06.06.2025

EMA workshop on primary efficacy endpoints for antivirals and monoclonal antibodies intended to treat COVID-19 and Influenza

REGULATORY PERSPECTIVE ON PANDEMIC PREPAREDNESS :

Challenges associated with the (pre-)approval of clinical study protocols

Nele STEENS

famhp

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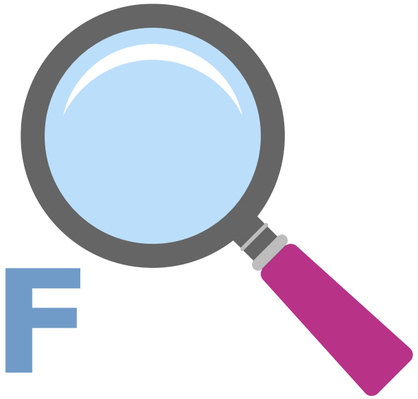
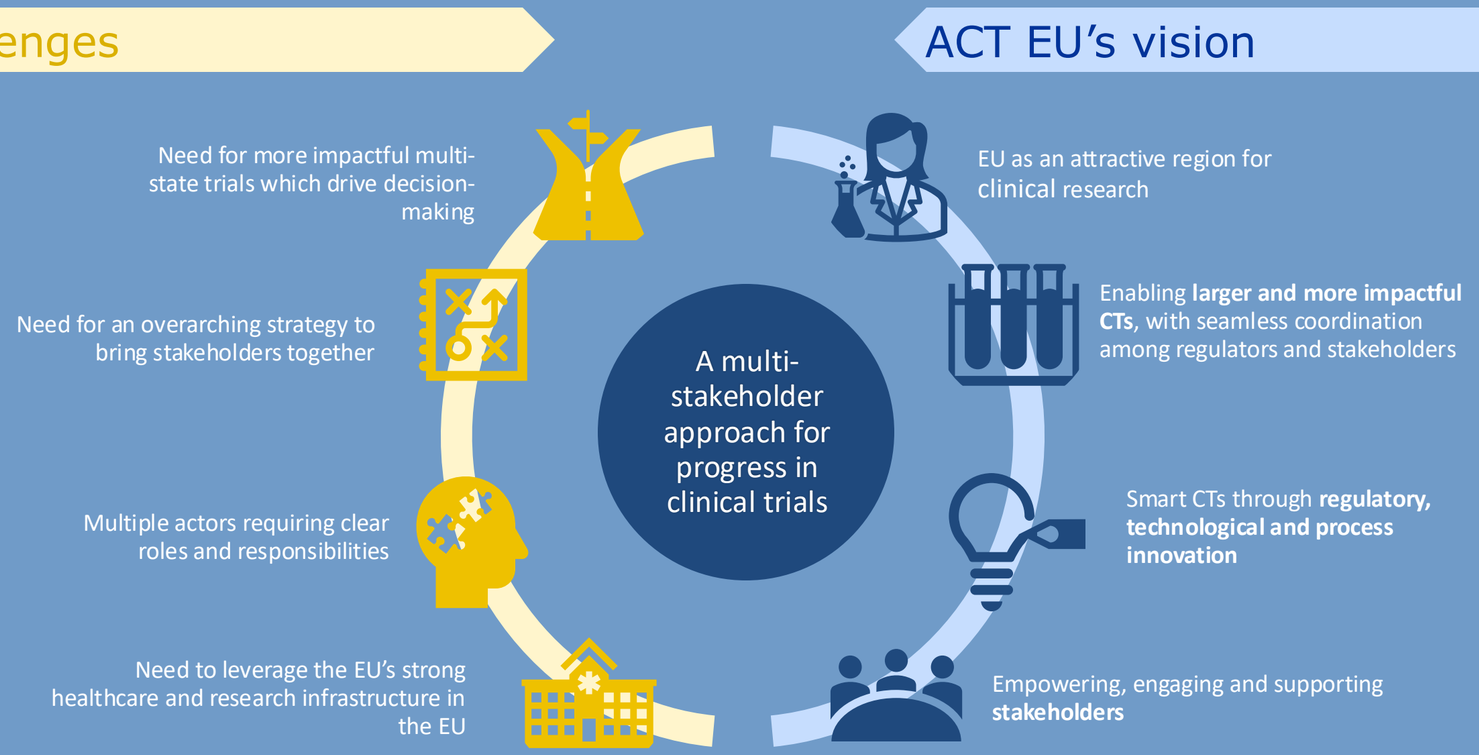


- Introduction to ACT EU priority action on CTs in PHE
- Developing a process for involvement of RECs
- Developing simplified packages
- Fit-for-purpose regulatory flexibilities
- Conclusion on challenges

PRIORITY ACTION ON CLINICAL TRIALS IN PHE

ACT EU

- A joint initiative by the European Commission, Heads of Medicines Agencies and EMA.
- Aiming to deliver on clinical trial innovation recommendations of:
  - the European medicines agencies network strategy and
  - the European Commission's Pharmaceutical strategy for Europe
- The three partners run the initiative together, via the ACT EU Steering Group.



PRIORITY ACTION ON CLINICAL TRIALS IN PHE

Mapping & governance

Implementation of the Clinical Trials Regulation

Support to non-commercial sponsors

Multi-stakeholder platform

Good clinical practice modernisation

Clinical trials analytics

Consolidated advice on clinical trials

Clinical Trials methodologies

Clinical trials safety

Clinical trials training curriculum

Clinical trials in public health emergencies

PRIORITY ACTION ON CLINICAL TRIALS IN PHE

Aims to facilitate large and multinational clinical trials in the EU to promptly tackle public health emergencies (PHE), by:

- basing on the experience gained in previous emergencies (EMA/ETF workshop, CT Cure)
- increasing collaboration across NCAs and ethics committees
- proposing exceptional flexibilities needed for the rapid approval of clinical trials

<u>Keywords</u>: expediting, harmonization, timely start, flexible conduct

INVOLVEMENT OF ETHICS COMMITTEES (TRACK 1)

- **Set-up of an ethics advisory group (EAG)**
  with representatives from ethics committees with interest/experience in PHEs
- **Include ethics in regulatory pre-CTA preparation**
  working closely with the EMA ETF on real cases ad hoc for scientific advice
- **Build experience**
  to help develop a process for efficient involvement of REC assessment of CTs in a PHE

SIMPLIFIED PACKAGES (TRACK 2)

- **Fit for purpose application package**

  surveys about national requirements for part I and part II, proposed simplifications under review CTCG, MedEthicsEU, consultation with CTAG

- **Harmonised templates**

  sort out language requirements

- **Use of templates outside application package**

  e.g. site agreement templates, material transfer agreement for biological samples

FIT-FOR-PURPOSE REGULATORY FLEXIBILITY (TRACK 3)

- **Initial source HMA/EMA/EC COVID-19 guidance**
  extended to any PHE

- **Linking with other guidelines**
  linking to existing other guidance and recommendation papers

- **Consultation with the EU network**
  highest acceptable level of flexibilities while still ensuring safety of the trial participants and the reliability and robustness of the data generated in the trial

TO BE CONTINUED: EXPEDITED ASSESSMENT!

CHALLENGES

- Agreement needs to be reached between all MS
- Divergent national legislations (e.g. IMP shipment)
- Flexibilities within legislation but also outside → legal support needed at EU level (e.g. GDPR, CTR)
- System of national ethics committees remains
- Pre-approved protocols without IMP
- Expediting: first patient within 15 days feasible?

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