CTSA Coordination, Communication, & Operations Support

Steering Committee Meeting

June 9, 2025

2:30-3:30pm ET

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Deloitte. ICF University of Rochester

Agenda

Time	Topic	Speaker(s)
2:30-2:35pm ET	Welcome & Announcements: - NCATS Impact Survey from Crowd-sourced Topic: Collaborations with State and Local Governments - Introduction of Amanda Scott	Michael Kurilla, Ted Wun
2:35-2:55pm ET	Report Out: Real World Data Workforce Development Across the Translational Spectrum	Melissa Haendel
2:55pm-3:10pm ET	BIDS EC Transition/Charter Review and Vote	Meredith Zozus and Thomas Campion
3:10pm-3:30pm ET	Concept Mapping Project	Cath Kane
3:30pm-3:40pm ET	Vote: WSVS Working Group Extension	
3:40pm ET	Adjourn	Michael Kurilla, Ted Wun

Request: CTSAs to share information about their engagement with State and Local Governments

- Crowd-sourced Topic from Dr. Rey Panettieri's (Rutgers) pod
  - Indiana University, University of Minnesota, University of Wisconsin, University of Florida, University of Iowa
- Background from March 24th SC Presentation by Dr. Panettieri:
  - How and Why Should CTSA Hubs Engage the State Government?
    - Recognition and marketing of who we are, what we do, and how we address challenges;
    - Acquisition of resources for our mission in partnership with the state governmental interests;
    - Shovel-ready: Nimble and dynamic problem-solving capabilities for health crises and state health concerns;
    - Established training, educational and workforce development platforms in translational research and science.
  - Summary
    - CTSA Hubs report robust and highly productive collaborations with state governments.
    - Hub-state partnerships occur across multiple domains.
    - Some but not all Hubs collaborate across all domains.
    - The education and training domain offers opportunity for greater collaborative efforts with state governments.

From: Panettieri, Rutgers Pod; SC Presentation 3.24.25

Request: CTSAs to share information about their engagement with State and Local Governments

Snapshot of Domains of Interaction

From: Panettieri, Rutgers Pod; SC Presentation 3.24.25

National Center for Advancing Translational Sciences

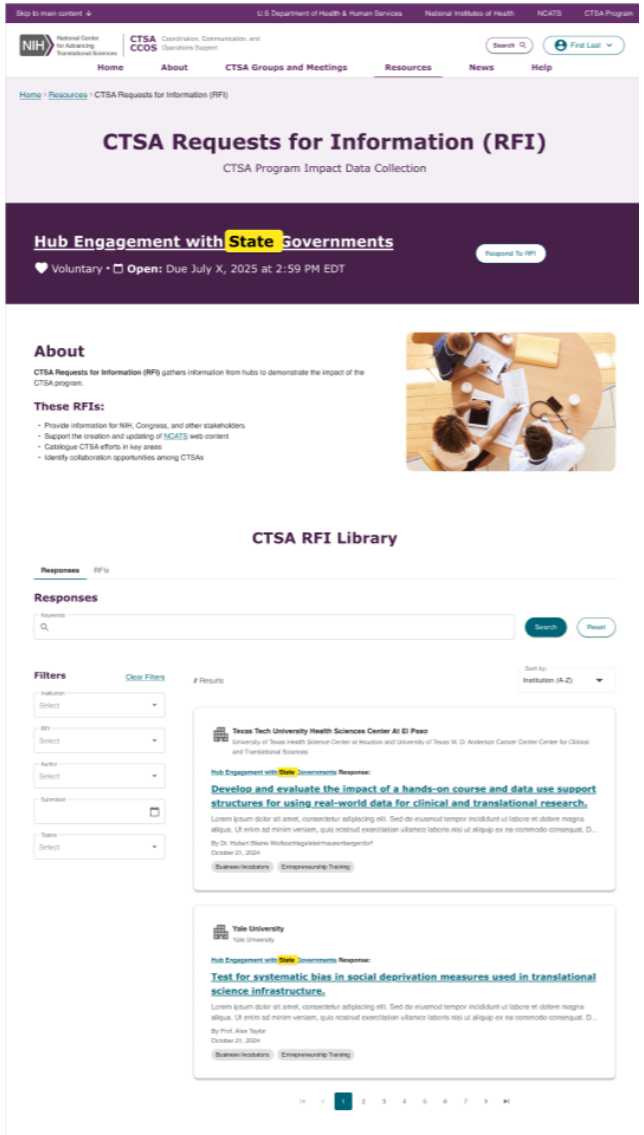
Request: CTSAs to share information about their engagement with State and Local Governments

- Idea communicated at the March 24, 2025, Steering Committee Meeting
- Why?
  - Spur new ideas for how and where else hubs can collaborate
  - Identify opportunities to find impacts of clinical and translational science in the communities
- How to share project information?
  - CCOS Website: with other CTSAs via the CCOS website (access limited to members of the CTSA Program as approved by CTSA Administrators)
  - NCATS Website: as impact stories using NCATS CTSA funding
- What information would be useful?
  - The RFI template request hubs report on impact, keywords/tags, publications, websites or resources, and any other relevant files
  - What tags for the dropdown box?
  - Anything else?
    - we are limited on changes to the webform

