

2020 CTTI ACCOMPLISHMENTS

In 2020, the research community united to crack the code to a global pandemic and the CTTI community, in particular, rose to the occasion.

Through ongoing research, collaboration, and a series of webinars and resources, CTTI helped clinical trial designers and sites make the switch to decentralized trials amid the pandemic. We also advanced the field of COVID-19 treatment trials, particularly through a collaboration with FasterCures and Duke-Margolis. This effort convened those running COVID-19 master protocol studies, fostering open discussion and helping them to align studies, incorporate new data, and use other novel approaches to obtain quick and reliable study results.

At the same time, CTTI forged ahead with other work – we finalized a bold, new vision, Transforming Trials 2030, which outlines five principles to ensure clinical trials are part of the future of evidence generation. We also launched new resources for conducting master protocol studies and evaluating Quality by Design (QbD), created a new framework to help with the evaluation of the NIH's sIRB policy, and much more.

Our work also made an impact on policy – being cited in FDA guidance and used to inform the revision of ICH E6 – and was used by many organizations to achieve higher-quality and more efficient clinical trials. These collective accomplishments emphasize CTTI's distinct impact on clinical research during an unprecedented and transformational year.

Supporting Ongoing Trials & Decentralized Approaches

New Resources for Conducting & Adjusting Trials during a Pandemic

Creating Impactful COVID-19 Treatment Trials

A Pathway for Running Reliable, Fit-for-Purpose, & Patient-Centric Research

Advancing Novel Design Approaches for Better, Faster Clinical Trials

New Master Protocol Resources & Findings from a First-Ever Study

Ensuring Trials are Designed with a Quality Approach

Enhancements to CTTI's QbD Toolkit & Efforts to Inform the Update of ICH E6

Making Trials Patient-Centered & Easily Accessible

Paving the Way for More Patient Engagement, Remote Access, & Diversity in Trials

Furthering sIRB Adoption

Developing a Framework for Evaluating the NIH's sIRB Policy

A Vision for the Next Decade of Clinical Research

Working Together to Ensure that Clinical Trials are Part of the Future of Evidence Generation

Supporting Ongoing Trials & Decentralized Approaches

New Resources for Conducting & Adjusting Trials during a Pandemic

As the clinical trials ecosystem grappled with the pandemic's impact on ongoing clinical trials, CTTI led the charge to help the research community adapt and move forward. Starting in March, CTTI conducted a series of intensive surveys, discussions, and collaboration that shaped the creation of two CTTI public webinars – [Identifying Best Practices for Conducting Clinical Trials with the New FDA Guidance During the COVID-19 Pandemic](#) and [Adapting Clinical Trials during COVID-19: Solutions for Switching to Remote and Virtual Visits](#) – and a [Best Practices for Conducting Trials during the COVID-19 Pandemic playbook](#).

“Our challenge now is to transfer some of that same speed, that same critical thinking, we have been forced to do in this emergency, to the next set of non-COVID-19 trials. Once these fundamental changes make trials learner and meaner, we should then be better poised after this pandemic to tackle some of the most pressing global public health challenges.”

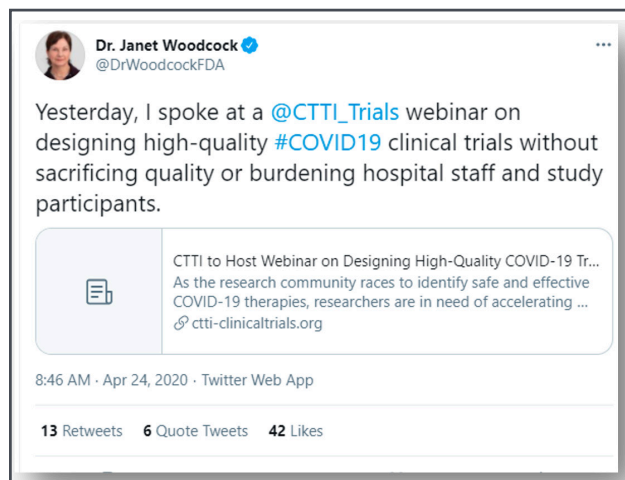
– Pam Tenaerts in [The Timmerman Report](#) (May 21)

Creating Impactful COVID-19 Treatment Trials

A Pathway for Running Reliable, Fit-for-Purpose, & Patient-Centric Research

CTTI's efforts also helped the research community successfully plan for launching new trials for COVID-19 treatments. Two webinars – [Designing High-Quality COVID-19 Treatment Trials](#) and [Engaging Racial and Ethnic Minority Patient Populations in COVID-19 Clinical Trials](#) – and a second playbook, [Best Practices for Designing High-Quality, Diverse COVID-19 Trials](#), helped share lessons learned and provided best practices for a way forward.

