EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role of EMA in facilitating Clinical Trials in emergencies

September 2023 PCWP/HCPWP meetings

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An agency of the European Union

The EMA Emergency Task Force (ETF)

- ETF established by Regulation 123/2022 with formal legal mandate as an **advisory and support body on medicines for public health emergencies and preparedness**
- List of members, Rules of Procedures, Workplan: https://www.ema.europa.eu/en/committees/working-parties-other-groups/emergency-task-force-etf
- Co-Chairs: EMA (Marco Cavaleri), CHMP vicechair (Bruno Sepodes)
- Composition based on expertise and on the foreseen type of and level of activities

Scientific Committees (CHMP, PRAC, PDCO, CMDh) **and EMA Representatives**

Working Parties' experts on vaccinology, biologics, infectious disease treatment, biostatistics, inspection, clinical trials, scientific advice assessment

Patients and Healthcare professionals identified by PCWP and HCPWP to bring the views of their respective communities

Clinical trial experts from various EU Member States (Clinical Trials Advisory Group (CTAG) and Clinical Trials Coordination Group (CTCG))

Additional experts and observers from academia, EU national or international regulators, EU bodies

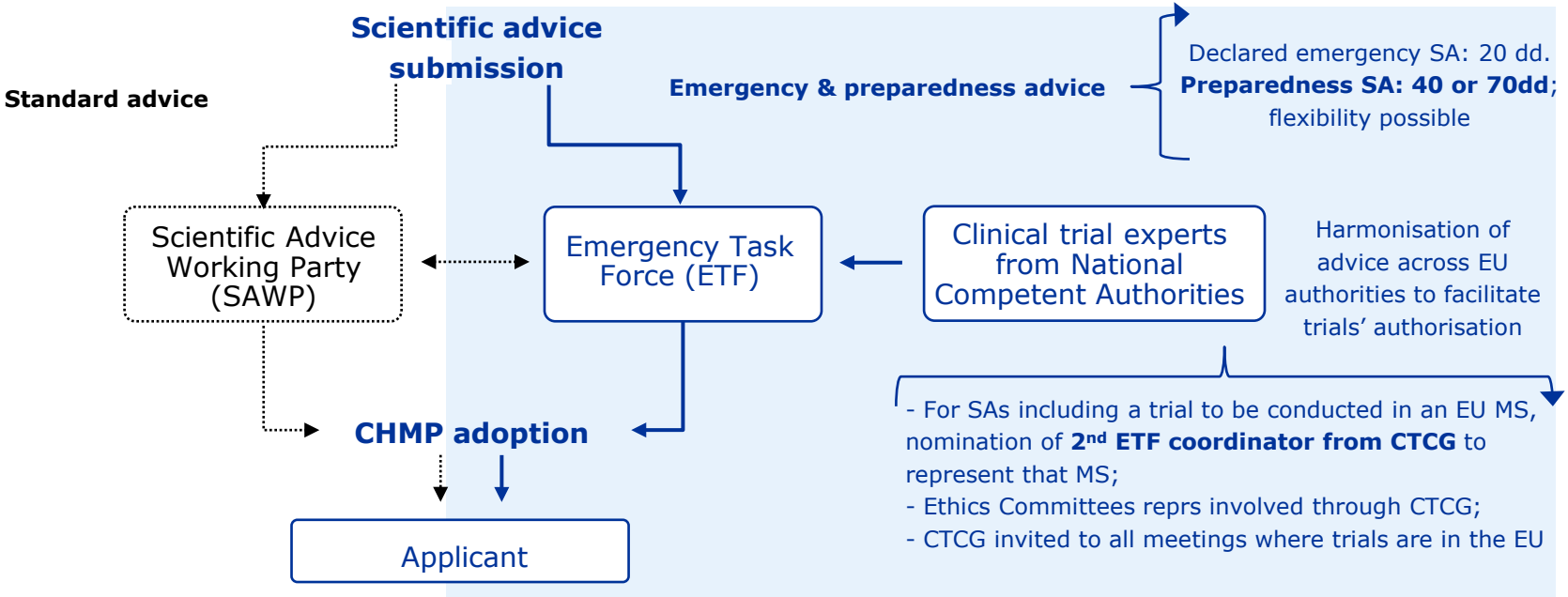
ETF procedures and activities

1. **Scientific advice to developers**
2. **Facilitate large multinational trials and platform trials** by providing sponsors with i) review of protocols and ii) interactions with Clinical trials experts for coordination/acceleration of trials approval;
3. **Review of available evidence** and (joint EMA/ECDC) **recommendations** on medicines, could be published by EMA on topics relevant for public health or used to support e.g. DG-HERA activities with MSs
4. Scientific support to CHMP/EC/MSs on the **use of imported/unauthorised medicines** for national exemptions / emergency authorisations
5. **Support activities with EU/international bodies** including DG-HERA, ECDC, WHO and other international regulators (research funding, advanced purchase agreement, recommendations to MSs and the public)

Outside of declared emergencies, ETF focus on selected pathogens with pandemic potential (e.g. ZIKA, influenza, Ebola) and other threats (chemical, radiological and nuclear origin) (Annex 1 of ETF workplan)

