



Clinical and Translational Science Awards Program

Coordination, Communication, & Operations Support

CTSA Steering Committee Meeting Summary September 14, 2026 | 2:30-3:30 PM ET

Steering Committee Attendees:

Michael Kurilla, **Co-Chair**

Grace McComsey, **Co-Chair**

Elmer Bernstam
Steven Bernstein
Manisha Desai
Vesna Garovic
Michael Holinstat
Fasiha Kanwal

Mimi Kim
Julie Lumeng
F. Gerard Moeller
Elizabeth Ofili
Joni Rutter
Mark Schleiss

Marisa Spann
Eric Vilain
Eric Vilain
Karen Wilson

NCATS Attendees:

Audie Atienza
Heather Baker
Patrick Brown
Dale Burwen
Soju Chang
Jennie Conroy
Pablo Cure

Anthony DiBello
Jamie Doyle
Stephanie Ezequiel
Gallya Gannot
Brittany Gibbons
Cynthia Gonzalez
Chris Hartshorn

Rebecca Katz
Irina Krasnova
Thomas Radman
Erica Rosemond
Annica Wayman

Guests: Felicity Enders

CCOS: Kerry James, Amanda Scott*

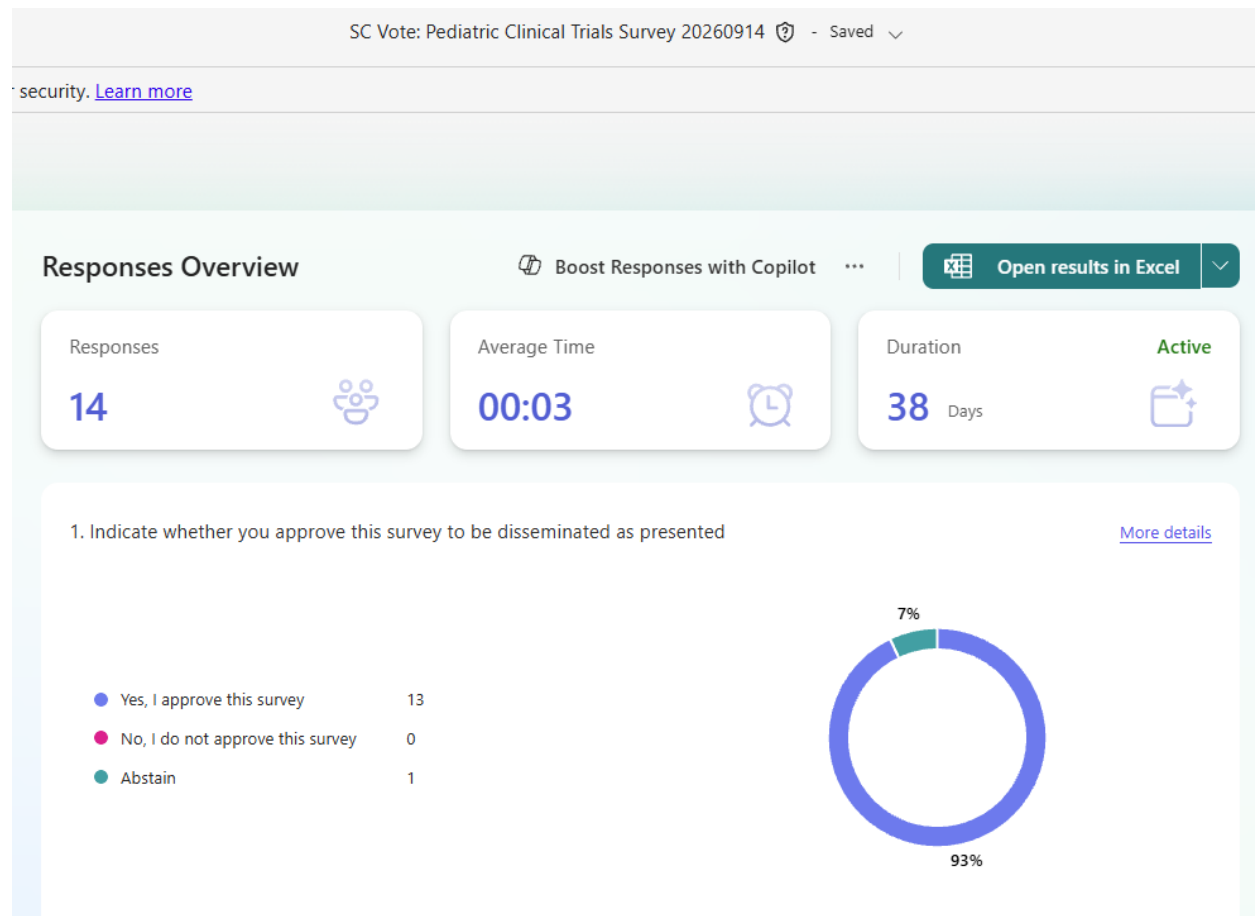
* SC Coordinator

Welcome, Announcement and Vote on Pediatric Clinical Trials Survey (Slides 1-6)

Speakers: Mike Kurilla, Grace McComsey, Amanda Scott

The meeting opened with brief remarks from Michael Kurilla and Grace McComsey, who noted the upcoming in-person Fall Annual Program Meeting and encouraged participation. The committee was also informed that recruitment is underway for five new Steering Committee members for the 2027-2030 term, and members were encouraged to nominate eligible PIs.

The committee revisited the Pediatric Clinical Trials Survey after revisions were made in response to prior Steering Committee feedback. Updates included clearer expectations regarding the time required to complete the survey and the addition of response options allowing hubs to indicate when information is unavailable or cannot be collected.



Operation TrialBlazer (Slides 7-9)

Speakers: Joni Rutter

Presentation Summary:

In preparation for the September 22 in-person Steering Committee discussion, Joni Rutter introduced Operation TrialBlazer, an HHS-wide initiative focused on accelerating clinical trial innovation through engagement with NIH, FDA, academia, industry, patient advocates, venture capital groups, and patients. It was explained that the presentation would be a listening session with CTSA Steering Committee members to gather practical recommendations on barriers to clinical trial efficiency and opportunities for innovation.

WG Report Out: Overcoming Barriers in Women's Health Research (Slides 10-22)

Speakers: Vesna Garovic, Felicity Enders

Presentation Summary:

