CTSA Coordination, Communication, & Operations Support

Attendees are muted | Ask questions using Q & A | Webinar is recorded | Materials posted to CCOS

July 22, 2026

CTSA Program Webinar

digital Infuzion® Deloitte. ICF University of Rochester Medicine

Agenda CTSA Program Webinar July 22nd, 2026

TIME	TOPIC	PRESENTERS
2:00 PM	**Welcome**	**Kerry James**, MPH, PMP - Project Manager, CCOS
2:01 – 2:10 PM	**NCATS/CTSA Updates**	**Mike Kurilla,** MD **-** Director, Division of Clinical Innovation, NCATS **Erica Rosemond,** Ph.D. **-** Deputy Director, Division of Clinical Innovation, NCATS
2:10 – 2:15 PM	**CCOS Updates**	**Kerry James**, MPH, PMP - Project Manager, CCOS
2:15 – 2:30 PM	**Overcoming Barriers to Women's Health Research Working Group**	**Vesna Garovic,** MD, PhD, Mayo Clinic Rochester
2:30 – 2:45 PM	**Pediatric Clinical Trials Working Group**	**Mark Schleiss**, MD, University of Minnesota **Karen Wilson**, MD, MPH, University of Rochester
2:45 – 3:00 PM	**Biostatistics, Biomedical Informatics and Data Science Enterprise Committee**	**Shari Messinger**, PhD, University of Miami School of Medicine
3:00 PM	**Adjourn**	**Kerry James**, MPH, PMP - Project Manager CCOS


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NCATS
COLLABORATE. INNOVATE. ACCELERATE.

NCATS/CTSA Program Updates

Michael G. Kurilla, MD, PhD

Director, Division of Clinical Innovation
NCATS

July 22, 2026

National Center for Advancing Translational Sciences

CTSA Program – Updates

- **Received NCATS Council approval for CTSA Program concepts: May 22, 2026**
  - **Watch the VideoCast (Day 2)**

- **Forecasts published on Grants.gov:**
  - CTSA Suite:
    - Clinical and Translational Science Award: UM1 (PAR-28-002)
    - Institutional Career Development: K12 (PAR-28-003)
    - Institutional Training: T32 (post-doc) + T32 (pre-doc) (PAR-28-004)
    - Education Research: R25 (PAR-28-005)
    - Specialized Innovation Programs: RC2 (PAR-28-006)
  - CTSA Consortium Activities:
    - Trial Innovation Network: Trial Innovation & Recruitment Innovation Centers (PAR-28-007)
    - CTSA Collaborative & Innovative Acceleration Awards (PAR-28-008)
- **Pending publication: https://www.nih.gov/challenges**
  - Real-world Evidence Innovation Challenge

NIH Notices

- **Request for Information: Proposal to Cap the Number of Simultaneous Research Project Grants per Principal Investigator to Support More Researchers and Maximize Scientific Productivity and Innovation (Released June 8, 2026) (NOT-OD-26-086)**
- **Purpose:** The purpose of this Notice is to solicit public input on the outline for a proposed policy that would cap the number of Research Project Grants (RPGs) an individual can simultaneously serve on as Principal Investigator (PI) or Multi-Principal Investigator (MPI).
- Research Project Grants are defined as activity codes DP1, DP2, DP3, DP4, DP5, P01, PN1, PM1, R00, R01, R03, R15, R16, R21, R22, R23, R29, R33, R34, R35, R36, R37, R50, R55, R56, R61, RC1, RC2, RC3, RC4, RF1, RL1, RL2, RL9, RM1, SI2, UA5, UC1, UC2, UC3, UC4, UC7, UF1, UG3, UH2, UH3, UH5, UM1, UM2, U01, U19, U34, and U3R.
- **Submitting a Response:** Comments should be submitted electronically to this webpage by **August 3, 2026**.
- More information in the Extramural Nexus Article: https://grants.nih.gov/news-events/nih-extramural-nexus-news/2026/06/feedback-sought-proposal-to-cap-the-number-of-simultaneous-research-project-grants-per-principal-investigator-to-support-more-researchers-and-maximize-scientific-productivity-and-innovation

NIH Notices

- **Request for Information: Request for Information on Measuring and Rewarding Scientific Impact (NOT-OD-26-087) (Released June 18, 2026)**
- NIH is engaging stakeholders in defining specific, measurable indicators and incentives that reflect the collaborative, rigorous, and mission-driven nature of modern biomedical science. Comments are welcome on all potential possible indicators and incentives, but are specifically encouraged on the following:
  - Rigor and Reproducibility, Data, Software, and Model Sharing, Training and Mentorship, Collaboration, Entrepreneurship and Translation, Foundational Scientific Exploration, and Public Impact.
- Responses due August 19, 2026: https://osp.od.nih.gov/comment-form-measuring-and-rewarding-scientific-impact/
- Nexus: How Would You Measure and Reward Scientific Impact and Replicable Research Practices?

