

CTSA Program Webinar

June 25, 2025

Agenda

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Lauren Fitzharris, M.P.H., P.M.P. CCOS
2:01 – 2:10 PM	NCATS/CTSA Updates	Erica Rosemond, Ph.D. NCATS
2:10 – 2:15 PM	CCOS Updates	Kerry James, M.P.H., P.M.P. CCOS
2:15 – 2:30 PM	Translational Impacts Working Group	Kristi Holmes, Ph.D. Northwestern University
2:30 – 2:45 PM	Translational Science Competency-Based Assessment Working Group Working Group	Wayne McCormack, Ph.D. University of Florida
2:45 – 3:00 PM	Engaging Individuals with Disability in the Research Process Working Group	Daniel Armstrong, Ph.D. University of Miami
3:00 PM	Adjourn	



NCATS/CTSA Program Updates

Erica K. Rosemond, PhD

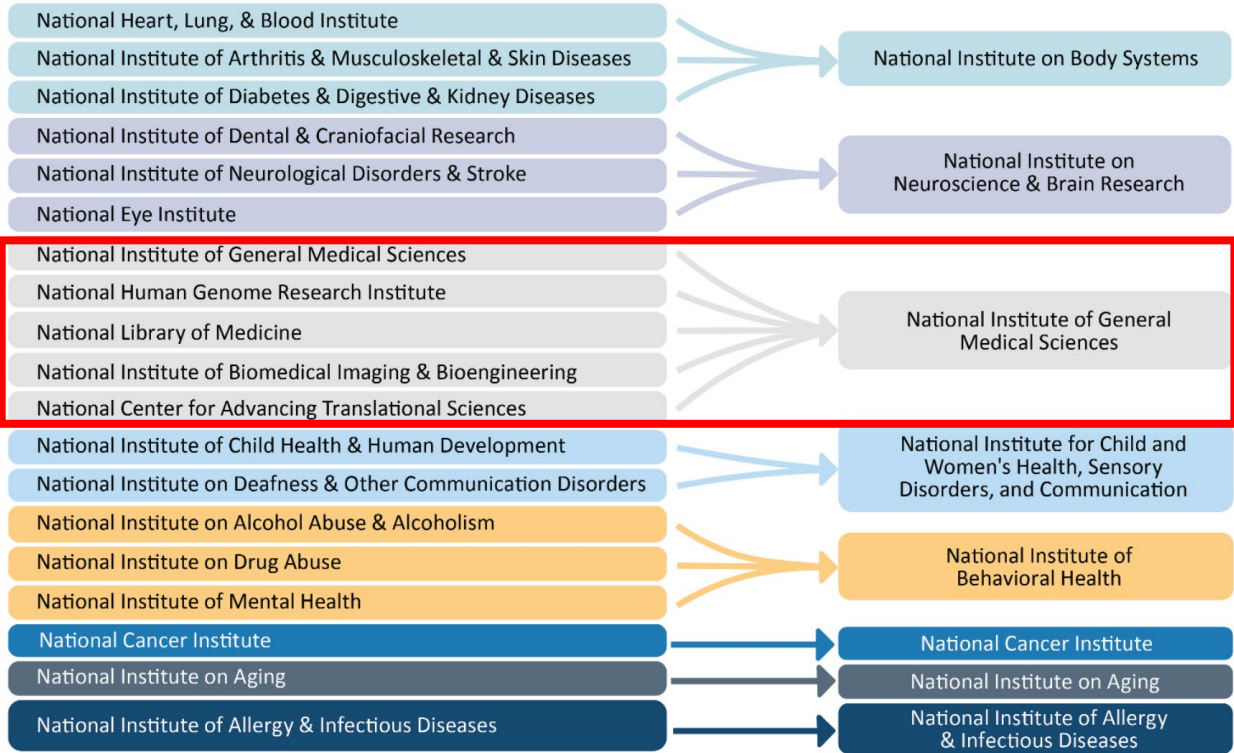
*Deputy (Division) Director, Division of Clinical Innovation
NCATS*

