with prioritisation, funding, approval and implementation

- Objectives:

  discuss lessons learned and possible actions to secure faster clinical trial approval across multiple countries in a public health emergency setting

  explore coordination and funding mechanisms enabling a rapid set-up and implementation of clinical trials that meet the regulatory requirement for clinical trial conduct and support product authorisation.

Aspiration: Can we start a clinical trial in 15 days?

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

- Presentations from stakeholders followed by discussion on proposed actions

Session 2: Framework for funding clinical research during emergencies in the EU

- Presentations from stakeholders followed by discussion on proposed actions

Conclusions on possible actions and follow-up on agreed next step

1. Regulatory approval of CTs in the EU during PHEs

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A number of possible actions were discussed, for example:

Setting up an EU level cooperation mechanism between ethics committees, open to all MS.

Pre-submission assessment and consultations of specific (individual) clinical trials with Ethics committees with expertise in the subject matter together with proposed Reference Member State (RMS)

Continue with the ETF role as one stop shop forum to coordinate clinical trial protocol review with RMS, CTCG and Ethics Committees

Continue to resolve issues and improve the features of CTIS to enable the necessary agility for public health emergency clinical trials.

Framework for funding CTs during PHEs in the EU

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Possible solutions discussed

- To **establish a Coordinating Committee** for improved coordination for decisions on the prioritisation of clinical trials in Europe.
    - This Coordinating Committee will make recommendations to support rapid decisions on which study is needed and which clinical trial network/platform should be used in an emergency, among those established and kept warm in inter-epidemic periods.
    - These recommendations can be linked to funding, taking into account scientific, including methodological and medical aspects, the envisaged CT authorisation process and ETF regulatory feedback.

During inter-epidemic periods the Coordinating Committee oversees an appropriate landscape of perpetual/warm-based trials and strategic cohorts in the EU, covering both vaccines and therapeutics, that are maintained in the interepidemic period, and for which the trial protocols have the in-built ability to pivot rapidly in case of a public health emergency.

Framework for funding CTs during PHEs in the EU

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Possible solutions discussed

- Increased harmonisation of trial site contract templates
- Creation of a network of pre-qualified clinical trial sites with a standard set of qualification documents and a standard contract to be updated as appropriate.
- EU coordination entities financed to dedicate resources also to address clinical trial monitoring and other issues (in a 'CRO-like' role).

Interaction with HERA

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Collaboration ongoing on the following

- Clinical trial networks governance set up
- Review of MCMs for CBRN emerging threats that could be part of procurement and/or stockpiling
- AMR and vaccines strategy
- HERA staff attends ETF as observers
- EMA provide information to HERA groups including MSs

Any questions?

Further information

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