NIH Notices

- Notice of NCATS Participation in Notice of Funding Opportunity (NOFO) PA-25-302 NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed) (Released July 16, 2026) (NOT-TR-26-011)
- Notice of NCATS Participation in Notice of Funding Opportunity (NOFO) PA-25-304 NIH Exploratory/Developmental Research Project Grant (Parent R21 Clinical Trial Not Allowed) (Released July 16, 2026) (NOT-TR-26-010)
- NCATS has signed on to the parent R03 and R21 as part of NIH's activities to streamlining the number of NOFOs. This is to ensure the center may participate in different programs. For more information about NCATS' specific interests see the description of highlighted topics here: https://grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices/NCATS
- The CTSA Program does not utilize the parent R03 or R21 due to limited competition.

N3C - Updates

- The National Clinical Cohort Collaborative (N3C) Community Forum is an opportunity for the N3C user community and the NCATS' N3C Team to convene and discuss important updates and future directions of the N3C Enclave.
- The National Clinical Cohort Collaborative (N3C) Community Forum will convene virtually on **Thursday, July 30, from 1 to 2 p.m. EDT.**
- Topics:
  - Updates on the evolution of the platform
  - Discussion of the revised N3C Community **Code of Conduct.** Please review the document and come to the meeting prepared with your comments. We will discuss the thoughts shared by the N3C community during the Forum.
- Please **register** to join us on **July 30 at 1 p.m. EDT.**

NCATS

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ncats.nih.gov @ncats_nih_gov @ncats.nih.gov NIH-NCATS

National Center for Advancing Translational Sciences

CTSA Coordination, Communication, & Operations Support

July 22, 2026

CCOS Updates

digital Infuzion® Deloitte. ICF University of Rochester Medicine

2026 Fall CTSA Program Annual Meeting

September 23-25 (Steering Committee Sept 22) | Marriott Marquis Washington, DC

From Discovery to Impact: Advancing the Translational Pathway

Registration now open for Fall Meeting: Agenda - 2026 Fall CTSA Program Annual Meeting

Room block available at Marriott Marquis, Washington DC.

- *Make your reservation before the room block closes on August 31*

Hub Attendance

- Up to 9 attendees per hub
- Hub limit does not include TIN meeting participants, General Session speakers, Poster Presenters, Steering Committee, or Fall Planning Committee members
- Hub Administrators and TIN meeting registration will be managed separately

Full details available on the 2026 Fall Meeting webpage

National Center for Advancing Translational Sciences

2026 Fall CTSA Program Annual Meeting
Draft Agenda

Tues, Sep 22	Weds, Sep 23 (EC Day)	Thurs, Sep 24 Day 2	Fri, Sep 25 Day 3
Steering Committee Mtg. 1:00pm – 5:00pm	**All-EC Plenary Session** 9:00am -12:00pm	**Sessions 1-5** 9:00am -5:30pm *Includes **Keynote: Karim Mikhail, FDA**	**Sessions 6-7** 9:00am – 10:15am *Includes **Fireside Chat: Jay Bhattacharya, NIH**
	TIN Meeting 9:00am – 1:00pm	**Poster Session** 3:00pm – 4:30pm	**NCATS Session / Closing** 12:00pm – 1:15pm 1:15pm – 1:45pm
	Enterprise Committee Mtgs. 1:00pm -3:00pm 3:30pm – 5:30pm	**UL1/UM1 PI Meeting** 6:00pm – 7:30pm	
	Hub Administrators Meeting 1:30pm – 5:30pm		

Full agenda here: Agenda - 2026 Fall CTSA Program Annual Meeting

Gen Session Topic Areas:

- AI use cases in real-world research
- Innovative trial designs
- Research Expansion into rural areas
- Workforce development and research staff career pathways
- Scaling recruitment services and infrastructure

2026 Fall CTSA Program Annual Meeting
Poster Session
20 Years of CTSA Impact - Past, Present, and Future

- Each hub may submit one poster, highlighting a project related to the theme
- Posters must align with one of the Translational Science Benefits Model (TSBM) domains:
  - Clinical
  - Community
  - Economic
  - Policy*
- The focus of this year's poster session is to showcase demonstrable impact in translational science and highlighting the contributions of CTSAs.
- **This is not a juried poster session**.

Poster Submissions open July 14 at 9:00 am ET and close August 31 at 11:59pm

Link for Poster Submission guidelines

** Hubs submitting to this category must clearly indicate that research was what the CTSA grant supported and NOT any advocacy or legislative influence activities. Per the NIH Grants Policy statement, hubs should pay special attention to reporting/describing activities focused on reporting Policy and Legislative Impacts under the TSBM model or any aspect of a NIH funded CTSA grant. However, no grant funds including personnel costs may be used for activities.*

2026 Fall CTSA Program Annual Meeting
Fall Planning Committee

Volunteers	Institution
Steven Bernstein, Co-Chair	Yale University
Elmer Bernstam	University of Texas Health Science Center Houston
Casandra Burrows	Rutgers University
Andrea Carnegie	University of North Carolina at Chapel Hill
Jennifer Edelman	Yale University
Jayne Fulkerson	University of Minnesota
Michelle Hernandez	University of North Carolina at Chapel Hill
Mike Holinstat	University of Michigan
Thomas Houston	Wake Forest University
Fasiha Kanwal	Baylor College of Medicine
Jennifer Majersik	University of Utah
Grace McComsey	Case Western Reserve University
Rey Panettieri	Rutgers University
Heather Reisinger	University of Iowa
Vicki Ellingrod Ringold	University of Michigan
Sanjay Sethi	State University of NY at Buffalo

