

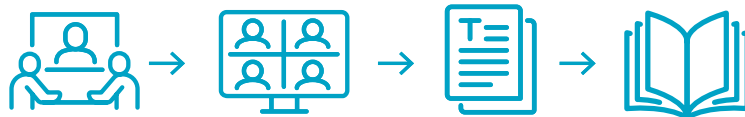
2022 CTTI ACCOMPLISHMENTS

2022 has been a year of transition, change, and growth. We have made great progress towards our goal to transform clinical trials by 2030 and increase the quality and efficiency of clinical trials. Recognizing that this important work can only be done in collaboration with others and with appreciation for their diverse perspectives, it was our great pleasure to foster and expand upon our established connections.

CTTI has been connecting and collaborating with other organizations that have similar missions in order to understand and support each other as we move forward together toward our bold vision of **Transforming Trials 2030**. To truly understand if we have achieved our goals, we must also use metrics to help us identify where progress is being made and where challenges remain.

In 2022, CTTI published five manuscripts, launched three sets of recommendations, announced two new projects, and held two expert meetings and two public webinars. We're excited about the opportunities that lie ahead as longstanding staff have moved into new roles, four new members have joined our Executive Committee, and we've welcomed six new member organizations. Altogether, more than 80 organizations came together through CTTI to make the work described in this report possible.

We look forward to many such collaborations in the year ahead, as we all work toward transforming the clinical trials enterprise.



Public Webinars

- CTTI Webinar Introducing New Digital Health Trials Hub
- CTTI Webinar Unveiling New Recommendations on Embedding Clinical Trials into Clinical Practice

Publications

- Journal of the American College of Cardiology (Statin Analysis)
- JAMA Network Open (Sentinel IMPACT-Afib)
- Open Forum Infectious Diseases (HABP/VABP Studies)
- Clinical Trials (Master Protocols)
- Journal of the American Geriatrics Society (Statin Analysis)

Embedding Clinical Trials into Clinical Practice

Advancing Novel Trial Designs

Disease Progression Modeling and Digital Health Trials Hub

Facilitating Transparency and Analysis

ClinicalTrials.gov Reporting Challenges and AACT Database

Increasing Diversity and Stakeholder Engagement in Clinical Trials

Transforming Trials 2030

Measuring Change in the Clinical Trials Enterprise

Embedding Clinical Trials into Clinical Practice

When clinical care informs research and research informs clinical care, we improve the quality and efficiency of trials and provide more representative evidence for clinicians and patients to reference when making health care decisions. Therefore, CTTI conducted the **Trials in Clinical Practice** project to create recommendations for embedding elements of clinical trials into clinical practice.

This project was conducted over two phases in 2022. The first phase involved evidence generation through in-depth interviews with study designers and implementers. At **CTTI's Expert Meeting in June 2022**, attendees discussed the findings from these interviews, refined a set of draft recommendations, and brainstormed how the recommendations could be implemented in the future.

At **CTTI's Expert Meeting in September 2022**, attendees developed strategies for implementing CTTI's recommendations, identified possible barriers, and brainstormed metrics for measuring the impact of the recommendations.

The **recommendations** for embedding clinical trials into clinical practice were released in December.

Key takeaways from our two Expert Meetings include:

- Clinical care outcomes and clinical research objectives should align
- Embedding interventional trials into clinical practice will require:
 - a paradigm shift;
 - the leveraging of technology and reusable networks; and
 - effective partnerships with sponsors, patient groups, health system leaders, clinicians and data and technology experts

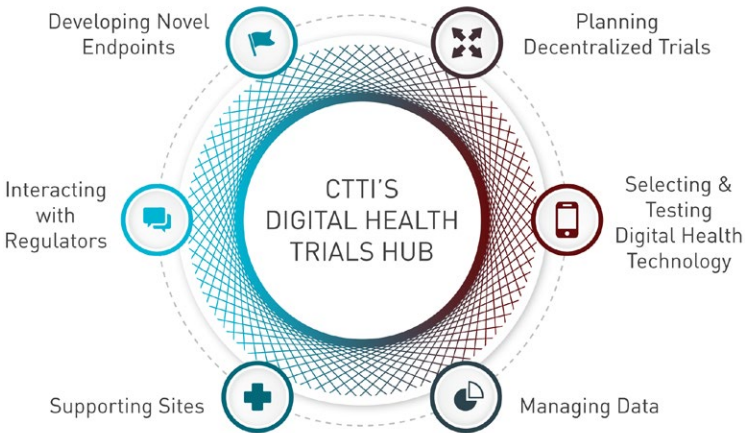
"We are very excited to see these recommendations come to fruition and hope they enable embedding elements of clinical trials into practice and reduce duplication of efforts. Achieving this goal promotes the development of a learning health care system, where care will inform research and research will inform care."
Lindsay Kehoe, CTTI Senior Project Manager

Advancing Novel Trial Designs

Disease Progression Modeling and Digital Health Trials Hub

In March, CTTI announced a **new project** to promote the use of disease progression modeling in the design and conduct of clinical trials. This project is exploring how multiple types of data from various sources can inform trial designs and support regulatory decision-making. The consistent application and integration of disease progression modeling can help accelerate the pace of clinical trials with the ultimate goal of bringing treatments to patients more efficiently.

