CTSA Coordination, Communication, & Operations Support

Steering Committee Meeting

May 11, 2026

2:30-3:30pm ET

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Agenda

Time	Topic	Speaker(s)
2:30pm – 2:35pm	Welcome	Michael Kurilla, Grace McComsey
2:35pm – 2:50pm	K and T Consortium Group Charter Review	Susan Pusek, Carmen Silvano
2:50 – 3:10pm	WG Report Out: Pediatric Clinical Trials	Karen Wilson, Mark Schleiss
3:10pm – 3:30pm	Clinical Trial Inefficiencies	Mike Kurilla

CTSA K & T Visiting Scientists Consortium Group

Supporting emerging investigators in translational science

Introduction

Planning Team

K Representatives

- Susan Pusek, University of North Carolina
- Joel Tsevat, University of Texas, San Antonio
- Steven Asch, Stanford University

T Representatives

- Carmen Silvano, Mayo Clinic
- Joshua Santiago, University of Chicago

NCATS

- Patrick Brown
- Heather Baker
- Jennie Conroy

CCOS

- Megan Stewart
- Lauren Fitzharris
- Kerry James

Unifying Established CTSA Visiting Scientist Programs

TL1 Visiting Scientist Programs

- T Grand Rounds
- TL1/T32 Mini-Symposia
- TL1/T32 Cross-Institutional Debate Forum

Former TL1 Working Group Context. This box represents the structural evolution of the former TL1 Visiting Scientist Working Group.

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KL2 Virtual Visiting Scholar Program

- A parallel structure to the T programs, representing the clinical research scholar activities.

Former KL2 Working Group Context. This box represents the structural evolution of the former KL2 Virtual Visiting Scholar Working Group.

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NEW: CTSA K & T Visiting Scientists Consortium Group

- The final consolidated entity coordinates all K and T visiting scientist activities into one group.

Strategic Consolidation

- This new group replaces separate working groups for a more efficient, unified CTSA structure.

A new group built on a foundation of successful programming - 1

K Virtual Visiting Scholar Program:

- 2020-2021: 56 Scholar speakers from 27 Hubs
- At 6 month survey, 36 (73.5%) Scholars had contacted at least one person at the host hub and for 17 (34.7%), new collaborations with the host hub ensued.
- Published Bredella MA, et al The Virtual CTSA Visiting Scholar Program to Support Early-Stage Clinical and Translational Researchers: Implementation and Outcomes. Acad Med. 2022 Sep 1;97(9):1311-1316.

T Grand Rounds Program:

- 2021-2024: 27 talks, 18 postdoc, 9 predoc, 16 institutions including NIH/NCATS
- 83% of presenters met “at least one person I am likely to contact in the future”
- Draft completed for Special Communication to JCTS: Frei et al: National Grand Rounds for PRedoctoral and Postdoctoral Translational Science Trainees: The William Schnaper Visiting Scientist Grand Rounds Program

A new group built on a foundation of successful programming – 1

T Mini-symposia:

- 2021-2025: Seven symposia, 62 Trainee presenters from 28 Hubs (79% predocs)
- 100% of presenters cited professional development value, 50% received useful feedback and 78% of attendees reported valuable learning experience
- Special Communication submitted to JCTS: Brunfeldt, et al: “NCATS TL1/T32 William Schnaper Visiting Scientist Program: Trainee Driven Mini-symposium

T Debate Forum:

- 2021-2025: Four debates, 32 trainee debaters, from 10 Hubs
- 100% of audience reported increase in knowledge
- Special Communication drafted: Kalkan and Piccirillo “NCATS TL1/T32 William Schnaper Visiting Scientist Program: Cross-Institutional Debate Form

Background and Rationale

Why the Consortium Was Formed

Benefits of Unification

Consolidating efforts under KTVS-CG maximizes resources, improves consistency, and supports long-term sustainability.

Need for Coordination

A national coordinated approach was necessary to streamline training and engagement for early-stage clinical investigators.

Increased Participation and Efficiency

The streamlined consortium reduces administrative burden and increases opportunities for participant engagement across hubs.

Demonstrating Career Pathways

Trainees and scholars received opportunities to learn from eachother and develop mentorship skills.

Mission and Vision

Mission and Vision Statements

Advancing Translational Science
The mission focuses on advancing clinical and translational science through knowledge exchange and professional development.

Connecting CTSA Emerging Scientists
Virtual forums and events connect trainees and scholars across multiple institutions nationwide.

Vision of Cohesive Environment
The vision aims for a nationally connected community engaged in innovative translational research with strong mentorship.

Collaboration
Emphasizes collaboration and excellence in translational science training and research visibility.