We also created and made available a searchable, real-time [AACT COVID-19 Trials spreadsheet](#). CTTI will continue this work into 2021, hosting a public summit, The Fastest Path to Effective COVID-19 Treatments: Using Master Protocol Studies, in January, and reporting an analysis of COVID 19 treatment trials in April.



Advancing Novel Design Approaches for Better, Faster Clinical Trials

New Master Protocol Resources & Findings from a First-Ever Study

This year, the value of agile clinical trials that foster collaboration and efficiency became crystal clear. In many cases, master protocol studies emerged as an ideal solution. Working with many stakeholders, CTTI developed a [robust set of resources](#) – including a value proposition guide, a protocol development map, and an FDA engagement tool – that guide the use of master protocols in novel disease areas.

Using a different novel approach, [CTTI and multiple U.S. organizations announced collaborative findings](#) from the Implementation of a randomized controlled trial to imProve treatment with oral AntiCoagulanTs in patients with Atrial Fibrillation (IMPACT-AFib) trial. This 80,000-patient, randomized clinical study was the first-ever trial to leverage the FDA-Catalyst System network of electronic health data, which consolidates data from a diverse group of national health plan data partners, setting the stage for future trials embedded into health plans.

CTTI's Real-World Data recommendations and resources were cited in the FDA's new guidance, [Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry](#), in November 2020.

CTTI added 172 new studies to its free [Feasibility Studies](#) database, for a total of more than 440 studies, helping the research community better match appropriate technologies to their research goals.

Ensuring Trials are Designed with a Quality Approach

Enhancements to CTTI's QbD Toolkit & Efforts to Inform the Update of ICH E6

Helping to shape higher quality, more efficient clinical trials, CTTI conducted research, issued a report, and co-hosted [a public event with FDA](#) to help inform the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as it revises ICH E6 Good Clinical Practice (GCP) – one of the most impactful guidelines on clinical trial conduct that affects a variety of stakeholders.

In addition, building on many years of Quality by Design (QbD) work, CTTI [announced new tools to help researchers implement QbD into their trial](#), including a QbD maturity model and metrics framework. The enhanced CTTI QbD toolkit serves as a one-stop-shop for any individual or organization looking to implement QbD, and may help meet the anticipated new guideline for ICH E8(r1), which is expected to be finalized in 2021 and emphasizes a QbD approach to trial design.

“Dr. John Alexander, Chair of the PROACT Xa trial and Professor of Cardiology at Duke, said, ‘We are excited to have started enrollment in the PROACT Xa study. This pragmatic trial, designed using the principles of Quality-by-Design, will generate high quality evidence on whether apixaban can safely be used as an alternative to warfarin in patients with a mechanical aortic heart valve.’”

–[CryoLife press release](#) (May 7)

The American College of Radiation Oncology's (ACRO) Decentralized Clinical Trials Working Party included CTTI's QbD recommendations in its “[A Quality-by-Design Manual for Decentralized Clinical Trials](#)”.

Making Trials Patient-Centered & Easily Accessible

Paving the Way for More Patient Engagement, Remote Access, & Diversity in Trials

Patient engagement continued to play a strong and steady role in CTTI's work this year. Perspectives from patients and patient organizations informed and guided our series of COVID-19 webinars, emphasizing their important role in being fully integrated in the design and governance of clinical trials. This work also provided important insights and lessons learned on topics like [switching to remote or virtual trials](#) and [engaging minority patient populations in trials](#) – approaches that will help drive patient access and participation regardless of geography and mobility.

CTTI also continued its work with the [Patient Engagement Collaborative](#) and announced a [new report](#) outlining variables to input into expected net present value (eNVP) models so that individual organizations can perform their own return on patient engagement assessments.

Software provider Curebase used CTTI's Decentralized Clinical Trials recommendations to build a completely virtual site leveraging its proprietary software technology.

Furthering sIRB Adoption

Developing a Framework for Evaluating the NIH's sIRB Policy

CTTI has helped lead the adoption of single IRBs (sIRBs) for over a decade, but our work was especially critical this year when changes to the Common Rule took effect, requiring all multi-site research studies to use a sIRB for review. Working closely with an NIH workgroup, we developed and announced [a new framework](#) that could help in evaluation of the NIH's sIRB policy.

This work, in addition to our existing [set of sIRB recommendations and resources](#), continues to equip the research community with the tools needed to address barriers to and drive adoption of sIRB implementation.

A Vision for the Next Decade of Clinical Research

Working Together to Ensure that Clinical Trials are Part of the Future of Evidence Generation

Looking ahead, CTTI will harness the great momentum from 2020 and lead a new vision: [Transforming Trials 2030](#). Finalized in early 2020 and accelerated by the pandemic, this vision forms the guide for CTTI's projects going forward.

Working closely with our member organizations, supporters, new partners, and other leaders, we can shape a more patient-centric, integrated, quality-based, and smarter clinical trials system poised to improve public health. We hope you will [join us](#) on this ambitious and revolutionary pursuit. Thank you.

