ACT EU – PA11

Guidance on the conduct of clinical trials during public health emergencies

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General considerations

- In line with the ACT EU Workplan for 2025-2026, EMA, HMA and the European Commission are working on a guidance document aimed at advising stakeholders on the management of clinical trials during a PHE.
- **The new guidance document will build on the experience from the COVID-19 guidance:**
  - It aims at describing **regulatory flexibilities** on adaptations to clinical trials in a wider context of a PHE compared to the specific characteristics of the COVID-19 pandemic (including considerations on the transfer of patients to different sites etc.).
  - It can apply also in case of major disruptions due to natural disasters, chemical or nuclear threats, military conflicts etc.
  - Regulatory flexibilities implemented during a PHE would still need to ensure the **safety** of the trial participants and the **reliability and robustness of the data** generated in the clinical trial.

General considerations

- The guidance will take into account the current legal and regulatory landscape:
  - CTR (applicable since Jan 2022)
  - Guideline on reporting serious breaches (v.1. ,December 2021)
  - ICH E8(R1) (effective date April 2022)
  - DCT recommendation paper (v.1., December 2022)
  - Guideline on computerised systems used in clinical trials (effective date September 2023)
  - Guidance on remote GCP inspections during PHE and other major disruptions (November 2023)
  - FDA Considerations for the conduct of clinical trials during major disruptions due to disasters and PHEs (September 2023)
  - ICH E6(R3) (Principles and Annex 1: step 5 – December 2024)

- CTR and ICH guidelines support the implementation of a **risk proportionate approach** to clinical trials and the need to design and conduct clinical trials with the focus on **critical to quality factors:**
  - ✓ these are key aspects which contribute to the **preparedness** for unforeseen challenges in clinical trials, including PHEs and ensure trial adaptability and robustness during major disruptions.

General considerations

However, some regulatory challenges remain, which would require harmonisation at EU level:

- Divergent national requirements in a few areas of trial conduct (e.g. related to IMP shipment to trial participants, IMP labelling by pharmacies);

- Some GDPR aspects which might be burdensome if applied strictly during a PHE (e.g. related to the possibility of verifying source data remotely).

Stakeholders' feedback

- Once agreed at EU level, the draft guidance will be subject to a **public consultation.**
- Before finalising the document, we would like to get the stakeholders feedback on the following key aspects:

Based on the COVID-19 experience, which are the aspects you consider would be the most challenging to implement during a PHE in order to ensure trial continuity/facilitate the initiation of clinical trials for the treatment or prevention of medical conditions related to the PHE ?

Is PHE/crisis preparedness considered at the trial design stage and if so, is this described in the protocol?

Thank you