Goals and Priorities

Key Goals

Scientific Exchange Opportunities

KTVS-CG creates regular opportunities for scientific exchange and professional development among trainees and scholars.

Building Professional Networks

The group fosters connections across institutions to build professional networks and facilitate expert feedback.

Alignment with CTSA Priorities

Ensuring all consortium activities support the broader goals of the CTSA.

Ongoing Charter Review

Leadership commits to annual reviews to align programming with CTSA priorities and improve consortium activities.

Evaluation and Annual Timeline

Assessment and Scheduling

Annual Planning Timeline
Spring begins charter finalization and leadership recruitment, with summer focusing on surveys and availability. (July-August)

Scheduling and Logistics
Fall and winter involve matching participants to activities and finalizing event logistics with flexible spring delivery. (August-September)

Evaluation
The strategy focuses on continuous process improvement with feedback surveys after activities.

Consortium Group Planning & Activities

Phase 1: Preparation & Recruitment
(Spring – June)

Spring: Finalize & Promote

Finalize charter, promote the Consortium Group, and recruit lead team membership and roles

June: Draft Surveys

Draft interest surveys for scholars/trainees and host availability

Phase 2: Launch & Finalization
(July – Early September)

July: Launch Surveys

Launch host hub availability surveys and interest surveys for T and K scholars

Late Summer Focus Areas
(Host Hub Activities)

August/Early September: Finalize Program

Leadership team finalizes program plan, matching approach, and SOPs for all activities

This roadmap outlines the recurring annual lifecycle of the Consortium Group, moving from initial leadership recruitment and promotion in the Spring to the finalization of program plans and SOPs by early September. It serves as a guide for scholarly engagement and host hub coordination.

Consortium Group Planning & Activities

Spring:

- Finalize charter and promotion of group (launch year only)
- Promote (new) Consortium Group
- Recruit lead team membership and roles

Summer (June)

- Draft interest surveys for scholars/trainees and host availability

Late Summer (July)

- Launch host hub availability surveys (for Grand Rounds and Visiting Scholar activities as well as hosting debate forum or mini-symposia)
- Launch interest surveys for T and K scholars

August/Early Sept):

- Leadership team finalizes program plan for the upcoming academic year based on responses to surveys
- Finalize matching approach
- Confirm mini symposia and/or debate forum with host sites
- Finalize SOPs for all activities

Consortium Group Planning & Activities

Fall (Oct-Dec):

- Initiate matching for all programs participating in Virtual Scholar Visits and Trainee Grand Rounds
- Final match lists sent to hubs & scholars
- Schedule events for the year

Winter (Dec-Feb) (or as needed depending on event schedule):

- Finalize all event logistics
- Conduct events (if scheduled during Winter)
- Prepare cross-hub advertisement and confirm presenters

Spring (Feb-May):

- Conduct events

Summer:

- Refine programming and prepare next-year planning

Membership and Governance

Participation and Leadership Structure

Balanced governance driven by cross-hub leadership and specialized operational support

Membership

- Includes program directors, faculty, administrators, coordinators, trainees, and scholars.

Balanced Cross-Hub Governance

Leadership is co-led by representatives from both K and T programs

Strategic Leadership Oversight

Sets priorities, oversees programming, and liaises with the steering committee.

CCOS Infrastructure Support

Manages communications, meeting coordination, surveys, and resource maintenance.

Host Hubs Logistics

Handles event logistics, promotions, and support for visiting scientists.

Roles and Support

Operational Responsibilities

Leadership Strategic Role

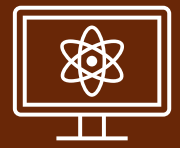
Leadership sets priorities, oversees programming, reviews feedback, and liaises with the steering committee.

Host Hubs Coordination

Host hubs handle event logistics, faculty meetings, promotions, and support visiting scientists.

CCOS Infrastructure Support

CCOS manages meeting coordination, communication campaigns, surveys, and resource maintenance.



Thank You!

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Steven Asch: sasch@stanford.edu

Carmen Silvano: silvano.carmen@mayo.edu

Joshua Santiago: joshua.santiago@bsd.uchicago.edu

Vote: K & T Consortium Group Charter

CTSA Coordination, Communication, & Operations Support

CTSA Pediatric Clinical Trials Working Group Report Out

CTSA Steering Committee

May 11, 2026

Presented by: Karen M. Wilson, MD, MPH, University of Rochester

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Overview

- The Pediatric Clinical Trials Working Group is committed to **transforming how pediatric clinical research and clinical trials are understood and conducted across the CTSA Consortium.** By identifying systemic barriers, sharing best practices, and promoting innovative trial designs, the group aims to **increase the number and quality of clinical trials involving children and adolescents.** Its work will culminate in practical tools and strategies that empower researchers and networks to better serve pediatric populations. Ultimately, the working group seeks to accelerate the development of **inclusive, high-impact research that improves health outcomes for all children.**

