At CTTI, we’re on a singular mission to transform clinical trials for everyone.

We’re doing it by convening the brightest minds from academic institutions, life sciences, patient advocacy groups, and regulatory bodies. Together, we share, debate, brainstorm, and surface answers to challenges in order to create a more effective and efficient research process.

These advances would not have been possible without our collaborators across the clinical research enterprise. Through CTTI, 473 individuals and 176 organizations came together in 2023 to shape new ideas and better ways to conduct clinical studies. As we move forward into 2024 and beyond, CTTI is committed to maintaining this momentum to propel a new era in clinical research: one where collaboration and innovation pave the way for more impactful, efficient, and patient-centered trials. We hope you will join us on the journey.

In 2023, we have developed evidence-based, multi-stakeholder recommendations and advanced progress on a range of important topics, including:

- Clinical trial diversity and inclusion
- Digital health technologies in clinical studies
- Early stakeholder and patient engagement in research
- Measuring progress toward our 2030 vision
Putting Patients & Caregivers at the Heart of CTTI’s Work

Good studies consider all relevant evidence, and no evidence is more relevant than the human experience. That’s why patients and caregivers are at the core of all CTTI work, from our Executive and Steering Committees, to our multi-stakeholder project teams, to the Patient Engagement Collaborative (PEC), an ongoing forum in which PEC members, FDA, and CTTI discuss a variety of topics, such as improving communications, education, and patient engagement related to medical product regulation.

“I bring ALS to CTTI, but I also bring a huge amount of knowledge from CTTI back to the ALS community. CTTI really gives me the opportunity to have the biggest impact on my disease.”

Phil Green, Patient Representative on CTTI’s Steering Committee
Read Phil’s journey to CTTI

“My mother was diagnosed with triple-negative breast cancer, which is one of the more challenging types to treat. Clinical trials offer hope, and yet when she was diagnosed, we were told that no trials were currently taking place for her condition. This kind of disconnect between the options available within the ivory towers versus what real patients and local communities need is a problem that seems to occur time and again.”

Nuru Noor, Patient Representative on CTTI’s Steering Committee
Read Nuru’s journey to CTTI

“I see a future where clinical trials are underpinned by equity best practices, and trials are easier to access for diverse communities through more transparent, balanced, representative eligibility criteria. With the combined power of The Chrysalis Initiative, CTTI and other visionary organizations, I believe we will get there.”

Jamil Rivers, CTTI Steering Committee Patient Representative
Read Jamil’s journey to CTTI
Our Members: Uniting to Pioneer the Next Era of Clinical Trials

In 2023, 77 member organizations worked together to develop recommendations, sharing expertise at topic-focused meetings and convening to identify and address the most pressing issues across the clinical trials enterprise.

As a public-private partnership, our work would not be possible without the ongoing support, participation, and contributions from our FDA colleagues and our member organizations. It is a privilege to work together toward our shared mission: quality and efficiency in clinical trials.

Did you know?
CTTI’s multi-stakeholder membership identified four areas of interest for new work:
• Participant Access & Flexibility in Clinical Trials
• Artificial Intelligence
• Planning and Implementing Diversity Action Plans
• Building Community Trust and Sustained Engagement
Convening Multi-Stakeholder Expert Groups

In 2023, CTTI convened stakeholders from across the clinical trials enterprise to advance our work on Engaging All Stakeholders in Trial Design and Disease Progression Modeling with the following mix of expertise.

> “I’ve seen first-hand at our expert meetings the collective power of our members and other experts sharing knowledge and excitement for methodologies, like disease progression modeling, that can shorten medical product development times, enabling faster insights for patients.”

Lindsay Kehoe, CTTI Senior Project Manager
Collaborating for Impact

We know that to solve the most pressing challenges in clinical research, we need to enlist the insights and resources from organizations with missions that align with ours. CTTI is continuously pursuing opportunities to work in collaboration with other organizations that focus on related issues through their unique lens.

Collaboration Spotlight: Diversity Convergence Project

Multiple efforts to address the lack of diversity, inclusion, and representativeness in clinical trials have been underway and new efforts continue to emerge. In early 2023, the leaders of CTTI, the Multiregional Clinical Trials Center of Brigham and Women’s Hospital and Harvard, FasterCures (a center of the Milken Institute), and the National Academies Drug Forum on Drug Discovery, Development, and Translation converged on the idea that no one entity could effectively make transformative change alone. In order to realize the potential impact and scalability of the diversity work happening across the enterprise, including our own, we needed to align goals to achieve changes at the system level. The four organizations have met weekly since March to identify actions that, if taken collectively, could drive system-level changes across eight domains. To date, three of four planned convenings have engaged over 200 individuals representing diverse organizations and government agencies. The National Academies of Sciences, Engineering, and Medicine will host the fourth convening as a public workshop in March 2024.

