



Clinical and Translational Science Awards Program
**Coordination, Communication, &
Operations Support**

CTSA Steering Committee Meeting Summary
May 11, 2026; 2:30-3:30 PM ET

Steering Committee Attendees:

Mike Kurilla, Co-Chair
Grace McComsey, Co-Chair

Steven Bernstein
Andrea Carnegie
Vesna Garovic
Michael Holinstat
Fasiha Kanwal

Julie Lumeng
Gerry Moeller
Elizabeth Ofili
Reynold Panettieri
Dominic Reeds

Mark Schleiss
Marisa Spann
Eric Vilain
Sarah Wiehe
Karen Wilson

NCATS Attendees:

Audie Atienza
Heather Baker
Kris Bough
Patrick Brown
Patrick Brown
Dale Burwen
Soju Chang
Jennie Conroy

Jennie Conroy
Pablo Cure
Anthony DiBello
Jamie Doyle
Stephanie Ezequiel
Gallya Gannot
Chris Hartshorn
Rebecca Katz

Irina Krasnova
Francisco Leyva
Joan Nagel
Thomas Radman
Erica Rosemond
Joni Rutter
Annica Wayman

CCOS: Stephan Bour, Kerry James, Amanda Scott*, Megan Stewart

* SC Coordinator

Guests: Susan Pusek, Carmen Silvano

Welcome (Slides 1-2)

Speakers: Mike Kurilla, Grace McComsey

The meeting opened with welcome remarks from Mike K. and Grace M. There were no additional announcements.

WG Report Out: Pediatric Clinical Trials (Slides 26-41)

Speaker: Karen Wilson, Mark Schleiss



Presentation Summary:

Karen W. presented the working group's progress on efforts to improve the number, quality and inclusivity of perdiatric clinical trials. While progress is strong, some delays have occurred due to survey approval processess, the group remains on track for key deliverables.

Key Questions & Responses:

Q: From ~3000 abstracts, how many are expected to move forward to full review?

A: Likely fewer than 10, which is typical; many abstracts are excluded because they focus on adult populations rather than pediatric trials.

Q: Are studies involving adolescents (e.g., ages 13-18) included?

A: Yes- studies including adolescents (roughly ages 13-25) are included, as long as they are not primarily adult-focused.

Q: Is there evidence of increasing reluctance among families to enroll children in clinical trials?

A: No formal data was cited, but there is anecdotal evidence suggesting increased reluctance, particularly since COVID.

Q: Are recruitment challenges due to poor recruitment strategies or flawed trial design?

A: It is typically multifactorial- issues include feasibility overestimation, design limitations, and sometimes lack of compelling study value

Q: How will guidance and best practices for novel methodologies and preclinical-to-clinical translation be incorporated?

A: This will be addressed through the virtual meeting and especially within the final toolkit, with a focus on clearly designed best practices.

K and T Consortium Group Charter Review (Slides 3-25)

Speakers: Susan Pusek, Carmen Silvano

Presentation Summary:

Susan P. and Carmen S. provided an overview of the proposed consortium group for steering committee consideration. Following the presentation, the SC voted unanimously to approve the group's charter.

Clinical Trial Inefficiencies (Slides 42)

Speaker: Mike Kurilla

Presentation Summary:

Mike K. updated the SC on a growing concern within HHS that the US is losing competitiveness in clinical research and drug development due to inefficiencies in IRB processes, IND workload, and broader regulatory pathways. While initiatives like Smart IRB have improved coordination, persistent challenges- especially around local IRB requirements and sequential approval processes- continue to delay study startup. In response, the FDA and HHS are actively exploring reforms, including potential decentralization and collaboration with the academic community to streamline regulatory oversight and improve overall clinical trial efficiency.

Adjourn (Slide 43)

The next SC meeting is scheduled for Monday, June 8.