June 25, 2025

FY26 President's Budget-in-Brief



PROPOSED REORGANIZATION OF NIH INSTITUTES AND CENTERS



National Institutes of Health

National Institutes of Health

The following tables are in millions of dollars

Institutes/Centers ^{26 27 28}	2026
National Cancer Institute	4,531
National Institute on Body Systems	4,152
National Institute on Neuroscience and Brain Research	2,445
National Institute of Allergy and Infectious Diseases	4,175
National Institute of General Medical Sciences ²⁹	3,677
National Institute for Child and Women's Health, Sensory Disorders, and Communication	1,414
National Institute on Aging	2,687
National Institute of Behavioral Health	2,785
Office of the Director	1,650
21st Century Cures Innovation Account ³⁰	31
Buildings and Facilities	210
Mandatory Funding	2026
Special Type 1 Diabetes Current Law	--
Special Type 1 Diabetes Proposed Law	159
Subtotal, Special Type 1 Diabetes	159
Total NIH Funding	2026
Total, Program Level	27,915
Less Funds from Other Sources	-409
<i>Public Health Service Evaluation Funds</i>	-250
<i>Mandatory Funding – Type 1 Diabetes (Proposed and Current Law)</i>	-159
NIH Total, Discretionary Budget Authority	27,506
Full Time Equivalents (FTE) ³¹	16,297



Update on CTSA Applications Assigned to October Council Review Panels

NIH has consolidated all grant applications for review at the Center for Scientific Review.

CTSA applications have been sorted into the following review panels at the Center for Scientific Review:

- **07/21/2025:** CTSA specific panel: RC2 / CCIA / R03
- CTSA specific panel: UM1
- CTSA K12s with CTSA T32s [and some other similar grants]
- CTSA R25s in an NIH-wide R25 panel

*these review panels are Special Emphasis Panels and meeting dates **are scheduled**

* Thirty days before the meeting, the meetings should be posted publicly here:

<https://public.csr.nih.gov/StudySections/SpecialEmphasis>

*management of the organization of these review assignments is now under the purview of the NIH Center for Scientific Review and subject to change



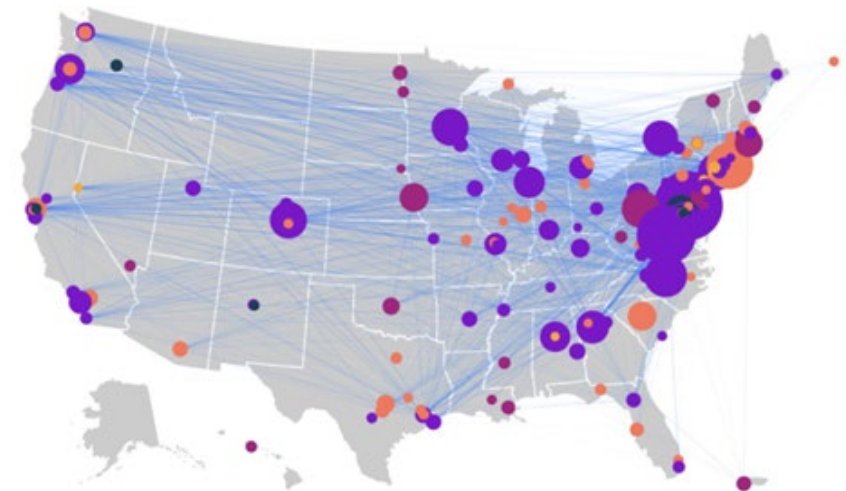
National Center
for Advancing
Translational Sciences

National Clinical Cohort Collaborative (N3C)

- National Clinical Cohort Collaborative (N3C) Community Forum took place June 2 where NCATS introduced the new N3C Vision
- **N3C Community Forum Page:**
<https://ncats.nih.gov/research/research-activities/n3c/n3c-community-forum>
 - [Recording](#) and [slides](#) from the Forum are now available!
 - If you have any questions, comments, or would like to volunteer for a Domain Team, please send them to ncatsn3cclinical@nih.gov
- N3C webpages have been recently updated [here](#)! Check them out!