Did you know?

Other countries look to CTTI when developing similar initiatives within their countries. In 2023, we’ve met in person with groups from South Korea and Saudi Arabia seeking to transform trials in their respective regions. We’ve continued relationships with colleagues doing similar work in Australia, Canada, Europe and the United Kingdom. Together, we are problem-solving and improving the conduct of clinical trials on an international scale.

Our Staff: The Backbone of CTTI

Our organization comprises 17 core staff members who support the development and execution of our projects and the dissemination of their results. Our staff members also organize and support the activities of the Executive and Steering Committees, as well as our multi-stakeholder project teams. Our unique position within the Duke system affords us access to world class teams of social science researchers, medical writers, data, and communications specialists that make the generation and dissemination of high-quality evidence possible.

“It is incredibly rewarding to be part of CTTI’s journey to positively transform clinical trials. I’ve witnessed the impact our members have in bridging gaps in the clinical research enterprise and enabling faster insights for patients when answers can’t wait. It’s a mission you want to give your best to every day.”

Karisa Merrill, CTTI Strategic Engagement Manager
CTTI Projects: Generating Knowledge and Evidence

Creating New Pathways
As science advances, the complexity and potential for innovation in clinical trials have expanded exponentially. Cutting-edge technologies, breakthrough therapies, and a growing emphasis on personalized medicine have transformed the landscape of healthcare. At the same time, there are evolving trial methodologies and tools, ranging from adaptive trial designs, to the incorporation of digital health technologies, and increasingly effective engagement of patients as active partners in the research process. At CTTI, we provide the information, frameworks, and tools that enterprise leaders need to leverage these advances in their day-to-day business.

CTTI makes publicly available all of the practical, hands-on resources we develop to support the clinical research enterprise in implementing new best practices. In 2023, we had 14 active projects tackling some of the clinical trials enterprise’s most pressing challenges:

- Aggregate Analysis of ClinicalTrials.gov (AACT) Database
- Assessing Protocol Data Rationale and Relevance
- ClinicalTrials.gov Reporting Challenges
- Disease Progression Modeling
- Diversity Convergence
- Engaging All Stakeholders in Trial Design
- FDORA Enhancing Study Diversity Public Workshop
- FDORA Mitigating Study Disruptions Public Meeting
- Increasing Diversity in Clinical Trials
- Measuring Trials Transformation
- Oncology Trial Modifications
- Patient Engagement Collaborative
- Quality by Design Implementation
- Trials in Clinical Practice

“My advice is to look across all CTTI recommendations and resources, even if they aren’t intended specifically for your need or purpose. So much of our work is interconnected, and CTTI’s recommendations offer value across the entire research spectrum. Whatever your next research effort, go there first.”

Theresa Strong, Foundation for Prader-Willi Research
Read how Theresa used CTTI’s recommendations
CTTI Project Spotlights

Project Spotlight: Measuring Trials Transformation
When CTTI launched Transforming Trials 2030, we laid out an ambitious vision for the research enterprise. The Measuring Trials Transformation project launched in 2023 with 15 members representing a wide array of perspectives, including team members from Florence Healthcare, the Mayo Clinic, the National Institutes of Health, TransCelerate Biopharma, TriNetX, and others. The goal is to create a robust metrics framework to track progress toward the Transforming Trials 2030 vision, and that framework today is well underway. This fall, CTTI launched an open comment period for the public on a draft set of metrics. Over a six-week period, CTTI received over 100 comments. The next step for the Measuring Trials Transformation project team is to develop a case study using CTTI’s metrics on a subset of clinical trial data to simulate how the framework may be used to assess progress on achieving the Transforming Trials 2030 vision.

By 2030, clinical trials need to be:
- Patient-Centered & Easily Accessible
- Fully Integrated Into Health Processes
- Designed With A Quality Approach
- Maximally Leveraging All Available Data
- Improving Population Health

Project Spotlight: Increasing Diversity in Clinical Trials
Diverse populations have been historically underrepresented in clinical trials, which creates knowledge gaps about the risks and benefits of drugs and devices for the public. To address this discrepancy, CTTI launched recommendations and resources in 2023 that help stakeholders adopt new organization-level practices to increase diversity in clinical trials. The result? Deep, long term, organizational commitment to developing clinical trial research infrastructure that is more responsive to the needs of diverse populations.

