

2018 CTTI ACCOMPLISHMENTS

At the beginning of 2018, we celebrated “One Decade of Impact, One Vision Ahead”—collectively commemorating CTTI’s 10 years of blending diverse viewpoints, challenging the status quo, creating evidence-based solutions to critical clinical trials issues, and shaping policies and procedures across the enterprise.

Thanks to support from members, experts, and other supporters, CTTI continued this great momentum throughout 2018, and formed new building blocks for constructing the future of clinical trials. We made significant progress in areas like mobile technologies, real world evidence, and patient engagement, while also continuing to impact policies and organization in other key areas of clinical trial improvements. And finally, the year culminated with a Reagan-Udall Foundation Innovation Award, recognizing CTTI’s achievements, contributions, and influence as a regulatory science leader.

Setting the Bar High for Trial Quality

New CTTI work promotes higher-quality trials and a stronger investigator community

Making Mobile Clinical Trials a Reality

Two new sets of recommendations add to CTTI’s comprehensive roadmap for using mobile technologies in trials

Engaging Patients Early and Often

CTTI and the FDA collaborate to increase patient participation in regulatory discussions about medical products

Driving sIRB Adoption

New solutions are in development to advance the implementation of sIRBs

Moving Real World Evidence Forward

Creating resources to effectively use real world data sources to enhance clinical trials

Setting the Bar High for Trial Quality

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Our work doesn't end at issuing recommendations. Last year, CTTI kicked off a new effort to drive adoption of the Quality by Design recommendations and toolkit. Our QbD work encourages prospective examination of the "errors that matter" in a trial to improve quality and outcomes. We are now working to ensure that stakeholders are equipped with the resources they need to implement CTTI's QbD work and improve the quality of clinical trials in their respective roles.

We also announced a new approach for investigator qualification that goes beyond repetitive training and includes individual experience and protocol-specific preparation. At the same time, we began work to obtain and evaluate stakeholder input to inform ICH E6 renovations—efforts that aim to contribute to better, stronger clinical trials across the enterprise.



Making Mobile Clinical Trials a Reality

Two new sets of recommendations add to CTTI's comprehensive roadmap for using mobile technologies in trials

As follow-on to our existing novel endpoint work, we released recommendations and resources for using mobile technologies in clinical trials—from selecting a technology at the beginning of a trial to preparing for FDA submission using data generated from the technology—and outlining new approaches for overcoming hurdles associated with decentralized clinical trials.

In early 2019, we will release our fourth and final set of work from the Mobile Clinical Trials (MCT) program—recommendations and resources for engaging patients and research sites when planning and conducting mobile clinical trials. We will also release an interactive database featuring 275 feasibility studies on mobile clinical trials. Our MCT work is reaching new audiences and inspiring current ones, showing it is possible—and beneficial—to use technologies to improve the efficiency and quality of clinical trials.

Engaging Patients Early and Often

CTTI and the FDA collaborate to increase patient participation in regulatory discussions about medical products

For over 10 years, CTTI has included patient advocates as equal partners in its organization and work. Today, nearly all of its 25 sets of recommendations suggest inclusion of patients as a critical part of the clinical trials process. Reinforcing this work, CTTI and the FDA held the inaugural Patient Engagement Collaborative meeting in August 2018. This group of 16 patients, caregivers, and patient group representatives will meet with the FDA several times a year to discuss topics such as communication, transparency, and the best ways for patients to participate in the FDA's regulatory discussions about medical products. In the year ahead, CTTI will release new resources to support greater inclusion of patients during planning and execution of regulated and other trials across the clinical research enterprise.

The FDA cited CTTI's Patient Groups & Clinical Trials recommendations in a discussion document released in November 2018, on promoting patient engagement in the medical device clinical trial process. The feedback will be used to help develop a draft guidance for incorporating patient input into clinical trials, which has the potential to enable better participant enrollment, successful trial completion, and the collection of more meaningful data.

Driving sIRB Adoption

New solutions are in development to advance the implementation of sIRBs

Furthering our efforts to drive the use of single institutional review boards (sIRBs) in multi-center trials, CTTI continues to identify and develop solutions for the remaining gaps in knowledge around implementing a sIRB model. In addition, the NIH has selected CTTI to support a workgroup that will develop a comprehensive plan for assessing the NIH's new single institutional review board (sIRB) policy. This important effort will help create a standard approach for assessing whether sIRB review is improving quality and efficiency in multi-center clinical research.

CTTI's work on real world evidence and registry trials was referenced in the FDA's recently announced 2019 strategic framework for advancing opportunities to use electronic tools to gather health-related data. Evidation is using CTTI Registry Trials recommendations to inform a large digital registry.

Moving Real World Evidence Forward

Creating resources to effectively use real world data sources to enhance clinical trials

In 2018, CTTI conducted research and convened experts to ask the question, "How do we effectively use real world data sources to enhance clinical trials?" We are now developing "how to" resources to answer this question and, this year, will release actionable solutions for sponsors, investigators, and contract research organizations.



We are excited for what 2019 brings and look forward to our continued work together to make advances that speed the development of critical medical products for people who need them. **Thank you!**