National
Clinical
Cohort
Collaborative



National Center
for Advancing
Translational Sciences

TRIAL INNOVATION NETWORK

JAMA
Network | Open



Research Letter | Statistics and Research Methods



Enhancing Multicenter Trials With the Trial Innovation Network's Initial Consultation Process

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2834555>

Published Online: May 29th, 2025

The Trial Innovation Network (TIN) recently published the experiences and insights gained during the last 8 years of initial consultations process.

Purpose of initial consultations: Provides researchers and the CTSA with resources and recommendations to address complex aspects of planning and conducting more informative clinical trials; data-driven solutions for site identification, representative recruitment, and retention planning; data management; and regulatory compliance

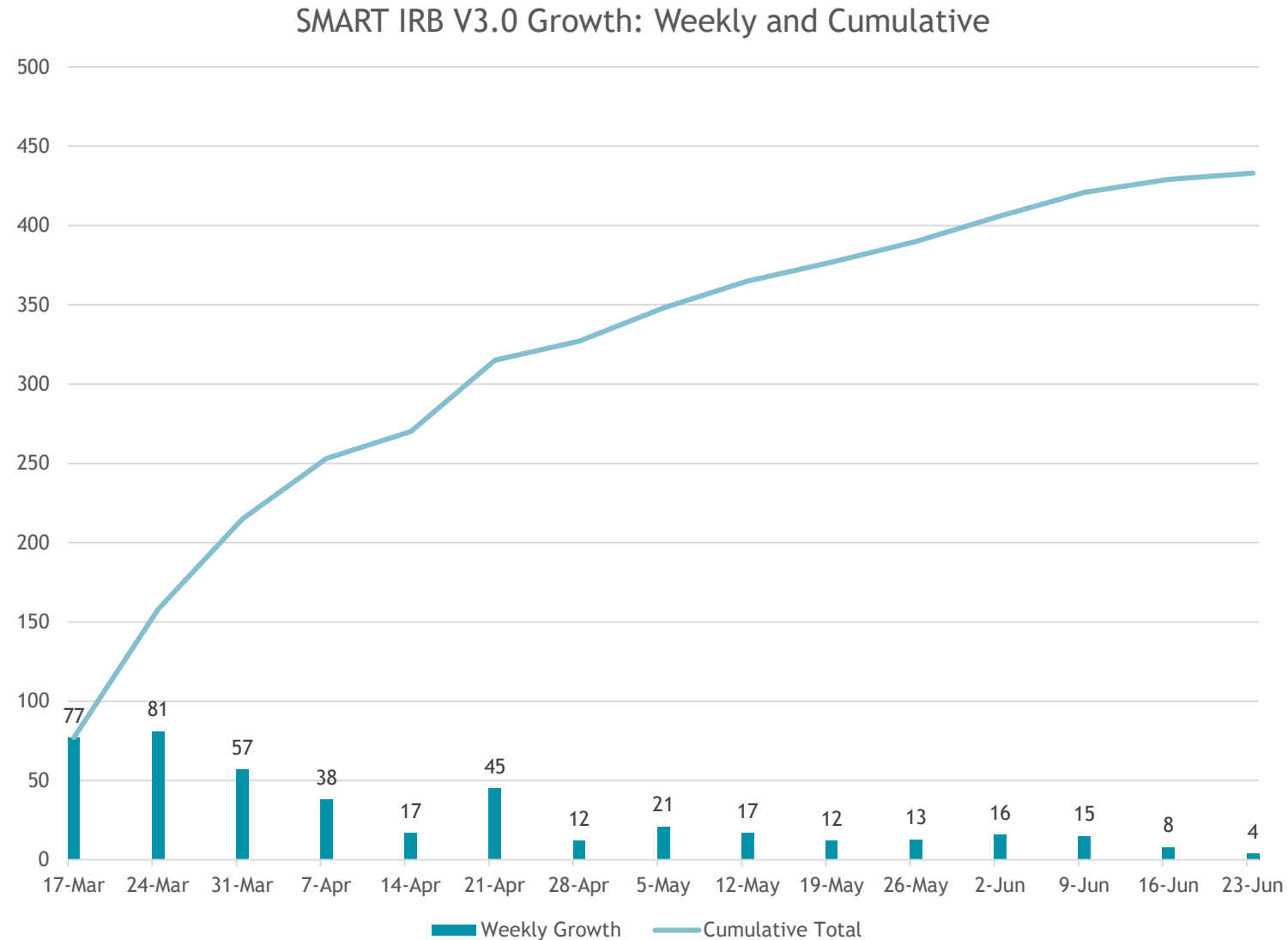
How your CTSA program can access the TIN initial consultation: Through your TIN Liaison or the TIN website

<https://trialinnovationnetwork.org/elements/trial-innovation-network-proposal-process/>

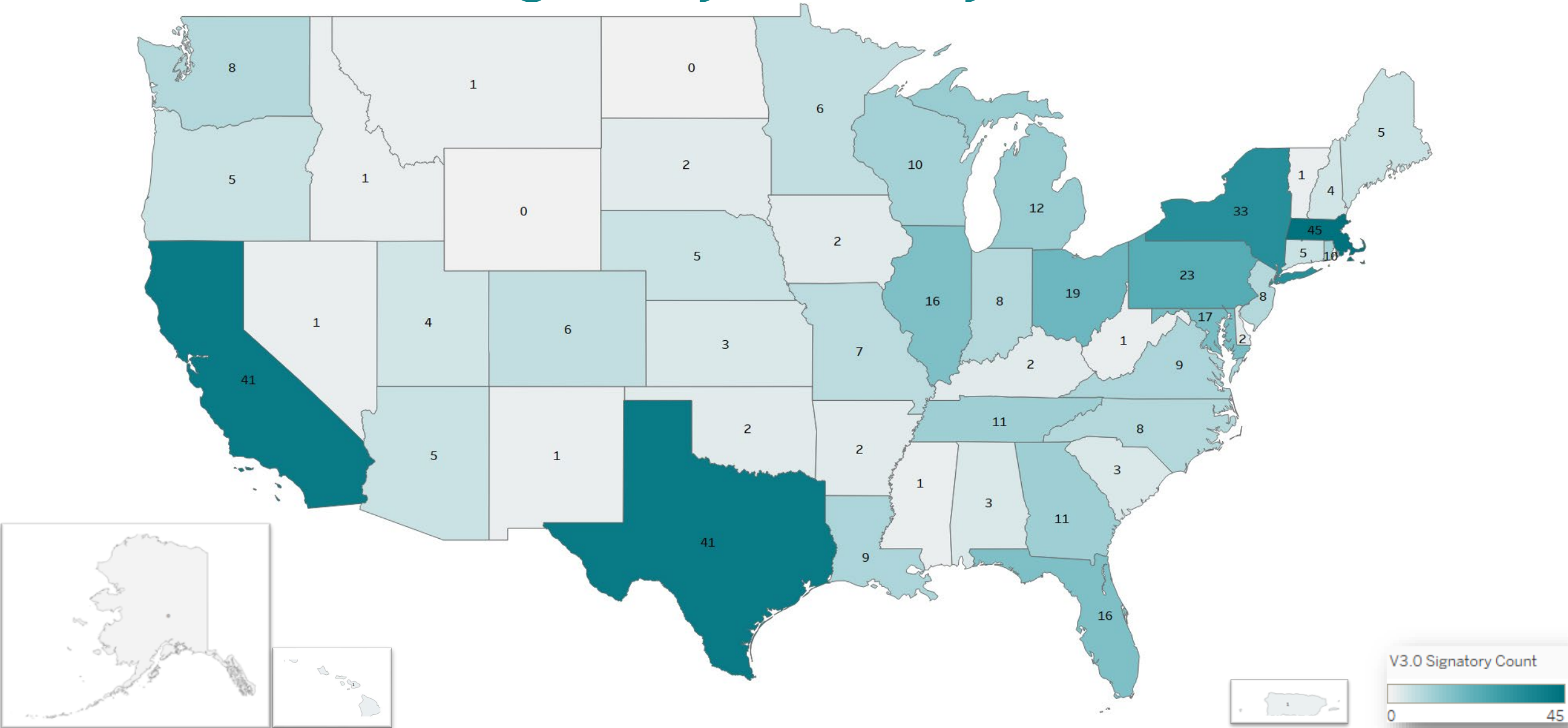
SMART IRB Version 3.0: Growth in First 100 Days

