



Clinical and Translational Science Awards Program

Coordination, Communication, & Operations Support

CTSA Steering Committee Meeting Summary September 22, 2026 | 2:30-3:30 PM ET | Marriott Marquis Washington, DC

Steering Committee Attendees:

Michael Kurilla, **Co-Chair**
Grace McComsey, **Co-Chair**
Steve Bernstein, **Incoming Co-Chair**

Elmer Bernstam
Andrea Carnegie
Manisha Desai
Daniel Ford
Vesna Garovic
Michael Holinstat
Kerry James

Fasiha Kanwal
Mimi Kim
Julie Lumeng
F. Gerard Moeller
Elizabeth Ofili
Reynold Panettieri
Joni Rutter

Mark Schleiss
Marisa Spann
Eric Vilain
Sarah Wiehe
Karen Wilson
Ted Wun

NCATS Registrants:

Audie Atienza (Presenter)
Heather Baker
Sydella Blatch Alexander
Patrick Brown
Soju Chang
Jennifer Cho
Jennie Conroy
Pablo Cure
Anthony DiBello
Jamie Doyle

Stephanie Ezequiel
Stacia Fleisher
Gallya Gannot
Brittany Gibbons
Caroline Hagedorn
Chris Hartshorn
(Presenter)
Andy Kelly (Presenter)
Irina Krasnova
Francisco Leyva

Joan Nagel
Ashley Parker
Thomas Radman
Anna Ramsey-Ewing
Erica Rosemond
Salina Waddy
Annica Wayman
Ken Wiley

Guests: Barbara Bierer, Willy Chertman, Susan Gregurick (Virtual), Scott Steele

CCOS: Kerry James, Amanda Scott*

* SC Coordinator

Welcome (Slides 1-2)

Speakers: Mike Kurilla, Amanda Scott

The meeting opened with logistics, introductions, and remarks from CTSA leadership. Michael Kurilla noted that Grace McComsey was delayed due to travel issues but expected later, and leadership previewed a discussion-heavy agenda focused on real-world data, N3C, enterprise committee activities, and clinical trial modernization.



N3C Overview, N3C and CMS Data, N3C Challenge (Slides 3-22)

Speakers: Nathan Hotaling, Andrew Kelly, Christopher Hartshorn

Presentation Summary:

The presenters described N3C's evolution from a COVID-focused resource to a national real-world data ecosystem supporting multiple therapeutic areas. Discussion emphasized N3C's value through harmonized data, CMS linkage, governed access, training, reduced infrastructure burden, and faster research timelines. Presenters requested input from hubs on features that would encourage data contribution and agreed to assemble examples and use cases for health systems considering participation.

Real World Data & AI Perspective (Slides 23-41)

Speakers: Susan Gregurick (virtual), Joni Rutter

Presentation Summary:

The session outlined NIH's vision for a coordinated real-world data ecosystem, positioning N3C, Data COUNTS, CMS, VA, All of Us, and other national resources as part of a shared infrastructure supporting high-quality AI-enabled research. Attendees discussed governance, provenance tracking, use-case approval processes, data quality, and expansion of participating organizations, with next steps focused on expanding partnerships, standing up the Data COUNTS coordinating-center structure, and broadening participation from additional health systems and data-service providers.

Enterprise Committee Updates (Slides 43-91)

Integration Across the Lifespan: Mark Schleiss (Slides 43-62)

Mark Schleiss described committee growth, strategic priorities, active working groups, and efforts to improve lifespan-focused translational research, including disability engagement and pediatric clinical trials. Discussion centered on increasing rates of cancer and aging-related conditions in younger adults, older adult exclusion from trials, representation across the entire lifespan, and the concept of "healthspan" as an important complement to lifespan research; follow-up actions included advancing the disability toolkit and manuscript, completing pediatric clinical trial projects, creating an expertise database, and bringing identified aging and cancer issues back to the committee for future programming.

Workforce Development: Marissa Spann (Slides 63-71)

Marissa Spann reported on mentorship initiatives, workforce pipeline programs, CTSA partnerships, AI-related programming, and new working groups supporting clinical research professionals and future investigators. Discussion focused heavily on AI's impact on workforce development, differences in training needs across career stages, and opportunities to engage

organizations such as SOCRA and ACRP; next steps include continued AI-focused workforce programming, advancing Launchpad and CRP initiatives, and exploring additional professional-society partnerships.

BIDS: Elmer Bernstam (Slides 72-83)

The BIDS committee highlighted efforts to unite biostatistics, biomedical informatics, epidemiology, and data science communities around AI, research infrastructure, workforce readiness, and reproducibility. Discussion explored reactions to combining informatics and biostatistics communities, emerging AI competencies, and differing training needs among junior and senior researchers, with planned follow-up including AI-focused workforce initiatives, BIDS publications, white paper development, and continued cross-disciplinary collaboration.

Collaboration & Engagement: Sarah Wiehe (Slides 84-91)

The Collaboration & Engagement Committee described its work advancing community engagement science, health equity, partnership sustainability, and impact measurement across CTSA hubs. Discussion focused on demonstrating the measurable impact of engagement activities, Medicaid and rural-health challenges, trust in science, and strengthening the evidence base for rural populations, resulting in continued work on rural-health engagement approaches, cross-enterprise committee collaborations, and strategies for better demonstrating engagement outcomes.

Dissemination & Implementation Landscape Analysis & Discussion (Slide 93-106)

Speaker: Audie Atienza

Presentation Summary:

Audie Atienza reviewed the importance of dissemination and implementation (D&I) science to NCATS and CTSA goals and presented the case for establishing D&I as a permanent Enterprise Committee rather than relying solely on temporary working groups. Committee members discussed workforce implications, overlap with existing activities, infrastructure needs, learning health systems, AI, and resource considerations, leading to a request for continued Steering Committee discussion on creating and appropriately scoping a future D&I Enterprise Committee charter.

Operation TrialBlazer (Slide 107-118)

Speakers: Joni Rutter, Willy Chertman, Scott Steele, Barbara Bierer

Presentation Summary:

Operation TrialBlazer was presented as a coordinated federal effort to improve U.S. clinical trial competitiveness by accelerating startup, reducing administrative burden, modernizing regulatory pathways, and enabling more parallel processes across research and regulatory activities. Discussion generated numerous recommendations, including national physician licensing, master contracting, streamlined IRB processes, participant compensation reforms, cybersecurity

standardization, better clinician incentives for trial participation, stronger engagement of community-based practices, and improved liability frameworks; attendees were encouraged to continue participation in listening sessions, submit recommendations through TrialBlazer channels, contribute comments to relevant RFIs, and provide additional CTSA-generated solutions for future policy development.

Adjourn (Slide 119)

The next Steering Committee meeting is scheduled for October 26, 2026