



CTSA Coordination,
Communication, &
Operations Support

September 14, 2026
2:30-3:30pm ET

Steering Committee Meeting

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Seeking New CTSA Program Steering Committee Members!

THE OPPORTUNITY & DIAGNOSTIC



NCATS is seeking

5 UL1/UM1 PIs

to serve for the next 2-3 years (2027 – 2030).



Pass/Fail



PI must be officially named in an active CTSA Program hub Notice of Grant Award (NGA).



Hub award must have at least 3 years remaining during the project period.



PI has not served on the Steering Committee since December 2022.

[Review Expectations & Responsibilities](#)

THE ACTION PROTOCOL



DEADLINE:
Wednesday, October 14th

Self-nominate or suggest a fellow PI by submitting:

- PI Name
- Institution
- Brief Explanation

[Submission Link](#)



Agenda

Time	Topic	Speaker(s)
2:30pm – 2:35pm	Welcome & Announcements - Pediatric Clinical Trials Survey - SC Recruitment	Michael Kurilla Grace McComsey
2:35pm- 2:45pm	Operation TrialBlazer	Joni Rutter
2:45pm – 3:00pm	WG Report Out: Overcoming Barriers in Women’s Health Research	Felicity Enders, Vesna Garovic Liaisons: Mark Schleiss, Elizabeth Ofili
3:15pm – 3:30pm	Pod Spotlight: Institute for Clinical and Translational Science at the University of California-Irvine	Eric Vilain
3:00pm – 3:15pm	Pod Spotlight: Baylor College of Medicine	Fasiha Kanwal



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Steering Committee Vote

Pediatric Clinical Trials Survey

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University
of Rochester
Medicine

Pediatric Clinical Trials: Resources, Barriers, and Opportunities Across CTSA Hubs Survey Overview

- **Target Audience:** Hub Lead Administrators; will be requesting one submission per hub. (updated)
The survey instructions have been updated within the dissemination communication with the following: Key administrators are encouraged to work closely with Principal Investigators (PIs) to gather the necessary information. For the best results, distributing the attached PDF is recommended before any discussion or attempts to complete the survey. This initial review allows participants to familiarize themselves with the content, which then makes the collaborative meeting more effective. Engaging in this collaborative approach offers significant advantages, ultimately ensuring the final response is a comprehensive and accurate reflection of the institution's collective expertise.
- **Survey Length:** 27 questions; this survey takes approximately 30 minutes to complete.
- **Timeline:** Launch September 28, 2026, Close November 9, 2026. (updated)
- **Purpose** to survey hubs and assess the scope of involvement in pediatric clinical trials, infrastructure/support, barriers and needs.
- **Revision History:** NCATS review and approval for Executive Order compliance on June 9, 2026. Review and approval of the final draft of the survey by the WG Survey Primary Lead on April 28, 2026.
- **Primary Leads for the Survey:** Cynthia Gerhardt and Jessica Kahn.

Vote: Pediatric Clinical Trials Survey





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Presenter: Joni Rutter

Operation TrialBlazer

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Operation TrialBlazer and the CTSAs

A listening session with the CTSA Steering Committee on Sep. 22

- Operation TrialBlazer is an HHS-wide effort to strengthen clinical trials.
- The listening session is a chance to hear about:
 - Opportunities for the CTSAs to accelerate clinical trial innovation
 - Challenges that need to be addressed as TrialBlazer moves toward implementation.



Joni Rutter
NCATS Director, NIH



Willy Chertman
Counselor to the Deputy
Secretary, HHS



Scott Steele
Senior Science Advisor,
FDA



Barbara Bierer
Faculty Director, MRCT Center
of Brigham and Women's
Hospital and Harvard



Photo from the launch of Operation TrialBlazer, June 22, 2026



SAVE THE DATES!

NCATS Director's Roundtables

Join us to hear about the latest happenings at NCATS and for an interactive discussion with Dr. Joni Rutter.



Public Roundtable



October 9, 2026



12:00—1:00 pm EDT



Roundtable with CTSA PIs and Deans



October 8, 2026



1:00—2:00 pm EDT

**Invitations sent by email*





OVERCOMING BARRIERS TO WOMEN'S HEALTH RESEARCH WORKING GROUP UPDATE

Vesna D. Garovic, MD, PhD

CTSA Steering Committee
September 14, 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: menopause, 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 CTSA's 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