National Center for Advancing Translational Sciences

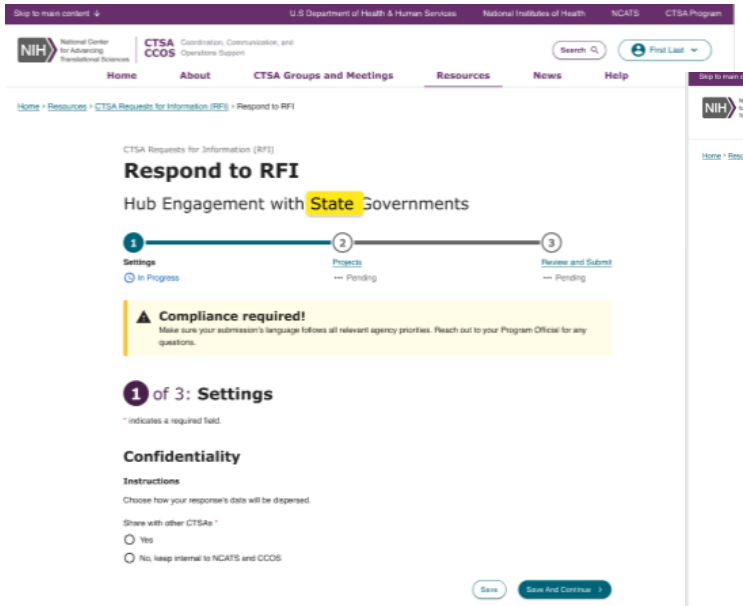
Request: CTSAs to share information about their engagement with State and Local Governments

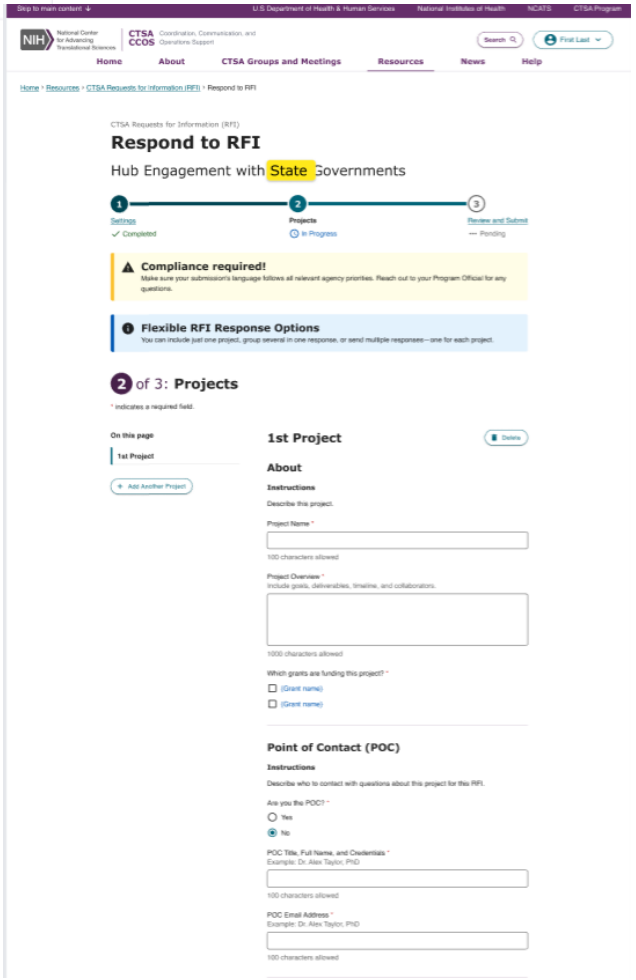
- Request for Information (RFI) Form and Library to be released in mid-June
- Anticipate ~ 4 RFIs per year (one per quarter) on various topics of interest
- Next RFI topic will be focused on Hub Engagement with State and Local Governments
- Located under “Resources” tab on CCOS website
- Must have CCOS account to access form and directory



National Center for Advancing Translational Sciences

Request: CTSAs to share information about their engagement with State and Local Governments





RFI page mockups (not on CCOS website yet)

National Center for Advancing Translational Sciences

UNC
THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

Real World Data workforce development across the translational spectrum

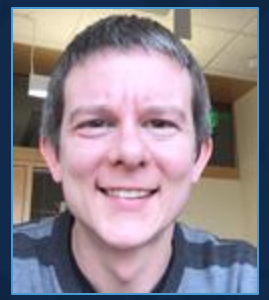
Co-sponsored by the Workforce Development and Biostatistics, Biomedical Informatics and Data Science (BIDS) enterprise committees

Annual report out to the CTSA Steering Committee

June 9th, 2025

RWD Working Group Leadership

Melissa Haendel
Director of Precision Health & Translational Informatics, Deputy Director of Computational Science – NC TraCS
University of North Carolina



Shawn O'Neil
Assistant Director for Academic Excellence
University of North Carolina

Anita Walden
Associate Director of Translational and Integrative Initiatives
University of North Carolina

Jiang Bian
Chief Data Scientist, Regenstrief Institute
Deputy Director, Indiana Clinical and Translational Sciences Institute (CTSI)
BIDS EC co-Lead

Julie McMurry
Professor, School of Data Science and Society
University of North Carolina

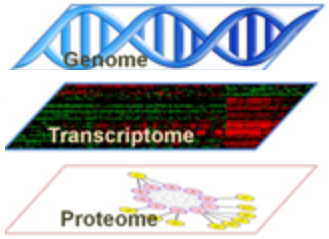
Jamie Mihoko Doyle
Program Director, Digital & Mobile Technologies, CTSA
NCATS Representative

Lenore Roca
Meeting Coordinator, CCOS

What is Real World Data?

