

The State of Clinical Trials: Charting the Path to 2030

May 22, 2025

8:30 a.m. – 4:00 p.m. EDT

The Westin Downtown Washington, D.C.

Rock Creek Ballroom

CTTI MISSION: Develop and drive adoption of practices to increase the quality and efficiency of clinical trials

MEETING OBJECTIVES:

- ▶ Create shared understanding of how the clinical trials enterprise is performing
- ▶ Advance solutions to catalyze trial efficiency, in line with CTTI's Transforming Trials 2030 vision
- ▶ Identify individual and collective actions to ensure a thriving trials enterprise moving forward

MAY 22, 2025

7:30 a.m. Breakfast (Provided)

8:30 a.m. Welcome & Purpose

Session Objectives:

- ▶ Introduce this unique opportunity to come together to identify and drive solutions in the clinical trials enterprise
- ▶ Reflect on the opportunities presented by the current policy and economic landscape

Welcome: Morgan Hanger (CTTI)

Opening Remarks: Mark McClellan (Duke Margolis Institute)

8:50 a.m. State of Clinical Trials: Where Are We Now?

Session Objectives:

- ▶ Establish a baseline for understanding the ground truth in clinical trials today
- ▶ Hear what's going right, what we can measure, and what's impeding our ability to achieve progress

8:50 a.m. A Look at the Data: Ken Getz (Tufts CSDD), Summer Starling (CTTI)

9:15 a.m. Reflections on our Progress

Pillar 1: Trials for people: Donna Cryer

Pillar 2: Trials where people are: Ramita Tandon

Pillar 3: Balancing quality and efficiency: Rob Califf

Pillar 4: Balancing privacy and data access/use: Brad Hirsch

Pillar 5: Aligning incentives around evidence: Esther Krofah

10:20 a.m. Discussion

10:40 a.m. Instructions for Workshops

10:45 a.m. Break (Refreshments provided)

11:00 a.m. Workshop Part One: Scoping the Issue

Session Objectives:

- ▶ Define the core issue
- ▶ Consider past efforts to address the core issue
- ▶ Note incentives, interdependencies, business models, challenges

Pillar 1	Pillar 2	Pillar 3	Pillar 4	Pillar 5
Patient Centered & Easily Accessible	Integrated into Health Processes	Designed with a Quality Approach	Maximally Leveraging all Available Data	Improving Population Health
Moderators: Ella Balasa	Moderators: John Alexander	Moderators: Stacey Adam	Moderators: Chris Boone	Moderators: Barbara Bierer
Michelle McMurry-Heath	Allison Shimooka	Khair ELZarrad	Rachael Fleurence	Nakela Cook
Megan O'Neil		Sir Martin Landray	Stephen Pyke	Carla Rodriguez-Watson
Pamela Tenaerts			Azizi Seixas	

12:15 p.m. Lunch (Provided)

1:00 p.m. Workshop Part Two: Charting the Path Forward

Session Objectives:

- ▶ Develop solutions to address the core issues
- ▶ Determine key leaders and collaborators
- ▶ Identify success metrics

Pillars 1-5 Breakout Groups cont.

2:15 p.m. Break (Refreshments Provided)

2:45 p.m. Sustaining Excellence in the Clinical Trial Enterprise

Session Objectives:

- ▶ Reflect on key ideas and discuss drivers for achievable changes in the next 5 years
- ▶ Explore the future of research excellence and scientific advancements amidst shifting policies, financial pressures, and market trends

Discussants:

- Stacey Adam (fNIH)
- Chris Boone (Oracle)
- Tala Fakhouri (FDA)
- Morgan Hanger (CTTI)
- Susan Landis (ACRP)

3:50 p.m. Closing Comments

4:00 p.m. Adjourn