OPTIMIZING DATA QUALITY & FLEXIBILITY IN CLINICAL TRIALS

Expert Meeting

CLINICAL TRIALS TRANSFORMATION INITIATIVE

MEETING SUMMARY | February 26, 2025

BACKGROUND

Implementing less rigid, more flexible operational approaches to clinical trials can enhance patient and site access to research, improve participant satisfaction, facilitate the use of real-world data, and enroll the patients who will use the medical product. However, there are questions around how to maintain data quality when offering flexible approaches, such as decentralized approaches or integrating research into routine clinical care. To support regulatory decision-making, trial data must be fit-for-purpose, credible, and reliable—free from errors that could compromise participant safety or the integrity of the results.

CTTI's Optimizing Data Quality and Flexibility in Clinical Trials project seeks to clarify how to maintain adequate data quality when including flexibility to support patient needs in interventional clinical trials. As part of the CTTI project, this Expert Meeting convened a group of experts to evaluate the benefits and feasibility of offering flexible approaches in clinical trials, identify critical data quality concerns, and explore solutions for maintaining data quality.

MEETING OBJECTIVES

- Evaluate the benefits and feasibility of offering flexible operational approaches to support participant needs and preferences
- Discuss how flexible operational approaches might affect data quality
- Explore solutions for mitigating errors that matter to data quality

MEETING THEMES

Throughout the meeting, attendees discussed considerations for maintaining data quality in clinical trials when providing flexible operational approaches. Attendees shared many ideas, and the following key themes emerged:

- **Increased participant satisfaction** and **improved retention** are anticipated benefits to implementing flexible approaches in clinical trials.
- **Reliably answering an important question, a robust trial design, efficient recruitment,** and **participant safety** are factors that matter most to trial quality.
- From a regulatory perspective, clinical trial **data should be fit-for-purpose such that the data are sufficiently complete, accurate and verifiable, and demonstrate that a medical product provides a meaningful clinical benefit to patients that outweighs its risks.**
- **Flexibility and data quality in trials are not opposed and should be fit-for-purpose.**
- Challenges of maintaining data quality while offering flexible approaches include **consistency and accuracy of data collection, ensuring data privacy and security,** and **outlining responsibility and monitoring expectations.**
- To avoid unnecessary complexity in trials, **clearly define the goal, incorporate a Quality-by-Design approach, and focus on trial attributes critical to the interpretability, reliability, and verifiability of trial data.**
- **Relating to patients' personal motivations for participation; carefully considering data sources, training, and communication; and aligning incentives with the realities of healthcare system practices** are best practices for clinical trials with flexible operational approaches.

NEXT STEPS

Meeting attendees discussed solutions for addressing data quality concerns in clinical trials with flexible operational approaches, including the need to:

- Define early on, engaging patients, caregivers, sites and other partners involved in research, what is critical to quality in a study and agree to a balance between flexibility and data quality
- Design trials to avoid unnecessary complexity
- Map out data flow to identify and address potential risks to critical to quality factors
- Ensure the validity and consistency of data collected from multiple sources, focusing on critical data
- Create systems to harmonize clinical trial data with electronic health records and facilitate bi-directional transfer of data
- Implement real-time monitoring of collected data to align with the Quality-by-Design approach, potentially using AI
- Ensure secure data transfer and storage to maintain patient privacy and trust
- Educate participants on how their data will be collected and used
- Be intentional in what training is required of study staff, participants, and participants' families/caregivers to collect and record data remotely and provide accessible, ongoing technical support for troubleshooting errors

The CTTI Social Science team will review the key themes and insights discussed during this meeting to inform CTTI's next steps.

ADDITIONAL RESOURCES

- Meeting materials, including agenda, participant list, and presentations
- Read more about CTTI's Optimizing Data Quality and Flexibility in Clinical Trials Project

ABOUT THE CLINICAL TRIALS TRANSFORMATION INITIATIVE (CTTI)

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the FDA, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Bringing together organizations and individuals from across the enterprise, CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges.

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