In April, CTTI **introduced** a new online **Digital Health Trials Hub** which includes significantly updated recommendations, revised reference documents, and two new resources – the Question Bank for Identifying Meaningful Outcome Measures and a Process Map for using a digitally-derived endpoint in an individual drug development pathway. The goal of the Hub is to make information relevant to digital health trials readily accessible and useable. The Hub includes work from the existing CTTI projects, **Development of Novel Endpoints** and **Decentralized Clinical Trials**.



Facilitating Transparency and Analysis

ClinicalTrials.gov Reporting Challenges and AACT Database

As part of the clinical trials ecosystem, it is critical that we develop reliable pathways to communicate findings in ways that are accessible to all stakeholders. Dissemination is a multi-pronged process, whether it be through reporting on ClinicalTrials.gov, dissemination through webinars and peer-reviewed literature, or direct communication with our members, collaborators, and colleagues.

ClinicalTrials.gov

Our project on [ClinicalTrials.gov Reporting Challenges](#) aims to improve clinical trial reporting and transparency. Clinical trial registration and the reporting of summary results to ClinicalTrials.gov is an important part of providing those seeking and planning clinical trials with this essential information.

“We hope that ClinicalTrials.gov will include more timely and complete information for those seeking knowledge about clinical trials and their results. The goal is transparency in the science we do and accessibility to information for patients, caregivers, health care providers, researchers, and the public.”
Sara Calvert, CTTI Director of Projects

The project team conducted in-depth stakeholder interviews and launched a survey to describe and explore the key challenges to clinical trial registration and results reporting and identify potential solutions. The data collected will be used to develop best practices and recommendations.

Aggregate Analysis of ClinicalTrials.gov (AACT) Database

The [AACT Database](#), a publicly available relational database that contains information about every study registered in ClinicalTrials.gov, continues to be a widely used CTTI resource with over 800 active users in 2022. In the coming year we plan to survey AACT users to better understand the research questions they are probing and to share what they are learning with the clinical trials community.

Increasing Diversity and Stakeholder Engagement in Clinical Trials

One of CTTI’s ongoing projects involves increasing the inclusion of [diverse populations](#) throughout the entire medical product development lifecycle – from early target identification all the way to data lock, submission and post approval. The underrepresentation of diverse populations in clinical trials creates knowledge gaps about the risks and benefits of drugs and devices for the public.

Additionally, a new project that was announced in February aims to [engage all stakeholders in trial design](#). This project is creating an engagement roadmap, multi-stakeholder recommendations, and supporting resources to help clinical trial designers efficiently and effectively engage all stakeholders across the trial design process – in alignment with CTTI’s Transforming Trials 2030 vision.

The Engaging Stakeholders in Trial Design project aims to identify:

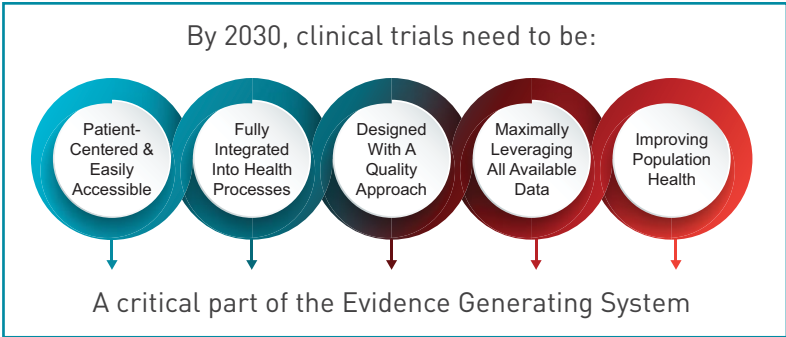
- Specific opportunities and high-value approaches/methods/tools for study designers to engage with internal and external stakeholders across the clinical trial design and planning process
- Situation-specific considerations for ensuring engagement is appropriately equitable, effective, and feasible

“There is a clear need for long-term, organizational-level commitments and action to develop clinical trial research infrastructure that is more responsive to the needs of historically underrepresented patient populations.”
Sara Calvert, CTTI Director of Projects

Transforming Trials 2030

Measuring Change in the Clinical Trials Enterprise

In 2021, CTTI announced a vision for Transforming Trials 2030, comprising of five pillars to guide CTTI’s work for the next nine years. In 2022, CTTI began to explore how and what to measure change in the clinical trials enterprise. As part of this work, CTTI is creating a roadmap for meaningfully contributing to the implementation and adoption of our recommendations and developing a framework to measure the impact of our recommendations.



The Measurement Initiative Project aims to assemble a parsimonious set of metrics to help us monitor, evaluate, and analyze progress toward the Transforming Trials 2030 vision. In 2022, we conducted interviews, surveyed members and external experts, and reviewed available measures sets. We have compiled an initial list of about 60 measures, divided into near-, medium- and long-term measures. In 2023, we seek to prioritize and add specifications to a sub-set of measures so that we can begin assessments.

“We recognize the difficulty of trying to assess the trials enterprise as a whole, but believe we can select a set of indicators that – alongside expert opinion – give us a meaningful look at where there is stagnation and where there is genuine transformation within the system. This is a necessary input to guide CTTI’s conversations, priorities, and investments in the years to come.”

Morgan Hanger, CTTI Director of Strategy

Thank you!

And now, we look toward to 2023. Our staff and members are excited to work closely with colleagues from across the clinical trials enterprise to advance innovation and transformative change.