Considerations for Ukraine's Clinical Research Context

Pharmaceutical Forum

Clinical Trials in Ukraine: European Integration

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Learnings from ALLEA's Symposium on Crisis and the Importance of Research, the EU-US Trade & Technology Council's Standardization for Emerging Technologies, and Data Governance in ICH E6(R3)

The Clinical Research Enterprise

- An essential structure within a society for responding to the realities and/or threats of disease, suffering, and the healthcare needs of individuals and populations
- An essential element in society for the following:
  - Medicine, including the creation of medical knowledge as well as responding to individual and population health needs
  - Science, contributing to specific knowledge on human biology and health as well as to general knowledge about ourselves and the world
  - Education, as a foundation for medical education while also contributing to many other related and ancillary sciences
  - Profession, as a framework for essential professions in society
  - Public health, as a sine qua non for public health systems to ensure that the diseases and health of populations are addressed in the specificity and generality
  - Industry & Economy, it contribute to an important socio-economic force in society, developing wealth through its generation of knowledge, products, and a healthy workforce

→It is impossible to imagine a healthy society without a healthy medical research enterprise

The ethical justification of research

- Informed Consent
- Ethics Review (IRB/IEC)
- The requirement to continually improve our knowledge and tools for responding to disease, suffering, and the healthcare needs of individuals and populations
- The assurances that the results of the research will be used to improve the medical community's response to disease, suffering, and the healthcare needs of individuals and populations

Adaptive Design Clinical Trial

- ‘a design that allows modifications to the trial and/or statistical procedures of the trial after its initiation without undermining its validity and integrity. The purpose is to make clinical trials more flexible, efficient and fast.’

Situationally Adaptive Design

We need to rethink and redesign our “adaptive design” models for clinical trials such that they are also fit for purpose for war, crisis, and disaster situations, sometimes including go/no-go decision algorism in extremely difficult situations. In cases where study protocols are fundamentally disrupted, adaptive design should mean adapting to the needs of study participants—not abandoning the participants, not abandoning the health intervention, not abandoning the science.

Two Important Documents

- ‘Clinical Study Report Considerations for Studies Disrupted by the COVID-19 Pandemic’ TransCelerate
- ‘Points to consider when developing a Clinical Study Report (CSR) for a clinical trial that has been disrupted due to unforeseen circumstances’
  ACRO & TransCelerate

The Royal Society & ALLEA

'Crisis & the Importance of Research'

London, 22 June 2023

'As European scientists and scholars, we have become increasingly aware that adequate social transmission and political adoption of scientific results is just as important as the academic production of good science. But we have also become aware that this transmission and adoption of science needs to address quite a different audience and respond to different needs from those we usually produce science for. In our knowledge-intensive societies, science has gradually acquired what we might call a *translational* component.'

Professor Antonio Loprieno, President ALLEA, Opening Remarks

Why Clinical Research in a Crisis

The interfaces between clinical research and government, clinical research and society are also the coalface of science and health. A society is more than a land and an identity, it is perhaps primarily a set of shared enterprises, a community (or group of communities) that share a common engagement and a common concern for one another's prosperity and happiness.

EU-US Trade & Technology Council's (TTC) Standardization for Emerging Technologies

- To identify priorities, facilitate cooperation, engage stakeholders, address regulatory challenges
- To set common (global) standards and promote interoperability (particularly in our digital societies) to facilitate trade, innovation, and market access for emerging technologies
- For the development and deployment of emerging technologies

TTC's Goals in Health

Working Group 1: Technology Standards

- common data interoperability standards and exchange formats for health data
- a coherent approach to access and processing of data
- a set of contractual clauses for transatlantic health data transfers
- common definitions for pharmaceutical research and regulatory purposes, such as for real-world data and evidence (FDA & EMA)

ICH E6(R3) GCP

- A risk-based quality management in CTs: a proactive approach to identifying, assessing, and mitigating risks associated with clinical trial conduct and data integrity
- A focus on data integrity and reliability
- Evolving technologies: guidance on incorporating electronic systems, data standards, and innovative technologies while ensuring the integrity, privacy, and security of data
- Flexible approaches in clinical trial design and execution, e.g., adaptive trial designs and decentralized trials

Our Appreciation

- Of course, we want to support Ukraine's clinical research enterprise during this terrible period
- More importantly, we can learn from Ukraine's clinical research enterprise lessons that are critically important for science and health the world over