

Steering Committee Meeting

March 23, 2026
2:30-3:30pm ET

Agenda

Time	Topic	Speaker(s)
2:30pm – 2:40pm	Welcome - SC Survey Approvals	Michael Kurilla, Grace McComsey
2:40pm – 2:50pm	Pod Feedback	Chris Hartshorn
2:50pm – 3:10PM	WG Report Out: Catalyzing Impact on Health and Health Care through Effective Partnerships with Learning Health Systems	Leads: Cheryl Gatto, Lisa Welch Liaisons: Elmer Bernstam, Dan Ford
3:10pm – 3:30pm	Pod Spotlight: Dartmouth Clinical and Translational Science Institute	Steve Bernstein
3:30pm	Adjourn	Amanda Scott

Real-World Data Workforce Development Across the Translational Spectrum Survey Overview

- **Target Audience:** Biostatistics, Biomedical Informatics and Data Science Enterprise Committee, Workforce Development Enterprise Committee, and Administrators Group will be encouraged to share survey within their organization
- **Survey Length:** 90 questions; this survey takes approximately 15 minutes to complete.
- **Timeline:** Launch March 26, 2026, Close April 9, 2026
- **Purpose:** The survey's purpose is to identify the training needs of the CTSA community, inventory existing resources, and develop a Real-World Data (RWD) Training Maturity Model to guide organizations in advancing their maturity pathway
- **Revision History:** NCATS review/approval for Executive Order compliance on February 17, 2026. Review/approval of the final draft of the survey by the WG Survey Primary Lead on February 25, 2026.
- **Primary Lead for the Survey:** Anita Walden

SC Liaisons to WG: Mimi Kim, Eric Vilain

Recommendation: Revise and Resubmit

Terminology, structure, and assumptions are inconsistent and unclear (e.g., outdated use of "Translational Science," undefined acronyms, ambiguous matrices, and poorly specified questions), which will likely lead to unreliable and uninterpretable responses across a highly heterogeneous audience. As written, these design flaws risk producing data that cannot validly inform priorities or training needs, undermining the survey's stated purpose.

Overcoming Barriers to Women's Health Research Survey Overview

Phase 1

- **Phase 1 Target Audience:** Hub PIs, Hub Lead Administrators and Hub Informatics Leads
- **Survey Length:** 11 questions; this survey takes approximately 10 minutes
- **Timeline:** Launch April 13, 2026, Close April 27, 2026
- **Purpose is** to identify researchers and groups focusing on women's health-related conditions, including those that disproportionately affect women, present differently in women, or are exclusive to individuals assigned female at birth. By gathering this information, the survey aims to facilitate networking and collaboration opportunities across CTSA Hubs, enhancing research efforts and fostering partnerships in this critical area of study.
- **Revision history:** NCATS review/approval for Executive Order compliance on December 5, 2025. Review/approval of the final draft of the survey from the WG Survey Co-Leads on January 6, 2026.
- **WG Survey Co-Leads:** Dr. Enders and Dr. Garovic

Phase 2

- **Target Audience:** Targeted distribution to the names collected in the Phase 1 Survey
- **Survey Length:** 16 questions; this survey take approximately 15 minutes to complete.
- **Timeline:** Launch April 30, 2026, Close May 14, 2026
- **Purpose is** to identify researchers and groups focusing on women's health-related conditions, including those that disproportionately affect women, present differently in women, or are exclusive to individuals assigned female at birth. By gathering this information, the survey aims to facilitate networking and collaboration opportunities across CTSA Hubs, enhancing research efforts and fostering partnerships in this critical area of study.
- **Revision history:** NCATS review/approval for Executive Order compliance on December 5, 2025. Review/approval of the final draft of the survey from the WG Survey Co-Leads on January 6, 2026.
- **WG Survey Co-Leads:** Dr. Enders and Dr. Garovic

SC Liaisons to WG: Elizabeth Ofili, Mark Schleiss

Recommendation:

Pod Feedback

Chris Hartshorn

Pod Feedback Summary: January-February 2026

Total summaries submitted for January- February Pod meetings: 8

Overall Cross-Pod Themes:

- Across all eight Pods, there is a strong and consistent focus on compliance pressure, infrastructure sustainability, and adapting to evolving NIH/NCATS expectations amid growing uncertainty. Pods are grappling not only with how to scale compliance, data, and administrative support, but also with structural questions about access models, governance, and long-term positioning (e.g., membership frameworks) as funding timelines and review processes become less predictable. Together, the discussions reflect a network balancing rising oversight demands and operational complexity with the need for clearer guidance, sustainable models, and cross-hub coordination to reduce risk and duplication.
- **Three themes cut across nearly every Pod:**
 - Rising compliance and oversight expectations
 - Strain on data and informatics infrastructure
 - Need for clearer, more efficient institutional models (membership, cost sharing, centralized services)

Pod Feedback Summary: Jan - Feb 2026 cont.

Common Challenges Identified Across Pods:

1. Compliance Burden Is Increasing

- ClinicalTrials.gov registration and reporting is a growing risk area, with heightened scrutiny even for smaller or pilot studies.
- Oversight expectations are expanding beyond trials to include RPPRs, FFRs, training documentation, research security disclosures, & publication compliance.
- **Shared concern:** Institutions need earlier classification, tighter IRB coordination, better education, and more proactive monitoring — but these require staff time and funding that are not always available

2. Data & Informatics Infrastructure is Hard to Sustain

- ENACT: valuable but difficult to scale, especially for multi-institutional or smaller hubs.
- TriNetX: increasingly viewed as an alternative or complementary option, though cost and access remain issues.
- N3C: reactivation and long-term governance, security, and sustainability questions persist.
- There is broad agreement that current data tools are essential but resource-intensive, and not all hubs can support them equally.

3. Funding Delays and Financial Uncertainty

- Uncertainty around funding tiers and NIH process changes.
- Concerns that simplification efforts (e.g., changes to budget thresholds) may reduce the number of funded projects even as individual budgets increase.

Pod Feedback Summary: Jan - Feb 2026 cont.

Shared Action Areas/Emerging Practices:

While no single standardized solution emerged, Pods are converging on similar approaches:

- Centralized, high-touch models for compliance (e.g., ClinicalTrials.gov oversight tied closely to IRB processes).
- Clearer internal guidance on cost sharing, in-kind support, and institutional commitments to avoid audit or reporting risk.
- Early engagement with NIH Program Officers to navigate shifting policies and expectations.
- Peer sharing across Pods to reduce duplication of effort, particularly around compliance workflows and training

Q & A for Pod Reports: January/February 2026

- Any comments or questions related to Pod overview?
- Any questions to NCATS or SC from your January Pod meetings?
- SC / NCATS Feedback to bring to your Pods

LHS-CTSA Partnerships Working Group

Full title: Catalyzing Impact on Health and Health Care Through
Effective Partnerships with Learning Health Systems

Steering Committee Meeting
March 23, 2026

Co-Chairs

Lisa Welch, Tufts CTSI

Cheryl Gatto, Vanderbilt CTSA (VICTR)

Purpose

Facilitate **effective partnerships** between CTSA hubs & local learning health systems to **increase impact** on health & health care



Engagement

136 Participants

53 Organizations Represented

And growing!!!

TuftsMedicine

VANDERBILT UNIVERSITY
MEDICAL CENTER



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UNIVERSITY OF MICHIGAN

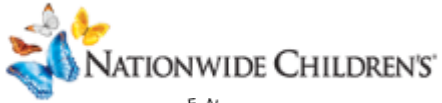


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ROCHESTER

UC San Diego



WashU

UT Southwestern
Medical Center



UCSF
University of California
San Francisco



CWRU

JOHNS HOPKINS
UNIVERSITY

THE UNIVERSITY OF
NEW MEXICO



University
at Buffalo
The State University
of New York

THE OHIO STATE UNIVERSITY

Cleveland Clinic

University of Colorado Anschutz

GEORGETOWN
UNIVERSITY

UMass Chan
MEDICAL SCHOOL

UVA Health



NIH National Center
for Advancing
Translational Sciences

pcori PATIENT-CENTERED OUTCOMES
RESEARCH INSTITUTE

UAB THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM.

Montefiore
HEALTH SYSTEM, INC.

Goals & Deliverables

Generalizable Landscape Assessment

Snapshot of current
CTSA-LHS configurations,
challenges, & lessons learned

Sustainable Community of Practice

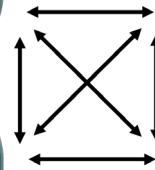
CTSA hubs, health systems,
and funding agencies

Partnership Success Stories

Impact on health and healthcare
Effective partnership
development pathways

Best Practice / Best Opportunity Resource

Guidance on avenues for CTSA
hubs to engage with and facilitate
learning health systems



Broad Dissemination

Widely accessible, searchable, user-friendly platform
Social media for community building
Manuscripts or white papers

Challenges and Strategies

Does the Steering Committee have recommendations on:

- Effective avenues to encourage additional health system operations experts to participate in the working group?

- A strategic and feasible leadership model to sustain the Community of Practice long term?



- Future directions for the CTSA Program related to learning health systems?



Thank you!

LHS-CTSA Partnerships Working Group Co-Chairs

Lisa Welch, PhD

Evaluation Director, Tufts Clinical and Translational Science Institute

Email: lisa.welch@tuftsmedicine.org

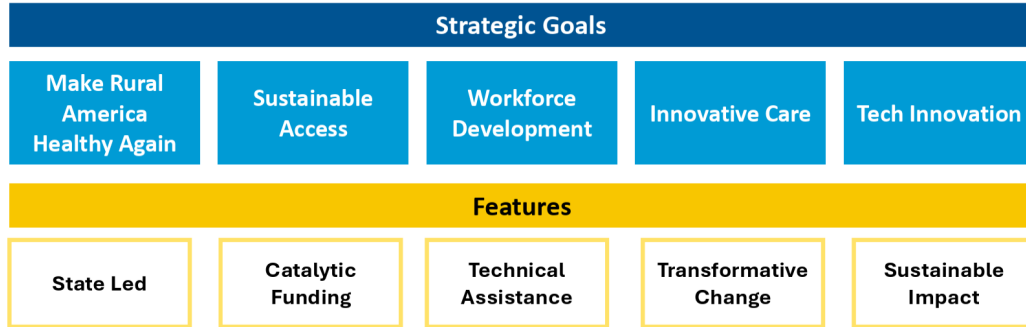
Cheryl Gatto, PhD, PMP

Directors Group, Vanderbilt Institute for Clinical and Translational Research (VICTR)

Operations Director, VICTR's Center for Learning Healthcare

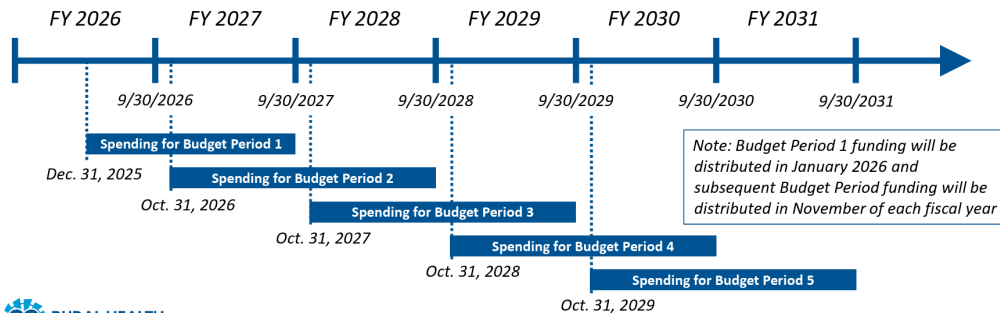
Email: cheryl.gatto@vumc.org

Rural Health Transformation Initiative and CTSAs: Steven Bernstein, MD – SYNERGY (Dartmouth CTSI)



Funding At A Glance

- \$25 billion distributed evenly among 50 States
- \$25 billion allocated based on rural factors, application initiatives, state policies, and quality of application



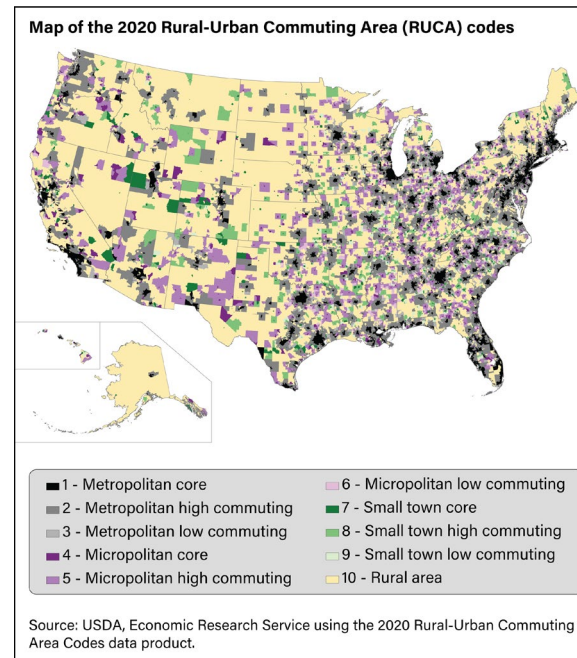
RHT Program Funding Scope

Use funding to pay for...

- ✓ Transformation of care delivery
- ✓ Improved access to, quality of, and cost of healthcare in rural America
- ✓ Expanded or enhanced services but not duplicate programs
- ✓ Technological & infrastructure investments and startup costs that will have sustainable impact beyond the end of the program

Do not use funding to pay for...

- ✗ New construction
- ✗ Clinical services that duplicate billable services and/or attempt to change payment amounts of existing fee schedules
- ✗ Other specified limitations outlined in the NOFO



Potential CTSA Opportunities

- Program evaluation
- Community engagement
- Dissemination/implementation of programs
- Digital health
- Workforce development
- Partnerships w/health systems, FQHCs, CBOs, etc.
- CORES, land grant CTSAs

<https://www.cms.gov/priorities/rural-health-transformation-rht-program/overview>

Next Meeting: April 13, 2026

Agenda

- NIH Priorities discussion in preparation for Fall Annual Meeting
- K and T Consortium Group Charter Review
- Pod Spotlight: MI Institute for Clinical & Health Research

**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.*