Scientific Advice procedure (art 16): collaboration with CTCG critical

Aim: no pre-assess CTA but tackle potential bottle necks and harmonise views



CTCG: CLINICAL TRIALS COORDINATION GROUP
CTA: CLINICAL TRIAL APPLICATION

Support to clinical trial conduct is a legal requirement for EMA

- **Article 15(2) Reg 123/2022**. *During public health emergencies, the ETF shall undertake the following tasks:*

  *(c) providing **scientific support to facilitate clinical trials** for medicinal products intended to treat, prevent or diagnose the disease causing the public health emergency;*

  *The support referred to in the first subparagraph, point (c), shall include **advice to sponsors of similar or linked planned clinical trials on the establishment of joint clinical trials** and may include **advice on establishing agreements to act as a sponsor or as co-sponsor** in accordance with Article 2(2), point (14), and Article 72 of Regulation (EU) No 536/2014.*

- The overall objective of articles 15 and 16 of Regulation 123/2022 is to support the conduct of coordinated, well-designed, and adequately powered randomised controlled clinical trials

Scientific support to facilitate clinical trials - Mpox

- First case an academic study for tecovirimat against Mpox
- ETF actions: i) ultrarapid scientific review of the protocol; ii) facilitate larger multinational trial with same protocol
- ETF contacted by sponsors and several MSs of the EU plus UK: help with defining interventional vs. observational, harmonisation of protocol, harmonisation of approval in a centralised and accelerated way, help with CTIS application (clinical trial database for EU)
- ETF involved HERA, Commission, CT authorities where the study was planned to be conducted, and facilitated an emergency Clinical trial coordination group (CTCG) meeting to reach EU-level consensus

- **Need to improve process (coordination, timelines (national approval faster?), roles)**

ETF support to clinical trial conduct

- ETF to liaise with sponsors & investigator networks who might conduct research to address the public health emergency – Sponsors can initiate contact via phesupportct@ema.europa.eu

more info Clinical trials in human medicines | European Medicines Agency (europa.eu)

- ETF includes 4 permanent members from clinical trials coordination groups CTCG and CTAG
- COORDINATOR PLATFORM: involve additional /all members of the CTCG + reprs from Ethics committees, provide scientific comments on protocols, coordinate / support interactions across all entities to facilitate merging of smaller trials/protocols/applications, support CTIS filing (database for clinical trials in EU)
- This activity is key in preparedness for future emergencies

EU workshop on Clinical Trials in emergencies

- On 9 June 2023, the EMA and Commission organized a Lessons-learned workshop on Clinical Trials in Public Health Emergencies, chaired by the Director General of SANTE for Health and Food Safety.

- The aims of the workshop were to:

  - Review current processes for clinical trials 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 trials.

- Academic sponsors of clinical trials, ethics committees' representatives, National Competent Authorities (NCAs), EMA, and the Commission participated in the discussion.

- Published set of recommendations (report) for Commission, MSs and relevant bodies to set up a concrete roadmap to tackle identified bottlenecks, create coordination committee at the central level, sustainability

Workshop on Clinical Trials in emergencies: outcome

PROBLEMS → *SOLUTIONS*

- **Process and regulatory approval of CT in EU for emergencies:**
  - Insufficient coordination within MSs (between NCA and Commission) an across MSs (different egal requirements) → *cooperation mechanism across MSs*
  - Slow clinical trial application assessment and authorization
  - Lack of flexibility in Clinical Trial Regulation for the approval process
  - Functioning and knowledge of CTIS (clinical trials database) → *simplification and improvement*

- **Framework for funding clinical trials during emergencies in the EU**
  - Insufficient coordination and fragmentation of clinical trials
  - Lack of consolidated mechanism for investigational products prioritization
  - Lack of flexible funding mechanisms for larger, multinational trials (mobilisation of funds slow and uncertain)

→ SOLUTIONS

- *Establish a coordinating committee and process for transparently identifying and ranking products for clinical trials during emergencies and in inter-epidemic periods*
- *Set-up efficient and predictable funding mechanisms for high-priority emergency or preparedness trials*
- *Creation of a network of pre-qualified clinical trial sites with a standard set of qualification documents and a standard contract and templates to be updated as appropriate.*

Make the EU more attractive for investigational clinical research

- In January 2022 the Commission, the Heads of Medicine Agencies (HMAs) and the EMA launched a clinical trials initiative: Accelerating Clinical Trials in the EU (ACT EU) to make the clinical trial research environment flourish
- Vaccelerate is project publicly funded in 2021 to create in the EU a stable network of clinical trials sites to be ready to act rapidly in emergencies and during preparedness to answer important questions on vaccines addressing public health threats.
- Initiatives on therapeutics: REMAP-CAP, EU RESPONSE and SOLIDACT
- Gather efforts and synergise initiatives on facilitating trials in the EU
- The regulatory part of the actions proposed in the June EMA workshop will be developed in ACT-EU.
  The financial/legal part in discussions between various EU bodies and the Commission, building on existing networks and lessons learned.

Any questions?

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