Setting the scene on the current regulatory framework

EMA Lessons learned workshop on Clinical Trials in Public Health Emergencies , 9 June 2023

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CT during Public Health Emergency (PHE)

- ***Serious Cross Border Threats to Health Regulation*** *(Regulation (EU) 2022/2371): declaration of the state of Public Health Emergency by European Commission*
- ***Emergency Framework Regulation*** *(Council Regulation (EU) 2022/2372): measures activated by Council of Member States*
- *NOT TO CONFUSE with 'Clinical Trials in emergency situations' (art. 35, Regulation (EU) 536/2014 on Clinical Trials)*

CTR implementation status

- *CTR adopted 2014, became applicable on 31 January 2022*
- *Application through CTIS mandatory for initial CT since 31 January 2023*
- *Still challenges with the implementation of the CTR by the MSs in terms of national coordination within MSs (CTAG) and divergent requirements across MSs (CTCG)*
- *Importance to align national laws with the harmonized provisions of the CTR*

CTR timelines

- *CTR provides for maximum timelines for the assessment of the CTA but does not set minimum*
  - **Validation: 10 days**
  - **Assessment Part I and II : 45 days**
  - **Notification of the decision : 5 days**

- *CTR does not impede for a faster assessment and decision*

Opportunities beyond CTR

- *CTR does not prevent collaborative approaches on a voluntary basis outside CTR: any pre-work or coordination done by interested parties involved in CT is possible*

- *on the scientific aspects*
- *on ethical aspects*
- *on procedural aspects*

- *EC/EMA/HMA guidance on management of clinical trials during COVID-19 pandemic*
- *EMA extended mandate (Regulation (EU) 2022/123)*

Take away messages

- The current regulatory framework does not prevent shorter of the timelines
- Build on experience from previous crisis and existing structures
- Collaborative solutions beyond the CTR among the interested parties involved in CT can be triggered during public health emergencies