NCATS
Michael Kurilla, Co-chair
Heather Baker
Jennie Conroy
Christopher Hartshorn
Erica Rosemond
Jennie Conroy

CCOS
Amanda Scott, **Planning Lead**
Melissa Brady
Kerry James

EC Day: Connecting Enterprise Committees Around Shared Translational Science Priorities

Wednesday, September 23rd

EC Plenary Session 9am-12pm

Theme: Translational Science in a Changing Research Environment: Innovation, Trust, and Human Connection

Work Force Development EC Meeting
1pm -3pm

Integration Across the Lifespan EC Meeting
1pm – 3pm

Collaboration & Engagement EC
3:30pm – 5:30pm

Biostatistics, Biomedical Informatics & Data Science EC
3:30pm -5:30pm

- **New** in 2026, EC day opens with a joint plenary session that brings all Enterprise Committees together for a joint session focused on cross-pollination, consortium-wide priorities, and practical take-home value for CTSA hubs.
- **Plenary Session Theme: *Translational Science in a Changing Research Environment: Innovation, Trust, and Human Connection***
- Individual Enterprise Committee sessions are planned in the afternoon

EC Plenary Session Planning Committee Volunteers

Joan Nagel, NCATS Tom Radman, NCATS • Nichole Carlson, BIDS EC Jodi Lapidus, BIDS EC • Tricia Piechowski, C & E EC Elisabeth de la Rosa, C & E EC • VJ Periyakoil, Integration EC Chester Koh, Integration EC • Vicki Ellingrod, WFD EC Judy Cannon, WFD EC • Kerry James, CCOS Lenore Roca, CCOS

Thank you!

Do you have an idea for the next Collaborative Workshop Topic?

Is your hub interested in being a Co-Sponsor?

Coming Soon!

to an inbox near you!

CCOS Team Science will be releasing a solicitation in the coming weeks for hubs to submit a proposal to co-sponsor the Collaborative Workshop in Spring 2027.

New Working Groups

- For Cycle 16, the CTSA Steering Committee approved 3 out of 7 proposals at the June 22nd meeting.
- Click links below for Group pages on CCOS website and to join the group.

Questions? Please reach out to Group email below.

New Working Group	Submitted by:	Group Email:
CTS Launchpad: National Training Criteria from Classroom to Career	James Holahan, New York University Langone	cts.launchpad@ccos.ctsa.io
Scaling a Reproducible CTSA/CTR Framework for Clinical Research Professionals Training Using a Collaborative Network Model	Alexandria Carey, Rutgers University	CRPtraining@ccos.ctsa.io.
Measuring Success in Translational Science	Sydney Bollinger, Medical University of South Carolina	measuringts@ccos.ctsa.io

Share Your Work with the CTSA Community

	Events	News Articles	Impact Stories
Examples:	Meetings, symposia, webinars, trainings, workshops	Event recaps, notable publications, awards, profiles, new resources	Success stories, case studies, or comparative analyses with **clear & measurable outcomes** across TSBM domains
How to Submit:	CCOS Calendar -> **Pitch an Event** button	CCOS News -> **Pitch an Article** button	Impact Story submission form (direct link)
For more info:	**CCOS Events Guidance Document (in development)**	CCOS News Article Guidance Document	CCOS Impact Story Guidance Document

All submissions can be promoted in *The Ansible* and/or on CCOS social media platforms (X, LinkedIn, and Bluesky), by checking a box during submission.

*All Impact Stories posted in the first release will be shared via CCOS social media over the next few weeks.

CTSA Meetings Snapshot: July-August 2026

Enterprise Committees

July 28 | Integration Across the Lifespan | 1:00 PM ET

Aug 3 | Collaboration & Engagement | 1:00 PM ET

Aug 7 | BIDS | 1:00 PM ET

Aug 26 | Integration Across the Lifespan | 1:00 PM ET

Working Groups

July 30 | Translational Science Case Studies | 2:00 PM ET

Aug 5 | Learning Health Systems-CTSA Partnerships | 12:00 PM ET

Aug 20 | Translational Case Studies Commercialization | 4:00 PM ET

Aug 25 | CTSA Launchpad | 1:00 PM ET

Aug 27 | Translational Science Case Studies | 2:00 PM ET

CTSA Program

July 27 | CTSA Steering Committee | 2:30 PM ET

Aug 26 | CTSA Program Webinar | 2:00 PM ET

Consortium Groups

July 22| TL1/T32/R25 PI Directors | 4:00 PM ET

July 30| Communicators | 1:00 PM ET

Aug 11 | KL2/K12 PI Directors | 1:00 PM ET

Aug 19 | Administrators Group | 1:00 PM ET

Other Events

July 30 | Community Engaged Research Symposium | 1:00 – 5:00 PM ET ***(Sponsored by external group)***

CCOS Calendar

CCOS Reminders

Scan to Receive CTSA-wide Communications

Join CTSA Groups on the CCOS Website:

- Step by step instructions here to join CTSA groups from your CCOS member account.

Need a CCOS Account?