Vesna Garovic reported on the working group's efforts to assess and improve women's inclusion in clinical research, particularly the exclusion of pregnant women from clinical trials. The presentation highlighted the clinical consequences of excluding pregnant women from research and noted examples where evidence gaps may have adversely affected care. Preliminary analyses found that roughly one quarter of reviewed observational studies excluded women without clear justification. The working group is building AI-supported screening tools and creating a CTSA-wide network of women's health investigators. During discussion, committee members encouraged engagement with FDA around unjustified exclusions and broader inclusion strategies.

Pod Spotlight: Institute for Clinical & Translational Science at the University of California-Irvine (Slides 23-24)

Eric Vilain summarized discussions from the UCI-led pod, focusing on three strategic questions: what CTSA hubs can accomplish collectively that cannot be achieved individually, how CTSA impact should be defined, and the future role of N3C within the consortium. Significant discussion centered on impact measurement. The pod questioned whether traditional metrics such as publications and grants adequately capture the value of CTSA activities and suggested greater emphasis on policy impact, clinical implementation, health outcomes, and lives affected. N3C was viewed as a promising national capability, though questions remain around governance, institutional concerns, ownership, and access. Michael Kurilla emphasized the importance of documenting policy and guideline changes as evidence of impact for stakeholders outside academia.

Pod Spotlight: Baylor College of Medicine (Slide 25-31)

Fasiha Kanwal presented a framework for using CTSA pods as continuous learning systems. The pod identified common challenges across institutions, including compliance burden, informatics platform fragmentation, cost-sharing models, and defining translational science in pilot programs, while emphasizing learning from peer institutions and spreading successful practices. Discussion focused on methods for preserving institutional learning, tracking unresolved issues, sharing effective practices, and translating pod-level discussions into consortium-wide improvements. NCATS leadership praised the model as closely aligned with the original purpose of the pod structure.

Adjourn (Slide 3)

The next SC meeting is scheduled for Tuesday, September 22nd at the Marriott Marquis Washington, DC.