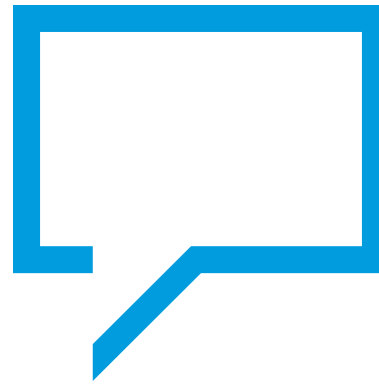
Continuing Collaboration

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





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Presenter: Eric Villain

Institute for Clinical and Translational Science at the University of California-Irvine

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Pod Spotlight-ICTS at UCI

University of New Mexico Health Sciences Clinical and Translational Science Center

University of California, San Francisco Clinical and Translational Science Institute

Colorado Clinical and Translational Sciences Institute

Utah Clinical & Translational Science Institute

University of Washington Institute of Translational Health Sciences

- **What can the CTSA network accomplish together that individual Hubs cannot?**

Should NCATS actively encourage thematic networks, shared data/AI capabilities, multicenter studies, and other cross-Hub platforms—or should these emerge organically?

The POD has discussed both theme-based networks and PI-driven collaborations, as well as the potential for real-world data/AI capabilities.

- **What should “CTSA impact” actually mean?**

Publications and grants? Trainees? Clinical implementation? Health outcomes? Policy? Lives touched?

The POD has repeatedly raised the need to define value through successful translation, lives touched, and policy impact.

- **What should the future role of N3C be within the CTSA network?**

How can we ensure that N3C remains a trusted, sustainable and genuinely useful platform for multicenter translational research while addressing governance, data ownership, access, and institutional concerns? The POD has raised questions about governance and access.



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Presenter: Fasiha Kanwal

Pod Spotlight: Baylor College of Medicine

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Pod Member Institutions

BCM / UH

Baylor College of
Medicine
University of Houston

Consortium for
**TRANSLATIONAL &
PRECISION HEALTH**



Pod Lead

UK

University of
Kentucky



Center for Clinical and
Translational Science

CCTST

UC

University of
Cincinnati

CCTST | Center for Clinical
& Translational
Science & Training
Ideas to Impact — Faster. Together.

CCTST

UAB

University of Alabama
at Birmingham



CCTS

UTSW

UT Southwestern Medical Center

CTSA

BU

Boston University



Clinical & Translational Science Institute

CTSI

General approach to POD activities

A Continuous Learning System



Learning & sense making

Issues that surfaced at March, May, and July Pod meetings

01

Compliance Burden

ClinicalTrials.gov, RPPRs, training documentation — rising oversight, flat staffing (“the year of compliance”).

02

Informatics Fragmentation

ENACT vs. TriNetX vs. N3C vs. Cosmos: hubs choose by convenience (not fit)

03

Cost-Sharing Transition

Moving from free services to chargeback models without shutting out early-career investigators.

04

Pilot Program Design

Defining “translational science” for applicants and reviewers

Convergent practices emerging across hubs

Cost-Sharing Convergence

Hubs are independently arriving at similar solutions: institutionally supported “extended support” pools

Two-Stage Pilot Review

LOI → full proposal, developed independently at multiple hubs, now shared as best practice for teaching “translational science” before formal review.

EAB Redesign

Cincinnati’s model — cut presentation time, maximize discussion

RPN Workshops (Boston University)

Peer-led CRP training practice that scaled into a two-year national working group.

Next Steps: Converting learning loops into practice

1. Hub Spotlight Rotation

Every meeting one hub presents what they tried, what happened, and what another hub could copy

1 BCM/UH

2 University of Kentucky

3 University of Cincinnati

4 UAB

5 UT Southwestern

6 Boston University

2. Issue Capture & Escalation

1

Capture

Shared backlog, open between meetings — any hub can add an issue anytime.

2

Prioritize

Quick pass before each meeting; top 1–2 items get discussion time.

3

Track Status

New → Being Worked → Escalated.

4

Escalate

Unresolved → routed to CCOS/NCATS

Question for other PODS

Our approach



What are other PODs learning about how to do this well?

Capturing learning, spreading promising practices, closing the loop?

Next Meeting: September 22, 2026

In-Person prior to start of Fall Annual Program Meeting

Marriott Marquis Washington, DC

Meeting Location: Archives

Meeting Time: 1pm – 5pm ET

Agenda:

- Welcome
- N3C Overview
- N3C and CMS Data
- N3C Challenge
- Real World Data & AI Perspective
- Enterprise Committee Updates:
 - Integration Across the Lifespan
 - Workforce Development
 - Biostatistics, Biomedical Informatics and Data Science
 - Collaboration & Engagement
- Break and Group Photo
- Dissemination & Implementation Landscape Analysis and Discussion
- Operation TrialBlazer



**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.*