

## WHO WE ARE

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, is a dedicated group of individuals and organizations who want change and improve clinical trials.

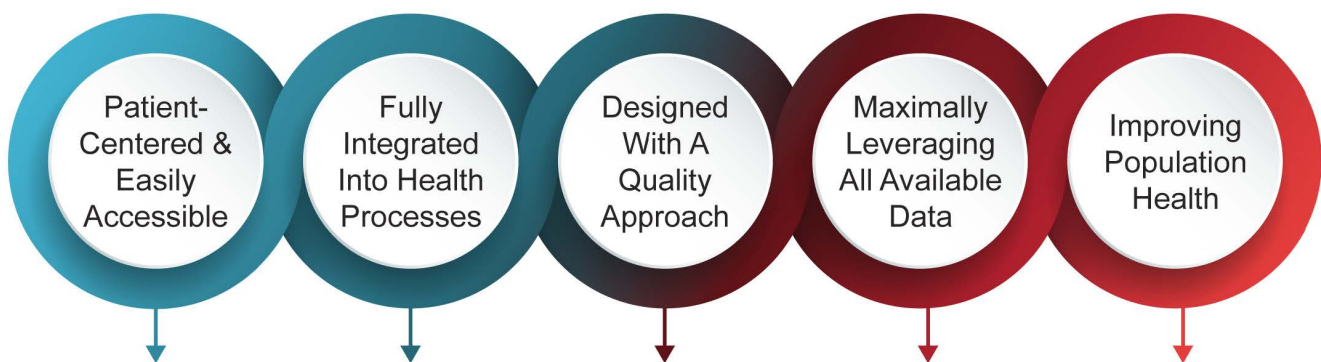
CTTI uniquely fosters an open forum for all stakeholders – from academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and other groups – to come together as equals and take on the greatest challenges and opportunities in the clinical trials space.

Uniting leaders, pioneers, and change agents across more than 500 organizations and approximately 80 member organizations, CTTI works to exchange ideas, build consensus, and develop solutions that can be used to drive real and positive change in clinical trials.

**Our Mission:**  
To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

## TRANSFORMING TRIALS 2030

By 2030, clinical trials need to be:



A critical part of the Evidence Generating System

We have a bold vision, **Transforming Trials 2030**, for how clinical trials should be done in 2030 – a goal that all stakeholders can aspire to achieve together. We use this vision to guide our priorities and work, and encourage others to do the same.

## BUILDING SOLUTIONS

To achieve Transforming Trials 2030, we unite the best and brightest with diverse viewpoints to explore challenges and develop solutions to make better clinical trials a reality. CTTI has issued more than 30 sets of evidence-based recommendations and associated frameworks and tools to inform and drive change across the research community within six areas:

### Design with a Quality Approach

Build quality into clinical trials at the outset to help reduce errors that matter to patient safety and data integrity, and to help ensure adequate, safe enrollment of a diverse population.

### Build Digital Health Trials

Identify and overcome challenges related to FDA-regulated clinical trials that use mobile technologies; explore novel endpoints, decentralized trials, and engaging patients and sites.

### Use Novel Trial Designs

When appropriate, conduct novel clinical trials such as master protocol studies, trials in healthcare settings, large simple trials, registry trials, and trials that use the electronic health record.

### Enhance Patient Engagement

Achieve meaningful patient engagement that leads to better research questions, more feasible studies, and enhanced recruitment, retention, and trust in clinical research.

### Support Investigators & Sites

Create an environment where investigators and site staff have the training, infrastructure, and support they need to thrive and conduct high-quality clinical trials.

### Ensure Ethics & Human Research Protections

Improve the efficiency of processes involving Data Monitoring Committees, informed consent, safety reporting, and single IRBs.

## CREATING IMPACT

We don't just generate ideas – we create change.

Numerous organizations have implemented CTTI's recommendations and resources and are reaping the benefits of more efficient and higher quality clinical trials. **Building Better Trials: A Case Study Exchange** captures many of these stories, providing a resource for sharing best practices, examples, and lessons learned with each other and, thereby, helping the research community grow at a faster pace.

CTTI is also informing new policies related to clinical research. Our recommendations have been cited by the FDA, EMA and NIH, among others.

As CTTI's work continues to grow, so do the many examples of our impact – together, we are shaping the future of tomorrow's better, safer clinical trials.

