Pursuit of Efficient and Quality Clinical Trials

CTTI has conducted more than 25 projects within 5 strategic focus areas\(^1\) and issued recommendations for specific actions and considerations to improve the design and execution of clinical trials,\(^1\) 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 upfront; 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 CTTI’s current or past projects, and relationship to other organizations.

**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 and addressed.

**REFERENCES:**

1. Clinical Trials Transformative Initiative. [https://www.ctti-clinicaltrials.org](https://www.ctti-clinicaltrials.org)

**TECHNOLOGY PRESENTS NEW OPPORTUNITIES**

Advances in novel technologies and increasing access to health data, such as electronic health records (EHR) provide opportunities to improve 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 trial and eHealth Research projects consider the impact of technology on study design, participant experience, and communication.

**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 retrain investigators every 3 years and accept other sponsors training under certain circumstances. You will find many recommendations that carry forth on the theme such as embedded in CTTI's ABDD program and safety reporting projects.