Randomized Trial Data


Surveys



'Omics


Mortality Data

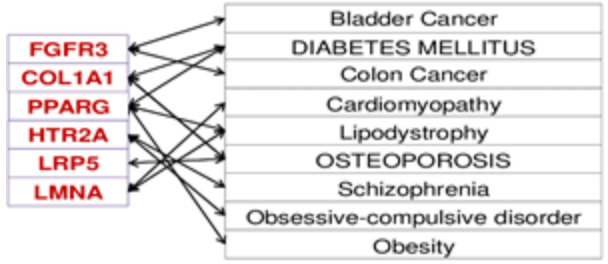

Imaging


Wearables


EHR & Billing Data

Not 'Real World' ⟵ ⟶ **'Real World'**

Biomedical Knowledge




Environmental and Social

Many translational uses: Defining and characterizing cohorts for clinical studies, post-market surveillance and drug repurposing, public/environmental health, disease characterization and mechanistic discovery, trial emulation, and RWD is increasingly part of clinical trial designs

A Real World Example of a Real World Data Training Trajectory

Dr. Joe Schmo is a rheumatologist at the University of Narnia Center for Translational Science Institute. He taught himself, and learned on his own, everything needed to do studies from TriNetX and publish them. He had to figure out how to sign up, how to get an IRB approved, how to understand and work with the data, how to analyze the data, how to avoid pitfalls due to common biases in the data, how to develop computable phenotypes (and I don't think he knew specifically that that was what he was doing or even that that is what they're called), how to write up his studies, and how to get them published.

He was dedicated, persistent, and was sufficiently enthusiastic to invest the time required. **It took him about 2-3 years.**

Now, consider:

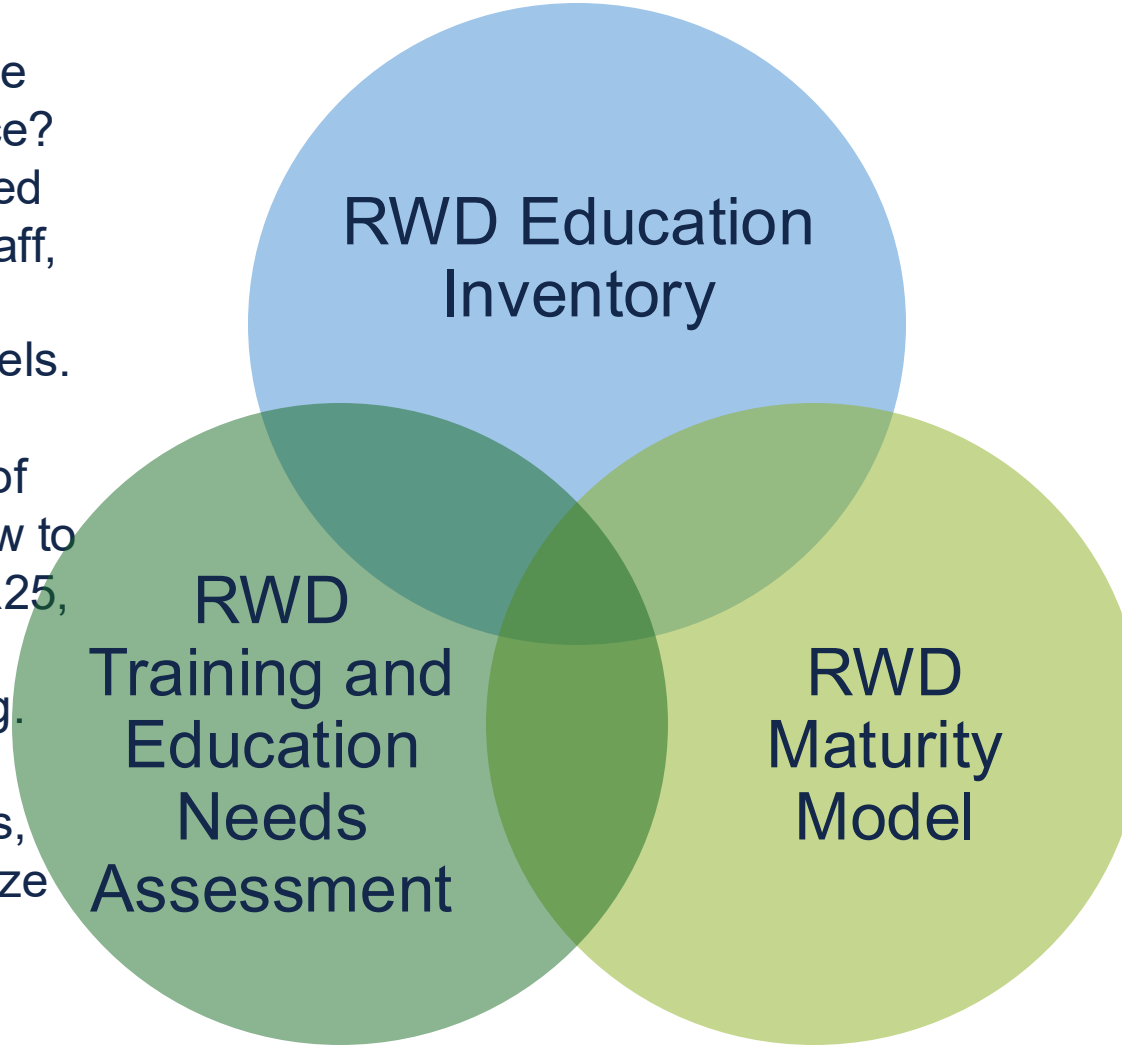
1. That is a very high threshold. Imagine how many more clinician-scientists we could get over that threshold if there were training, guidance, support, and services to help.
2. How much more quickly he himself could have been productive if he had had those things. It took him 2+ years. **It could have been 6 months (roughly).**

Real World Data Workforce Development Across the Translational Spectrum Working Group: Goals and Deliverables

RWD Training and Education Needs Assessment - what are the educational needs for people in using RWD in translational science? K & T scholars, early career researchers, CTSA, CTR, and affiliated institutional leadership, local biomedical informatics faculty and staff, and other domain experts including data scientists, clinical practitioners, regulatory specialists, legal/policy, and all career levels.

RWD Education Inventory - what is currently available in terms of educational resources and events to aid investigators learning how to use RWD in translational science? Do in collaboration with T, K, R25, AMIA, and other programs to increase educational collaboration opportunities and promote higher-quality, accessible RWD training.

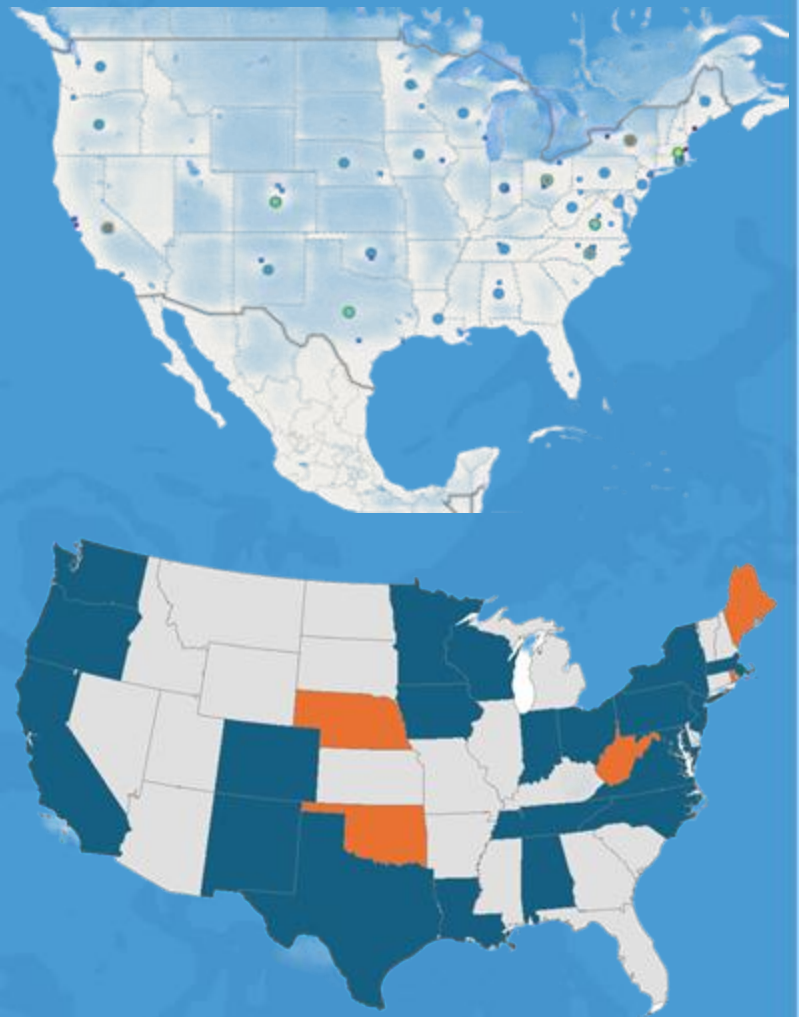
RWD Maturity Model - What educational materials, environments, data, and opportunities does an institution need to provide to realize the professional development needed to effectively utilize RWD in translational science?



Real World Data Workforce Development Across the Translational Spectrum Working Group

- 139 members from 37 CTSA Institutions & 8 community members

Albert Einstein College of Medicine
Boston Medical Center
Brown University*
Case Western Reserve University
Duke University
Indiana University
Johns Hopkins University
LSU Health Sciences Center
Main Health Institute for Research*
Medical College of Wisconsin
Montefiore Medical Center
New York University School of Medicine
Ohio State University
Oregon Health & Science University
Research Institute at Nationwide Children's Hospital
Rockefeller University
Rutgers Biomedical/Health Sciences
Stanford University
Tufts University Boston
University of Alabama at Birmingham
University of California Berkeley
University of California Los Angeles
University of California San Francisco
University of Colorado
University of Colorado Denver
University of Iowa
University of Minnesota
University of Nebraska*
University of New Mexico Health Scis Ctr
University of North Carolina Chapel Hill
University of Oklahoma*
University of Pittsburgh at Pittsburgh
University of Puerto Rico*
University of Rochester
University of Southern California
University of Texas Med Br Galveston
University of Texas San Antonio
University of Virginia
University of Washington
Vanderbilt University
Virginia Commonwealth University
Wake Forest University Health Sciences
West Virginia University*



Sub-Workgroups Progress

Each subgroup meets biweekly. Note: ~6 month delay and narrowed scope due to loss of anticipated funding.

Needs Assessment

- Finalizing Needs Assessment survey
- Identifying best process for dissemination to the CTSAs and translational science community
- Hosted training workshop at AMIA
- Presented to Workforce Dev EC meeting
- Planning to meet at ACTS!

Parsa Mirhaji
Albert Einstein ICTR

Elizabeth Fortune
VCU Wright CCTR

Lang Li
Ohio CTSI

Inventory

- Scoped types of inventory items to collect
- Identified metadata for inventory asset collection
- Drafted form for item submission
- Collecting initial assets
- Designing automation & sustainability strategy

Chindo Hicks
UAB CCTS

Mary Helen Mays
Puerto Rico CTSRC

Maturity Model

- Defined learning pillars, how to measure levels of maturity vs ad-hoc
- Model criteria drafted
- Outlined paper and key questions for each pillar in the RWD maturity model
- Coordination with AMIA Maturity model WG

Olga Jarrin Montaner
Penn ITMAT

Timothy Huerta
Ohio CTSI

Questions to SC

How to best engage the full translational community?
e.g. other ECs? Pods? should we have a newsletter?

What RWD information would be most helpful to the SC?

Questions from SC

- The methodological issues in working with RWD (e.g. bias, missing data) and the analytic strategies are so different depending on the source, e.g., imaging vs wearables vs EHR, etc… Will the WG address that heterogeneity in any way? Are there plans to organize the educational resources and initiatives by type of RWD?
  - *The Inventory subgroup includes RWD type as a metadata element in our developing catalog. The Needs Assessment subgroups is scoped to include the heterogeneity of RWD types; this may surface needs or competencies in specific areas.*
- The ability to effectively leverage RWD for CTR depends on access to multidisciplinary expertise—informatics, biostatistics, epidemiology, clinical (i.e. domain) knowledge. Will the WG be considering best ways to organize and integrate that expertise for both RWD training and research purposes?
  - *We have previously successfully coordinated multidisciplinary working groups that enable cross-sectoral training and impactful research. Fostering this approach will be part of our maturity model as we believe it is critical for rigorous use of RWD in research.*
- What metrics do they propose to use to measure the effectiveness of workforce development programs and how do they propose to assess the impact of the training initiatives?
  - *The Maturity Model subgroup aims to develop tools for insitutitions to measure their own effectiveness in workforce development.*
- A lot of RWD are produced by the private sector. So a question is: How can partnerships with industry and businesses enhance workforce development efforts?
  - *Fostering partnerships with industry are outside the scope of this WG; however, we anticipate that aspects of all three of our tasks (inventory, maturity model, and needs assessment) will reveal needs and assets. We also plan to partner with AMIA to help foster better understanding of commercial data sources and partnership with those organizations.*

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

CTSA Steering Committee

Monday, June 9, 2025

Meredith N. Zozus, PhD and Thomas R. Campion, Jr., PhD

Objectives

- Develop a shared vision for Biostatistics, Biomedical Informatics, and Data Science (BIDS)
  - Illustrate a whole greater than the sum of its parts
  - Clarify a path forward
- Define a charter for CTSA BIDS Enterprise Committee (EC)
  - Share with CTSA Program Steering Committee for approval
  - Enable November 2025 election cycle for 2026 BIDS EC Lead Team

Background

- September 2024
  - NIH changed CTSA NOFO
  - CTSA SC and Informatics Enterprise Committee (iEC) discussed high-level changes
- October 2024
  - iEC compared and contrasted disciplines
  - CTSA SC and iEC discussed in-depth changes
- November 2024
  - CTSA SC approved change from iEC to BIDS EC with specific deliverables
  - iEC held elections for 2025 iEC Lead Team
- December 2024
  - BIDS EC gathered together with ACTS BERD SIG leaders for BIDS expansion
  - NCATS requested charter draft by April 2025

Background: CTSA BIDS EC Lead Team

- Nick Anderson (UC Davis)
- Jiang Bian (Indiana)
- Elmer Bernstam* (UTHSCH)
- Tom Campion** (Weill Cornell)
- Heath Davis (Iowa)
- Tim Huerta (Ohio State)
- Meredith Zozus** (UTHSCSA)
- Manisha Desai (Stanford)
- Chris Lindsell (Duke)
- Jareen Meinzen-Derr (Cincinnati)
- Shari Messinger (Miami)

