THE STATE OF CLINICAL TRIALS:

Charting the Path to 2030

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

MEETING SUMMARY | May 22, 2025

CTTI's inaugural State of Clinical Trials meeting brought together influential leaders, including high-level agency officials, policymakers, and key CTTI members, to engage in solution-driven conversations about advancing the clinical trials enterprise. **The goal was to identify concrete, realistic ways to improve efficiency and quality in trials.**

This summary contains major themes and ideas for action gleaned from **perspectives of attendees, not empirical conclusions**. The summary **is not exhaustive** of all detail from the day's rich discussions, but we hope it will serve as jumping off points for action and further conversation.

MEETING THEMES

Throughout the meeting, attendees reflected on the current state of the clinical trials enterprise, identified core issues impeding progress in each of the five Transforming Trials 2030 pillars, and proposed solutions. The following 4 key themes emerged:

- **Trust in trials is failing.** People are hesitant to participate in clinical research that doesn't appreciate real world constraints, systemic inequities, and realities for participants around protections, outcomes, costs, and access. Trials don't currently address common needs, and we aren't good at communicating the impact of them to the public. Without broad interest and participation, trials are unable to impact population health.

  Path forward: ***Reframe trial participation as a healthexperience.*** Treat participants as health consumers. Include needs assessment to understand choice, flexibility, and personalization.

  > **"We need to change how the public feels about research."**

  Provide meaningful, non-tokenistic compensation—tailored to individual needs. Humanize communication about trials with storytelling and media partnerships to shift the public narrative, recognize and honor the contribution of participants as partners in research, and offer clear, dynamic consents with opt-in updates about trial progress and results. Normalize trials as part of routine care.

  Path forward: ***Generate clinical research buy-in among payers, medical students, and emerging professionals.*** Enlist clinical professionals and communities in the trial design phase to identify trial outcomes that matter for population health at the community level. Focus on the value of a product for public payers so that the product is not just approvable, but *worthwhile*, to help with the speed of regulatory approval to uptake, sales and coverage. Build and track the clinical research workforce with clear pathways.

  Path forward: ***Enhance transparency and shared goals.*** Find consensus around what truly confers competitive advantage and what doesn't. Engage payers with data on cost savings and improved outcomes from trial participation. Comply with reporting requirements in clinicaltrials.gov and other global reporting sites. Share what works and lessons learned across companies at conferences and through public private partnerships. Create federated data sharing to advance scientific knowledge. Leverage public private partnerships and member organizations to illustrate risk of inaction or failure to adapt.

- **Data is not shared.** Trialists are primarily incentivized to collect participant data that will be reimbursed, which is not in line with participant desires to have access to their trial data long term. A fragmented data infrastructure along with static consent processes exacerbate the disconnect between sponsors incentives to collect and retain participant data and participants' desires and expectations to have access to their own data. Data privacy policies are strict and make assumptions about what the public wants. We are not utilizing real-world data to its full potential.

  Path forward: ***Create robust trial data repositories with collective incentives to participate.*** Government or public private partnerships should create or utilize existing data repositories with the specific intent of making them available for research purposes. Develop federated and centralized frameworks. Make participant consent for data included in federated data repositories part of the consenting process.

  > **"I fail to understand why protocols aren't public. I fail to understand why trial methods aren't public. The competition is about the drug."**

  Path forward: ***Empower more freely flowing data.*** Unpack and disseminate participant perceptions and expectations around data privacy. Implement policies that allow for data to flow more freely, granting greater access and control to participants. Align data collection with decision-making needs. Establish shared data governance and standards.

- **Trials are getting less efficient.** We are not keeping pace with theory and innovation. The system fails to account for the financial and regulatory incentives faced by sponsors: Quality by Design principles are not heeded, and there is a disproportionate impact of a 483 leading to conservatism around efficiencies like risk-based monitoring. There is a persistent perception of the importance to increase endpoints and data collection to maximize learning and "get your money's worth" from each trial. There is also ineffective change management (or insufficient imperative for change). We continue to be conservative in interpreting guidance, even as GCP and domestic regulators encourage focus on principles. We are not recognizing that different trials serve different purposes, requiring specific metrics for quality and efficiency.

  > **"there's a whole lot that we impose on ourselves and it's actually completely unnecessary."**

  Path forward: ***Adopt a realistic approach to trial design simplification.*** Leverage measurement bodies to assess stakeholder engagement in design process. Create open ROI models that demonstrate the impact of inclusive, patient-centered trials. Explore alternatives to placebo-controlled RCTs (e.g., real-world evidence, self-controlled designs). Develop tools that simulate protocol burden and predict attrition to guide better decision-making.

  Path forward: ***Enhance regulatory clarity and consistency.*** Continue to share wins. Make precedent more visible through shared forum and regulatory groups (e.g. FDA's C3TI). Given the well documented need to align inspection practices with guidance, be prepared to adapt quickly.

  Path forward: ***Recognize the differences across trial types, interventions and populations*** to yield actionable insights at the trial level, the portfolio level, and the system level. Acknowledge heterogeneity across different trial types and categorize trials so metrics of quality and efficiency are meaningful. Aggregate data accordingly to inform decision making. Consistently share protocols and lay summaries for design improvement.

- **Site infrastructure is insufficient.** Sponsors are failing to utilize the breadth of potential sites. We want to expand where research happens into more communities but use the same sites over and over again. We want to support a sustainable investment health system infrastructure, but underutilize the networks that are already established (e.g., NCCN). There is no public facing tracking of site capacity for research, or effective optimization and education strategies.

> **"if you put on the health care consumer lens you would have improved customer service"**

Misaligned financial and regulatory incentives across partners makes it operationally challenging to embed trials in healthcare. Systems are increasingly owned by private equity, with relentless pressure on clinicians to generate Relative Value Units (RVUs). The profit margin for research is not sufficient incentive for systems to participate. For many primary and specialty care, research is not their primary goal.

Path forward: ***Include sites fully as "point of sale" for trials.*** Recognize that sites are the front-line representative of recruitment and retention. Pursue contract standardization, building off of OSTP work post-Covid. Create collective sponsor investment in training for sites Listen to and use tech solutions that sites have tested and prefer that free up site staff time to perform other tasks. Adapt those solutions to new uses to avoid adding another tech system. Move beyond project-by-project funding to long-term investment in research infrastructure; government cannot be the only group responsible to build the infrastructure.

Path forward: ***De-risk selection of new researchers.*** Introduce competency standards. Design nimbler, trial-specific training based on those standards. Educate community centers together, rather than for individual programs. Focus on fitness for purpose, by role. Enable access to experienced sites for mentorship. Reduce duplication of site qualification; consider the re-invigoration of the Shared Investigator Platform (TransCelerate). Create better data for site segmentation, to leverage site strengths for specific trials.

Path forward: ***Enable thoughtful integration into routine practice.*** Design protocols to align with routine care. Centralize what can be centralized. Clarify roles and train clinicians and staff to navigate dual roles transparently and ethically. Synch multiple, non-integrated systems to decrease operational friction and improve efficiency.

Meeting materials, including agenda, participant list, and presentations are included on CTTI's State of Clinical Trials webpage

NEXT STEPS

The CTTI team will continue to review the insights discussed during this meeting to inform action items for collaborative partners and future CTTI projects.

ABOUT THE CLINICAL TRIALS TRANSFORMATION INITIATIVE (CTTI)

CTTI is a public-private partnership co-founded by Duke University and the FDA, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials.