



CTSA Coordination,
Communication, &
Operations Support

September 22, 2026

1:00pm – 5:00PM ET

Marriott Marquis Washington, DC

Steering Committee Meeting

digital
Infuzion® Deloitte.



Agenda

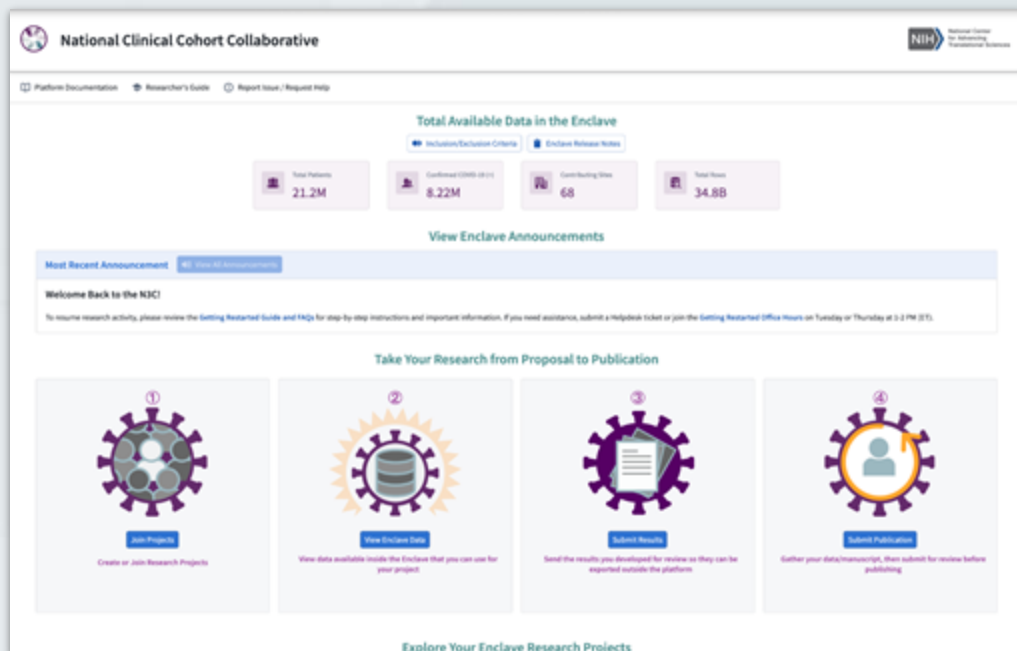
Time	Topic	Speaker(s)
1:00pm – 1:15pm	Welcome	Michael Kurilla Grace McComsey
1:15pm – 1:45pm	N3C Overview N3C and CMS Data N3C Challenge	Nathan Hotaling Andrew Kelly Christopher Hartshorn
1:45pm – 2:15pm	Real World Data & AI Perspective	Joni Rutter & Susan Gregurick (virtual)
2:15pm – 3:15pm	Enterprise Committee Updates: • Integration Across the Lifespan • Workforce Development • Biostatistics, Biomedical Informatics and Data Science • Collaboration & Engagement	Mark Schleiss Marisa Spann Elmer Bernstam Sarah Wiehe
3:15pm – 3:45pm	Break and Group Photo	
3:45pm – 4:00pm	Dissemination & Implementation Landscape Analysis and Discussion	Audie Atienza
4:00pm – 5:00pm	Operation TrialBlazer	Presenter: Joni Rutter Discussants: Scott Steele (FDA), Willy Chertman (HHS); Barbara Bierer (MRCT/Harvard/SMARIRB)

N3C Overview: Nathan Hotaling
NRC and CMS Data: Andrew Kelly
N3C Challenge: Christopher Hartshorn

1:15pm – 1:45pm

NCATS

COLLABORATE. INNOVATE. ACCELERATE.



Discover the N3C: Unlocking Real-World Data to Accelerate Translational Impact

2026 Fall CTSA Meeting

Nathan Hotaling, Ph.D., Andy Kelly, MBA, Chris Hartshorn, Ph.D.



NIH National Center
for Advancing
Translational Sciences

What is the N3C?



Discover the National Clinical Cohort Collaborative (N3C)

<https://n3c.ncats.nih.gov>



Secure.



Trusted.



Collaborative.



2020-2023 - NCATS U24 TR002306, Melissa Haendel (UNC) & Team
2023-2024 - Contract # 75N95023D00001, Melissa Haendel (UNC) & Team

2024-2025 - Contract # 75N95024F00013, Axle Informatics & Team
2025-2026 - Contract # 75N95025F00079, Axle Informatics & Team

[Full N3C Community
Acknowledgement List](#)



[Full Code Contribution
Attribution List](#)



[Click for Video](#)



NIH National Center
for Advancing
Translational Sciences

N3C is a national real-world data ecosystem

Data, governance, infrastructure, and community working together to accelerate translational research

N3C translates health data into health solutions.



Distinctive data

National Scale Harmonized EHR, mortality, claims, geospatial, social, and environmental data with the ability to link approved clinical datasets.



Governed access

Secure access, standardized agreements, transparent review, and collaborative analytical workspaces.



National community

Institutions, investigators, methods experts, and reusable knowledge working at national scale.



Faster, more rigorous, more reproducible research

A shared national path from
research question to
evidence and impact.



Value to the Research Community

N3C can create institutional, scientific, and public value—not simply provide access to a platform



CTSA Hubs & Partners

National reach, lower infrastructure burden, shared governance, no-cost training, and clearer visibility into participation and impact.



Data contributors

Extend the research value of local data, contribute to national evidence, raise visibility, view new N3C project proposals, and help shape future data and platform capabilities.



Investigators & programs

Ask richer questions, reduce startup friction, collaborate securely across institutions, and reuse validated methods and analytic assets.



Patients & communities

Generate more representative evidence, strengthen the public return on existing health data, and support better health and care.

For CTSA, the strongest value proposition is a shared path from institutional participation to translational impact.



Value to Data Contributing Sites

Contributing to the national research community isn't the only value



Data quality and feedback

- Data quality scorecards, real-time feedback on data schema/format
- Survey for key comparisons of their data to other sites (anonymous).



Cleaned data back

- Returned cleaned, harmonized, and standardized OMOP data.
- USCDI compliant FHIR (coming in 2027)



Workspace for just your data?

- Just your site's data cleaned and harmonized to OMOP
- Linked to CMS, geospatial, mortality, etc.
- Separate legal agreement needed == time



We want to hear from you!

For CTSAs, the strongest value proposition is a shared path from institutional participation to translational impact.



Value to the Researchers - Speed

Build Your Own 80+ weeks (20+ months)

Platform and storage costs

Large staff needed

Less reproducible research



Other Platforms 28+ weeks

Platform/compute/data fees

Linked data harmonization

Less reproducible research



With N3C ~8 weeks

Free platform/compute/data

Linked data clean & harmonized

Built in reproducibility



Value to the Researchers - Harmonized Data

Securing a comprehensive, multi-dimensional view of health through deeply integrated data linkages

Category	Examples	Sources and Variables
Claims & Patient	CMS + Mortality Data	6 Sources & ~8000 Variables
Population Insights	American Community Survey + Environmental Justice Index + Landscan + etc.	5 Sources & 85 Variables
Environmental Exposures	Air Quality & Climate + Hazards & Infrastructure + Water/Terrain + etc.	30 Sources & 233 Variables

All datasets are cleaned, harmonized, modeled, and research-ready from Day 1 of access to a workspace



N3C + CMS Chronic Conditions Warehouse

N3C + CMS

N3C is establishing a direct linkage to CMS claims via the Chronic Conditions Warehouse.

Both Medicare and Medicaid Data will be available

Brought to you in the same secure enclave that researchers are already working in

Value Adds, Done for You

Get straight to research without the data wrangling problem

Access: Same N3C DUA, no separate ResDAC process or per site costs

Integration: Harmonized to OMOP alongside your EHR data



N3C is already delivering value across the CTSA community

Participation, publications, training, and collaboration provide a strong foundation for the next phase

CTSA REACH

2,000+ CTSA-affiliated
N3C members

of 5,600 total N3C members

SCHOLARSHIP

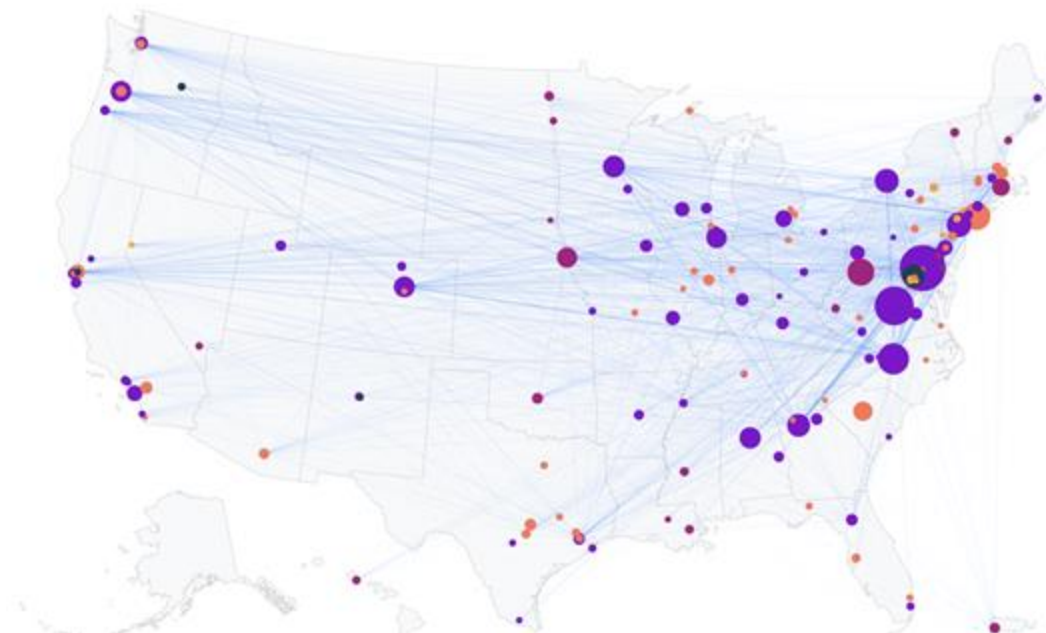
300+ Publications with
CTSA authors

WORKFORCE

100+ CTSA clinical
and data
scientists trained

A national collaboration network

Connections among N3C members and institutions across the United States



N3C Academy: A no-cost resource for CTSA Hubs & Partners

Flexible learning and synthetic-data practice can strengthen T-/K- awardee, fellowship, workforce, and faculty development programs



Open learning

Courses, tutorials, and the Researcher's Guide build core skills in N3C, RWD, OMOP, and health AI.



Hands-on practice

Synthetic datasets support exercises, workshops, and model development without real patient data.



Program-ready resources

Reusable code, concept sets, and shareable materials can be adapted for local learners.



Research pathways

Help faculty and trainees progress from foundational learning to responsible, collaborative RWE research.

Explore N3C Academy: n3c.ncats.nih.gov/education



N3C in 2027: Stronger safeguards, greater institutional control

Planned enhancements strengthen trust, transparency, readiness, and responsible use.



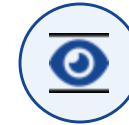
Multilayer safeguards

Stronger separation, monitoring, minimum-necessary data, controlled results release, and secure project closeout.



Institutional controls

Clear institutional roles, project visibility, review points, and contributor choices throughout the research lifecycle.



Greater transparency

Self-service status, dashboards, notifications, documentation, and clearer public information about approved work.



No-cost N3C Academy resources

Training, tutorials, synthetic-data practice, and reusable materials to help CTSA programs prepare faculty, fellows, trainees, and staff.



Transition to NIH CADR standards

The renewed pathway calls for new institutional agreements and registration aligned with NIH Controlled-Access Data Repository requirements.

For CTSAs: stronger trust, clearer oversight, and a more consistent path to approved research.

Planned 2027 features, agreement language, and implementation sequencing are subject to NCATS approval.



N3C Orbit: the institutional front door

Register, manage people and projects, and access self-service dashboards and documentation.



Institutional registration

Create the organization profile, identify institutional officials, and establish verified points of contact.



People & roles

Maintain affiliated personnel, officials, PIs, and project team roles in one place.



Projects & approvals

Track requests, institutional reviews, project personnel, approvals, and current status.



Dashboards & documentation

Access agreement status, activity views, notifications, forms, FAQs, and support documentation.

Get ready now: Create your institutional profile in N3C Orbit
orbit.n3c.ncats.nih.gov

Specific dashboard and documentation capabilities will roll out in phases.



NIH National Center
for Advancing
Translational Sciences

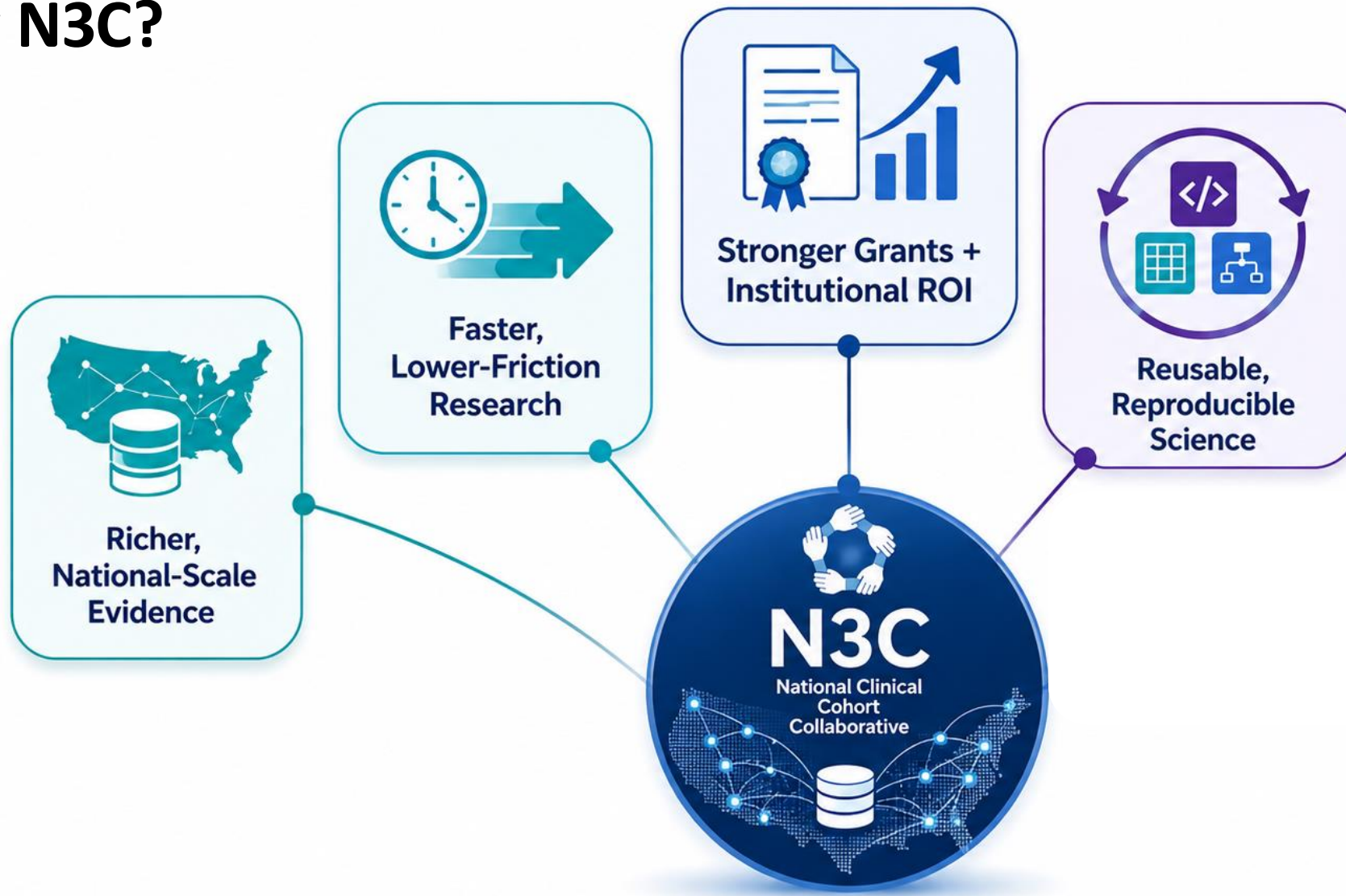
Real-world Evidence Innovation Challenge

CTSA Fall Meeting: September 2026

Christopher M. Hartshorn, PhD

*Acting Chief, CTSA Program Branch, Division of Clinical Innovation (DCI),
NCATS*

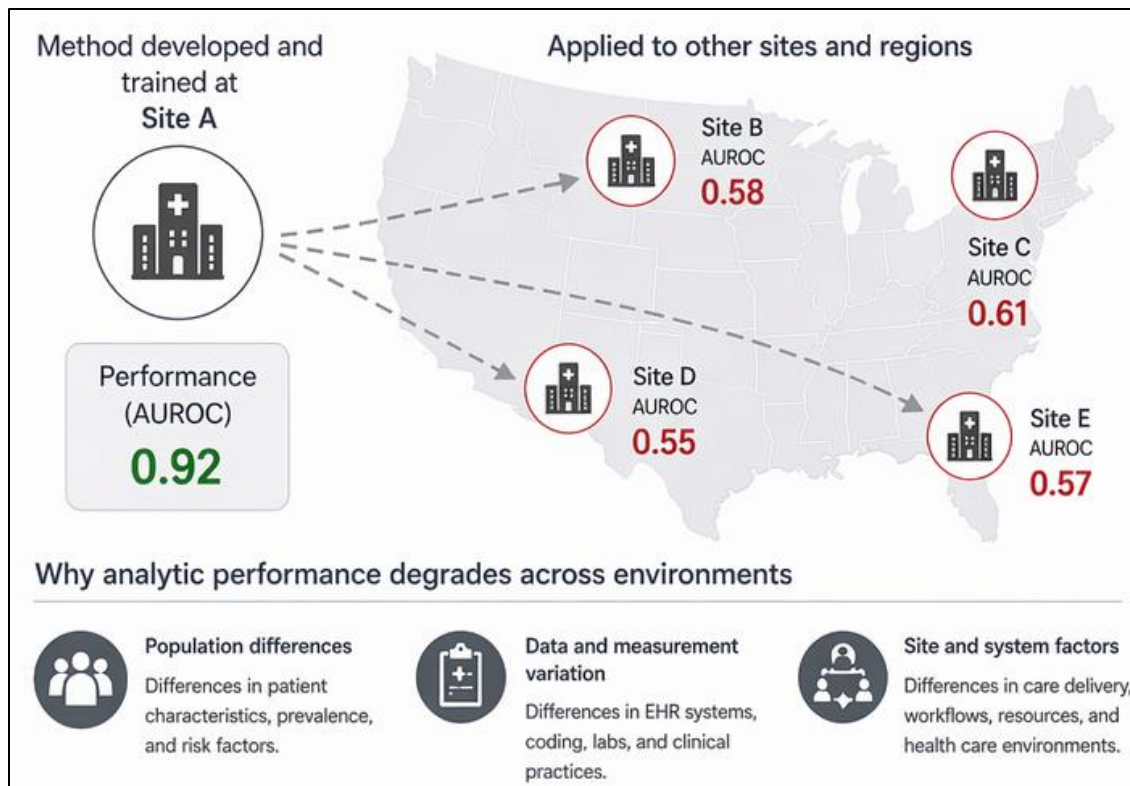
Why N3C?



Why N3C?



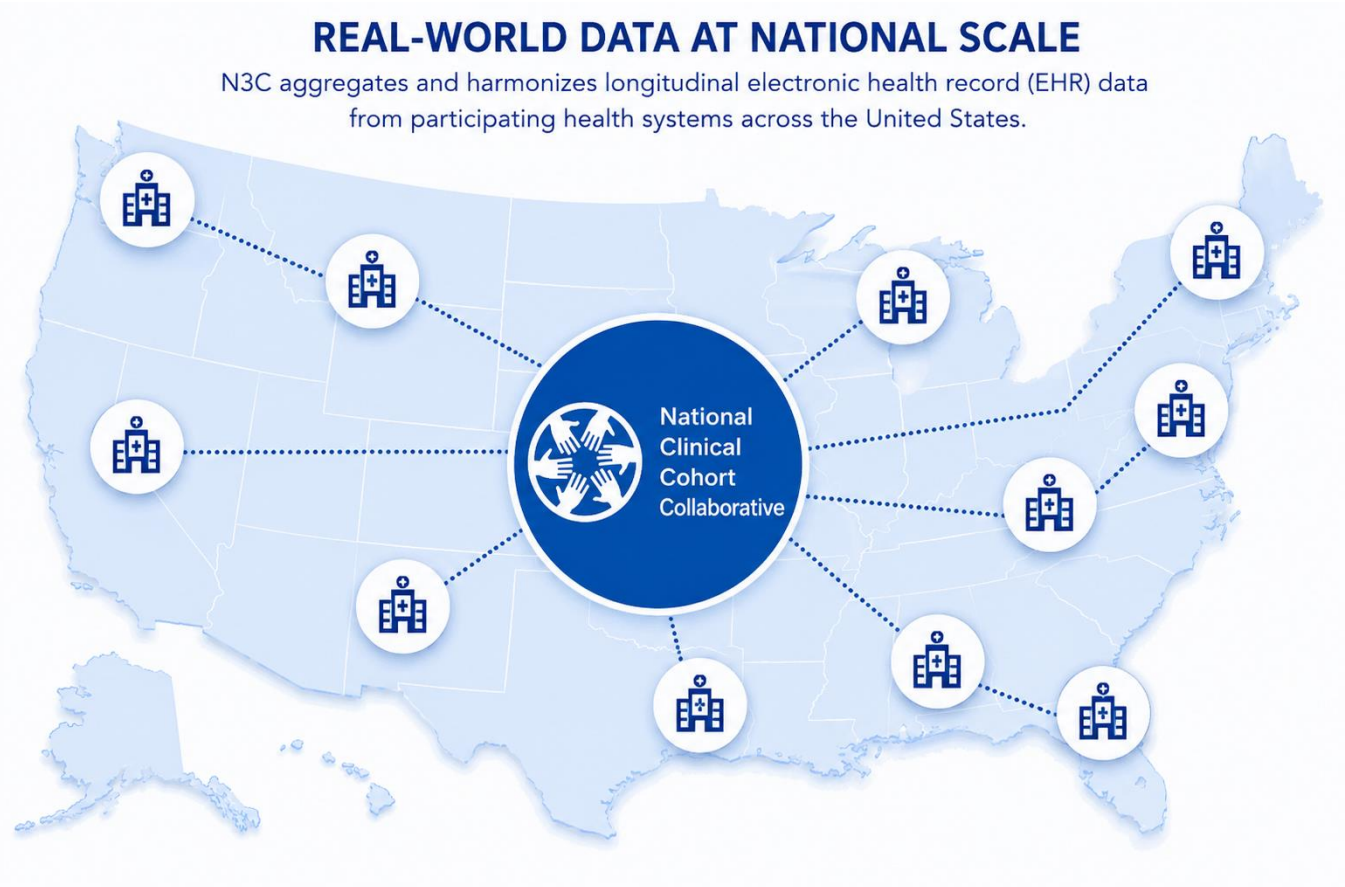
Background: Clinical and Translational *Problem*



	Development (Local Optimization)	Methods capture local patterns in data, not generalizable relationships. High performance in development, low performance in the real world.
	Limited External Validation	External validation across sites is often limited or not done. Results look good on paper, but fail in new settings.
	Deployment in New Environments	Methods deployed in new environments underperform. More overrides, more alerts ignored, less clinical benefit.
	Impact at Scale	Inconsistent performance limits scalability and return on investment. Hard to improve outcomes at scale.

Analytic models developed in one environment rarely demonstrate stable, reproducible performance across health systems and are rarely validated at scale. As a result, findings that appear promising in development, often fail to produce reliable evidence, or consistent impact, in real-world clinical and translational settings

Clinical and Translational Opportunity: *N3C as a National Proving Ground of Generalizability*



NATIONAL VALIDATION ENVIRONMENT (PROVING GROUND FOR GENERALIZABILITY)



Multi-Source Real-World Data

EHR, claims (CMS/Medicaid), registries, imaging, mortality, and public datasets enable comprehensive, longitudinal analyses.



National Scale

Aggregates data from health systems across the U.S., representing variation in populations, practices, and data capture.



Real-World Variation

Captures differences in patients, care delivery, workflows, and data characteristics across settings.



Direct Measurement of Generalizability

Enables systematic, repeatable evaluation across many independent health systems within a single, governed platform.



Foundation for Trustworthy Evidence

Provides the infrastructure to establish validated benchmarks that drive confidence in real-world analytics and decision-making.

Leverage N3C as a national proving ground for analytic performance, enabling validated benchmarks and reliable real-world evidence generation at scale.



National Center
for Advancing
Translational Sciences

N3C Real-world Evidence Innovation Challenge

Builds on existing infrastructure (CTSA + N3C)

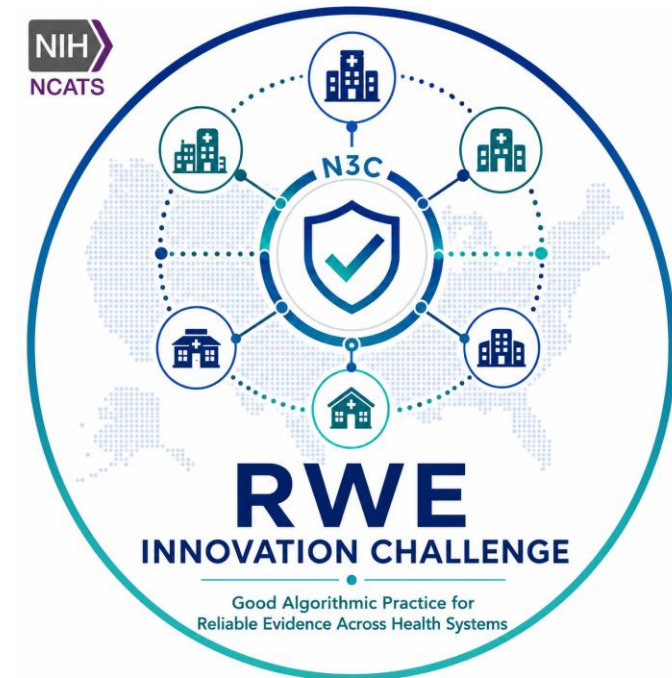
No new platform required; structured as a **two**-stage Challenge Prize competition; validation conducted within the secure N3C multi-site environment

Directly targets the core translational bottleneck of analytics that aren't reliable across sites

Will help establish national standards for analytic performance testing and *Good Algorithmic Practice* (e.g., establish measurable expectations for reproducibility, transportability, and stability, across real-world environments)

Shifts from the traditional data-challenge model

Rewards validated model reliability across independent real-world sites (*aka* external validation) versus model novelty and performance to a single data set



NCATS

COLLABORATE. INNOVATE. ACCELERATE.

QUESTIONS?



NIH National Center
for Advancing
Translational Sciences



National Institutes of Health

Enabling a Real-World Data Network

Dr. Joni Rutter,

Director NCATS

Dr. Susan Gregurick,

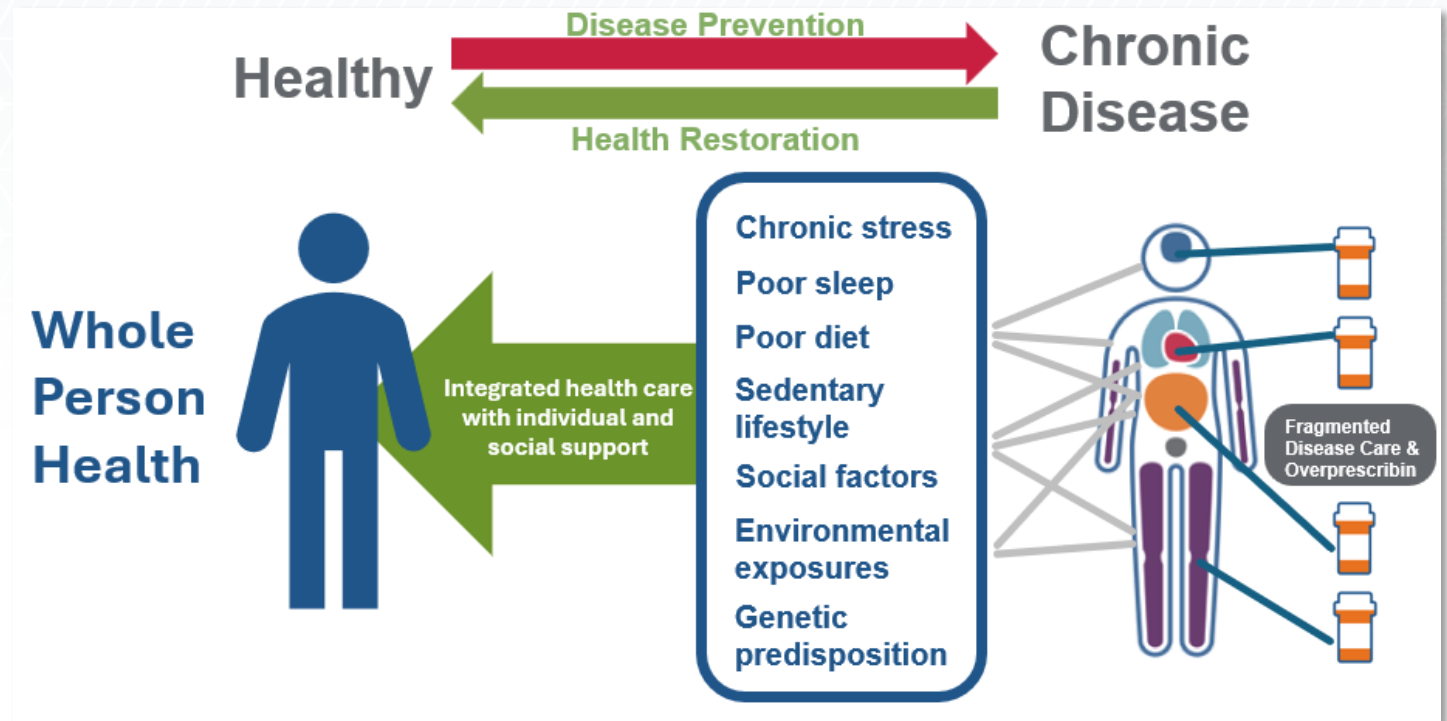
Associate Director for Data Science, NIH

CTSA Steering Committee, 09/22/2026

Strengthening the Foundations of Real-World Evidence

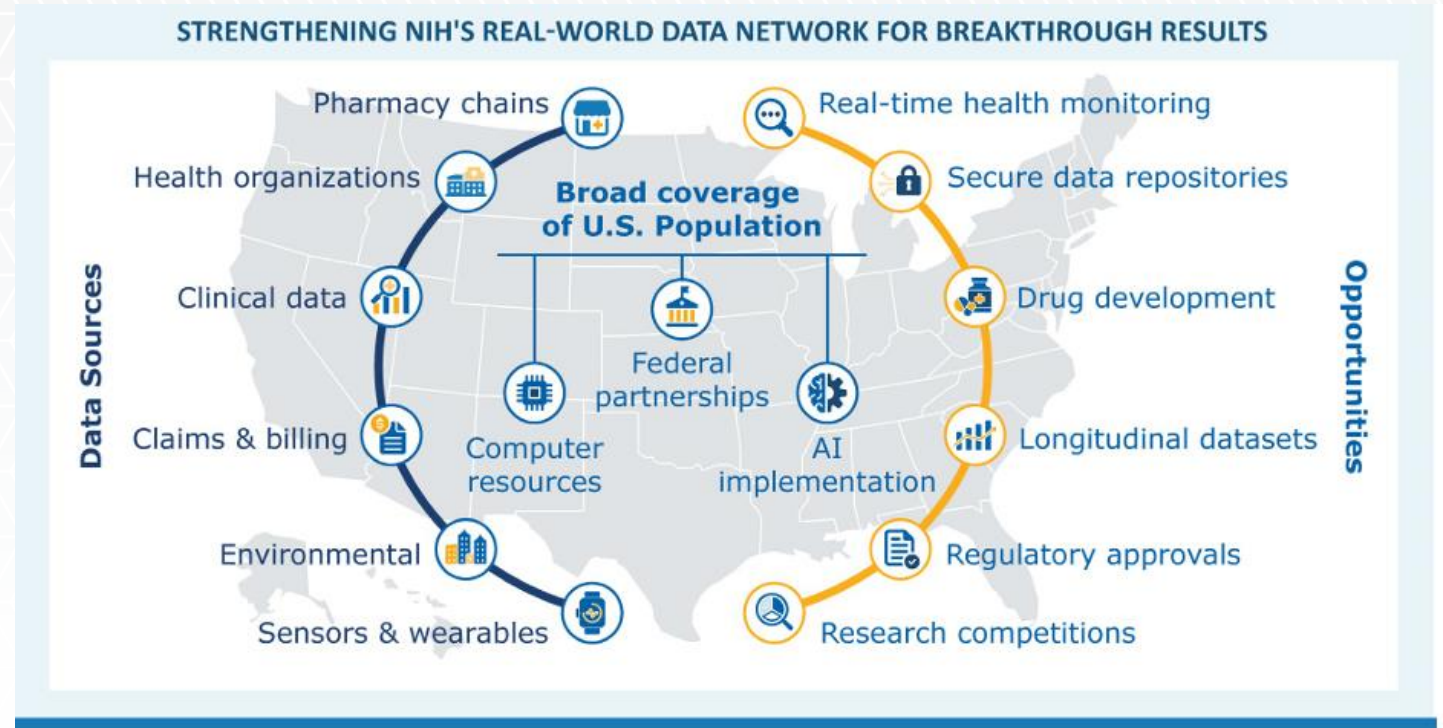
Transforming the quality, capture, sharing and use of health data to enable creation of a well-protected utility for improved health and health care outcomes as common interests of individuals and society.

Diverse sources include vital statistics, medical care, and patient-reported outcomes, commercial products, public health, and social services.



The Opportunity: Creating a Real- World Data Network

Data COUNTS enables the RWD Network, through N3C and other systems, to leverage high fidelity upstream datasets, streamlined technology, and simplified governance to enable research.



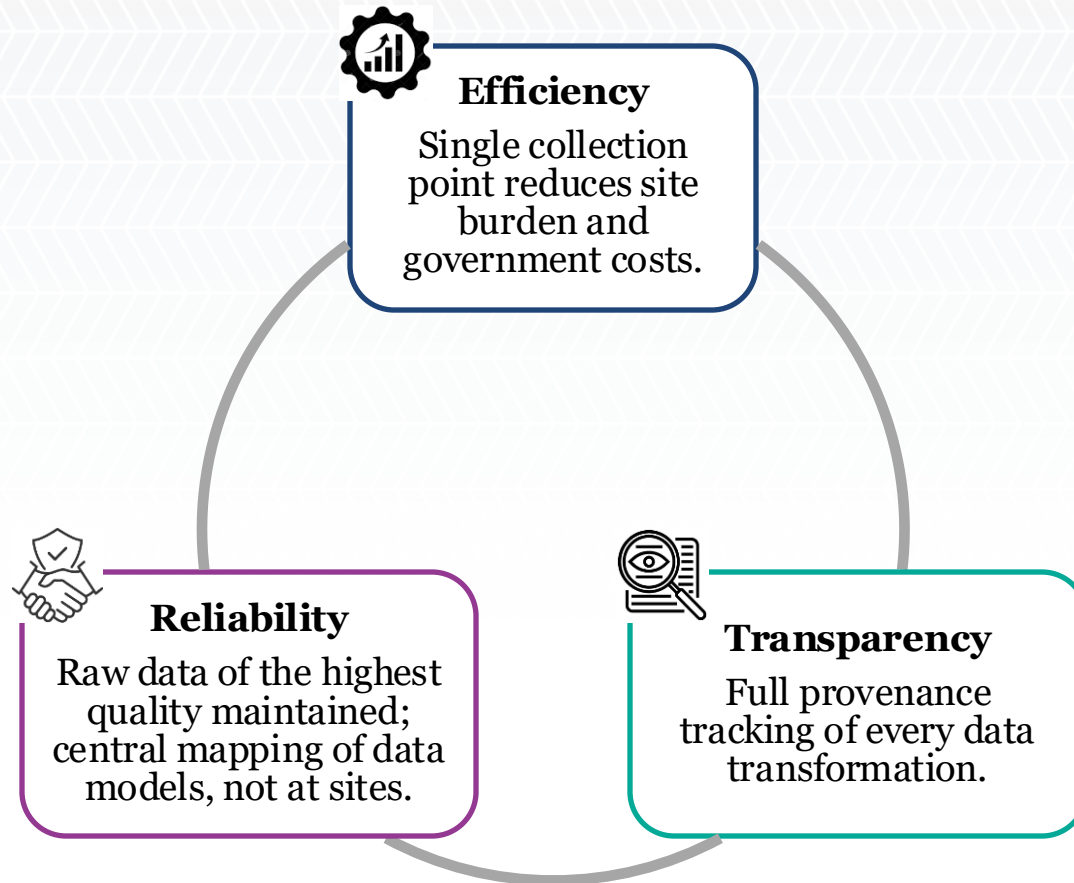
“Building upon investments in FY 2025 and 2026, NIH’s Real-World Data Platform will support an interoperable research infrastructure by harnessing AI to integrate real-world data from electronic health records, wearable sensors, genomics data, and environmental exposures. The FY 2027 budget includes \$60 million to scale and further operationalize the platform to support a broader range of diseases with scalable, privacy-preserving data sharing across NIH institutes and partners such as the CMS, the Food and Drug Administration, and the U.S. Department of Veterans Affairs.”

Issues with current data aggregation



- Data provenance is not maintained
- Data context is lost through transformation in ways that cannot be re-evaluated post-transformation
- On-site data formatting introduces information loss and potential bias when aggregating data from multiple sites
- Pooled data produced by this method are ineffective for training, validating and updating many desirable AI applications
- Does not allow patients to be aware of how their data are used

Data COUNTS™ Streamline and Improve collection of Health Data



In partnership with health systems, this initiative enables rapid collection of health data in line with "zero trust" data privacy principles and can be leveraged for multiple purposes, including post-market surveillance, large-scale population health research, and more.

Core Innovation:

Deploy AI and modern data technology at sites to enable fast querying and reuse of data

Data COUNTS™ enables fully reproducible, rapid research utilizing medical from data across USA

Research Question : Lupus-Voclosporin Study

Research Question: Characterize blood pressure changes in patients with Lupus initiating voclosporin.

Extraction counts: ~650 patient records from 3 sites in <2 weeks

Standard extraction:

- Clear medication identifier
- Structured BP measurements
- Defined SLE diagnosis codes
- Standard EHR workflow

Research Question 2: Dietary Supplements Study

Research Question: Characterize bone density changes (DXA T-scores) post-vitamin D for osteoporosis.

Extraction counts: ~40k patient records from 2 sites in <2 weeks

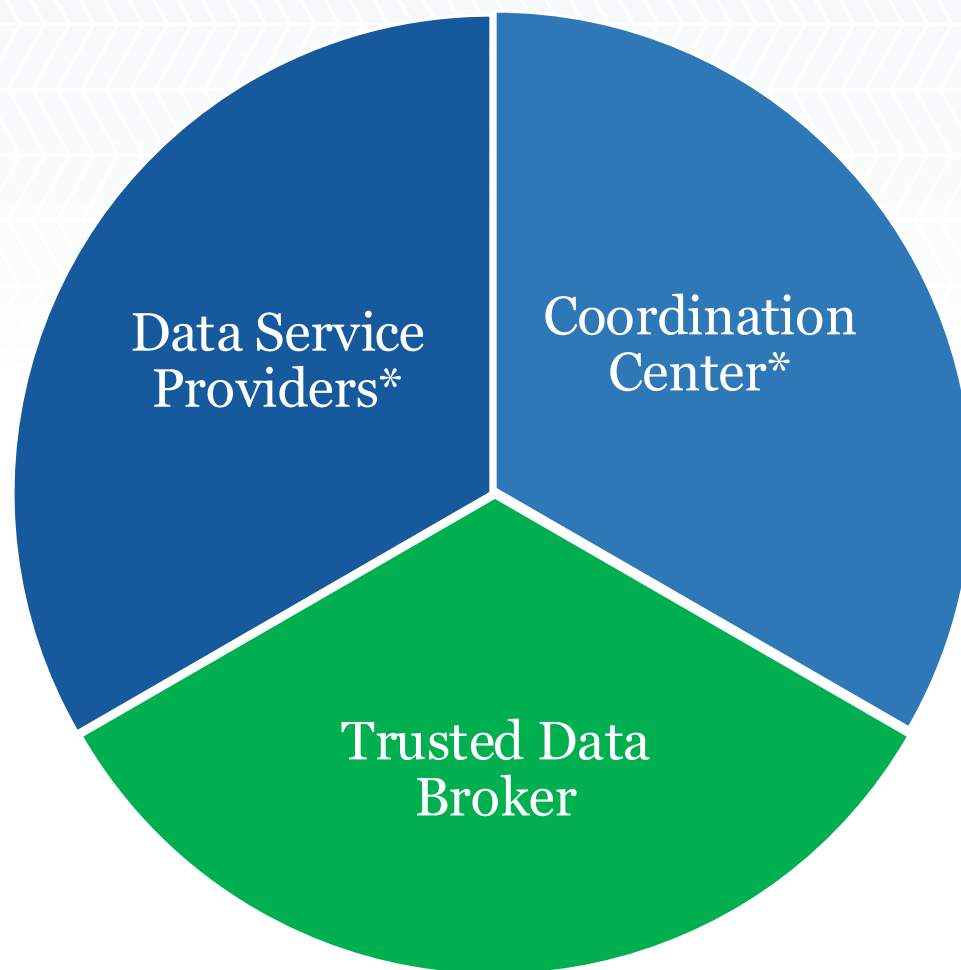
Complex extraction:

- Inconsistent supplement documentation
- Bone density scan data are often in unstructured clinical notes
- Variable Vitamin D doses/formulations
- Requires linking clinical, lab, patient data

Data COUNTS Advantage: Raw data with full provenance enables straightforward cohort identification and outcome tracking.

Data COUNTS Advantage: Raw data of diverse types can be extracted, including data from clinical notes.

Data COUNTS™ Team



Data COUNTS is a team effort between data technology teams, coordinators, and federal staff to enable research and healthcare partner goals

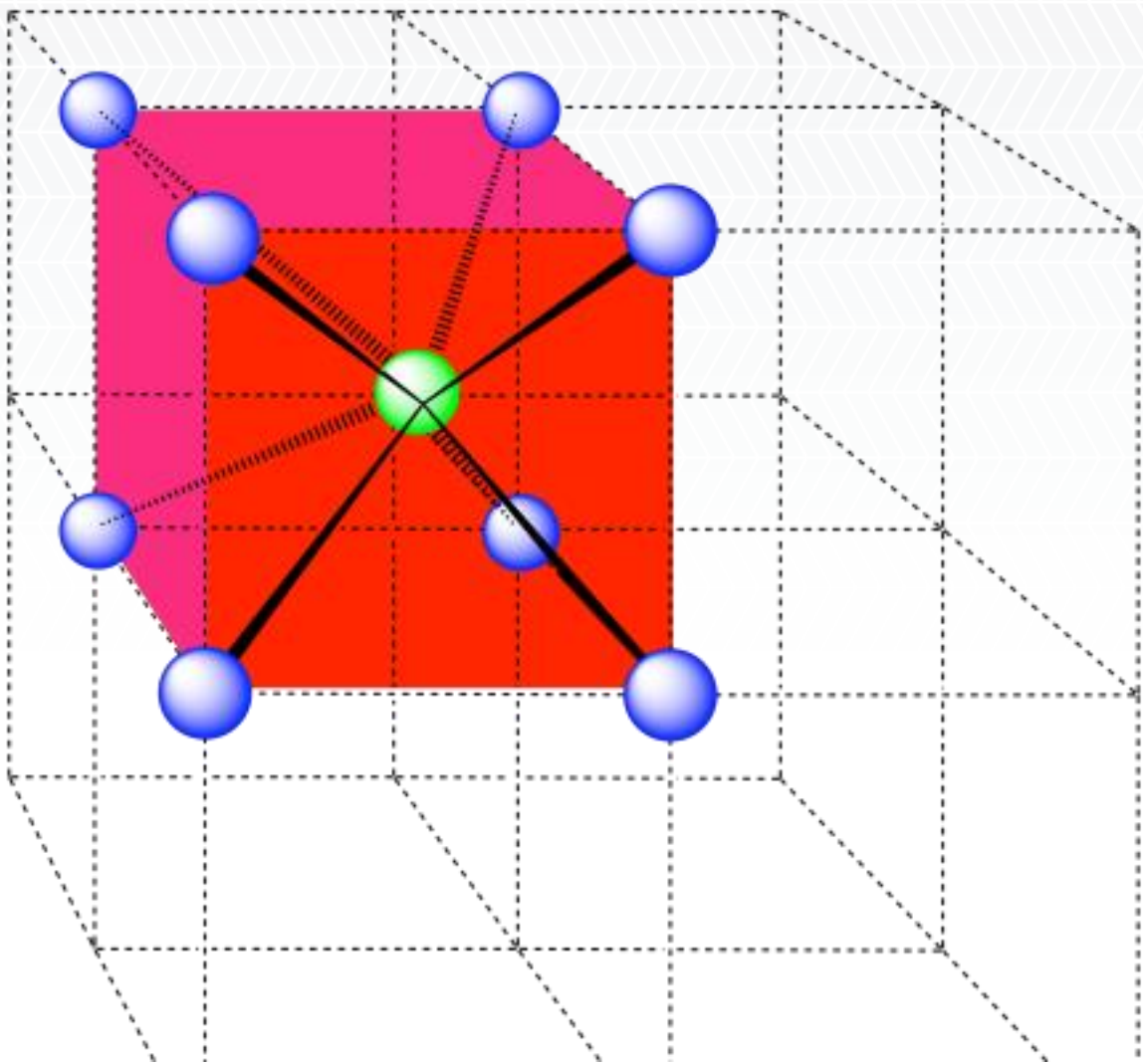
*Fall Solicitation for Data COUNTS Coordination Center and multiple Data Service Providers

RFI for Data COUNTS in SAM.GOV
(75N95C26R00005) **Due 9/21**

RFI TOPICS RELATED TO TECHNOLOGIES

- Leave Behind Technology that will provide real-time institution approved data extraction, fully provenanced.
- De-identification per 45 CFR §164.514(b): remove 18 direct identifiers, with data shifting capability specification
- PPRL tokenization capabilities
- Metadata preservation including permissions, and ontology fields (SNOMED CT, LOINC, ICD-10, RxNorm, UCUM, etc.)
- Initial data quality validation
- Attestation to HIPAA Security compliance, with security and audit logging capabilities
- TLS 1.2 minimum for data transit
- Technology training to healthcare partner institutions if needed and desired





- Assist in site readiness
- Support agreements processes
- Support partners and Data COUNTS Research Use Cases
- Enable long-term collaborative efforts
- Provide public facing information on program

**COORDINATION
EFFORT ACROSS DATA
COUNTS**

Trusted Data Broker

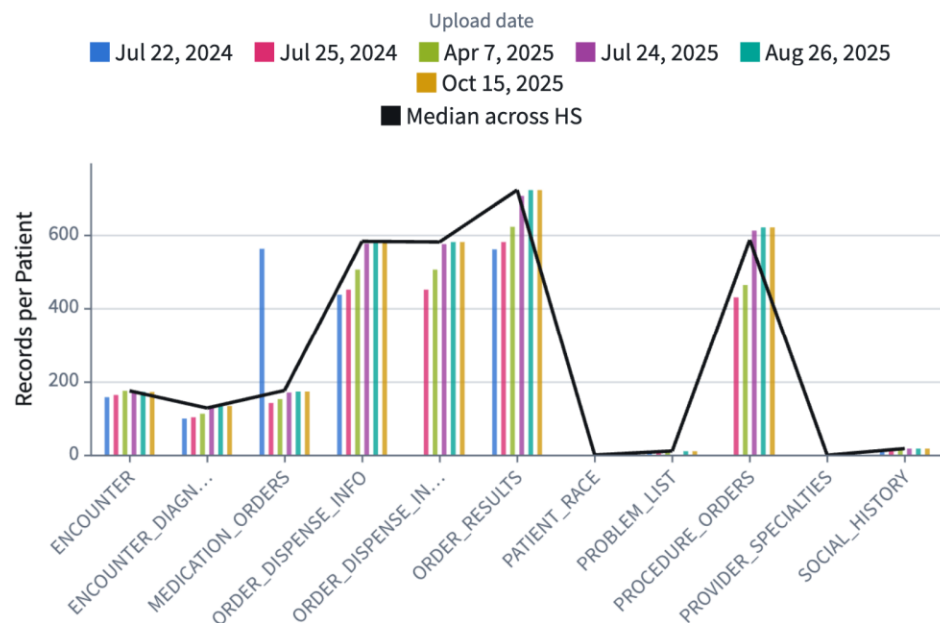


- Data ingestion and management
- Cybersecurity standards for clinical data
- Data quality check, enables data Improvements
- Data mapping and linkage, as needed
- Data provisioning for NIH Data Research Platforms
- Federal and Data COUNTS partner workspaces and tools

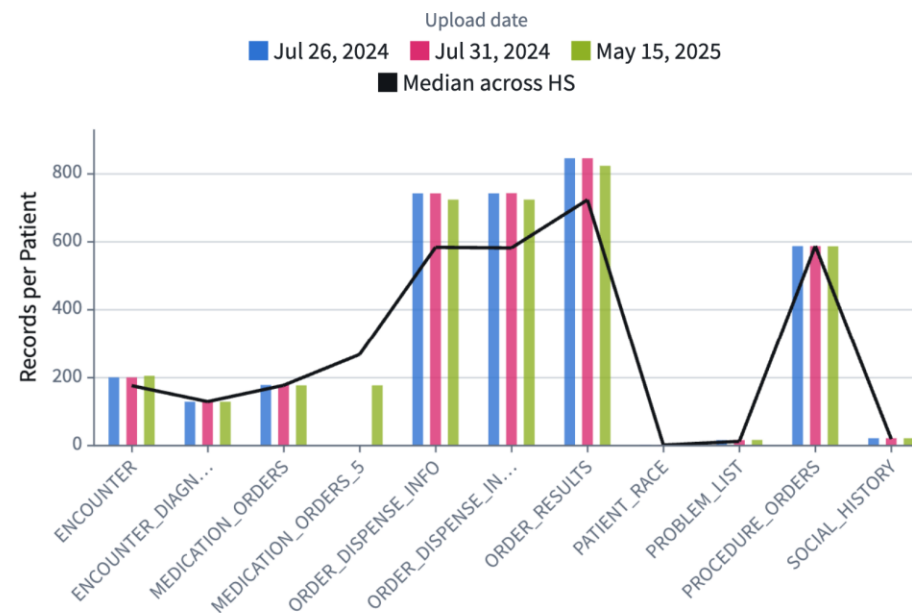
Example of data integration over time - *site data integration*

Site	Site data set for GLP-1 refreshed on 7 April (~36000 to ~43000 patients ; +8478 added; -1520 removed)
Data	Demonstrate the ability to manage and display data over time, across multiple sites
Quality	Spike on medication orders on 7/22/2024 illustrates that data from a healthcare site can have errors in formatting, as was the case with this site

University Health Institution



Community Hospital



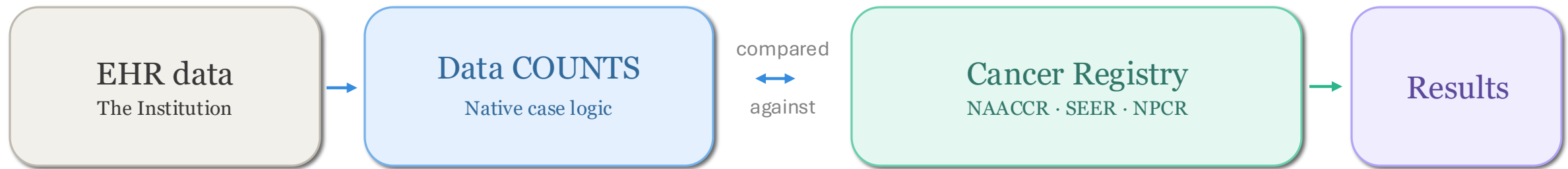
Example of validating NIH Data COUNTS for cancer case identification*

CAN IT FIND THE RIGHT CASES?

- Does Data COUNTS correctly flag newly diagnosed (incident) patients — without mislabeling prevalent or other-site cases?

CAN IT ABSTRACT DATA ACCURATELY?

- When Data COUNTS extracts elements like histology, primary site, and diagnosis date — how closely do those values match registry-quality abstractions?



Partnership: Data COUNTS and N3C



DataCOUNTS

The foundational EHR data collection engine that ensures **full provenance, traceability, and minimal data loss** directly from health systems



N3C

The analytical platform, **harmonizing and standardizing datasets** using a common data model, offering researchers a secure, well-proven collaborative environment to **accelerate discovery**



Research Communities

DataCOUNTS

Geospatial
Linked Data

Residential History
RUCA Codes
Environmental Justice
Environmental GIS
EPA & USDA Indices



Data Ingest



Census and
Zip Code
Mapping



Data Quality
Assessment



Geospatial
Data
Remediation

Health
Systems

EHR
Labs & Imaging
Patient Consents
Trial Data
PPRL tokens



De-ID, Patient
consent eval,
tokenize



Patient
Phenotype
Translation



Data Quality
Remediation
& Linkage



Release
management

N3C



Master Participant
Index, Master
Linkage Map,
Deduplication, Final
Risk Assessment



Data
Standard-
ization



Phenotype
development



Geospatial
Interpolation
& Integration



Data
Harmonization



NLP & AI
Enrichment



Data Quality
Assessment
& Control



Dynamic Tenants,
Researcher
Workbench, Logic
Liaison Templates,
Concept
Sets, Training, etc.

Linked CMS and Mortality Data

CTSA and CTR Pathways to provide data to N3C

DIRECT TO N3C

- Data Transfer Agreement options:
 - Option A: N3C Administered DAC Review (set once)
 - Option B: Preset Data Use Limitations (periodic updates)
 - Option C: Real Time Opt-Out (preset review cycles)

DATA COUNTS

- Partnership Agreement, similar to N3C DTA
- Institutions review each data research use case and approve datasets
- Includes N3C and other opportunities such as AllofUs, NCBD/NAACCR, CDC

Data COUNTS™ is Poised to Accelerate

- We work with healthcare provider sites to pull on-demand data over time and illustrate data quality challenges.
- All data is de-identified but fully provenanced with audits on all transactions.
- We can map data to standards AND illustrate the lossiness of mappings.
- We have improved data quality for *All of Us*, including richer data sets.
- We have developed a process to extract dietary supplements (Vit D) data from clinical notes and EMRs.
- **We have partnered with a major state cancer registry team to map and streamline their cancer reporting workflow from case finding through abstraction.**
- We are working with healthcare partners to streamline their workflow processes

UC Irvine

UK College of Medicine

UNMC™
Nebraska Medicine

Baylor
College of Medicine

TGH Tampa General Hospital

USF Health
Morsani College of Medicine

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

SANFORD
HEALTH

UND
UNIVERSITY OF
NORTH DAKOTA

UH University Hospitals
Cleveland Medical Center

THE OHIO STATE
UNIVERSITY
WEXNER MEDICAL CENTER

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.

AT THE FOREFRONT
UChicago Medicine
Comprehensive Cancer Center

Community Clinic

Community Clinic of
Northwest Arkansas FQHC
(CCNWA)

MetroHealth
Devoted to Hope, Health, and Humanity

The background is a dark blue gradient. Overlaid on this is a complex network of thin white lines connecting small white circular nodes. The nodes are scattered across the frame, with a higher density in the upper right and lower right areas, creating a sense of depth and connectivity.

Thank you!

What this looks like in practice

Programs translate principles into durable software, infrastructure and careers.

Research Software Excellence Initiative(s)



Innovation & best practices • community governance • reuse

RSE Career Award



recognition • career continuity • embedded engineering

Generalist Repo & Cloud Interop Initiatives



repositories • cloud interoperability • reusable infrastructure

Information Technology for Cancer Research (ITCR)



software for cancer research • sharing • sustainability

FAIR4RS + biomedical guidelines



metadata • licensing • versioning • interoperability

Sustainability is a collective property - not a single grant requirement.

A shared challenge needs a shared community

The opportunity for an international research-software community is to make good stewardship easier by default.

ALIGN

definitions, metadata,
licensing and FAIR practices
across funders and domains

CONNECT

researchers, RSEs, funders,
publishers, platforms and
industry around stewardship

SUSTAIN

people, communities and
shared infrastructure - not just
individual codebases

NIH is committed to learning with - and contributing to - this global community.

datascience.nih.gov • NIH Strategic Plan for Data Science

Software Best Practices

- ✓ Developing and Sharing software and code as “open source”
- ✓ Using a license when distributing code, for example through standard licenses approved by the [Open Source Initiative](#)
- ✓ Making my software citable and Acknowledging NIH support in software
- ✓ Restriction considerations
- ✓ Guidelines for research software for use in medical practice or clinical settings
- ✓ Checking software for security vulnerabilities
- ✓ Metadata that should be considered when releasing research software
- ✓ Documentation and Benchmarking the software

Enterprise Committee Updates:

- Integration Across the Lifespan- Mark Schleiss**
- Workforce Development: Marisa Spann**
- BIDS: Elmer Bernstam**
- Collaboration & Engagement: Sarah Wiehe**

2:15pm – 3:15pm

CTSA Integration Across the Lifespan Enterprise Committee: Report

Mark R. Schleiss, MD

Steering Committee Meeting

1:00 PM-5:00 PM



CLINICAL AND TRANSLATIONAL
SCIENCE INSTITUTE

UNIVERSITY OF MINNESOTA

Driven to DiscoverSM

IAL-EC 2026 Leadership Team



Elisabet Børsheim, PhD
Univ. of Arkansas for Medical Sciences



Barrett Bowling, MD, MSPH
Duke Clinical and Translational
Science Awards



Mark Schleiss, MD
University of Minnesota



Karen Wilson, MD, MPH
University of Rochester



Kristen Beavers, PhD, MPH, RD
Wake Forest University Health
Services



Jessica Lee, MD, MS, AGSF
University of Texas Health Science
Center at Houston



VJ Periyakoil, MD
Stanford University

- **NIH/NCATS Representative:** Gallya Gannot, DMD, PhD
- **TIN Representative:** Daniel Hanley, PhD
- **SC Representative:** Mark Schleiss, MD
- **CCOS Support:** Melissa Brady
- **Voting Members:** 66 Voting Members
- **Full Membership:** 148 Members

Mission & Goals

The Integration Across the Lifespan Enterprise Committee ensures translational science is integrated across its multiple phases and disciplines **within all populations' lifespans.**

Its goals are to:

1. Integrate translational science across all stages of life, with the ultimate goal of improving the health of all individuals.
2. Launch initiatives to investigate knowledge gaps in disease progression and treatment among special and complex populations.
3. Develop an integrated and cohesive approach to translational science that spans across all phases of research.



2026 Strategic Priorities

Goal 1: Optimize Lifespan EC monthly virtual meetings through improved speaker planning.

Deliberately plan and guide EC programming to ensure balanced representation across the life course:

- Strategically selecting and sequencing speakers to address all stages of the life course, with attention to gaps (e.g., middle age and transition periods).
- Applying a vertical (life stages) and horizontal (cross-cutting themes) framework for EC activities.
- Elevating understudied or under-addressed areas in lifespan and life-course research (e.g., engagement, retention/attrition, autonomy, vulnerable populations).
- Continuing to guide speakers with templated slides/structured prompts to ensure consistent attention to lifespan/life-course considerations.

Goal 2: Align in-person meetings and outputs to support large-scale dissemination of EC work.

Use EC meetings and activities to intentionally support high-quality dissemination of EC work. This includes:

- Completing and submitting the current conference paper.
- Intentionally planning the upcoming meeting:

1:00 PM ET

Integration Across the Lifespan EC Meeting

1:00 PM-3:00 PM

TIME	TOPIC	SPEAKER
1:00	Welcome & Opening Remarks	Elisabet Børsheim, PhD, University of Arkansas for Medical Sciences (Co-chair)
1:10	A Toolkit for investigators and People with Disability Experience (PWDE): Practical guidance to engage PWDE as members of research teams	Daniel Armstrong, PhD, University of Miami School of Medicine
1:15	Pediatric Clinical Trials Working Group	Karen Wilson, MD, MPH, University of Rochester
1:20	Rare Disease and an Evolving Regulatory Environment	Amy Comstock Rick, JD, Food and Drug Administration
1:45	Repairing DNA Damage to Reverse Vascular Aging in Progeria	Anahita Mojiri, PhD, Houston Methodist
2:10	Table Discussions / Networking	Barrett Bowling, MD, MSPH, Duke University (Co-chair)
2:40	Report-outs & Full-group Discussion	Barrett Bowling, All Attendees
2:55	Closing Remarks & Adjourn	Barrett Bowling

Take-home Points for Our Speakers

1. If not already included, which life stage(s) does your work primarily focus on or impact (prenatal, childhood, adolescence, adulthood, older adulthood)?
2. In what way does your work contribute to advancing lifespan/life course research?
3. What barriers and facilitators might researchers encounter when applying your findings across different life stages, and how could these be mitigated?
4. What is the key takeaway you want members of the Integration Across the Lifespan EC to remember?



Engagement + Follow-up

Please include one of the following questions at the start of your presentation and the other at the end.

1. What is one question where you would most value feedback from the Integration Across the Lifespan EC members?
2. Who do you like to collaborate with, why, and what is one clear next step for interested members?



Past Presentations - IAL

Date	Presenter	Presentation Title
September 23, 2025	Sharad Wadhwani	Addressing economic hardships to improve long-term outcomes for children after liver transplant
November 25, 2025	Sarah Urbut	Aladynoulli: A Bayesian Walkthrough the Lifespan
November 25, 2025	Janelle Liu	Foundations of Lifespan Health: How Prenatal Substance Exposure Shapes Early Brain Development
January 27, 2026	Michelle Grady	The Evaluating Life Course Stress Experience (ELSE) Scale: A Novel Age-Related Life Course Stress Screening Measure
March 24, 2026	Theresa Keegan, Julie Schweitzer	Retention and recruitment survey results
April 22, 2026	Uche Aneni	Leveraging digital technology for adolescent substance use prevention: risk prediction, intervention access and implementation strategies
June 24, 2026	Robert Steel	Ethical Considerations for Early Study Closures
July 28, 2026	Julie Heneghan	Mapping Life After the Pediatric ICU
September 9, 2026	Barrett Bowling	IAL conference paper: Using the 5Ts Across the Lifespan
October 28, 2026	Naomi George	ICU survivorship

Focus of past presentations: Heat map

Method / Focus	Infancy/Childhood/ Adolescence	Early Adulthood & Midlife	Later Life
Recruitment & Retention			
Technology / Digital Health			
Interventions			
Measurement / Screening			
Precision Medicine / Biomarkers			
Social Determinants			
Workforce Development / Training			
Life-course Modeling			

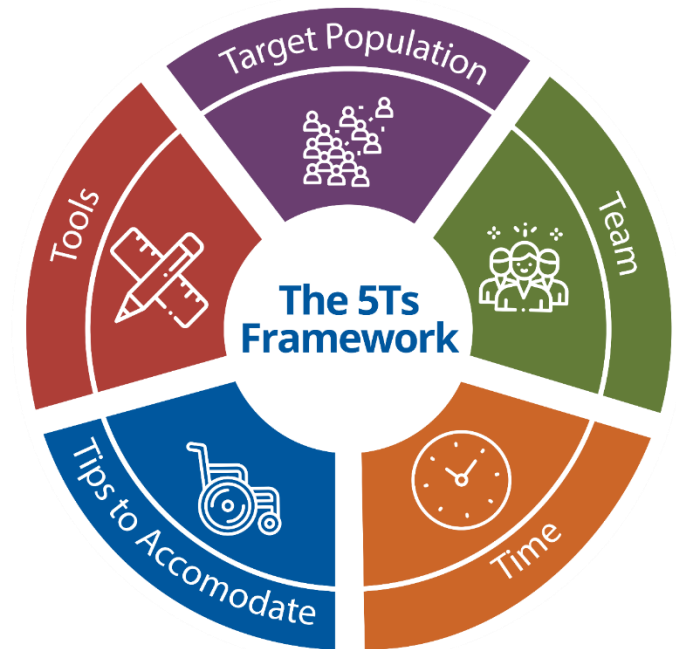
Legend: High coverage = Red (good) | Moderate = Yellow | Emerging = Green | Low = Gray (bad)

Progress Update: Using the 5Ts Across the Lifespan

We have been using the 2025 Fall In-person Meeting to discuss barriers to research representation across the lifespan

KEY FINDINGS:

- Recruitment challenges span the lifespan but differ by life stage
- 5Ts framework (Target population, Team, Time, Tips to accommodate, Tools) is helpful for organizing themes
- Cross-cutting themes:
 - (1) Trust and engagement are foundational across all age groups
 - (2) Structural barriers (time, transportation, caregiving) are pervasive
 - (3) Workforce and infrastructure gaps limit research across the lifespan



Find out more
about 5Ts
supported by
Duke CTSI



Implications and Next Steps

Implications

- Research teams should shift toward lifespan-informed recruitment strategies
- Expand research teams to include community and intergenerational partners
- Reduce burden and increase flexibility for participants
- Consider both low- and high-tech engagement approaches

Next steps

- Finalize and submit conference manuscript
- Add these findings to 5Tsframework.duke.edu
- Consider workforce training to support representation and engagement across the lifespan

Active Working Groups

Engaging Individuals with Disability in the Research Process

Chair: Daniel Armstrong, PhD, University of Miami School of Medicine

- **Purpose:** This Working Group's purpose is to provide the context and strategies for investigators to actively engage with the lived experience community in the conduct of research and individuals with lived experience to contribute to the research process. To accomplish this, we focus on outcomes that both contribute to scientific knowledge and are meaningful to the disability community and individuals in that community and help address factors that limit meaningful scientific progress.
- **Goals:**
 1. Provide the research community with knowledge, resources, and tools that will facilitate engagement of individuals with lived experience in the conduct of research.
 2. Provide the research community with a process that enhances the quality of scientific outcomes and meaningfulness of the research to the community that is the focus of the research.
- **Deliverables:** Toolkit, Publication

Pediatric Clinical Trials

Chairs: Karen Wilson, MD, MPH, University of Rochester & Mark Schleiss, MD, University of Minnesota

- **Purpose:** 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:** Read the WG's goals on the [CCOS website](#).
- **Deliverables:** Survey, Scoping Review & Manuscript, Virtual Meeting, Toolkit



CLINICAL AND TRANSLATIONAL
SCIENCE INSTITUTE

UNIVERSITY OF MINNESOTA
Driven to DiscoverSM

Scoping Review Updates

- Change in Co-lead
- Abstract review is complete
- Full-text review taking place 7/21 – 10/1
 - 43 Done
 - 28 One vote
 - 41 Conflicts
 - 458 left to review
 - 28 volunteers expressed interest in participating



Dr. Nora Singer



Dr. Susanna McColley

Julia Heneghan	35	
Stephanie Rolsma	27	
Nadia Sneed	26	
Jeffrey Yaeger	19	
Gurinder Kumar	18	
Giulia Adele Dinicola	15	
Elizabeth Thompson	13	
Katherine McDonell	11	
Aspen Streetman	10	
Karen Wilson	9	
Sohye Kim	7	
Mitchell Ladd	3	

Survey Updates

- Steering Committee Feedback
 - The survey opens saying it will take 30 min to complete. I believe it will take several hours of institutional staff time to collect this information with accuracy.
 - Most questions would benefit from having an additional option that is, “Don’t know” or “Unable to collect these data”.
- The team has responded to the feedback and it’s been sent back to the Steering Committee



Dr. Jessica Kahn



Dr. Cynthia Gearhardt

Steering Committee
Meeting September 14
– Revised Survey
Approved by the
Steering Committee

PCT WG GCA CCIA

- Accelerating Pediatric Clinical Trials: Collaborative Development and Implementation of an Innovative Toolkit Across the Golisano Children's Alliance (GCA)
- **Objective:** To refine the Pediatric Clinical Trials (PCT) Toolkit developed through the CTSA Consortium Working Group for children's hospitals with diverse needs and resources, assess its feasibility and disseminate and implement the Toolkit across GCA institutions. We will achieve this objective by accomplishing the following specific aims:
 - (UG3): Refine the PCT Toolkit for small to medium-sized children's hospitals with diverse resources
 - (UG3) Assess the feasibility of implementing the refined PCT Toolkit at GCA institutions;
 - (UH3) Disseminate and implement the modified PCT Toolkit at the participating GCA institutions
 - (UH3) Evaluate the impact and sustainability of the PCT Toolkit implementation at the participating GCA institutions
- 13 sites signed on (possibly 2 more)
- Deadline 10/19; UG3/UH3 CCIA



Karen Wilson, MD, MPH
University of Rochester



Team:

- **Core team:**
 - Rochester - Karen Wilson (PI), Jeff Yaeger (Co-I), Jenn Foley (PM)
 - Buffalo- George Porter (Site PI)
 - Penn State University- Neal Thomas (Site PI)
 - University of Kentucky- John Bauer (Site PI)
 - University of Maryland- Steve Czinn (Site PI)
- **Advisory Board:**
 - Edress Darsey- Pfizer
 - Others? FDA? NIH? Networks?
- **Additional support:**
 - CTSI Hub Evaluation Teams
 - CTSI Hub Research Professional groups
 - CTSI Hub Dissemination and Implementation Cores
- **Additional Sites (Site PIs):**
 - Akron Children's- Michael Forbes
 - Connecticut Children's- David Hersch
 - Dayton Children's- Cynthia Sieck
 - University of Arkansas- Tamara Perry
 - University of Vermont- Jessica Heath
 - Upstate University – Leonard Weiner
 - Wellstar- Brian Stanfield
 - West Virginia University- Lee Pyles
- **Trial Innovation Network:**
 - Dixie Thompson, Utah



Karen Wilson, MD, MPH
University of Rochester

Virtual Meeting Planning



- Karen Wilson will lead the subcommittee
 - Volunteers?
- Collaborative Workshop Proposal submitted; would allow for in-person meeting in the spring in Rochester
- Two, 2-hour meetings in March and April
 - Meeting 1: Present findings and identify opportunities
 - Meeting 2: Develop toolkit structure and form working groups



CLINICAL AND TRANSLATIONAL
SCIENCE INSTITUTE

UNIVERSITY OF MINNESOTA

Driven to DiscoverSM



Karen Wilson, MD, MPH
University of Rochester

Action Items for Coming Year

- Explore partnerships and potential “Co-Labs” (Collaborative Labs) with other ECs
- Schedule guest presentations for 2027 Full Membership meetings
- Finalize 2025 Fall Conference manuscript
- Disability working group manuscript and toolkit
- Manuscripts for Clinical Trials working group
- Develop database of expertise for IAL representatives for individual hubs to better capture depth and breadth of IAL expertise.



Danny Armstrong



Barrett Bowling

Integration Across the Lifespan

Overview

The goal of the Integration Across the Lifespan Enterprise Committee is to integrate translational science across complex populations and throughout an individual's lifespan.



Integration Across the Lifespan EC Meeting

1:00 PM-3:00 PM

September 23, 2026

Thank you!



Elisabet Børsheim, PhD

Univ. of Arkansas for Medical Sciences



Karen Wilson, MD, MPH

University of Rochester



Kristen Beavers, PhD, MPH, RD

Wake Forest University Health
Services



Jessica Lee, MD, MS, AGSF

University of Texas Health Science
Center at Houston



VJ Periyakoil, MD

Stanford University

- **NIH/NCATS Representative:** Gallya Gannot, DMD, PhD
- **TIN Representative:** Daniel Hanley, PhD
- **SC Representative:** Mark Schleiss, MD
- **CCOS Support:** Melissa Brady
- **Voting Members:** 66 Voting Members
- **Full Membership:** 148 Members



CLINICAL AND TRANSLATIONAL
SCIENCE INSTITUTE

UNIVERSITY OF MINNESOTA

Driven to DiscoverSM

WORKFORCE DEVELOPMENT ENTERPRISE COMMITTEE (WFD EC)

MARISA SPANN, PHD
COLUMBIA UNIVERSITY

2026 Lead Team



Vicki Ellingrod, PharmD
Co-Chair
University of Michigan



Maija Neville-Williams, MPH
Co-Chair
Rockefeller University



Marisa Spann, PhD
Steering Committee Rep.
Columbia University



Jennie Conroy, PhD
NCATS Liaison



Judy Cannon, PhD
University of New Mexico



Doris Rubio, PhD
University of Pittsburgh



Terri Edwards, RN
TIN Representative
Vanderbilt University



Dixie Thompson, BSN
TIN Representative
University of Utah



Alex Paquet
CCOS Coordinator

Purpose and Priorities

- Purpose and Focus Areas

- Promote training and career development
- Foster impactful partnerships and collaboration
- Nurture development of the entire workforce involved in translational science and research
- Serve as an effective communication channel across all CTSA Hubs, NCATS, NIH

- Goals

- Provide a venue for sharing lessons learned (what does and does not work)
- Share new ideas, programs and peer-group problem-solving
- Span the entire workforce from trainees to clinical research professionals to translational scientists/researchers

Updates

- Since June 2025 we have:
 - Hosted 6 virtual full membership meetings
 - Average attendance: 70 participants
 - Topics:
 - Integration Across the Lifespan: Duke 5 Ts framework
 - Clinical research mentorship programs
 - Undergraduate clinical research training programs
 - Annual planning
 - Community college – CTSA partnerships
 - AI in workforce development
 - Hosted 1 in-person meeting (October 2025)
 - AI in workforce development
 - Mentorship programs

Highlights of the Year

Building partnerships with other ECs:

- Co-Lab meeting with **Collaboration & Engagement and Trial Innovation Network** in October 2026
- Collaboration are underway with **Biostatistics, Informatics, and Data Science EC** – for a possible Co-lab

Membership supported NCATS AIM-Ahead curriculum review

Sponsorship of Working Groups (Sunset June 2026)

Translational Scientist Competency-Based Assessment

Wayne McCormick, University of Florida

Real World Data – Workforce Development Across the Translational Spectrum

Melissa Haendel, University of North Carolina Chapel Hill

Shawn O'Neil, University of North Carolina Chapel Hill

Anita Walden, University of North Carolina Chapel Hill

Sponsorship of Working Groups (Starting July 2026)

CTS Launchpad

Aims to address the clinical research workforce shortage by establishing standardized, competency-based curricular frameworks for high school and undergraduate education.

- James Holahan, NYU Langone Health
- Stephanie Freel, Duke CTSI
- Jessica Fritter, The Ohio State University

Building and Scaling a Collaborative Continuing Education Training Program for Clinical Research Professionals

Aims to establish and scale a reproducible framework for training Clinical Research Professionals (CRPs) across CTSA and CTR hubs using a Collaborative Network Model (CNM).

- Kris M. Markman, Tufts Medical
- Mary-Tara Roth, Boston University

Focus for next year

- AI in workforce development
- Collaboration with other Enterprise Committees
- CRP Training

THANK YOU

Co-Chairs

Vicki Ellingrod vellingr@med.umich.edu

Maija Neville-Williams
mneville@rockefeller.edu

EC Representative to the Steering Committee

Marisa Spann
mns2125@cumc.columbia.edu

CCOS Staff

Alex Paquet
alex.paquet@icf.com

NCATS Liaison

Jennie Conroy
jennie.conroy@nih.gov

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

- *Transforming data into clinical and translational impact*

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 broad representation 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
Biostatistics



William Hogan,
Co-chair
Medical College of Wisconsin
Informatics



Elmer Bernstam
UTHealth Houston
Informatics



Thomas Campion
Weill Cornell Medical College
Informatics



Kristi Holmes
Northwestern University
Bioinformatics
Informatics



Shari Messinger
University of Miami
Biostatistics



Gina-Maria Pomann
Duke University
Data Science
Biostatistics



Thomas Radman
NCATS Representative
National Institutes of Health



Christopher Hartshorn
NCATS Representative
National Institutes of Health

COMMITTEE GOALS

Scientific Leadership

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

Cross-Hub Collaboration

Foster multidisciplinary collaboration across CTSA hubs to address shared scientific and operational challenges.

Research Excellence

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

Data Infrastructure

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

Workforce Development

Support education, training, mentorship, and knowledge exchange across the CTSA workforce.

Responsible Innovation

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

Knowledge Sharing

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

National Impact

Advance data-driven solutions that accelerate translational research and improve health outcomes.

2026 FOCUS AREAS



Strengthen the BIDS Community

- Build connections across biostatistics, biomedical informatics, data science, epidemiology, and related disciplines
- Increase visibility of BIDS expertise and contributions across the CTSA Consortium
- Create more opportunities for networking, knowledge exchange, and cross-hub collaboration



Prepare the Translational Research Workforce

- Identify emerging competencies for an increasingly data-intensive and AI-enabled research environment
- Share sustainable training models, learning approaches, and workforce development practices
- Connect quantitative and data expertise with researchers earlier in the translational process



Advance Trustworthy and Reproducible Research

- Promote rigor, reproducibility, data integrity, and responsible AI practices
- Share practical tools, methods, infrastructure, and successful approaches across CTSA hubs
- Develop collaborative activities and resources that address shared consortium needs

WHO WE ARE

397

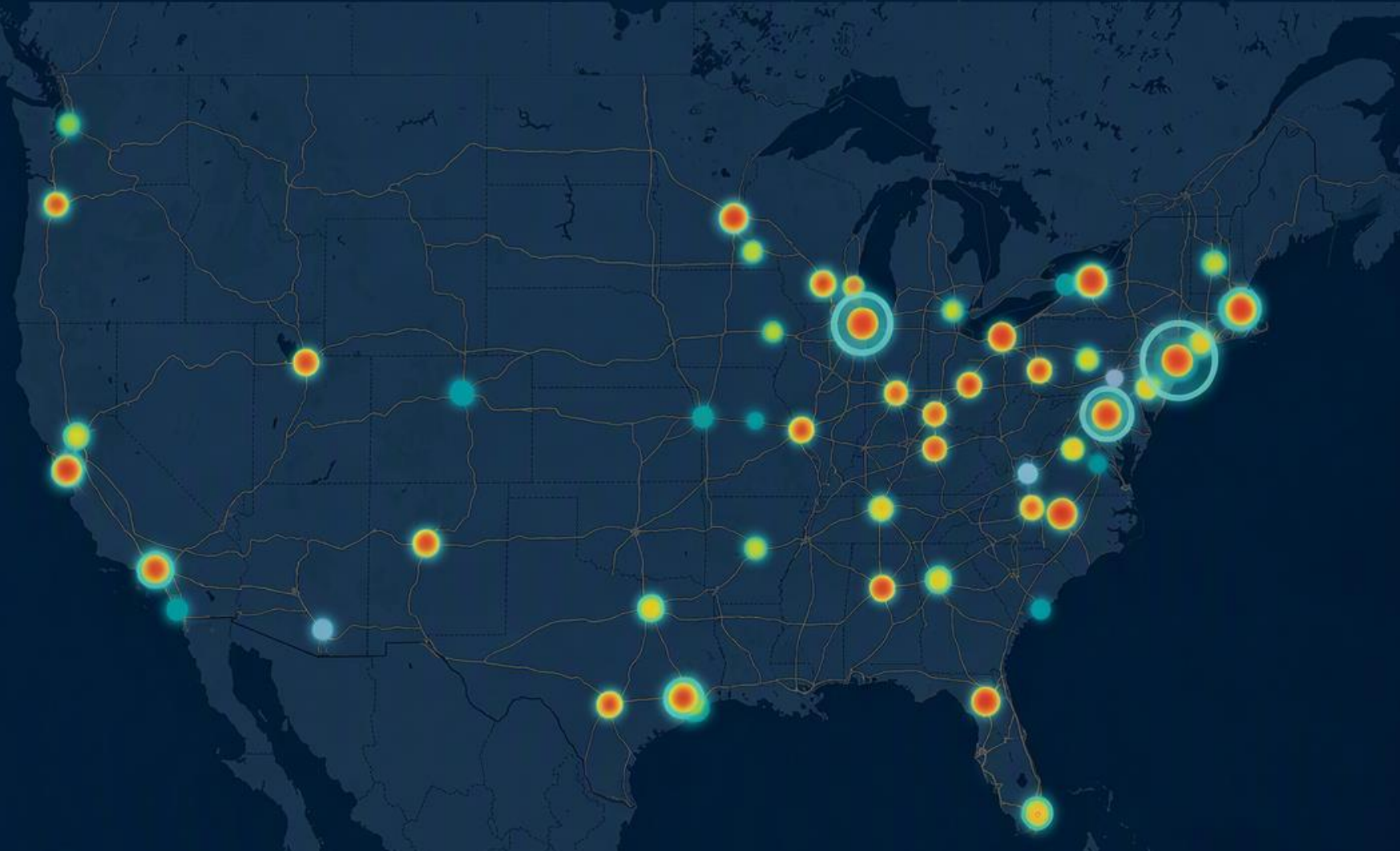
Members

65

CTSA Hubs

82

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

January



Nichole Carlson

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

March



Mike Kurilla

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

Jaime Doyle

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

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.

July



Abu Mosa

- DataLENS: Simplified Pathway for Data Access & Delivery

February



Alifia Hasan

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

Gina-Maria Pomann & Heather Kitzman

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

April



Gina-Maria Pomann

- BERD best practices and reproducible quantitative science.

Paul Harris

- REDCap+ innovations and research infrastructure.

June



Tony Pan

- OMOPCompass: natural language access to OMOP data.

Nathan Hotaling

- N3C modernization, governance, and scalable research infrastructure.

Key Themes Across Presentations

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

BIDS EC UPDATES

Advancing the BIDS Workforce

Advancing the BIDS Workforce

BIDS is bringing together biostatistics, biomedical informatics, data science, epidemiology, and related disciplines to prepare the translational research workforce for an increasingly data-intensive future.

Current Activities

- Convening discussions on sustainable training models for quantitative and data professionals
- Identifying emerging competencies needed across biostatistics, informatics, data science, and AI
- Exploring workforce readiness, training needs, learning pathways, and responsible AI use
- Strengthening collaboration between BIDS disciplines and the broader translational research workforce
- Highlighting successful institutional models that connect quantitative expertise with research teams

Building Community and Sharing Expertise

- Monthly community presentations highlighting tools, methods, infrastructure, and emerging practices
- Cross-disciplinary discussions on reproducibility, data access, AI, research infrastructure, and team science
- Opportunities for members to propose presentations, initiatives, and collaborative activities

Impact

- Builds connections across BIDS disciplines and CTSA hubs
- Supports workforce development and knowledge exchange
- Elevates quantitative and data expertise within translational research
- Identifies opportunities for future consortium-wide collaboration

The September 23 BIDS session focuses on sustainable training models and emerging competencies for quantitative professionals.

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

BIDS EC UPDATES

Principles for AI Translation in Healthcare Working Group

Current Progress

PATH has moved from identifying pilot-to-practice barriers to conducting a CTSA-wide readiness assessment and organizing solution-domain teams to develop evidence-based recommendations.

AI Translational Readiness Survey

- Survey is now open for coordinated institutional responses
- Assesses readiness across governance, technical infrastructure, workforce, model lifecycle, clinical integration, and assurance readiness
- Findings will identify strengths, variation, and opportunities for improvement across the CTSA network
- Survey findings will help inform a future federated AI assurance framework
- You can access the survey here:
<https://ccosredcap.urmc.rochester.edu/surveys/?s=3PFN9A4WP8YMMAD>

Solution-Domain Workstreams

- Domain teams are refining research questions and review criteria
- Teams are coordinating evidence searches with librarian support
- Shared literature review, screening, and manuscript templates are supporting consistent work across teams
- Cross-cutting contributors are helping identify overlap and alignment across domains

What Comes Next

Teams will screen and extract evidence, compare findings across workstreams, and develop solution-focused manuscripts and practical recommendations. The current target is manuscript submission by mid-December 2026.

BIDS EC UPDATES

White Paper Subcommittee

Led by: Shari Messinger, Ph.D.

- The White Paper Subcommittee is developing a peer-reviewed paper that defines the strategic role and value of biostatistics, biomedical informatics, and data science within the CTSA Consortium.
- The group is refining the paper's central message around the importance of connecting quantitative and data expertise when research questions, data, and methods first come together.
- Current discussions address team science, trustworthy AI-enabled discovery, workforce sustainability, service versus science, reproducibility, data integrity, collaboration, and institutional infrastructure.
- The subcommittee is revising the paper structure, developing section content, and coordinating writing responsibilities across contributors.
- The paper will help articulate how BIDS disciplines strengthen rigorous, scalable, and impactful clinical and translational science.

KEY TAKEAWAYS



Building a connected national community across biostatistics, biomedical informatics, data science, epidemiology, and related quantitative disciplines



Preparing the translational research workforce for an increasingly data-intensive and AI-enabled future



Promoting team science by connecting quantitative and data expertise earlier in the research process



Sharing practical tools, infrastructure, methods, and successful approaches across CTSA hubs



Advancing responsible AI, reproducibility, rigor, data integrity, and trustworthy research practices

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!

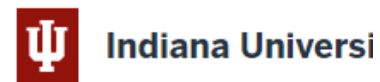
CTSA Biostatistics, Biomedical Informatics, and Data Science (BIDS) Enterprise Committee

Questions & Discussion

Biostatistics • Informatics • Bioinformatics • Data Science • Epidemiology



2026 Steering Committee Report Collaboration & Engagement Enterprise Committee



Collaboration & Engagement EC Leadership



Elisabeth Martinez de la Rosa

Co-Chair



Gia Mudd Martin

Co-Chair



Heather Kitzman

Lead Team Member



Tiffany Haynes

Lead Team Member



Sarah Wiehe

Lead Team Member



DeShauna Jones

Lead Team Member



Patricia Piechowski

Lead Team Member



Joan Nagel

NCATS Representative



Consuelo Wilkins

TIN Representative

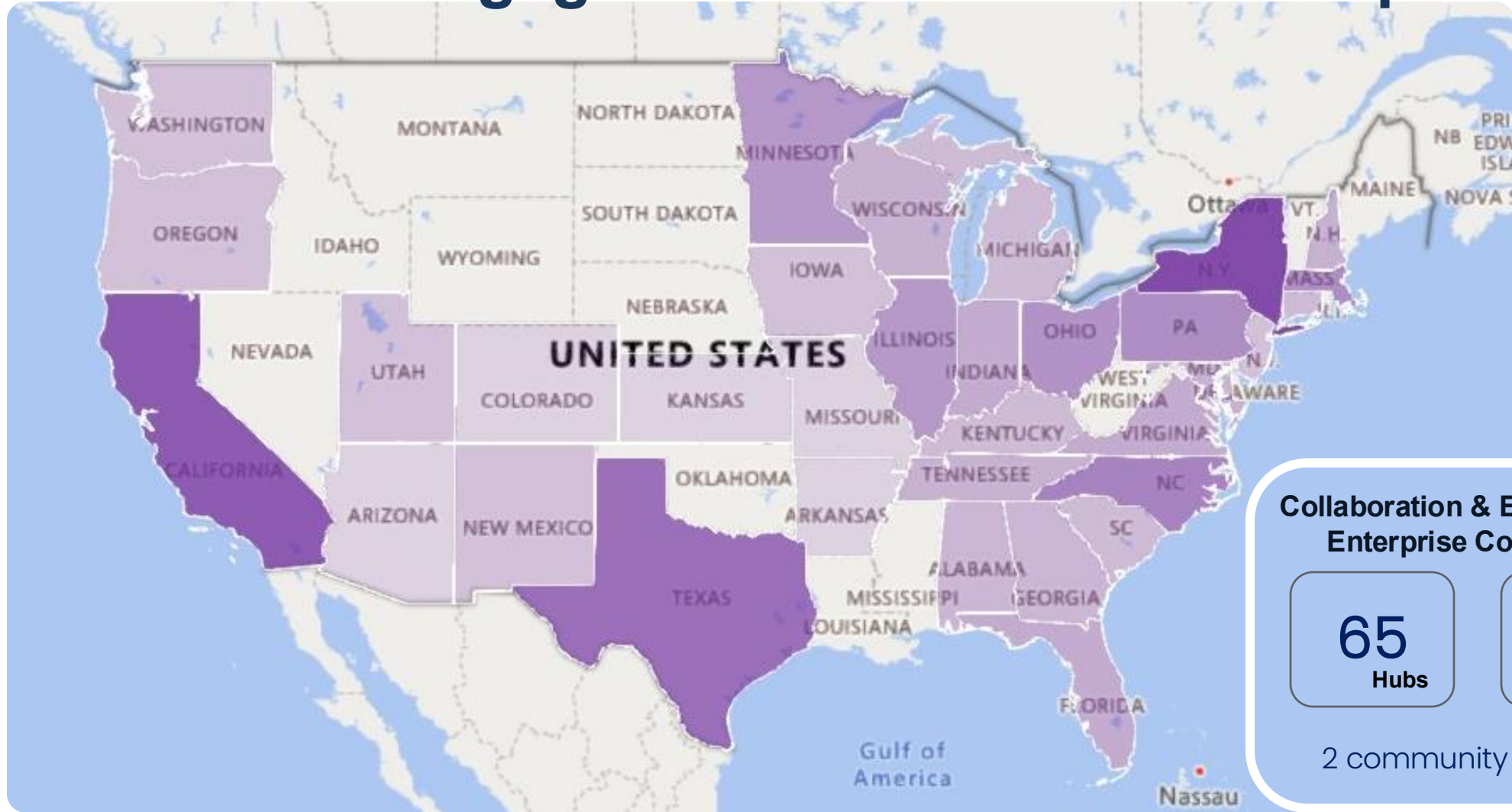


Lenore Roca

CCOS

Non-Voting Members

Collaboration & Engagement EC Member Participation



Collaboration & Engagement Enterprise Committee Goals



Working together with stakeholders and their communities through active engagement and promotion of team science to foster collaboration.



Engaging stakeholders and communities so they contribute meaningfully across the clinical and translational science spectrum.



Leveraging existing knowledge and research to enhance the health of underserved communities by addressing biological, structural, and social factors that influence health, and promoting health for all.



Promoting team science to become a major academic model that embraces or reflects the perspectives of community members as equal contributing partners in all clinical, translational, and related scientific endeavors.



Enhancing the availability of Dissemination & Implementation (D&I) methods and tools and promoting D&I efforts across the CTSA Consortium.

Collaboration & Engagement Enterprise Committee Presentations Mapped to Group Goals

EC programming addressed all five committee goals through presentations, workshops, collaborative discussions, and initiative development.

PRESENTATION / INITIATIVE		MTG	Active engagement & team science	Meaningful stakeholder contribution	Knowledge, research & community health	Equal community partnership	D&I methods, tools & coordination
Research access: institutional policies		OCT 25	■	●	●	■	●
RE-AIM evaluation & Net Effect diagrams		DEC 25	●	●	●	■	●
Strategic priorities discussion		FEB 26	●	●	●	●	●
Cross-EC takeover initiative	BIDS	FEB 26	●	■	■	■	●
Communities Driving Impact		APR 26	●	●	●	●	●
Faith-Based Organizational Network		APR 26	●	●	●	●	●
Community risk communication		APR 26	●	●	●	●	●
Community-led research symposium		JUN 26	●	●	●	●	●
Impact stories and Impact Page		JUN 26	●	■	●	■	●
TSBM Impact Profile Builder		JUN 26	●	●	●	●	●
Community-led initiatives / CPRN		AUG 26	●	●	●	●	●
Partnership mapping WG proposal		AUG 26	●	●	■	●	●

ALIGNMENT ■ Strong ■ Moderate ■ Supporting

COLLABORATION & ENGAGEMENT ENTERPRISE COMMITTEE

Pattern: programming links community partnership and health impact with practical infrastructure, evaluation, and D&I tools.





Biostatistics, Biomedical Informatics & Data Science

- Alifia Hasan, HealthAI Partnership (HAIP)
- February 6, 2026

Workforce development

- Trial Innovation Network coordinated with Dr. Consuelo Wilkins
- October 5, 2026

Integration Across the Lifespan

- Dr. Kathryn Nearing – OARS (Older Adult Research Specialist Training Program)
- December 7, 2026

Theme 1: Measuring Impact

Theme 2: Sustainable Community Partnerships

Theme 3: Community Engagement as a Scientific Discipline

Theme 4: Scaling Innovation Across Hubs

Many successful approaches exist locally
Need for mechanisms for broader dissemination and adoption
Shared learning opportunities can accelerate innovation across hubs



Discussion Questions

- What collaboration and engagement challenges are SC members hearing most frequently from CTSA hubs that should become priorities for the EC?
- Should advancing community engagement science and impact measurement become a consortium-level priority, and how might the EC contribute?
- Where does the Steering Committee see the greatest opportunity for the C&E EC to contribute to CTSA Program priorities over the next 1-2 years, particularly in working group development, meeting planning, and cross-committee collaboration?

Break & Group Photo

3:15pm – 3:45pm

Dissemination and Implementation to Advance Translational Science

Audie A. Atienza, PhD, NCATS



Cochrane News, 1995

Definitions (from NIH)

- **Dissemination and implementation science** emphasizes investigation and understanding of the processes involved in the adoption, implementation, and sustainability of research. (Glasgow et al., AJP, 2012)
- **Dissemination and implementation research** intends to bridge the gap between research, practice, and policy by building a knowledge base about how health information, effective interventions, and new clinical practices, guidelines and policies are communicated and integrated for public health and health care. (PAR-25-144)
 - **Dissemination research** is the scientific study of the targeted distribution of information and intervention materials to a specific public health, clinical practice, or policy audience... to understand how best to communicate and integrate knowledge and the associated evidence-based interventions.
 - **Implementation research** is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health.
 - **De-implementation research** is the scientific study of circumstances that create a need to stop or reduce the use of practices that are ineffective, unproven, low-value, or harmful.



NCATS Strategic Plan 2025-2030

2025 — 2030 NCATS Strategic Plan



Goal 1 - Our goal is clear: Increase the number of treatable diseases by increasing knowledge about their underlying causes, supporting the development of new treatments, and improving the reach, accessibility, and uptake of existing treatments. **Imperative in this work is pursuing effective dissemination and implementation strategies** that aim to bridge the gap between research and clinical practice.

Objective 1-3: Support and leverage existing national clinical and translational networks to conduct high-impact clinical research, clinical trials, and translational science and **disseminate and implement** successful interventions and treatments into the clinic and the community.

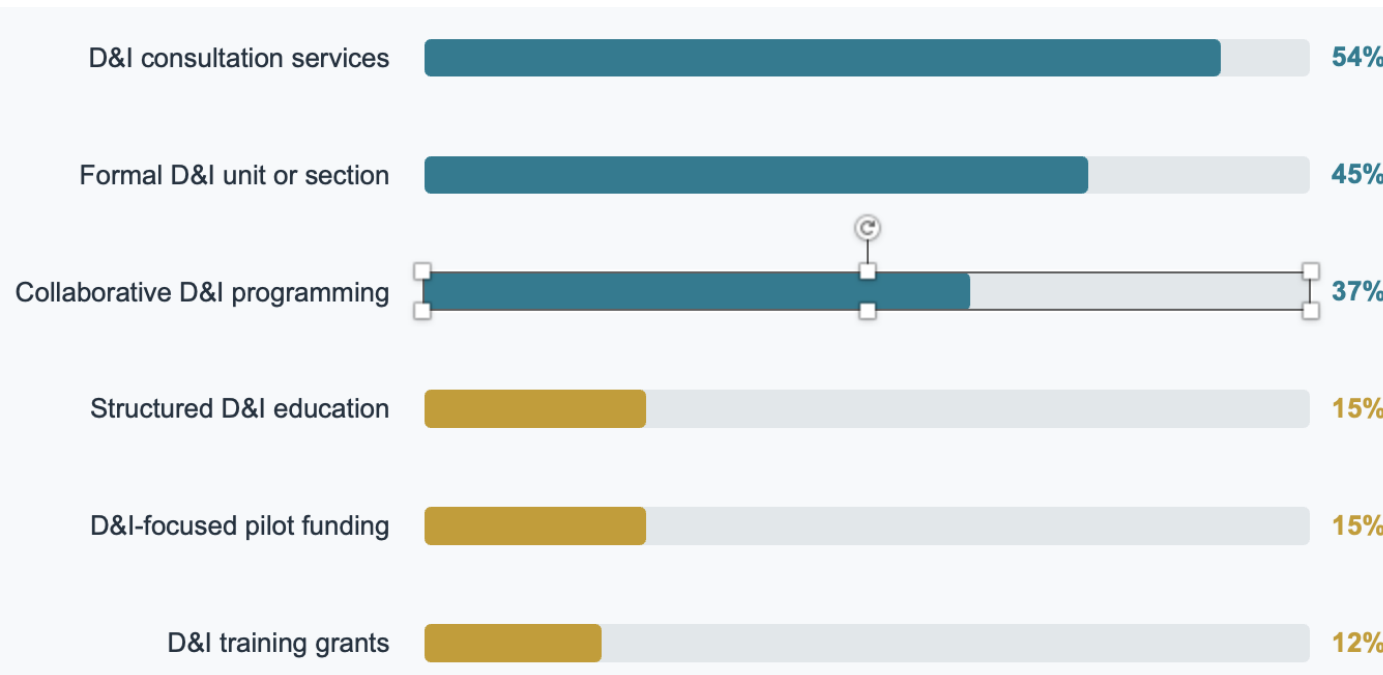
CTSA Program Goals

1. Advance clinical and translational science: develop, demonstrate and **disseminate** scientific and operational innovations that improve the efficiency and effectiveness of clinical translation from identification to first-in-human studies to medical practice **implementation** to community health **dissemination**.
2. Promote partnerships and collaborations to facilitate and accelerate translational research projects locally, regionally and nationally.
3. Create, provide, and **disseminate** innovative research programs and partnerships across institutions and communities to address health needs of their populations and deliver the benefits of translational science to all.
4. Create and **implement** scientific and operational innovations that increase the quality, safety, efficiency, effectiveness and informativeness of clinical research.
5. Provide a national resource for the rapid response to urgent public health needs.
6. Create, provide and **disseminate** clinical and translational science training programs for clinical research professionals of all disciplines on the research team.
7. Create, provide and **disseminate** clinical and translational science training and career support programs for translational scientists.
8. Foster the development of the emerging field of translational science.

Mapping the landscape of dissemination and implementation science across the CTSA consortium: A multi-domain environmental website scan

Journal of Clinical
and Translational
Science 10:e97,1–6.

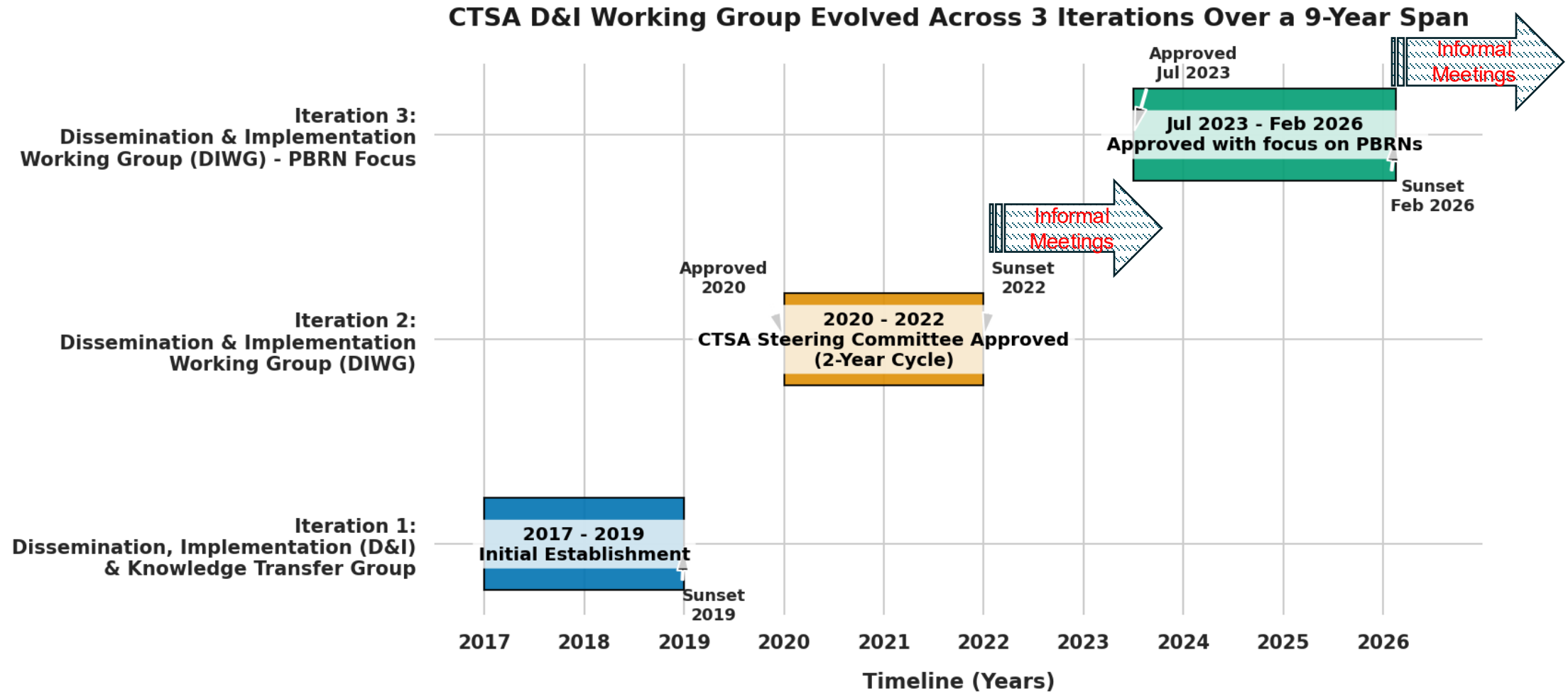
Jing Li¹, Naomi Duffort¹, Salisa Westrick², Renee Heffron¹, Abigail Gamble³, Bertha Hidalgo¹, Katherine Mills⁴, Kirsten Dorans⁴, Kristine Ria Hearld¹, Larry R. Hearld¹, Lisa Zubkoff¹, Peter T. Katzmarzyk⁵ and Michael Mugavero¹ 



Findings reveal substantial heterogeneity in D&I science activities across CTSA hubs; 45% had a formal D&I unit, 54% offered D&I consultation services, and 37% provided collaborative programming. Structured workforce development was limited: 12% offered D&I-focused training grants, 15% offered structured educational programs, and 15% provided D&I-specific pilot funding.