- Getting Started Page has detailed information or click here to get start
- Questions? Please email support@ccos.ctsa.io

CCOS All Communications Email List:

- Click here: http://eepurl.com/iw9nZA to join the list and receive CTSA Program communications and updates.
- Add communications@ccos.ctsa.io to your contacts list to prevent important CCOS emails from ending up in your spam folder

THANK YOU

MAYO CLINIC

OVERCOMING BARRIERS TO WOMEN'S HEALTH RESEARCH WORKING GROUP

UPDATE

Vesna D. Garovic, MD, PhD

CTSA Program Webinar
July 22, 2026

BACKGROUND

- Clinical guidelines and practice have historically focused on men
- CVD strategies in women were extrapolated from studies focused on men
- In the 1980s: the rate of decline of CVD in men > in women
  - *Women have been both under-evaluated for CVD and undertreated for modifiable risk factors*
  - *Female-specific conditions on the onset, clinical course, the efficacy of therapy and prognosis of CVD poorly understood*

EXCLUSION OF PREGNANT PARTICIPANTS FROM RCTs TIME FOR CHANGE

MEDICINE AND PUBLIC ISSUES Annals of Internal Medicine

Sins of Omission: Model-Based Estimates of the Health Effects of Excluding Pregnant Participants From Randomized Controlled Trials

Alyssa Bilinski, PhD*; Natalia Emanuel, PhD*; and Andrea Ciaranello, MD

1. Had thalidomide been tested in a completed RCT with 200 treated participants, about 33 children would have experienced severe AEs

Knowledge from the RCT would have prevented 8000 thalidomide-related birth defects, 99.6% of all thalidomide-related birth defects from 1956 to 1962

2. Had COVID-19 vaccine trials included pregnant participants, and if posttrial pregnant uptake were to mirror that of age- and state-matched nonpregnant women

A projected 20% of COVID19–related maternal deaths and stillbirths could have been prevented

OVERCOMING BARRIERS TO WOMEN'S HEALTH RESEARCH
WG GOALS

1. Enhance the Depth and Breadth of Women’s Health Research Across CTSA Hubs
2. Assess and Improve Inclusion of Women in CTSA-Funded and Supported Clinical Trials
3. Facilitate Networking and Collaboration Opportunities across CTSA Hubs
4. Facilitate Networking and Collaboration Opportunities for CTSA T and K Scholars in Women’s Health

MEMBERS

Chair: Vesna Garovic, MD, PhD (Mayo Clinic)
Co-chair: Felicity Enders, PhD (Mayo Clinic)
Joan Nagel, MD, PhD (NCATS)

Melissa Brady (CCOS)
Thomas Buchanan, MD (University of Southern California)
Lynn Cornelius, MD (Washington University)
Pamela Dillon, PharmD (Virginia Commonwealth University)
Terri Edwards (Vanderbilt University)
Fred Fan, PhD (Mayo Clinic)
Rini Ghosh (Case Western Reserve University)
Paul Harris, PhD (Vanderbilt University)
Rachel Hess, MD (University of Utah)
Vanessa Jacoby, MD, MAS (University of California, San Francisco)
Shokoufeh Khalatbari, MS (University of Michigan)
Colleen Lawrence, PhD (Vanderbilt University)
Michael Lin (Mayo Clinic)
Shelly Meese, MHA (Scripps Health)
Laura Meiners, MBA (Mayo Clinic)
Alex Paquet (CCOS)
Kathryn Sandberg, PhD (Georgetown University)
Julie Schwan, MS (CCOS)
Abby Spike (CCOS)
Lina Sulieman, PhD (Vanderbilt University)
Dixie Thompson, BSN, RN (University of Utah)
Jason Umans, MD, PhD (Georgetown University)
Nicole Woitowich, PhD (Northwestern University)
Rosalind Wright, MD, MPH (Icahn School of Medicine at Mt Sinai)

Women's Health in Eligibility Criteria

Extracted inclusion and exclusion criteria

Labels: Inclusion, exclusion, or both

Identified possible negated terms and excluded them (NEW)

Identified the existence of following keywords:

- Pregnancy: pregnancy, pregnant
- Menopause: menopaus, menopause, menopausal
- PCOS: PCOS, polycystic ovary syndrome
- Contraception: contraception, contraceptive
- Hormonal replacement therapy: hormone replacement therapy, menopausal hormone therapy, postmenopausal hormone therapy, estrogen replacement therapy
- Menstruation: menstruation, menstrual
- Fertility: fertility
- Vaginal infection: Vaginal infection, Vaginitis, Bacterial vaginosis
- Uterine fibroids: Uterine fibroids, Leiomyomas, myomas , fibromyomas
- Endometriosis: endometriosis
- Lactating: lactating, lactating
- Keywords in title or condition: Above keywords and the following: breast, Cervical , cervix, uterus, hysterectomy, ovary, ovarian, Uterine, Vaginal

23,605 trials: Interventional, 19079; Observational, 4526

NIH U.S. National Library of Medicine

ClinicalTrials.gov

23,605 CLINICAL TRIALS: ELIGIBILITY CRITERIA

	Pregnancy	Menopause	PCOS	Contraception	HRT	Menstruation	Fertility	Vaginal infection	Uterine fibroids	Endometriosis	Brest feeding
Inclusion only	1407	1423	23	3140	45	261	70	5	10	32	243
Exclusion only	8462	346	31	1025	173	98	43	25	7	21	1862
Both	2696	99	11	320	4	32	16	5	1	12	71
Total	12565	1868	65	4485	222	391	129	35	18	65	2176

91 OBSERVATIONAL STUDIES REVIEWED – PRELIMINARY RESULTS

84% (n = 76) overlapped with pregnancy-related inclusion/exclusion criteria

Code	N = 91	(100 %)
Concern (Justified exclusion)	54	59%
Potential Concern	9	10%
No Concern (Unjustified exclusion)	24	26%
Not Applicable	4	4%

WHAT CAN WE DO NEXT TO EXPAND THE ANALYSIS

- Manual review limitations:
  - Laborious
  - Some cases needs specialized Knowledge
  - Some facts might be overlooked in study plan
  - Not scalable

Current Work: Developing AI-assisted tool

Generated Using Gemini

USING LARGE LANGUAGE MODELS TO IDENTIFY POTENTIAL CONCERNS IN EXCLUDING WOMEN – PRELIMINARY

ChatGPT 4o

Manual	Concern (Pregnancy or Contraception)	No Concern (Both)
Concern	28	1
No Concern	5	7

SURVEYS
TWO PHASES

Phase 1: Identify individuals across CTSAs engaged in women's health research

- Solicited names and contact information from CTSA Hubs
- 69 Responses
- 339 Individuals across 35 Hubs

Phase 2: Gather details from individuals to foster collaboration

- Research phase, academic rank
- Research focus: women's health generally / disease focus? T Phase(s)? age groups?
- Are you willing to share your information with others in a secured workspace?

PLANS

NEXT 6 MONTHS AND BEYOND

Documenting recommendations

Fostering collaboration

Publication

Publish comprehensive bibliometric analysis, including assessment of incorporation of sex considerations

Virtual Event

Fall 2026: invitation to respondents of the survey

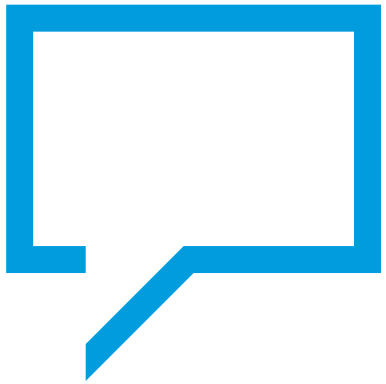
Continuing Collaboration

Proposing a Special Interest Group within the Association for Clinical and Translational Science

White Paper

Best practices and recommendations for designing more inclusive clinical trials

QUESTIONS & ANSWERS



CTSA Pediatric Clinical Trials Working Group Report Out

Karen M. Wilson, MD, MPH
Mark Schleiss, MD
CTSA Program Webinar
July 22, 2026

MELIORA

University of Rochester

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 **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** (e.g. 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; adjusted)

- Q1 (July – September 2025): Convene the working group and arrange monthly meetings; Organize subcommittees and leads for each deliverable;
- Q2 (October – December 2025): Draft the Hub survey, develop the PCC
- Q3 (January – March 2026): Begin literature review for the scoping review paper and toolkit; design and pilot the PCT network survey.
- Q4 (April – June 2026): Finish stage one of the scoping review; submit the pilot survey for steering committee approval

Timeline (Y2; adjusted)

- Q1 (July – September 2026): Send the PCT network survey to all CTSA Hubs; Analyze the survey data; continue the literature review, complete stage 2 of the scoping review, begin planning for the virtual meeting- identify attendees, schedule, plan the agenda.
- Q2 (October – December 2026): Analyze data for the survey paper and draft; finish extractions for the scoping review and draft, finalize meeting planning.
- Q3 (January – March 2027): Final draft and submit the survey paper (Deliverable #1); Final draft and submit the scoping review (Deliverable #2); Virtual meeting (Deliverable #3). Compile outcomes from the virtual meeting; begin to draft the toolkit.
- Q4 (April – June 2027): Plan toolkit dissemination. Send the toolkit out for reviews; disseminate the toolkit (Deliverable #4).

Working Group Sub-committees

Hub Survey Subcommittee

Name	Email
Cynthia Gerhardt (Lead)	cynthia.gerhardt@nationwidechildrens.org
Jessica Kahn (Lead)	jessica.kahn@einsteinmed.edu
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Neil Goldenberg	neil@jhmi.edu
Dwight Koeberl	dwight.koeberl@duke.edu
Mark Schleiss	schleiss@umn.edu

Scoping Review Subcommittee

Name	Email
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Survey Updates

- Next Steps
  - Survey has been drafted and piloted
  - Worked with CCOS on distribution and feedback
  - Reviewed by Steering Committee on 7/13 with request for additional feedback
  - Target launch date TBD
- Resources
  - Survey Page: Pediatric Clinical Trials Working Group | Survey | CTSA CCOS

Scoping Review Updates

- PCC and inclusion/exclusion criteria finalized in Covidence
- Search completed with >3500 abstracts identified for first round
- 24 volunteers identified to help with first level reviews
- 500 papers identified for high level full reviews
- Training completed on 7/20

Virtual meeting updates

- Discussions with potential attendees:
  - FDA
  - NICHD
  - Investigators
  - Industry
  - *Suggestions are welcome!*
- Forming a meeting planning committee- July 2026

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

Biostatistics, Biomedical Informatics, and Data Science (BIDS) Enterprise Committee

Transforming data into clinical and translational impact

Biostatistics, Biomedical Informatics, and Data Science (BIDS) EC Charter

The BIDS EC Charter, approved on June 9, 2025, outlines the committee's role in advancing clinical and translational science by fostering collaboration across biostatistics, informatics, epidemiology, and data science. It defines the EC's responsibilities in providing strategic guidance, supporting cross-hub initiatives, and aligning efforts with CTSA program goals.

