Advancing Efficient and Inclusive Clinical Trials

Meeting of the Directors of the NCI-designated Cancer Centers

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FDA Multipronged Approach to Facilitate Innovative, Efficient, and Inclusive Clinical Trials

- FDA Real-World Evidence Program
- Efficient Safety Reporting
- Increasing Diversity in Clinical Trials
- Decentralized Clinical Trials
- Digital Health Tools
- Lessons from the Pandemic
We want to provide the clarity needed to realize the full potential of Real-World Data.
We are improving IND safety reporting through guidance and outreach:

- **Sponsor Responsibilities IND Safety Draft Guidance (June 2021):** Clarifies Sponsor’s IND safety reporting requirements. Expands recommendations for aggregate reporting and safety assessment committees.
  - External [Webinar](#) provided to stakeholders

- **Investigator Responsibilities for IND Safety Draft Guidance (September 2021):** Focused investigator guidance in this space, including reporting to IRB.
  - External webinar will be provided to stakeholders

- **WCG Webinar “A Fresh Perspective from the FDA on the Final IND Safety Reporting Rule” (June 2021):** Dr. Temple and Dr. Corrigan-Curay presented regarding sponsor responsibilities for safety reporting.

- **PRIM&R Annual Conference (Nov 2021):** Collaborative presentation with OGCP highlighting IND safety responsibilities for sponsors, investigators and IRBs.
Inclusion and Diversity in Clinical Trials

• We are exploring ways to encourage the participation of racial and ethnic minorities and other underrepresented populations in clinical trials through:

  o Issuing guidance
    • *Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs* (2020)
    • *Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients* (2020)
    • *Inclusion of Older Adults in Cancer Clinical Trials* (2020)
    • *Collection of Race and Ethnicity Data in Clinical Trials* (2016)

  o Developing tools
    • CDER developed Drug Trials Snapshots ([https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots](https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots)) as part of an overall FDA effort to make demographic data more available and transparent.

  o Encouraging the use of innovative trial design
    • FDA is working on guidance pertaining to the use of decentralized trials and digital health technologies.
Facilitating and Encouraging Innovation
e.g., Decentralized Clinical Trials (DCTs)

A clinical trial where some or all the trial-related activities occur at a location separate from the investigator’s location

**Potential benefits:**

- Patient convenience (avoiding travel to sites, time off work, etc.)
- Improved inclusivity (patients with mobility, cognitive and economic challenges)
- Ability to study patients in widespread locations (rare or sporadic diseases)

**FDA Will Issue a Guidance on DCTs**

Facilitating and Encouraging Innovation

*e.g., Digital Health Tools (DHTs)*

A digital health technology (DHT) is a system that uses computing platforms, connectivity, software, and/or sensors, for healthcare and related uses

**Potential benefits:**

- Ability to study diseases in new ways
- Improved recruitment of patients (e.g., those with limited mobility)
- Data capture outside of health care setting
- Continuous data rather than snapshots
- Objective measurements
- Reduced missing data
- Capturing rare events

**FDA Will Issue a Guidance on Digital Health Technologies for Remote Data Acquisition in Clinical Investigations**
What Can We Learn From the Pandemic?

– Initial release date: March 18, 2020
– Most recent update: August 30, 2021

Lessons and examples from public health emergencies:

• Leveraging existing healthcare infrastructure
• Remote assessment and monitoring
• Identifying & prioritizing critical processes
• Leveraging technology and innovations
• Effective communication and documentation
Summary

• We recognize the great potential in many evolving areas to advance drug development.
• We are working to provide the needed regulatory perspective to not only facilitate, but also encourage innovations.
• We are developing multiple guidances to explore the utility of RWD & RWE, and to facilitate a more efficient clinical trial design and conduct.
• We are engaging with multiple partners across the Federal Government and the private sector to disseminate knowledge and to help facilitate innovative approaches.