CTSA D&I WGs Timeline



Source: CTSA DIWG Timeline



CTSA D&I Working Groups Deliverables

- **Overall Recommendations: Integrating D&I within CTSA Programs**

- Mehta et al. Integrating dissemination and implementation sciences within Clinical and Translational Science Award programs to advance translational research: Recommendations to national and local leaders. *Journal of Clinical and Translational Science* (2021), 5:e151, 1–7.

- **Training/Workforce Development**

- Baumann et al. A mapping review and critique of the literature on translation, dissemination, and implementation capacity building initiatives for different audiences. *Implementation Science Communications* (2025) 6, 1-34.
- Nooraie et al. A Modified Delphi Study of Essential Competencies in Dissemination & Implementation Science for Advancing Translational Research. (under review).

- **CTSA Compendium of D&I Resources**

- <https://cctsi.cuanschutz.edu/resources/dissemination#ft-ctsa-compendium-of-di-catalogs-3>
- Lennox et al. The Clinical and Translational Science Award compendium of dissemination and implementation science resource catalogs: Capacity building tools for clinical and translational scientists. *Journal of Clinical and Translational Science* (2025), 9: e154, 1–8.

- **PBRN Survey on D&I and CTSA Partnerships**

- Preliminary results - Stevens et al. *Hardwiring Trustworthy Translation: PBRN-Driven Real-World Impact and Workforce Development*. Symposium Presented at ACTS 2026, April 20-23, 2026, Milwaukee, WI.



CTSA Dissemination & Implementation (D&I) Work Group 2023-2026

(>170 members from over 60 institutions)

Matthew Aalsma	Alyssa Cabrera	Amit Gode	Kelly McConnell	Sapana Patel	Katherine Sterba
Ephrem Abebe	William Calo	Marjorie Gondré-Lewis	Mark McGovern	Cecilia Patino-Sutton	Kath Stevens
Erin Abu-Rish Blakeney	Lauren Caton	Alexandra Greenberg	Alan Mcguire	Bronte Penrose	Kera Swanson
Morolake Adeagbo	Valerie Chepp	Charlie Gregor	Scott McIntosh	Deborah Philp	Melanie Taverna
Omolola Adeoye-Olatunde	Robert Clark	Erricka Hager	Victoria McNamara	Harold Pincus	Emmanuel Tetteh
Prajakta Adsul	Allison Cole	Margaret Handley	Emma Meagher	Kathryn Purcell	Chantel Thomas
Caitlin Allen	Katherine Connors	Hannah Haynie	Tara Mehta	Andrew Quanbeck	Anna Thompson
Stephanie Andersen	Dan Cooper	Haley Hazlett	Paul Meissner	Borsika Rabin	Jonathan Tobin
Steven Asch	Lori Crosby	Rachel Hillhouse	Kristin Miller	Heather Reisinger	Matty Triplette
Carolyn Audet	Geoffrey Curran	Carol Howe	Andrea Min	Felice Resnik	Peg Tsao
Bijal Balasubramanian	Denise Daudelin	Shawna Hudson	Anita Misra-Hebert	Finie Richardson	Janet Van Cleave
Laura-Mae Baldwin	Pamela Davidson	Lakeysia Huger	Brian Mittman	Sharon Rikin	Elizabeth Vasile
Michael Bales	Bas de Veer	Octavian Ioachimescu	Stephen Mouldrem	Shari Rogal	Jennifer Vincenzo
Ana Baumann	Miriam Dickinson	George Jackson	Victor Montori	Erin Rogers	Karen Vitale
Sara Becker	Pamela Dillon	Patricia Jones	Justin Moore	Brittany Rosen	Alan Walkey
Rinad Beidas	Maja Djukic	Eunyoung Kang	Nallely Mora	Mercedes Rubio	Rikki Ward
Miriam Bender	Mary Dolansky	Stuart Katz	Elaine Morrato	Brittany Rudd	Bryan Weiner
Nancy Bennett	Rowena Dolor	Linda Ko	Michael Mugavero	Ramzi Salloum	Jenny Weis
Justin Benzer	Kirsten Dorans	Bethany Kwan	Molly Murphy	Nadia Sam-Agudu	Randy Williams
Maya Berdichesky	Yan Dunn	Simona Kwon	Orrin Myers	Ghosh Samiran	Veronica Williams
Steven Bernstein	Jill Ehrenreich-May	Robin Lanzi	Smiti Nadkarni	Elias Samuels	Reza Yousefi Nooraie
Sarah Birken	Johanne Eliacin	Briana Last	Christy Navarro	Brittney Sandler	Robyn Zender
Dara Blachman-Demner	Shellie Ellis	Lisa Lederer	Gila Neta	Mark Schleiss	Holly Zink
Kathryn Black	Karen Emmons	Rebekka Lee	Robin Newhouse	Stephen Schueller	Leah Zullig
Marc Blackman	Paul Estabrooks	Jennifer LeLaurin	Amanda Nguyen	Julie Schwan	
Leanne Boehm	Maria Fernandez	Lindsay Lennox	Stephanie Oppenheimer	Christopher Shea	
Demetria Bolden	Kristie Foley	Jing Li	Jamie Ostroff	Rachel Shelton	
Oliver Brant	Dee Ford	Michelle Maclay	John Ovretevit	Elizabeth Shenkman	
Heidi Brown	Janet Freburger	Jane Mahoney	Maggie Padek Kalman	Santana Silver	
Jeremiah Brown	Orsolya Garrison	Elizabeth Malcolm	Alex Paquet	Justin Smith	
Elizabeth Ann Brownell	Elvin Geng	Steven Masiano	Michael Parchman	Maureen Smith	
Alicia Bunger	Heather Gilmartin	Timothy McBride	Darpan Patel	Nicole Stadnick	



The Working Group created the foundation; the enterprise need persists

ADVANCING D&I SCIENCES WORKING GROUP

Established foundation

- Explore D&I in clinical, practice-based, and community-engaged research
- Examine competencies & local hub capacity
- Leveraged PBRNs and the D&I community
- Created a cross-hub constituency and evidence-generating agenda

TIME-LIMITED BY DESIGN

NEXT
STEP

D&I PRACTICE AND SCIENCE EC

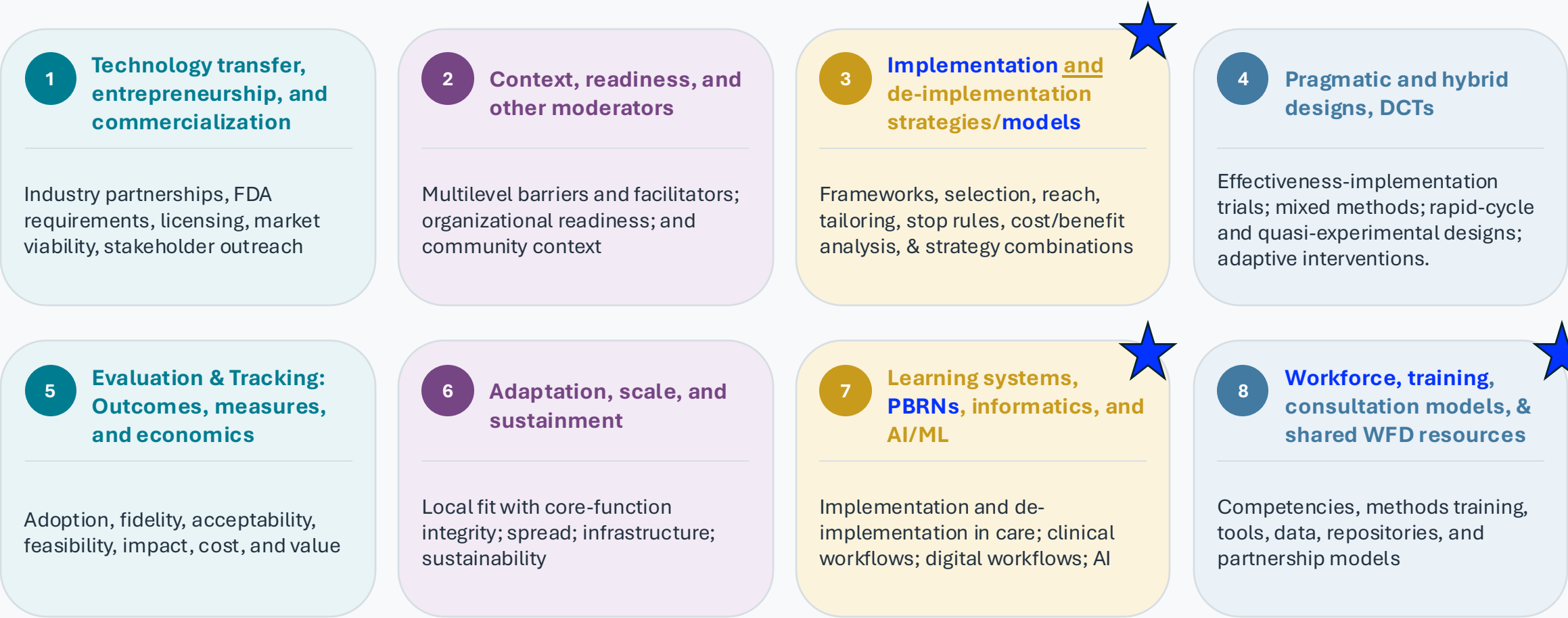
Promote collaboration and innovation

- Maintain a visible enterprise agenda for adoption, scale, and/or de-implementation
- Create continuity across successive, focused Working Groups
- Connect D&I to other ECs and WGs
- Translate dispersed hub expertise into shared methods, learning, and collaborations

STANDING STRATEGIC HOME

SAMPLE OF POTENTIAL CORE RESEARCH DOMAINS

The scientific agenda is broad, coherent, and distinctly D&I



Three Imperatives for the Next Decade

I

Train the Full Translational Arc

Prepare the next generation in hypothesis to community impact — not just T1 discovery. Statistical rigor AND **implementation science** AND community engagement.

II

Build T3–T4 Infrastructure

Implementation hubs · Community partnership networks · Learning health systems at CTSA scale. The translation gap will not close without institutional investment.

III

Hold Both Paradigms

Demand epidemiological rigor of AI/ML methods. Demand computational scale of classical epidemiology. Neither alone is adequate for the translational challenges ahead.

Precision public health: AI + epidemiological rigor + community engagement.

Request

- *CTSA Enterprise Committees: promote collaboration and innovation, create a space for discussion, disseminate best practices, and may develop plans for projects that fill gaps and further program objectives.*
- **Steering Committee request:** Consider dissemination and implementation (D&I) as a standalone, cross-cutting CTSA enterprise priority and authorize the development of an Enterprise Committee charter that carries forward and expands prior Working Groups' knowledge, relationships, and agenda.
- **Proposed D&I Practice and Science (DIPS) EC mission:** Systematically advance and integrate dissemination and implementation (and de-implementation) practice and science across the CTSA Consortium of 60+ hubs so that discoveries, innovations and trainings are designed for adoption, implemented broadly across hubs, adapted with fidelity, scaled responsibly, sustained where effective, and de-implemented when ineffective or burdensome.



NCATS

COLLABORATE. INNOVATE. ACCELERATE.

THANK YOU

QUESTIONS?



NIH National Center
for Advancing
Translational Sciences

NCATS

COLLABORATE. INNOVATE. ACCELERATE.

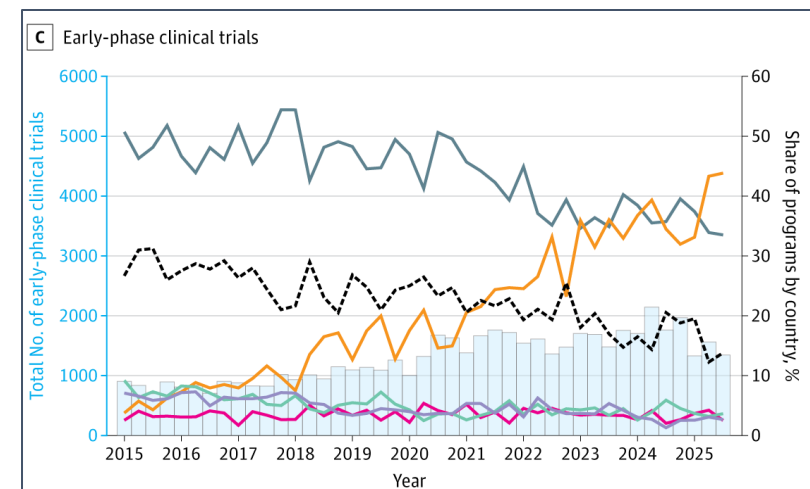
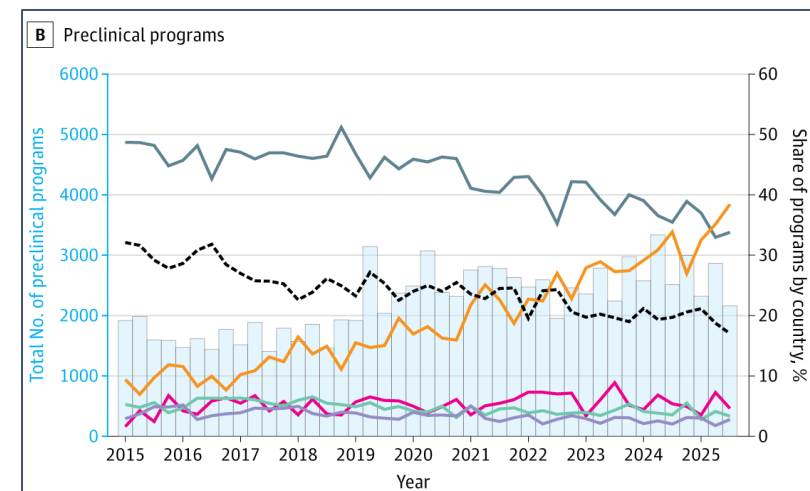
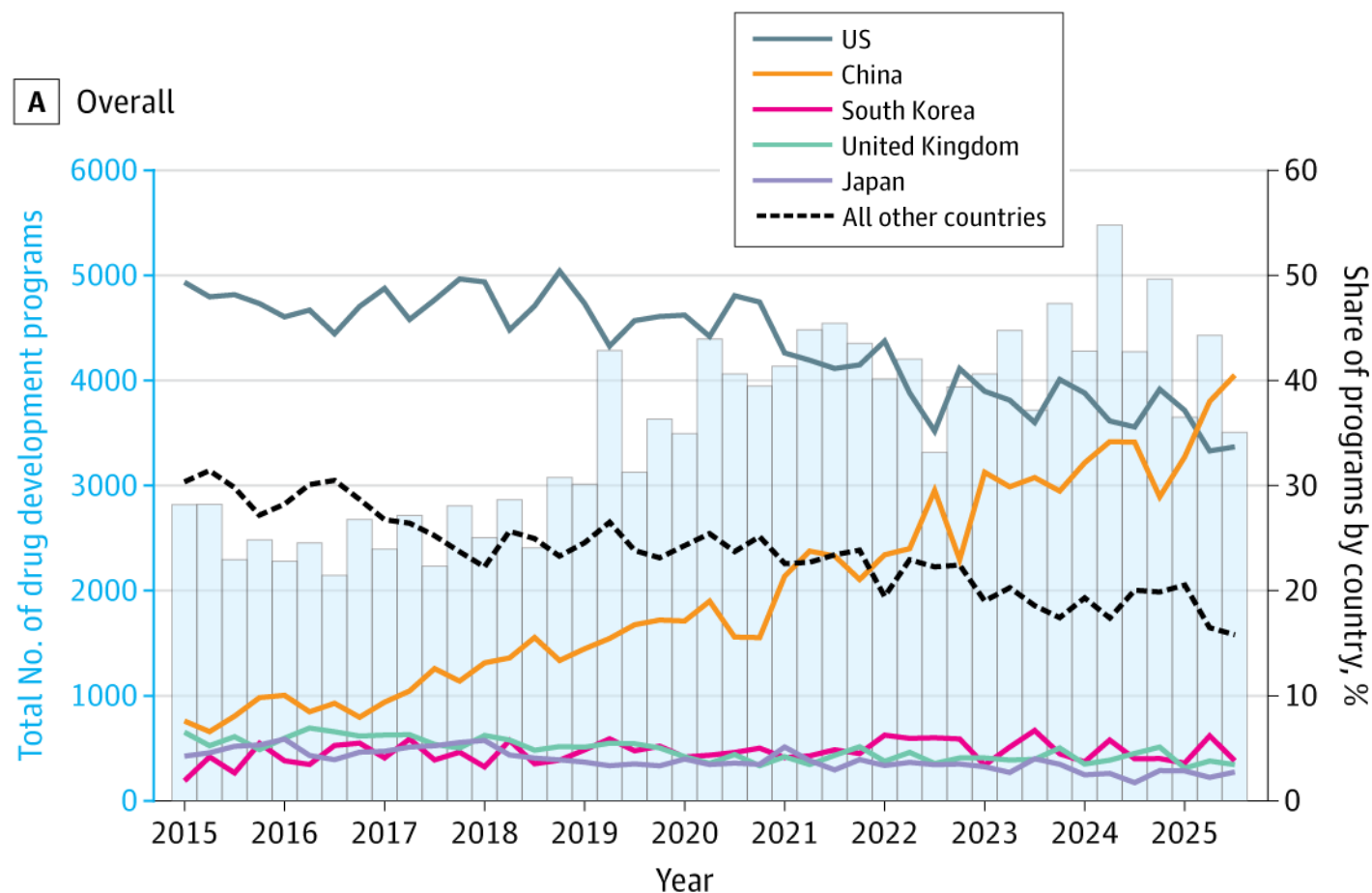


NIH National Center
for Advancing
Translational Sciences

Operation TrialBlazer:
Presenter: Joni Rutter
Discussants: Scott Steele (FDA), Willie Chertman (HHS), Barbara Bierer (MRCT/Harvard/SMARTIRB)

4:00pm – 5:00pm

Geographic Shifts in Early-Stage Biopharmaceutical Innovation

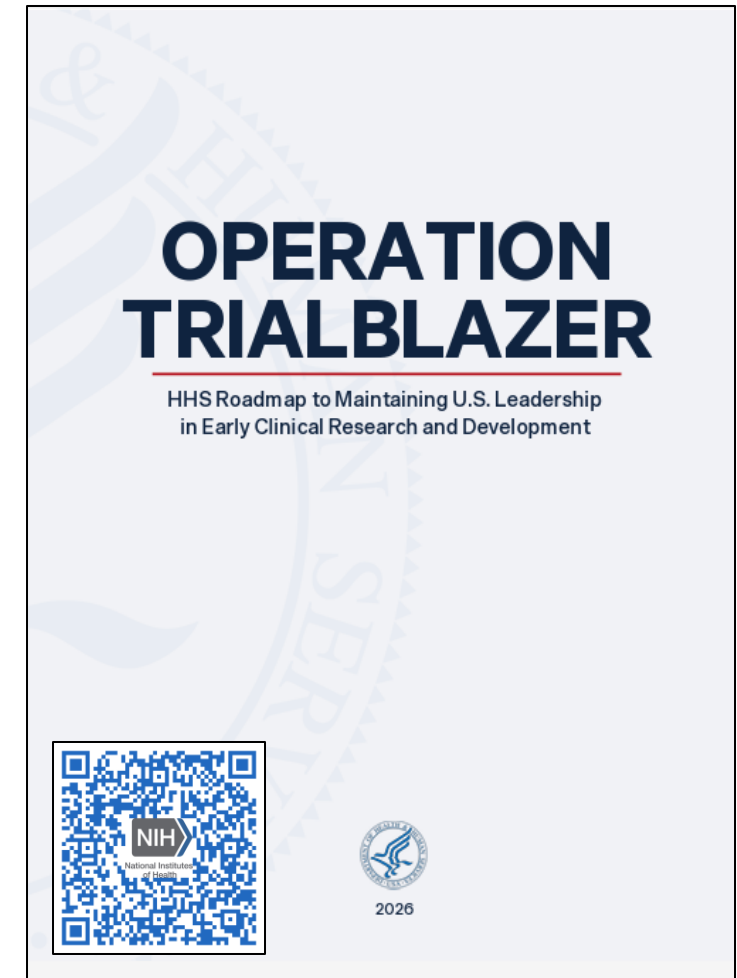


JAMA. 2026;335(15):1355-1357. doi:10.1001/jama.2026.1962



HHS Launches Unprecedented Department-Wide Effort to Strengthen Clinical Trials

The multi-department effort for Operation Trailblazer is headed by the FDA, NCI, NCATS, NIH, and ARPA-H



“NIH’s National Center for Advancing Translational Sciences (NCATS) is building on lessons learned from pioneering work that led to the first fully personalized CRISPR-based gene-editing treatment, helping accelerate the development of future therapies for patients with rare diseases.”

<https://www.hhs.gov/sites/default/files/operation-trialblazer.pdf>

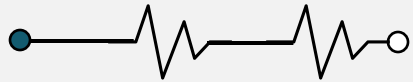


NIH National Center
for Advancing
Translational Sciences

From Serial to Parallel: Speeding Clinical and Translational Research

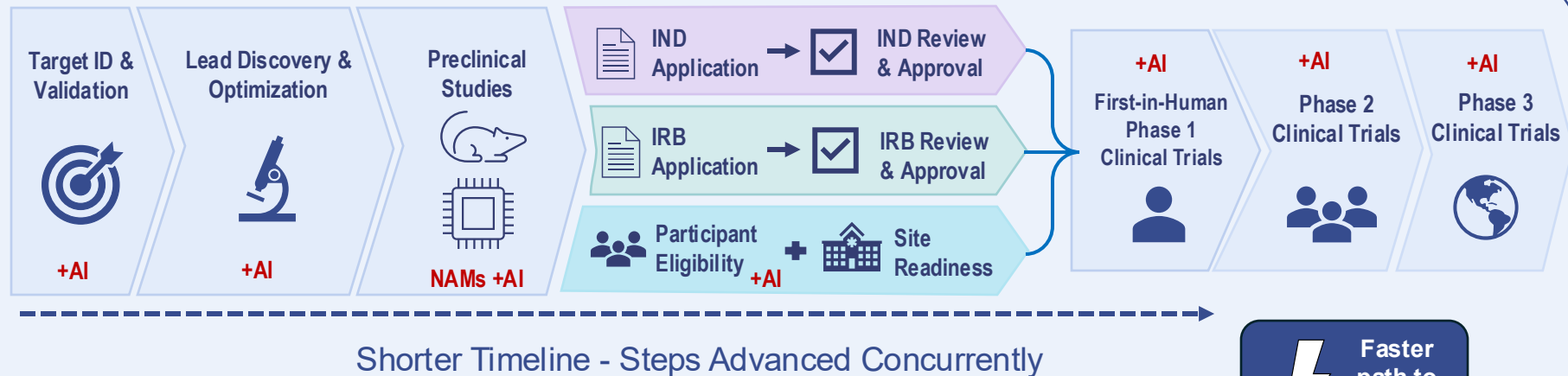
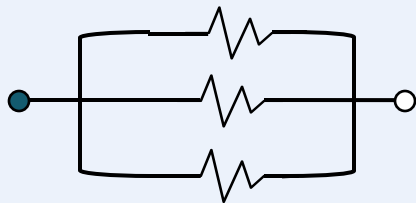
SEQUENTIAL APPROACH

Traditional linear process moves step-by-step



PARALLEL APPROACH

NCATS enables concurrent progress across translational and regulatory milestones



Faster path to patients

PARTNERSHIPS are critical (NIH, FDA, CMS, private partnerships, patient organizations, etc.)



NCATS Clinical Trial Platform Innovations

INNOVATIONS



Real-World Data Integration

- Linking EHR-based research data to real-world insights.



RARE DISEASES
CLINICAL RESEARCH NETWORK

National Research Network

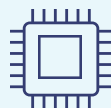
- Building connected, trial-ready sites nationwide.
- CTSA hubs
- RDCRN



Research Infrastructure

- Building reusable platforms and tools that accelerate discovery.
- CTSA TIN

INITIATIVES



Clinical Trials on a Chip

Preclinical safety & efficacy testing of candidate therapeutics.



N3C

National real-world health data resource.



SMART IRB

Streamlined multi-site review to accelerate study start up.



Trial Innovation Network (TIN)

Accelerated trial execution through shared solutions.

PaVe-GT

PaVe-GT

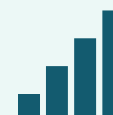
Gene therapy platform model.

IMPACT



Faster Trials

Less duplication, faster start-up, and streamlined operations.



Better Evidence

Rigor, generalizability, novel approach methodologies, AI/ML, and real-world insights inform better decisions.



Stronger Public Health

Inform clinical care guidelines and respond rapidly to emerging public health emergencies.



Better Patient Outcomes

Research insights lead to better diagnostics, treatments, and outcomes for all.

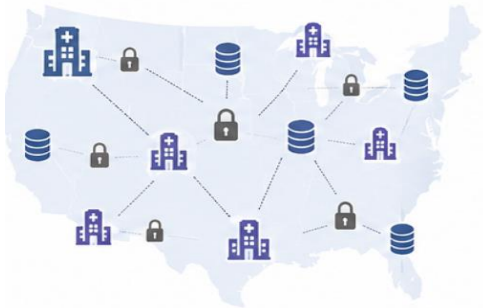


Harnessing Real-World Data

NCATS National Clinical Cohort Collaborative (N3C)

THE CHALLENGE

Fragmented and Siloed EHR Data

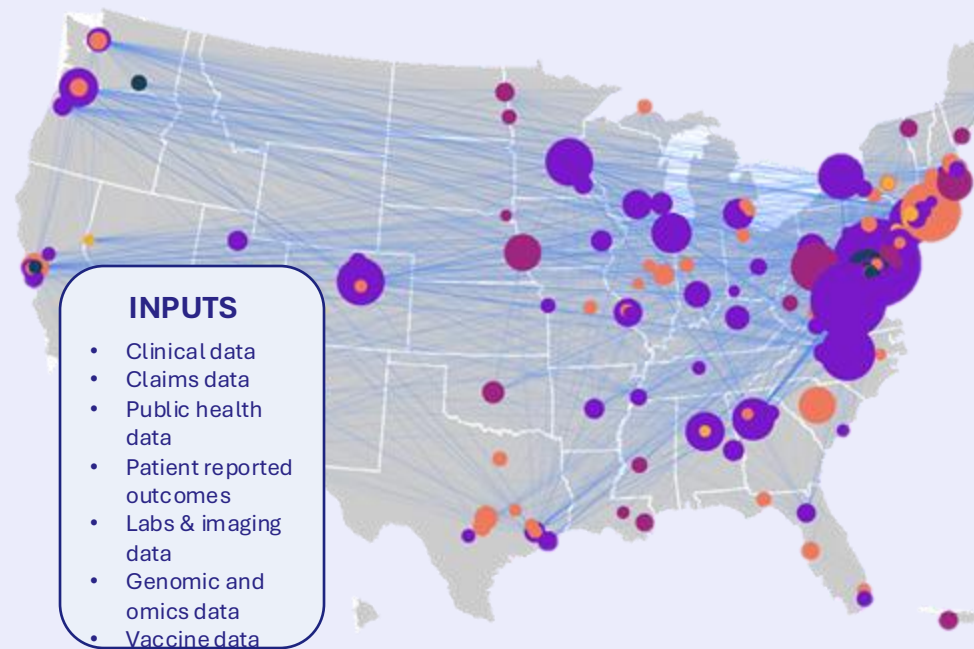


- ✗ Inconsistent data formats and standards
- ✗ Difficult and time-consuming data access
- ✗ Limited sample sizes and generalizability

Missed opportunities for discovery

THE SOLUTION

N3C Secure Research Enclave



INPUTS

- Clinical data
- Claims data
- Public health data
- Patient reported outcomes
- Labs & imaging data
- Genomic and omics data
- Vaccine data

THE IMPACT

The Power of Real-World Data



GAIN INSIGHTS INTO DISEASES AND CONDITIONS



DEVELOP PREDICTIVE MODELS FOR DISEASE



INFORM NEW CLINICAL GUIDELINES AND HEALTH POLICIES



ACCELERATE NATIONAL-SCALE RESEARCH COLLABORATION



90+
Health Systems
and Growing



Millions
of Patients
Represented



Billions
of Data Points
Harmonized



Limitless
Potential for
Discovery



Center
for
Advancing
Translational
Sciences



The Road to 1,500

CELEBRATING 10 YEARS · 2016 – 2026

Measuring Clinical Trial Efficiency

Standardized metrics to measure the speed of site startup and participant enrollment.

1

Site Activation



Contract Execution

Time from contract initiation to agreement execution.



Site Activation*

Time from site startup to site activation.



Regulatory Speed

Time from IRB submission to IRB approval.

2

Enrollment Performance



First Enrollment

Time from site activation to first participant enrollment.



Enrollment Efficiency

Time from site activation to enrollment completion (and enrollment rate).



Overall Enrollment*

Time from first to last participant enrollment.

***For Multisite Trials:** Time from first to final site activation, and enrollment per active site.



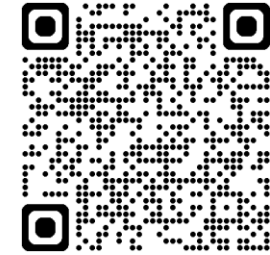
Return of Results

OUT NOW! Request for Information (RFI) Policy on Sharing Summary Level Study Results

NIH seeks comments on draft policy proposal and areas for which supplemental guidance would enable successful implementation while minimizing administrative burden

including:

- 1 Participant preferences & experiences
- 2 Best practices for researchers
- 3 Implementation needs



<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-113.html>

Comments accepted
until October 26, 2026



Applies to all clinical research supported in whole or in part by NIH.



Requires researchers and institutions to share summary level study results with participants in plain language for all NIH-supported clinical research.



Informed by engagement with the community through an online webinar and on-demand commenting.



FDA's Recent Initiatives to Accelerate Early Stage Clinical Research and Drug Development

Scott Steele, PhD

U.S. Food and Drug Administration

Early Clinical Development Challenges & Solutions

	Pre-IND	IND Submissions	Post-IND
Challenges	- Sponsor interactions with the FDA have been relatively limited - IND process is linear and lacks flexibility	- Sponsors submit additional data due to uncertainty around actual IND requirements - Current expectations may exceed what is scientifically appropriate for Phase 1 INDs	- IRB review takes place only after FDA IND approval - Contracts between stakeholders are lengthy - Clinician engagement & patient enrollment barriers for trial initiation
Solutions	Expedited IND Pilot to establish a network of qualified research institutions that partner with sponsors to develop Phase 1 IND submissions for FIH clinical trials	- Release updated guidance clarifying phase-appropriate clinical, nonclinical, and CMC expectations for INDs - Phase 1 IND Navigator webpage consolidates IND requirements, guidance, and practical examples	- Promote earlier IRB review prior to IND approval as part of Expedited IND Pilot - Drive cross-agency collaboration to reduce structural and administrative barriers to trial initiation (including metrics)

Potential Opportunities for CTSA-FDA Collaborations

Continued Dialogue

Plan additional engagements for feedback on barriers and opportunities to accelerate early clinical development

Regulatory Science

Advance the development and appropriate use of NAMs, RWE, Digital Health, AI, MIDD, innovative trial designs, and emerging methods and tools to accelerate drug development, expand the evidence base, and reduce the burden on patients and sponsors

Training

Enhance translational science and the clinical research workforce, including exploring opportunities for collaborative training, fellowships, and exchanges

Pilots

Explore collaborative pilots to advance regulatory science, training, clinical trial innovation, and other areas, leveraging the CTSA Network

Next Meeting: October 26, 2026

No 10/12 meeting due to holiday

Agenda

- Survey Vote: Assessing Clinical Trial Accrual Tracking Practices Across CTSA Hubs
- Annual T Report Out
- Annual K Report Out
- WG Report Out: Translational Case Studies in Commercialization

**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.*



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](#)