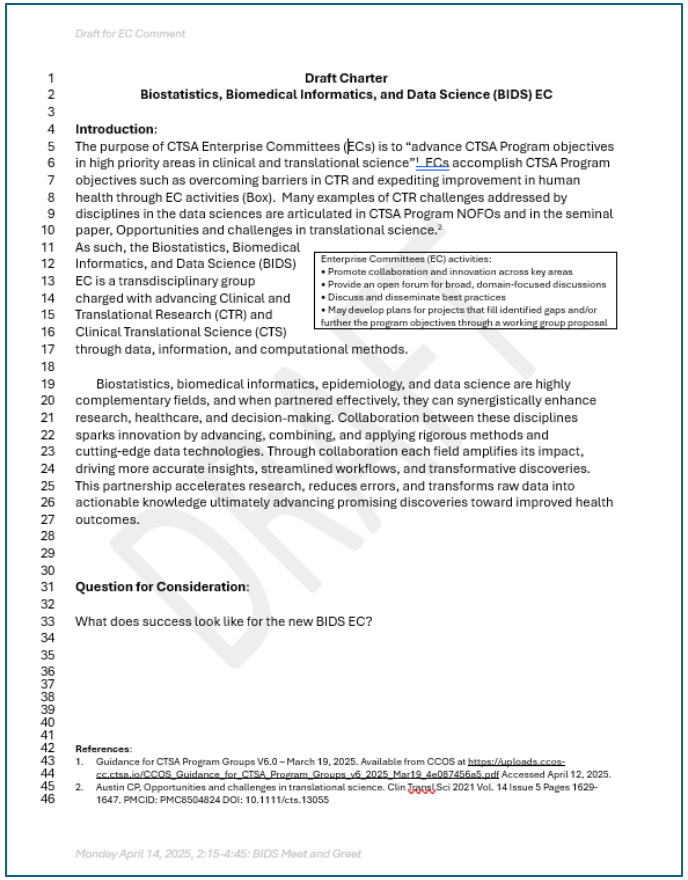
*CTSA Steering Committee representative for BIDS EC
**Co-chairs for BIDS EC

Approach

- Membership expansion
  - Soft launch
  - Formal messaging to CTSA PIs
  - Coordination with CCOS and NCATS
- Meetings
  - Virtual
    - Full Membership
    - Lead Team
  - In-person
    - BIDS EC Transition: March 14 w/ AMIA Informatics Summit
    - BIDS Meet & Greet: April 14 w/ ACTS Translational Science

Current State

- Full Members: 380+
  - Registration via NCATS BIDS Google Forms
- In-Person Meeting registrants
  - BIDS EC Transition (March 14th w/ AMIA): 32
  - BIDS Meet & Greet (April 14 w/ ACTS): 59 (20 hybrid)
- Finalization of charter
  - Available via NCATS BIDS Google Drive



Draft for EC Comment

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

Introduction:
The purpose of CTSA Enterprise Committees (ECs) is to "advance CTSA Program objectives in high priority areas in clinical and translational science"[1]. ECs accomplish CTSA Program objectives such as overcoming barriers in CTR and expediting improvement in human health through EC activities (Box). Many examples of CTR challenges addressed by disciplines in the data sciences are articulated in CTSA Program NOFOs and in the seminal paper, Opportunities and challenges in translational science.[2]
As such, the Biostatistics, Biomedical Informatics, and Data Science (BIDS) EC is a transdisciplinary group charged with advancing Clinical and Translational Research (CTR) and Clinical Translational Science (CTS) through data, information, and computational methods.

Enterprise Committees (EC) activities:
- Promote collaboration and innovation across key areas
- Provide an open forum for broad, domain-focused discussions
- Discuss and disseminate best practices
- May develop plans for projects that fill identified gaps and/or further the program objectives through a working group proposal

Biostatistics, biomedical informatics, epidemiology, and data science are highly complementary fields, and when partnered effectively, they can synergistically enhance research, healthcare, and decision-making. Collaboration between these disciplines sparks innovation by advancing, combining, and applying rigorous methods and cutting-edge data technologies. Through collaboration each field amplifies its impact, driving more accurate insights, streamlined workflows, and transformative discoveries. This partnership accelerates research, reduces errors, and transforms raw data into actionable knowledge ultimately advancing promising discoveries toward improved health outcomes.

Question for Consideration:

What does success look like for the new BIDS EC?

References:
1. Guidance for CTSA Program Groups V6.0 – March 19, 2025. Available from CCOS at https://uploads.ccos-cc.ctsa.io/CCOS_Guidance_for_CTSA_Program_Groups_v6_2025_Mar19_4e087456a5.pdf Accessed April 12, 2025.
2. Austin CP, Opportunities and challenges in translational science. Clin Transl Sci 2021 Vol. 14 Issue 5 Pages 1629-1647. PMCID: PMC8504824 DOI: 10.1111/cts.13055

Monday April 14, 2025, 2:15-4:45: BIDS Meet and Greet

Next Steps

- Obtain approval from Steering Committee (SC) for BIDS EC
  - Charter (pending SC edits/questions/feedback)
  - Voting member increase (2)
  - Election approach: new lead team members (7)
- Continue BIDS community growth
- Prepare elections

Acknowledgments

- CTSA BIDS colleagues
- ACTS
- AMIA
- CCOS
- iEC Lead Team 2024
  - Jim Cimino (UAB)
  - Peter Elkin (Buffalo)
  - Jomol Mathew (Wisconsin)
- NCATS