Last updated: May 27, 2025 (v1.0)

CTSA BIDS EC Charter v1

2026 BIDS EC LEAD TEAM

The group selected multidisciplinary co-chairs to ensure that leadership represents the full spectrum of expertise and backgrounds within the BIDS EC. This choice fosters inclusivity and collaboration, allowing the committee to benefit from the perspectives of members in biostatistics, informatics, data science, epidemiology, and other disciplines.

Nichole Carlson
Co-chair
University of Colorado Denver
Biostatistics

William Hogan
Co-chair
Medical College of Wisconsin
Informatics

Elmer Bernstam
University of Texas Health Science Center Houston
Informatics

Thomas Campion
Weill Cornell Medical College of Cornell University
Informatics

Kristi Holmes
Northwestern University at Chicago
Informatics Bioinformatics

Shari Messinger
University of Miami School of Medicine
Biostatistics

Gina-Maria Pomann
Duke University
Biostatistics Data Science

Christopher Hartshorn
NCATS Representative
National Institutes of Health
NCATS

Thomas Radman
NCATS Representative
National Institutes of Health
NCATS

COMMITTEE GOALS

Advance clinical and translational science through biostatistics, biomedical informatics, data science, epidemiology, and related quantitative disciplines.

Foster cross-disciplinary collaboration across CTSA hubs to address shared scientific and operational challenges.

Promote innovation, rigor, reproducibility, and best practices in research methods and analytics.

Strengthen research infrastructure, data sharing, interoperability, and learning health systems capabilities.

Support workforce development through education, training, mentorship, and knowledge exchange.

Encourage the responsible adoption of emerging technologies, including artificial intelligence and advanced analytics.

Facilitate consortium-wide networking, collaboration, and dissemination of successful approaches and lessons learned.

Serve as a national forum for advancing data-driven solutions that accelerate translational research and improve health outcomes.

2026 FOCUS AREAS

Strengthen BIDS Identity & Visibility

- Build awareness of the integrated BIDS EC across the CTSA Consortium
- Highlight the value of team science across biostatistics, informatics, and data science
- Advance a BIDS white paper to define community identity and impact
- Leads: Bill Hogan, Nichole Carlson, Shari Messinger

Advance BIDS Workforce Development

- Promote BIDS competencies across the CTSA workforce
- Support training in AI, data science, and translational research practices
- Partner with Workforce Development initiatives on future programming
- Lead: Gina-Maria Pomann

Promote Reproducibility & Rigor

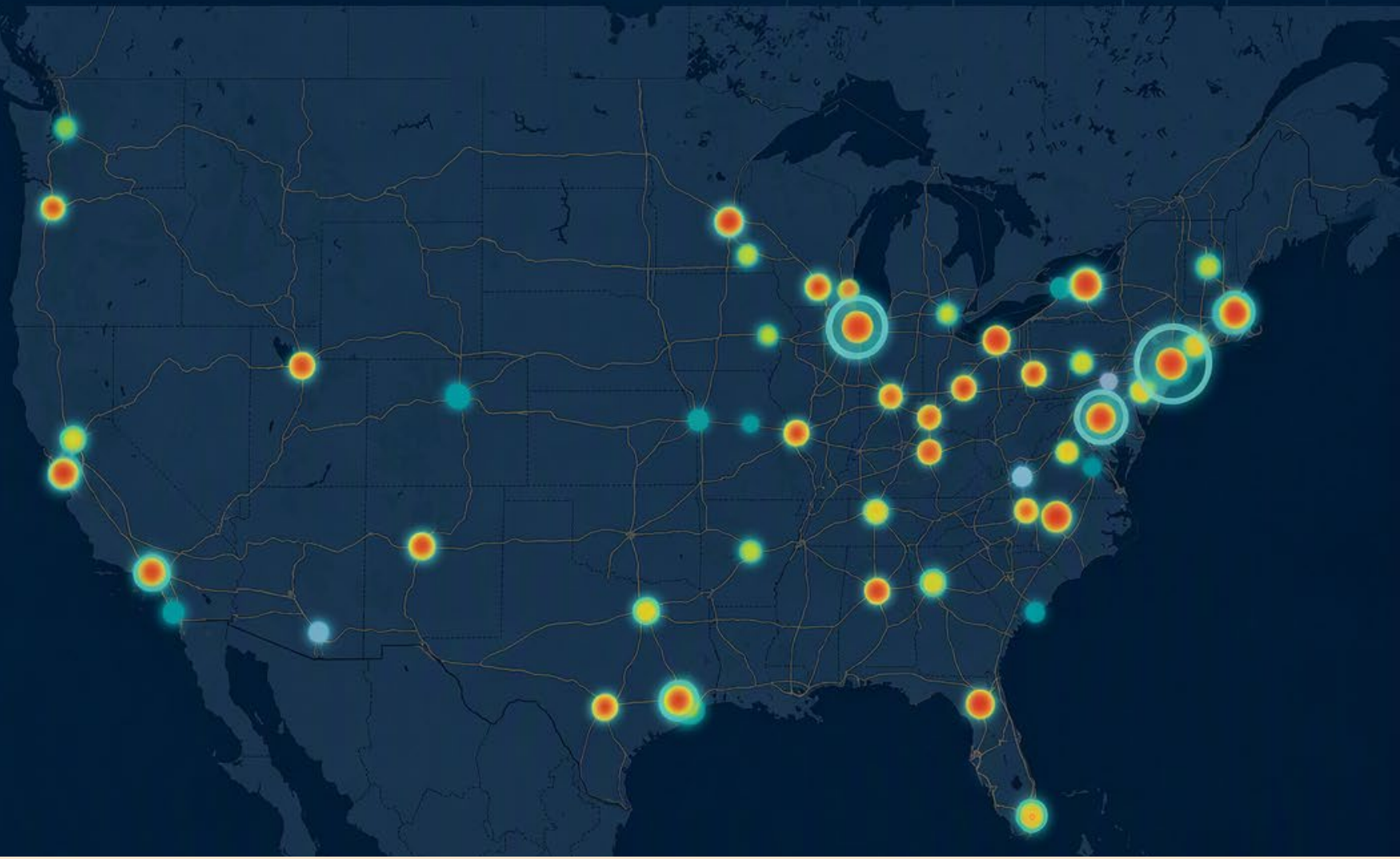
- Define priorities for reproducible and trustworthy research practices
- Identify opportunities for training, guidance, and collaboration
- Establish future initiatives and community recommendations
- Lead Team: In Development