Working Group Members

CTSA Pediatric Clinical Trials WG

Karen Wilson, MD, MPH
Chair, University of Rochester
karen_wilson@urmc.rochester.edu

Mark Schleiss, MD
Co-chair, University of Minnesota
schleiss@umn.edu

Pablo Cure, MD, MPH
NIH/NCATS Representative
pablo.cure@nih.gov

- **26 Total Members**
- **Representation from 16 Hubs**

- Daniel Armstrong, University of Miami School of Medicine
- Elisabet Borsheim, University of Arkansas for Medical Sciences
- Sunanda Gaur, Rutgers Biomedical and Health Sciences
- Cynthia Gerhardt, Research Institute at Nationwide Children's Hospital
- Neil Goldenberg, Johns Hopkins University
- Jessica Kahn, Albert Einstein College of Medicine
- Sunitha Kaiser, University of California, San Francisco
- Dwight Koeberl, Duke University
- Chester Koh, Baylor College of Medicine
- Susanna McColley, Northwestern University

- Peter Mourani, University of Michigan
- Paul Palumbo, Dartmouth College
- Tamara Simon, University of Southern California
- Nora Singer, Case Western Reserve University
- Ron Sokol, University of Colorado
- Dixie Thompson, University of Utah
- Miriam Vos, Emory University
- Guy Brock, Ohio State University
- Laura Baker, Seattle Children’s Hospital
- Jodi Smith, Seattle Children’s Hospital
- Jeanne Holden-Wiltse, University of Rochester

Purpose

Pediatric Clinical Trials WG

1. To enhance the CTSA Consortium and individual investigator **knowledge and expertise** in pediatric clinical trial development and implementation across the CTSA network and beyond.

2. To increase the **number, efficiency, and effectiveness** of pediatric clinical trials and expand access for all.

Goals

Pediatric Clinical Trials WG

The goals of the PCT-WG are to overcome translational science and research roadblocks to pediatric clinical trials by:

1. Identifying existing research networks nationally engaged in supporting pediatric clinical trials to enhance access for participation
2. Determining best practices from existing pediatric clinical trials networks that can be applied in emerging/underdeveloped areas of pediatric health
3. Identifying barriers and facilitators to conducting pediatric clinical trials
4. Understanding knowledge gaps in pediatric clinical trials
5. Developing strategies to increase access to pediatric clinical trials for all
6. Exploring innovative opportunities to facilitate pediatric clinical trials, including optimization of sIRB models, decentralized clinical trials, and remote clinical trials, in collaboration with the TIN.

Deliverables

Pediatric Clinical Trials WG

1. A completed **survey of CTSA Hubs** about (a) types of **study designs, populations, and methodologies** used in pediatric clinical trials, (b) identified **barriers and gaps** in access, infrastructure, and (c) partnerships with vendors that affect design, implementation, and completion of pediatric clinical trials. **A manuscript summarizing survey outcomes** will include recommendations about how non-traditional and innovative methods and designs are being used to improve pediatric clinical trials.
2. Using a **scoping methods review**, a manuscript will describe opportunities to (a) **expand and translate innovative clinical trial designs** (e.g., basket studies, real-word evidence, decentralized clinical trials, adaptive trial designs, personalized medicine, emergence of sequencing), (b) **develop new innovative designs** (e.g., virtual control groups/digital twins, AI), (c) explore study designs and methods that **address barriers to specific types of clinical trials** (ie rare diseases), and (d) **provide recommendations on innovations** in non- pharmaceutical or device pediatric clinical trials.
3. A **virtual meeting on Innovations in Pediatric Clinical Trials** will be hosted to bring together the CTSIs, the TIN, investigators working on innovative methods in pediatric clinical trials, research network leaders, and federal representatives. This meeting will include opportunities to review the findings from Deliverables 1 and 2 and will inform the toolkit below.

Deliverables

Pediatric Clinical Trials WG

4. **A toolkit for pediatric clinical research network leaders** will be created to collate best practices and innovative approaches to inclusion of children and adolescents in clinical trials, including (a) network governance structure; (b) clinical coordinating & analytic center functions; data coordinating center functions; (c) sIRB, establishing referral networks, (d) central biorepository functions, and e) approaches to drug and device trials. Recommendations to enhance recruitment through increasing enrollment of medically underserved populations in clinical trials (e.g. rare disease patients, infants, adolescents) and opportunities for using innovative methods in pediatric trials will be included.

