Clinical Trials Transformation Initiative Patient Summit

MEETING SUMMARY | April 28, 2026

The Clinical Trials Transformation Initiative (CTTI) Patient Summit brought together over 80 patients, caregivers, and patient advocates to discuss two topics that are rapidly reshaping clinical research: patient perspectives on risks and comfort with artificial intelligence (AI) in clinical trials and the reuse of patient data beyond the original trial. Provocative fireside chats kicked off these topics followed by breakout discussions that explored opportunities, concerns, and tradeoffs related to each topic. As AI-enabled tools, real-world data, and data-driven approaches become more integrated into clinical research, important questions are emerging about trust, transparency, informed consent, privacy, and patient involvement. The goal of the Summit was to better understand patient perspectives on these evolving approaches and the considerations needed to support responsible, patient-centered innovation in clinical research.

This summary reflects perspectives and experiences shared by attendees and is not intended to represent consensus findings or formal recommendations. The summary is not exhaustive of all detail from the day's rich discussions, but we hope it will serve as a starting point for further conversation and future work.

MEETING THEMES

Throughout the breakout discussions, participants explored opportunities and concerns related to the growing use of AI and patient data reuse in clinical research. Several key themes emerged:

1. **Trust, transparency, and patient agency are foundational.** Across discussions, support for AI and patient data reuse was closely tied to trust in the organizations deploying these approaches. Conversations highlighted the importance of transparency around how AI is used, who has access to patient data, how information may be reused, and whether patients retain meaningful visibility and control over participation and data-sharing decisions.

   Many attendees expressed willingness to engage with AI-enabled systems and share data when uses were clearly explained and benefits to patients and communities were evident. At the same time, concerns emerged around opaque systems, commercialization of patient information, and loss of visibility into how data may be used over time. Discussions repeatedly emphasized that transparency should extend beyond initial consent and continue throughout the research process.

2. **Patients support innovation when it improves access and reduces burden.** AI-enabled approaches were generally viewed as promising opportunities to improve trial awareness, participant matching, navigation, and access to research opportunities. Many attendees noted that identifying relevant clinical trials remains difficult, particularly for rare disease communities and patients seeking specialized research opportunities.

   Strong interest also emerged around innovative trial designs, including the use of historical data, real-world data, and AI-generated external control arms to reduce reliance on placebo groups when scientifically appropriate. This perspective was especially prominent among rare disease and high-need patient communities, where discussions highlighted the burden associated with traditional placebo-controlled trials and limited treatment options.

   At the same time, conversations reinforced that innovation should remain scientifically rigorous, transparent, representative, and appropriately governed.

3. **Existing consent and governance models are not keeping pace with emerging technologies.** Current consent processes were frequently described as insufficiently equipped to address evolving uses of AI and downstream data reuse. Concerns centered around broad, one-time consent models that attempt to account for unknown future uses of patient data.

Discussions highlighted the challenge of fully understanding downstream implications as AI capabilities, data-sharing ecosystems, and re-identification risks continue to evolve. At the same time, attendees acknowledged that requiring repeated re-consent for every future use could create operational burden and potentially slow urgently needed research.

Interest emerged around more flexible approaches to consent, including layered consent models, ongoing communication and updates, dynamic preferences, and greater patient participation in governance decisions.

4. **Data quality and representation must be addressed.** Concerns about data quality, representativeness, and equity surfaced consistently across groups. Conversations highlighted issues related to incomplete medical records, fragmented healthcare data, biased datasets, underrepresentation of marginalized communities, algorithmic bias, and re-identification risks for rare disease populations.

Attendees also emphasized that perspectives on privacy, innovation, and data sharing vary considerably across patient communities. Some communities may prioritize speed and broader data sharing to accelerate research, while others may place greater emphasis on privacy protections, transparency, and long-term stewardship of patient information. Discussions repeatedly reinforced that there is unlikely to be a one-size-fits-all approach to AI governance or patient engagement.

Meeting materials, including agenda, participant list, and presentations are included on CTTI's Patient Summit webpage

NEXT STEPS

Insights and themes from the Patient Summit will help inform future CTTI discussions and activities related to AI, patient data reuse, and patient engagement in clinical research. Perspectives shared throughout the meeting will also help shape discussions at a future State of Clinical Trials meeting planned for 2027, where partners from across the clinical trials enterprise will continue exploring opportunities and challenges related to innovation in clinical research.

CTTI looks forward to continuing engagement with patients, caregivers, advocates, and other partners to support ongoing dialogue and advance more patient-centered approaches to emerging technologies and research practices.

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.