WHO WE ARE

397
Members

69
CTSA Hubs

91
Institutions



The **Biostatistics, Biomedical Informatics, and Data Science** (BIDS) EC is a transdisciplinary committee within the CTSA Program dedicated to advancing clinical and translational science (CTS) through collaborative innovation across biostatistics, biomedical informatics, epidemiology, and data science. *A full roster of active BIDS members can be found on the CCOS website **here** (must be logged in to access).*

BIDS EC FEATURED PRESENTATIONS

Key Themes Across Presentations

- Artificial Intelligence & AI Translation
- Data Governance & Research Infrastructure
- EHR, OMOP & Data Access
- Workforce Development & Training
- Reproducibility & Quantitative Best Practices

January

Nichole Carlson

- From Consulting to Team Science: redefining BIDS partnerships and communicating the value of quantitative and data science collaborations.

February

Alifia Hasan

- HealthAI Partnership (HAIP): equitable, responsible AI implementation in healthcare.

Gina-Maria Pomann & Heather Kitzman

- Responsible health AI, trust, governance, and cross-EC collaboration.

March

Mike Kurilla

- N3C governance, DUAs/DTAs, and national data-sharing infrastructure.

Jaime Doyle

- AIM-AHEAD Health Data Science Training Program and workforce development.

April

Gina-Maria Pomann

- BERD best practices and reproducible quantitative science.

Paul Harris

- REDCap+ innovations and research infrastructure.

May

Izabelle Humes

- AI-driven mapping of translational research portfolios using NLP and LLMs.

Maryam Garza & Meredith Zozus

- CTSA-wide assessment of EHR-enabled research functionality.

June

Tony Pan

- OMOPCompass: natural language access to OMOP data.

Nathan Hotaling

- N3C modernization, governance, and scalable research infrastructure.

BIDS EC UPDATES

Advancing Clinical Trial Operations Through BIDS

REDCap Infrastructure & Innovation

REDCap Platform – widely adopted CTSA-developed clinical research platform supporting data collection, sharing, and study operations.

- **Recent Innovations**
  - REDCap Rewards – secure, compliant participant payments
  - REDCap Share – participant-directed EHR data sharing
  - Rapid Reference Chatbot – AI-assisted participant support using approved study documents
  - Remote Enrollment & eConsent – mobile identity verification and remote consent workflows

21 CFR Part 11 REDCap Framework – consortium-based approach to regulatory readiness.

AI-Enabled Clinical Trial Operations

Clinical Trial Recruitment & Cohort Identification

TrialGPT (UT Health San Antonio CTSA)

- Improved eligibility screening using unstructured clinical notes
- Identified substantially more eligible participants than traditional approaches

ADRD Phenotyping (MUSC CTSA)

- AI-based EHR text classification for identifying Alzheimer's disease and related dementia cohorts
- Supports more accurate cohort development and reduces selection bias

Delirium Detection (UT Southwestern CTSA)

- NLP-based identification of delirium from clinical notes
- Integrated with ENACT infrastructure to improve multicenter cohort development

Impact

- Accelerates participant recruitment and enrollment
- Expands access through decentralized trial models
- Improves identification of eligible trial participants
- Enhances regulatory readiness and data interoperability
- Strengthens scalable, multi-site clinical trial infrastructure

Key Resources: REDCap Platform • 21 CFR Part 11 REDCap Framework • TrialGPT Eligibility Screening • ADRD EHR Phenotyping • NLP-Based Delirium Detection

BIDS EC UPDATES

Principles for AI Translation in Healthcare Working Group

Purpose

PATH is a national CTSA forum focused on helping health systems move AI from pilot evaluation to sustained clinical and operational use.

