Message from CTTI’s Executive Director

From its inception, CTTI has been successful at generating evidence and formulating implementable recommendations that inform policy and practice, thus creating positive change in clinical trials. As an evidence-driven multi-stakeholder organization, we take the time to understand the reasons and incentives behind the status quo, as well as to evaluate potential better approaches. Once recommendations are issued, we shift efforts to facilitate adoption by broadly disseminating the results of projects, developing models for others to follow through demonstration projects, and creating tools and resources to make implementation easier.

-CTTI Executive Director, Pamela Tenaerts, MD, MBA
Despite many challenges facing clinical trials - investigator churn, faltering patient enrollment, and rising costs - they are the gold standard for determining safety and efficacy of treatment and prevention options.

For millions of patients and their healthcare providers worldwide, clinical trials deliver evidence for decision-making that may be related to life-saving treatments, prevention, and cures.

CTTI projects focus on streamlining and accelerating clinical trials, while maintaining high standards of quality and human subjects protection. We provide actionable, evidence-based, consensus-driven recommendations designed to:

- Accelerate study start-up times & streamline protocols
- Leverage new technologies to improve efficiency of clinical trials
- Enhance the quality of clinical trials without adding undue burden
- Identify streamlined strategies to meet regulatory requirements

2014 CTTI Highlights
In 2014, we focused on driving change in three key areas:

1. Influencing Culture
2. Changing Practices
3. Identifying Best Practices

This report highlights the many ways we have achieved these goals over the past year.
Influencing Culture for Patient Engagement 2.0

Patient partners are in the fabric of CTTI’s efforts to improve the clinical trial enterprise. In addition to creating a patient-driven project to understand best practices for engagement between patient groups and sponsors of research, patients and their representatives are involved as equal partners in every aspect of our organizational operations. CTTI has become a leader in true patient engagement, and others are taking note.

“Patient-centricity is among the top trends in industry and is top-of-mind for policymakers. Understanding the state of engagement and documenting its value proposition are two priorities for all stakeholders in the biomedical enterprise, so CTTI’s Patient Groups & Clinical Trials project is building a vital evidence base. Through this work, CTTI is also fostering cultural change and practical processes that will prime the pump for adoption of best practices in patient engagement and that maximize the return on investment by all parties.”

– Kim McCleary, Director, Strategic Initiatives, Faster Cures

“Recognizing the importance of patients’ interests and experiences as key inputs in the clinical research process is a growing and promising trend. CTTI’s Patient Groups & Clinical Trials project has played a vital role in advancing this exciting development. Through its efforts, CTTI is both encouraging the research community to more consistently take note of the value of patient engagement in research and helping to grow the evidence base on the potential impact of this trend in the evolution of the traditional research enterprise.”

– Sue Sheridan, Director of Patient Engagement, PCORI
Influencing Culture for Central IRBs

In 2013, CTTI published recommendations to facilitate the adoption of central IRBs through the use of a Considerations Document for central institutional review boards (i.e., having a single IRB-of-record for a given protocol).

At that time, there were few examples of industry sponsors requiring the use of a central IRB in the U.S., despite evidence showing that central IRBs can improve the efficiency of multi-center clinical trials without sacrificing human subjects protection.

Since that time, the Central IRB Advancement project team has actively engaged with sponsors, institutions, and organizations that serve as central IRBs of record for clinical trials. The team has also worked on an IRB authorization template and other tools as it became clear more tools were needed to allow a greater shift to central IRB adoptions. Public webinars outlined how sponsors and institutions had successfully moved to the use of central IRBs. Through these efforts, CTTI has been able to help facilitate a shift to greater use of central IRBs.

On December 3, 2014, the National Institutes of Health issued a draft policy for the use of single IRBs in multi-site clinical research studies, citing a CTTI publication.

“The National Cancer Institute is moving toward the NCIRB being the sole IRB of record and we are starting to see many sponsors require central IRB review as more institutions are coming on board and becoming comfortable with the model.”
– Cynthia Hahn, Chief Operating Officer, Feinstein Institute for Medical Research

“We implemented the CTTI recommendations within our company and made a commitment that all sponsors of clinical trials would be reviewed by a central IRB.”
- Soo Bang, Senior Director, Business Development and Global Alliances, Celgene Corporation

“We think that there is a lot of merit in supporting improvements in the clinical trial infrastructure itself. The Clinical Trials Transformation Initiative has contributed so much in terms of innovative trial design, as it is working on establishing centralized IRBs for multicentered trials, which is an important advancement.”
- Margaret A. Hamburg, MD, former Commissioner, FDA
Influencing Culture
for Quality by Design (QbD)

CTTI’s QbD Principles Document was designed to help organizations focus on “the errors that matter” in clinical trials. CTTI’s intensive workshops and webinars have enabled QbD principles to gain traction in a wide range of organizations, from commercial pharma, biotech, and device companies to academic and government sponsors.

Changing Practices
for Quality by Design (QbD)

CTTI inspired and enabled us to implement QbD principles at Pfizer. None of what we’ve done would have been possible without the backing, influence, and support of CTTI. It has been amazing to watch the dialogue in the industry change.”

– Coleen Glessner, Vice President, Clinical Trial Process and Quality, Pfizer

QbD is a concept whose time has come. The CTTI Principles Document provided a framework that helped Seattle Genetics practice QbD concepts and identify elements that are critical to quality.”

– Marta Fields, Senior Director, Compliance and Quality Systems, Seattle Genetics

PCORnet, the national patient-centered clinical research network, is applying CTTI’s QbD principles in its clinical trials task force work.
Identifying Best Practices for Accelerating Antibiotic Drug Development

Testing new antibiotics designed to treat bacterial pneumonia acquired as a result of a hospital stay or in association with a ventilator are notoriously complicated, lengthy, and expensive. The FDA engaged several parties, including CTTI, to address the need for more drugs to treat antibacterial infections:

► A number of ideas fostered through CTTI’s Streamlining HABP/VABP Project were adopted by the FDA in its HABP/VABP guidance document, re-leased in 2014.
► Former FDA Commissioner, Margaret A. Hamburg, cited CTTI as a contributor to the FDA’s effort to address antibiotic resistance.

Upcoming Products to Improve Clinical Trials

In 2015, we will be releasing recommendations and implementation tools for various CTTI projects:

► Additional recommendations and tools will be issued to facilitate the adoption of a central IRB in multi-site clinical trials.
► Recommendations and a risk calculator will assist protocol development teams to choose an evidence-based pregnancy testing protocol appropriate for their clinical trial.
► Recommendations will be issued to streamline hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) trials.
► Recommendations and a user’s guide for the Principles Document will facilitate the implementation of QbD principles.
► Recommendations will be issued on best practices for engaging with patient groups in the clinical trials process.
CTTI PORTFOLIO
CTTI is making a difference in clinical trials at every stage of the process -- speeding study start-up, strengthening investigational protocols, and improving study conduct -- all in the name of getting treatments to patients faster. Learn more about our entire portfolio of projects.

What Makes CTTI Unique
All Stakeholders Engaged as Equal Partners
Evidence-Based Recommendations

Join us in transforming clinical trials

CLINICAL TRIALS TRANSFORMATION INITIATIVE
Innovation Through Collaboration
To learn more about CTTI’s work, visit www.ctti-clinicaltrials.org