Questions

- BIDS EC Co-Chairs
  - Meredith Zozus: zozus@uthscsa.edu
  - Tom Campion: thc2015@med.cornell.edu
- References
  - BIDS EC Charter DRAFT: https://docs.google.com/document/d/1D1Xyhx3ZU4NNROCd-fHzKXYWc2JrYokN/edit
  - BIDS EC Meet & Greet Charter Gallery Walk Materials: https://docs.google.com/spreadsheets/d/1s4Lyo54Q-EfJqIaVDaXdqItic0D3hGEb/edit?gid=1664061997#gid=1664061997
  - BIDS EC Membership Registration: https://docs.google.com/forms/d/e/1FAIpQLSdzcPYtXluH7lN3XKzgaE9V1XpAGDCu8q78HUFt58a2P9153w/viewform

BIDS EC Charter Vote

COORDINATION

Practical Applications of CTSA Concept Mapping
2025 Follow-up Poll on Impact Measures

Project Overview for the Steering Committee
June 9, 2025

Presented by “National Co-Chair Emeriti”

Cath Kane
Director of Evaluation
NYU Langone Clinical Translational Science Institute (CTSI)

Gerry Stacy
Administrative Director
The Institute for Translational Medicine (ITM)

NYU CTSI
ITM
NIH
National Center for Advancing Translational Sciences

(Kurilla @ SC May 12th)

New Publication: Concept Mapping

"One specific measure I think should be used in an evaluation of the CTSA program is…"

>100 participants from 47 hubs

frontiers | Frontiers in Public Health

Navigating the road ahead: using concept mapping to assess Clinical and Translational Science Award (CTSA) program goals

Cathleen Kane[1]*, William Trochim[2], Haim Bar[3], Andie Vaught[4], Heather Baker[4], Munziba Khan[4], Robin Wagner[4], Kristi Holmes[5], Keith Herzog[5] and Jamie Mihoko Doyle[4]

TYPE Original Research
PUBLISHED 31 March 2025
DOI 10.3389/fpubh.2025.1562191

➢ Main Findings

- Broad range of measures (N = 81)
- **Divergence** on importance and feasibility by role
- **Consensus** on the importance of long-term impact measures

➢ Potential Next Steps

Concept Mapping as a Consortium Resource

- National leadership exploring rating to prioritize impact measures

National Center for Advancing Translational Sciences

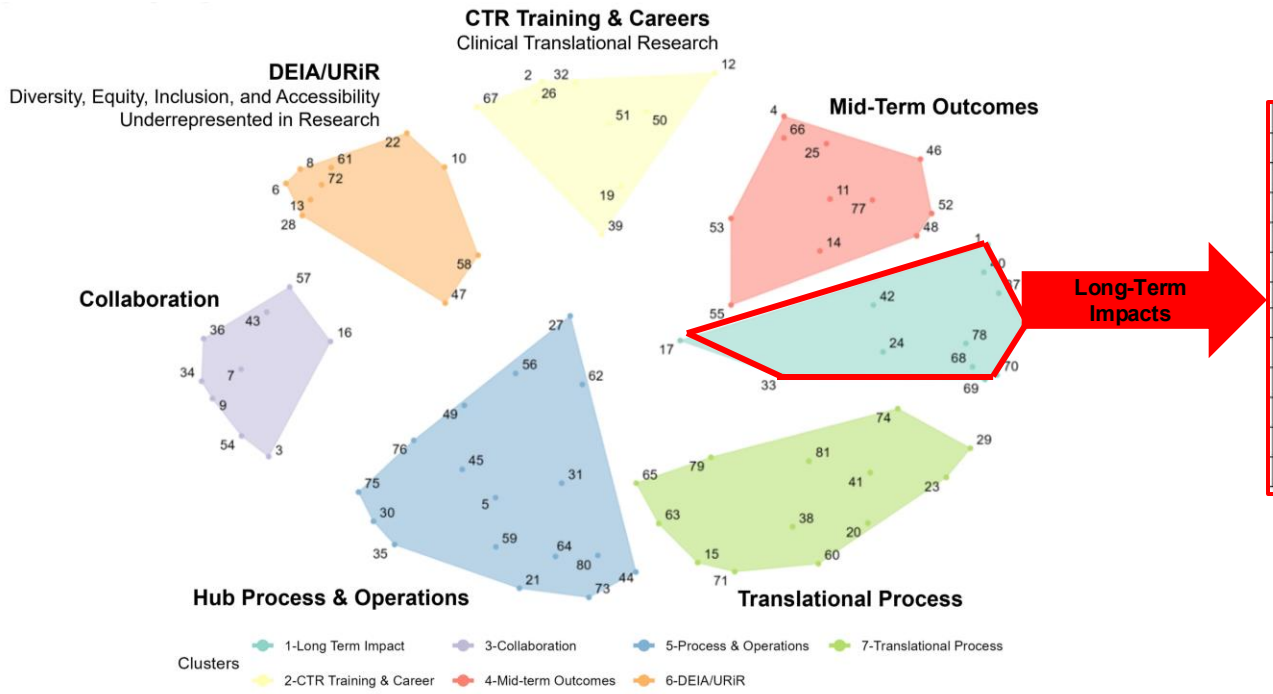
Columbia Irving Institute for Clinical and Translational Research · CTSI Miami Clinical & Translational Science Institute · Utah CTSI Clinical & Translational Science Institute · ITM · Northwestern Medicine Feinberg School of Medicine · NYU CTSI · CCTS Center for Clinical and Translational Science · OHSU Oregon Clinical & Translational Research Institute · Frontiers Clinical & Translational Science Institute at the University of Kansas · Case Western Reserve University Clinical and Translational Science Collaborative · Duke Clinical & Translational Science Institute