Timeline (Y1)

- Q1 (July – September 2025): Convene the working group and arrange monthly meetings; Organize subcommittees and leads for each deliverable;
- Q2 (October – December 2025): Begin literature review for the scoping review paper and toolkit; design and pilot the PCT network survey.
- Q3 (January – March 2026): Send the PCT network survey to all CTSA Hubs; Analyze the survey data; continue the literature review. First draft of the scoping review.
- Q4 (April – June 2026): Draft the survey paper; begin planning for the virtual meeting- identify attendees, schedule, plan the agenda.

Timeline (Y2)

- Q1 (July – September 2026): Final draft and submit the survey paper (Deliverable #1); Final draft and submit the scoping review (Deliverable #2); Revisions on the survey paper; Continue virtual meeting planning- invite attendees, finalize presentations and agenda. Revisions on the scoping review
- Q2 (October – December 2026): Virtual meeting (Deliverable #3). Compile outcomes from the virtual meeting;
- Q3 (January – March 2027): Begin to draft toolkit. Plan toolkit dissemination. Send the toolkit out for reviews. Collect and review collaborative grant application ideas.
- Q4 (April – June 2027): Disseminate the toolkit (Deliverable #4).

Working Group Sub-committees

Hub Survey Subcommittee

Name	Email
Cynthia Gerhardt (Lead)	cynthia.gerhardt@nationwidechildrens.org
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Mark Schleiss	schleiss@umn.edu

Scoping Review Subcommittee

Name	Email
Susanna McColley (Lead)	smccolley@luriechildrens.org
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Daniel Armstrong	darmstrong@med.miami.edu
Tamara Simon	tsimon@chla.usc.edu

COORDINATION

Scoping Review Updates

- PCC and inclusion/exclusion criteria finalized in Covidence
- Search completed with ~3000 abstracts identified for first round
- ~45 volunteers identified to help with reviews
- Abstract reviews are ongoing; plan to finish by May 15th
- Small team will review conflicting votes
- Next step will be assigning and reviewing complete papers
- Engaging with partners in preparation for virtual meeting

Survey Updates

- Next Steps
  - Survey leads are to review and approve the finalized survey in REDCap by Tuesday, 5/12
  - The Survey Team will begin beta testing this week or next week for functionality
  - Once approved, the survey will be sent to NCATS for review & IRB approval
  - Target launch date will be pushed back from 6/23 due to Steering Committee review & approval scheduled on 7/13
- Communications
  - Survey will be sent to the IAL-EC
  - Survey team to discuss co-signature by Cynthia, Jessica, and Pablo
  - Survey team to create announcement slide for July CTSA Program Webinar (7/22)
- Resources
  - Survey Page: Pediatric Clinical Trials Working Group | Survey | CTSA CCOS

Barriers

- More of a queue than expected for the survey
- Scoping reviews are complex and a lot of work!
- Still on target for a virtual meeting in early 2027

Questions for the Steering Committee

- Are we on the right track to make a difference?
- Are there additional goals or deliverables that we should include?
- Is our progress satisfactory?
- Any additional suggestions?


questions?

CTSA Coordination, Communication, & Operations Support

Clinical Trial Inefficiencies

Presented By: Mike Kurilla

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The CTSA Opportunity: Scaling Clinical Trial Innovation

The CTSA consortium serves as a national "operational innovation infrastructure" designed to identify, test, and scale solutions for clinical trial barriers. By moving from local experimentation to national standardization, the consortium aims to reduce administrative burden and accelerate evidence generation.

The Collective Mission

Operational Innovation Infrastructure

Identifying and scaling approaches that reduce unnecessary burden and improve participant access.

Local Experimentation

> **Solving the "Impossible" Independently:**
> Addressing friction points in ways that no single institution could accomplish alone.

National Standardization

> **Moving to National Standardization**
> Transitioning from local experimentation to shared, collective solutions for the entire research ecosystem.

Priority Barriers for Innovation

Participant & Administrative Burdens

Streamlining compensation, reducing paperwork, and solving recruitment/retention as efficiency problems.

Systems & Infrastructure Innovation

Advancing alternative IRB review models and supporting decentralized or hybrid trial delivery.

Workforce & Data Interoperability

Supporting clinical research professionals and ensuring research data can be reused across systems.

Cohesive Research Ecosystem

National clinical research network

with accelerated outcomes and improved patient access

Next Meeting: June 8, 2026

Agenda

- Fall Meeting Logistics
- WG Report Out: Principles for AI Translation in Healthcare (PATH)
- Pod Spotlight: University of Rochester

WG Proposal review extended until **May 19**

**If you are unable to attend a meeting, please inform us at steeringcmte@ccos.ctsa.io. Slides and summaries will be made available post-meeting. Substitutions are not permitted for Steering Committee meetings.*