V3.0 launched on March 17, 2025 and has seen significant growth. As of June 23, 2025:

- **1369** total SMART IRB Participating Institutions
- **438** V3.0 Signatory Institutions
- **65** Signatory Indemnification Addendum Institutions
- Representation across **47** states, D.C. and Puerto Rico



SMART IRB V3.0 Signatory Count by State



NIH Notices

- [NOT-OD-25-124](#) Notice of Rescission of Civil Rights Term and Condition of Award (released June 12, 2025)
 - NIH rescinds Guide Notice “Notice of Civil Rights Term and Condition of Award” ([NOT-OD-25-090](#)). NIH is awaiting further Federal-wide guidance and will provide a future update to the extramural community. The previous guidance is no longer in effect.
 - **this notice was defining the terms DEI and DEIA and indicating that by recipients accepting the grant award they will not operate any programs that advance or promote DEI, DEIA Etc
- * All recipients are expected to read, be familiar and comply with all terms and conditions on their Notice of Award. Terms and conditions of award are accepted when the recipient draws down funding from the HHS Payment Management System.



Upcoming Dates to Remember

Next CTSA Program Webinar

July 23, 2025; 2-3 PM ET.

[Register here](#) for the 2025 series



NCATS

COLLABORATE. INNOVATE. ACCELERATE.

 ncats.nih.gov

 [@ncats_nih_gov](https://twitter.com/ncats_nih_gov)

 [@ncats.nih.gov](https://facebook.com/ncats.nih.gov)

 [NIH-NCATS](https://linkedin.com/company/NIH-NCATS)



NIH National Center
for Advancing
Translational Sciences

CCOS Updates

Kerry James

CTSA Member Directory

A powerful new feature that allows you to:

- Easily find and connect with members based on their affiliations with CTSA Working Groups, Consortium Groups, and Enterprise Committees.
- Foster collaborations by identifying potential partners for your projects.
- Expand your network and engage with peers across various disciplines.

