



Clinical and Translational Science Awards Program

Coordination, Communication, & Operations Support

CTSA Steering Committee Webinar Summary September 22, 2025; 2:30-3:30 PM ET

Steering Committee Attendees:

Michael Kurilla, Co-Chair
Ted Wun, Co-Chair

Elmer Bernstam
Steven Bernstein
Stephan Bour
Arleen Brown
Andrea Carnegie

Daniel Ford
Chris Hartshorn
Mike Holinstat
David Ingbar
Mimi Kim
Irina Krasnova
Julie Lumeng
Grace McComsey

Gerry Moeller
Elizabeth Ofili
Reynold Panettieri
Mark Schleiss
Eric Vilain
Sarah Wiehe
Ken Wiley
Rosalind Wright

Not In Attendance:

Robert Toto

NCATS Attendees:

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

Anthony DiBello
Jamie Doyle
Stephanie Ezequiel
Vesna Garovic
Francisco Leyva
Carol Merchant
Joan Nagel

Katie Patel
Thomas Radman
Erica Rosemond
Amanda Vogel
Salina Waddy
Ken Wiley

Invited Guests:

Theresa Baker, Alex Cheng

CCOS: Lauren Fitzharris, Kerry James, Amanda Scott

Welcome (Slides 2-5)

Speakers: Mike Kurilla, Ted Wun

Mike K. provided updates on the current federal government budget situation, specifically the status of the continuing resolution (CR) and its implications for NIH funding. It was clarified that funds must be obligated by September 30th, and that different types of appropriations (annual, multi-year, no-year) have different rules.

The committee also reviewed an extension request for the Translational Science Case Studies Working group and request for approval of the IDLEs Toolkit Survey

Action Item(s):

CCOS will communicate the extension approval for the Translational Science Case Studies Working group and report the committee's feedback on the IDLEs Toolkit Survey.

Pod Feedback (Slides 6-11)

Speakers: Chris Hartshorn, Pod Leads

Presentation Summary:

Pod leaders provided updates on recent activities, challenges, and strategic discussions. Topics included funding delays, AI integration, workforce development, and planning for upcoming meetings.

Key Questions & Responses:

- Q (*Chris H*): On the flexibility, consolidating of RC2 and Element E funding—was that a request towards NCATS?
A (*Eric V.*) Yes, it was a request towards NCATS. We don't have the feasibility to move things around independently.
- Q (*Chris H*): Was the RC2 program talked about in the same way as reported by other pods?
A (*Julie L.*) NCATS wants to prioritize it and fund it, but it's tough in the current budget climate.
- Q (*Elmer B.*): There was an RFA out, and people are applying, so if there are not funds available, isn't that problematic?
A (*Mike K.*) We have ongoing out-of-year commitments from prior awards. If budgets don't increase, we have to take it from somewhere.
- Q (*Eric V.*): If there is so little funds for RC2s, why not suspend this program and redistribute whatever is left to the hubs?
A (*Mike K.*) That's always a potential option, but we're not doing that at this point.

Final Report Out: 21 CFR Part 11 Compliance for REDCap (Slides 12-30)

Speaker: Alex Chang

Presentation Summary:

Alex Cheng presented the closeout report on achieving FDA 21 CFR Part 11 compliance for REDCap. The working group developed a rapid validation process, an implementation guide, and templates to help institutions achieve compliance with minimal external consulting.

Key Questions & Responses:

- Q (*Ted W.*): How many FTE do you estimate it takes to maintain this?
A (*Alex C.*) It depends on expertise, but at least one FTE, spread across several staff, is needed.
- Q (*Mike K.*): The compliance for REDCap is for each institutional instance, correct?
A (*Alex C.*) Yes, each institution must validate their own instance.

Annual T Report (Slides 31-38)

Speaker: Mike Holinstat

Presentation Summary:

Mike Holinstat reported on the structure and activities of CTSA training programs (TL1, T32, R25), highlighting the diversity of institutional participation and collaborative activities such as the 3-Minute Thesis competition, webinars, visiting scholar programs, and inter-institutional debates.

Key Questions & Responses:

- Q (*Mike K.*): On balance, do you think we're holding our own?
A (*Mike H.*) Yes, feedback from trainees is positive, and the program remains highly valued.

Adjourn (Slide 39)

Next Steering Committee Webinar Wednesday, October 22, 2025 , at the 2025 CTSA Fall Annual Program Meeting