Project Spotlight: Supporting the FDA on Virtual Public Events
In 2023, the FDA collaborated with CTTI to convene two critical meetings mandated by the Food and Drug Omnibus Reform Act of 2022 (FDORA). The first was a public meeting, held October 18-19 with 720 global attendees, to discuss recommendations provided by the FDA during the COVID-19 public health emergency (PHE) to mitigate disruption of clinical studies. The second, a virtual public workshop, held November 29-30 with 2,645 global attendees, to solicit input on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence of the disease or condition among demographic subgroups. CTTI’s established commitment to these topics provided a springboard for discussions, and our work continues to help our members and other stakeholders navigate the current landscape.
Sharing Our Insights

In 2023, CTTI shared insights and multi-stakeholder recommendations via 25 meetings and presentations spanning Boston, Montreal, New York, Riyadh, and Washington, D.C., as well as virtual forums, including:

**Increasing Diversity in Clinical Trials**
- **119 Organizations** attended our launch event unveiling this new set of recommendations

**Diversity Convergence Project**
- **228 Individuals** joined the first three meetings hosted by CTTI, MRCT, FasterCures and NASEM

**ICH M11 Webinar**
- **994 Participants** logged on from around the globe to get the latest update on the new guideline, protocol template and technical specification

**Did you know?**
CTTI’s work was highlighted in leading media outlets in 2023, including:

- **Applied Clinical Trials**
  - Harnessing the Power of Statistical Surveillance

- **Clinical Leader**
  - Putting it into Practice: Why We Need Embedded Clinical Trials

- **pharmaphorum**
  - DCTs: Building Trust with Collaboration and Technology

**In 2023, 76 speakers representing 43 organizations joined as presenters at CTTI meetings, underscoring our deep partnership with stakeholders across the clinical trials enterprise.**

**Our published manuscripts are also frequently cited as thought leadership in clinical research. In 2023, our publications helped communities better understand:**

- The use of preventive statins among older patients with cardiovascular disease

- Organizational strategies to promote diversity and inclusion in clinical trials

- Challenges and solutions surrounding digitally derived endpoint acceptance

- Stakeholder reflections on implementing the National Institutes of Health’s policy on single institutional review boards
Showcasing Our Work

As part of our commitment to open science and shared learnings, CTTI collaborates with the stakeholders who leverage our resources and recommendations with a goal to understand how they used them, the value they reaped, and advice for future users. In 2023, we reached a significant milestone of 50 in-depth case studies showcasing how our outputs are used across the clinical research enterprise from patient groups to academia to industry.

2023 Roundup: Our Recommendations & Resources in Action

Read how our work is...

Supporting Quality by Design (QbD)
The Michael J. Fox Foundation used CTTI’s Quality by Design (QBD) recommendations to find a more systemic way to package advice and recommendations to help sponsors optimize their Parkinson’s trials. Read about their experience.

Improving Investigator Qualification Design
Northwell Health’s 23 hospitals and 5,000 researchers and staff needed to align research processes. CTTI’s Investigator Qualification recommendations helped them develop a first-of-its-kind central administrative hub, The Office of Research Policy and Training (RPT). Read about their experience.

Enhancing Patient Group Engagement
The Duke Clinical Research Institute (DCRI) used CTTI’s Patient Group Engagement recommendations to successfully develop Research Together, DCRI’s stakeholder engagement program that brings together sponsors, investigators, and patients to drive more meaningful research outcomes. Read about their experience.

Enabling Large Simple Trials
Inspired by a CTTI manuscript, the National Institutes of Health (NIH) funded six low-cost, pragmatic, patient-centered, randomized controlled intervention trials. Five of the six funded trials advanced to completion, and all have published results. Read about their experience.

Matching Participants and Relevant Research Opportunities
CTTI’s AACT Database played a foundational role in the development of the Jason Carter Clinical Trials Search & Support (CTSS) program, which removes barriers for families and helps them locate relevant and enrolling trials for blood cancer or blood disorders. Read about their experience.

Thank You!

The true measure of our success rests not within our organization, but beyond it — with the stakeholders across the research enterprise who have made such important work possible since CTTI began in 2008. Thank you to the thousands of individuals and organizations who have contributed insights, helped create actionable resources, and rolled up your sleeves to make lasting, transformative change possible.