The CTSA Concept Map: Parallel Modes of Analysis

(Kane @ACTS April 14th)

Two modes of analysis with two different uses and relative "shelf life"

- **Sorting:** A map of common themes via multidimensional scaling
- **Rating:** Average score for importance and feasibility using medians from Likert scales



Long-Term Impacts

(N=12) Long-Term Impact Measures*

1	*Clinical and Medical Benefits (from Translational Science Benefits Model. e.g. procedures, guidelines, tools, and products)*
2	*Economic Benefits (from Translational Science Benefits Model. e.g. commercial products, financial savings and benefits)*
3	*Community and Public Health Benefits (from Translational Science Benefits Model. e.g. health activities, care, and promotion)*
4	*Policy and Legislative Benefits (from Translational Science Benefits Model. e.g. advisory activities, policies and legislation)*
5	High-level success stories (e.g. novel approaches or collaborations, mitigating translational science roadblocks)
6	Award-winning innovations developed at CTSA Hubs
7	Scientific and operational innovations developed, demonstrated and disseminated
8	New programs(e.g. entrepreneurship, translational science.)
9	Patents or trademarks filed and/or received (e.g. IP data, implementation science etc.)
10	Number of FDA approvals received by CTSA Hubs
11	Datasets made discoverable as Informatics resources
12	Systematic reviews and/or meta evaluation (e.g. the Cochrane or Campbell Collaboration showing the reproducibility of results published in a discipline over a set time period)

***82% of hub evaluators said Impact was a priority.**

(62 CTSA hubs responded to the 2024 Evaluator Survey)

The ACTS Lightbulb

Building on these concept mapping findings, Admin & Eval leadership could collaborate to launch a targeted Impact Measures Rating Poll, asking 60+ PIs to rate the 12 existing CM measures by their "*likelihood of use*" in their hub-level work, providing actionable new data to support hubs in navigating uncertain times and perhaps leading to consortium-level action.

Why This? Why Now?

Hub-Level Value

- Helps hubs show local impact, identify gaps, align with national goals, and share practices

Consortium-Level Value

- Provides a network-wide view of priorities, guides existing work groups and can further inform OPEAR support

Strategic Timing

- Builds on concept mapping extensive input and findings
- Responds to rising pressure on CTSA hubs to demonstrate impact
- Significant changes in agency priorities at the federal level

Goals & Objectives - Scope & Deliverables

The Goal

To capture leadership perspectives on the near-term utility and relevance of CTSA impact measures, especially under current funding pressures

The Objective

Launch a focused and practical poll to re-rate priority impact measures collectively identified through the CTSA Concept Mapping initiative

The Collaborators

Admin & Eval national leadership will help design, analyze and disseminate

Deliverables

- A clear snapshot of impact measures currently in use at multiple hubs that could be combined to provide higher-level impact

  "I could use this tomorrow!"

- Gap analysis of missing measures useful in the current climate/context

  "I wish I had this. This is where we need to focus our work together"

Poll Basics “At a Glance”

Scope: *Four Short Questions*

1. Retrospective Use: 12 Concept Mapping Impact Measures (Yes/No)
2. Prospective Use: 12 Measures (Likert Scale on “Likely to Use”)
3. Retrospective Gaps: Open Text (“I use X and it’s not on this list”)
4. Prospective Gaps (“I need to use X and I wish it was on this list”)

Who’s Involved:

- Admin & Eval leadership (Cath & Gerry as liaisons to current co-chairs)
- CTSA PIs (all 60+) with explicit support from Admin & Eval at each hub

Proposed Timeline & Milestones

DATES (2025)	MILESTONES
March	Paper published on Concept Mapping (CM) findings
April	ACTS session – genesis of poll idea
May	Kurilla PPT at Steering Committee (SC) meeting – CM next steps discussed
June	Status update for SC (Cath & Gerry)
June-July	Poll finalized, reviewed by Admin & Eval, sent to SC for approval
July-August	Poll distributed widely, responses supported by Admin & Eval
August	Poll closed, analysis begins, preliminary results shared with Admin & Eval
October	Fall Conference “stretch goal”: new findings formally presented and discussed

Questions for the Steering Committee

Assuming the poll moves forward as planned…

- **We'll go through normal channels for SC approval, but does this idea resonate?**
- **Can you imagine the SC benefiting from or using this information?**
- **What's the best way to share findings and disseminate results?**
  - **Open to having this at the Fall meeting?**
  - **Various Work Groups**
  - **OPEAR**
  - **White Paper etc.**

Discussion

Cathleen.Kane@nyulangone.org
Gerald.Stacy@uchicagomedicine.org

WSVS Working Group Extension Vote

COORDINATION

Adjourn

- Next Meeting: June 23, 2025