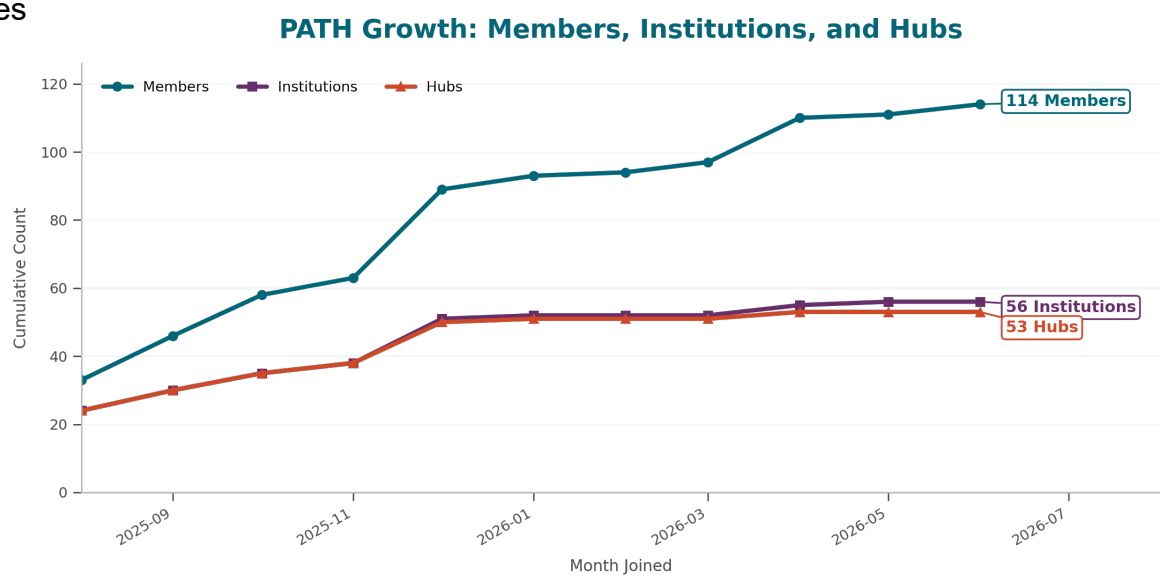
Why It Matters

Most AI pilots do not become routine care because the biggest challenges are often organizational, not just technical. PATH focuses on closing this pilot-to-practice gap within the learning health system.

Areas of Focus

Current Reach

PATH includes 114 active members, representing 56 CTSA institutions and 53 CTSA hubs across the CTSA network.



BIDS EC UPDATES

Principles for AI Translation in Healthcare Working Group

Year 1 Progress

PATH has moved from convening the national forum, to diagnosing barriers at the pilot-to-practice boundary, to translating findings into readiness tools, guidance, and solution pathways.

Key Activities to Date

- Hosted **3 expert panels** on AI governance, industry–academic partnerships and translating medical AI into sustained clinical practice.
- Advanced **4 manuscripts** focused on institutional barriers, industry–academic alignment, solution pathways, and T2-to-T3 governance.
- Shared PATH work through a national scientific session at Translational Science 2026, an in-person working group meeting, and the Yale Medical AI Symposium.

Current Flagship Initiative

PATH is developing a CTSA-wide AI Readiness Assessment to understand hub readiness across governance, technical infrastructure, workforce, implementation readiness, sustainability, and barriers to AI adoption.

What Comes Next

Findings will inform follow-up interviews/focus groups, a readiness brief for CTSA and NCATS leadership, and practical recommendations or a white paper to support pilot-to-practice translation.

BIDS EC UPDATES

White Paper Subcommittee

Lead by: Shari Messinger, Ph.D.

- The White Paper Subcommittee continues to meet regularly under the leadership of Shari Messinger, Ph.D., with ongoing monthly subcommittee meetings scheduled through 2027.
- The group is developing a peer-reviewed white paper focused on articulating the identity, roles, and strategic value of Biostatistics, Biomedical Informatics, and Data Science (BIDS) within the CTSA Consortium.
- Current discussions are focused on topics including team science, the role of BIDS disciplines in the AI era, service versus science, sustainability, collaboration, reproducibility, data integrity, and the infrastructure needed to support BIDS across institutions.
- The subcommittee continues to refine the paper structure, assign writing responsibilities, and develop recommendations that reflect the diverse expertise and contributions of the BIDS community.

KEY TAKEAWAYS

- A growing national community representing 397 members across 69 CTSA hubs
- A shared vision for advancing team science across BIDS disciplines
- Active initiatives focused on identity building, workforce development, reproducibility, and AI translation
- New opportunities for collaboration through PATH and the White Paper Subcommittee
- Continued commitment to supporting the CTSA mission through data-driven innovation

Join the BIDS EC and help shape the future of biostatistics, biomedical informatics, and data science across the CTSA Consortium. To become involved, update your CCOS group memberships by visiting your CCOS profile and selecting **Manage Memberships**.

THANK YOU

CTSA Biostatistics, Biomedical Informatics, and Data Science (BIDS) Enterprise Committee

Questions & Discussion

Biostatistics • Informatics • Bioinformatics • Data Science • Epidemiology

Next CTSA Program Webinar

Next CTSA Program Webinar August 26th

Register here

Updates on the CCOS Webinar Page

Today's meeting materials posted here

THANK YOU