CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

WHO WE ARE

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

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration in 2007, comprises approximately 80 member organizations—representing academia, clinical investigators, government and regulatory agencies, industry, IRBs, patient advocacy groups, and other stakeholders—and participation from more than 500 organizations from across the clinical trials ecosystem.

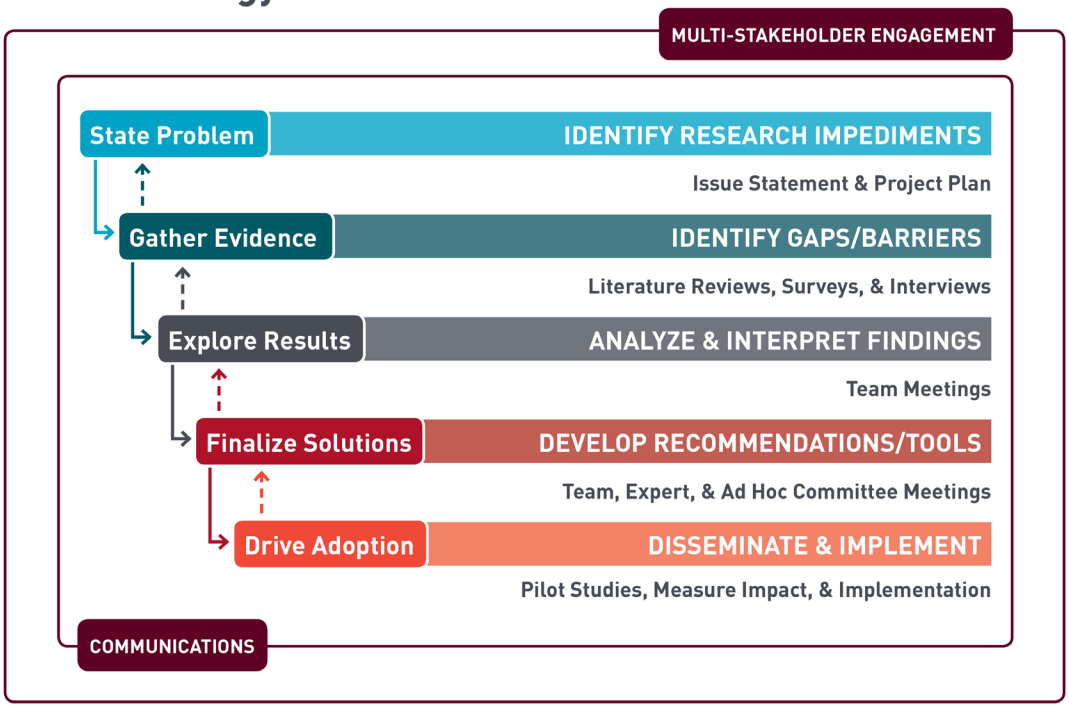
Our unique approach to transforming clinical trials involves:

- Equally engaging multiple stakeholders in all aspects of the organization and projects
- Developing evidence-based, actionable recommendations
- Improving clinical trials through implementation of our recommendations and tools

WHAT WE DO

We unite the best and brightest with diverse viewpoints to improve clinical trials. Our multi-stakeholder project teams use various research methods to gain a complete and objective understanding of a particular issue. We then apply this evidence to develop and drive adoption of recommendations and tools that change the way stakeholders think about, design, and conduct clinical trials.

CTTI Methodology



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RECOMMENDATIONS & TOOLS

CTTI has issued more than 30 sets of evidence-based recommendations, frameworks, and tools to make better clinical trials a reality:

- Apply **Quality by Design** principles to create better protocols
- Involve **Patient Groups** as equal partners
- Move **Recruitment** planning upstream to reduce barriers to participation
- Perform higher quality **Informed Consent** process
- Improve ethics review process via use of **Single IRB**
- Reduce inefficiencies of investigator **GCP Training**
- Develop a better **IND Safety Reporting** system
- Create **Pregnancy Testing** plans for improved clinical trials
- Organize **DMCs** to ensure patients' safety
- Use **Registries** to conduct more efficient clinical trials
- Identify the best pathways for developing **Novel Endpoints** generated by digital health technologies
- Provide guidance for conducting trials that use **Digital Health Technologies**
- Streamline **Antibacterial Pediatric and HABP/VABP Trials**
- Strengthening the **Site Investigator Community** & **Improve Investigator Qualification**
- Overcome hurdles for planning & conducting **Decentralized Clinical Trials**
- **Engaging Patients & Sites** in trials using digital health technologies
- Use **Real-World Data** to evaluate trial eligibility criteria & recruit participants
- Design & conduct **Master Protocol Studies**

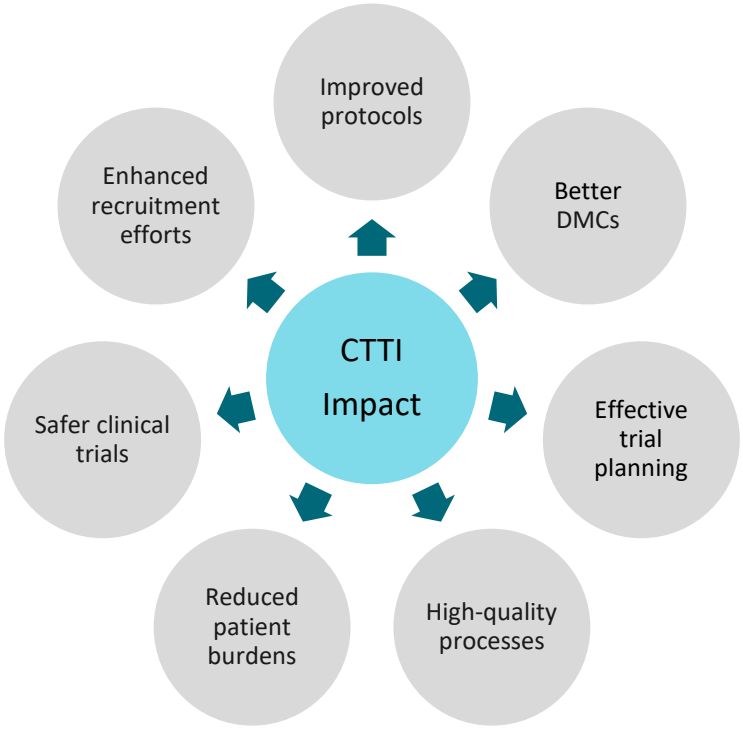
OUR IMPACT

We don't just generate ideas—we create change. To help implement improvements, we develop tools and hold workshops to facilitate the adoption of CTTI recommendations.

Numerous organizations, institutions, and other entities have taken advantage of these resources and are reaping the benefits of more efficient and higher quality clinical trials.

CTTI is also informing new polices 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.



LEARN MORE

Visit our website at www.ctti-clinicaltrials.org to access to all of CTTI's recommendations, frameworks, tools, webinars, and more. You can also follow us on Twitter and LinkedIn.