Pursuit of Efficient and Quality Clinical Trials

CTTI has conducted more than 25 projects within 5 strategic focus areas and issued recommendations for specific actions and considerations to improve the design and execution of clinical trials, with a goal of assuring meaningful, high quality data and appropriate protections for participants (Figure 2).

Results and recommendations have been cited by government bodies and are being implemented by sponsors, academic organizations, patient advocacy groups, and others (Figure 3).

Lessons Learned: Successes and Challenges

PROJECT SELECTION

Targeting the collective needs and priorities of industry, academia, clinical trial sites, patients, and government bodies is fundamental to project success, and optimal adoption of the project recommendations occurs when the project results address the needs of relevant stakeholders.

CTTI has fine-tuned its selection of projects to ensure key questions are considered: examples include anticipated impact, criticality of issue, potential for transformation, regulatory needs, relationship to CTTI’s current or past projects, and relationship to efforts of other organizations.

PROJECT TEAM DYNAMICS AND EXECUTION

Enlisting knowledgeable, engaged, committed project leaders and team members representing diverse perspectives is crucial throughout the duration of the project. With a typical project spanning approximately 2 years, multi-stakeholder teams collaborate on all project activities, from gathering evidence related to the topic of interest, formulating project recommendations and associated resources.

MULTI-STAKEHOLDER MEETINGS AND DISCUSSIONS

CTTI strives to engage multi-stakeholder groups from project inception through project execution and beyond. CTTI has witnessed tremendous value in team discussions that lead to moments of common understanding between diverse stakeholders. These discussions are expanded during expert meetings designed to engage the wider trials community and allow issues to be explored further, solutions to be identified, and additional work can be catalyzed.

Background

CTTI was co-founded by the U.S. Food and Drug Administration and Duke University to improve efficiency and quality in clinical trials.

CTTI now comprises a diverse membership reflecting the range of organizations involved in the design, conduct, and evaluation of clinical trials, and engages a vast array of stakeholders in its work. Our approach to stakeholder engagement is much broader than membership, with individuals from more than 430 organizations having been involved in CTTI projects or meetings. CTTI’s mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Through a series of projects and collaborative efforts, CTTI offers solutions for significant improvements or advancements in clinical trials to stakeholders in the clinical trials enterprise (CTE) (Figure 1).

Common Themes Identified in CTTI Projects and Recommendations

IMPORTANCE OF ENGAGING MANY STAKEHOLDERS

One of CTTI’s core principles is to value the input and participation of all stakeholders, and we encourage others to do the same in nearly every set of project recommendations.

ADVANCED PLANNING TO ADDRESS CRITICAL ISSUES

Many problems that may occur during a clinical trial can be prevented or mitigated through effective, proactive thought and planning. CTTI’s Quality by Design (QbD) project developed a new approach to build quality into the scientific and operational design of the clinical trial in a prescriptive and ongoing fashion. This is accomplished by focusing on activities that are critical to ensure the credibility of study results and ensure the safety of trial participants, engaging a broad range of stakeholders in trial planning, creating a culture that values critical thinking, as well as prospectively identifying and periodically checking critical to quality factors.

DISCONTINUE NON-VALUE ADDED PRACTICES

Recommendations from many projects suggest specific opportunities to focus on critical data and activities, with strategies to avoid activities that are not essential. As noted above, the QbD process asks us to consider whether nonessential activities may be eliminated from the study to simplify conduct, improve trial efficiency, and allocate resources to the most critical areas. Another example are the recommendations of the GCP projects where sponsors are encouraged to only retrain investigators every 3 years and accept other sponsors training under certain circumstances. You will find many recommendations that carry through that theme such as embedded in CTTI’s ABDD program and safety reporting projects.

TECHNOLOGY PRESENTS NEW OPPORTUNITIES

Advances in novel technologies and increasing access to health data, such as electronic health records (EHRs) provide opportunities to increase the efficiency of many clinical trials and to improve the quality of the information that they provide. CTTI is working with many stakeholders to understand how we can take advantage of technology, while making sure that the results are reliable, and participant protections remain robust. CTTI’s Mobile Clinical Trials (MCT) program focuses on reducing barriers to the incorporation of mobile technology in FDA-regulated clinical trials. Other CTTI projects are exploring the application of existing data sources, such as the FDA Sentinel System, registries and EHR systems for clinical trials.

Impact to Date and a Look to the Future

While there is more work to be done to truly transform clinical trials, much has been accomplished in the past 10 years, and CTTI has made a difference (Figure 4).

No effort is without its challenges, but as CTTI celebrates 10 years of successfully driving change in the CTE, we are committed to efforts that question the status quo and work with all stakeholders to make clinical trials more efficient, quality-driven, and patient-focused.

REFERENCES:


FUNDING STATEMENT

CTTI is funded by payments for products or services rendered, consistent with the Federal Drug Administration guidelines. This statement is to be provided in all presentations, publications, and other communications to indicate that this project has been funded in part by an industry source.

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