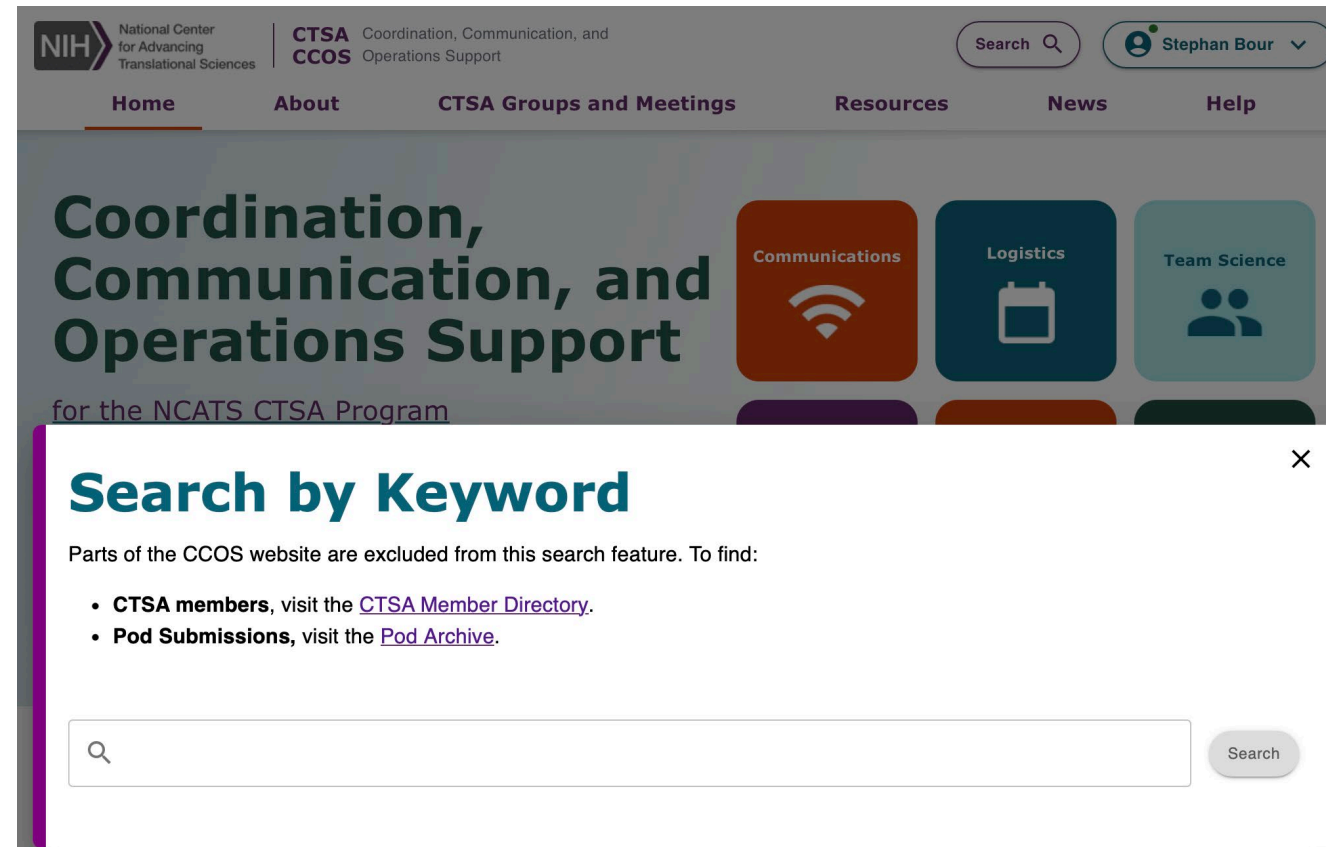
The screenshot shows the CTSA Member Directory web application. At the top is a purple header with navigation links: U.S Department of Health & Human Services, National Institutes of Health, NCATS, and CTSA Program. Below this is a secondary navigation bar with links: Home, About, CTSA Groups and Meetings, Resources (highlighted), News, and Help. A search bar and a user profile icon are on the right. A dropdown menu for 'Resources' is open, showing options: Calendar, Governance, CTSA Hub Directory, CTSA Member Directory (highlighted with a mouse cursor), and Surveys. The main content area is titled 'Member Directory' and includes a sub-header 'Resources > CTSA Member Directory'. Below the title is a brief description: 'View all active members in the CTSA Program. If you would like to correct any information displayed in the directory, contact support@ccos.ctsa.io.' The interface features a search section with 'Search By' and 'Search by Name' dropdowns, both set to 'Name', and an 'Apply' button. A 'Count: 2510' is displayed. On the left, there are 'Filters' for 'Institution', 'Hub', and 'CTSA Group', each with a 'Select' dropdown. On the right, there are 'Sort By' and 'Sort Order' dropdowns, set to 'Name' and 'Ascending (A-Z)' respectively. The main table has columns for 'Name', 'Institution', 'Hub', and 'CTSA Group(s)', with the first row currently empty.

Questions? Please email [**support@ccos.ctsa.io**](mailto:support@ccos.ctsa.io)

CCOS Site Search

With our improved search capabilities, you can:

- Effortlessly find the information and resources you need.
- Access meeting materials and documentation with ease.
- Stay up-to-date with the latest updates and announcements.



Questions? Please email support@ccos.ctsa.io

CTSA Element E Form + Directory

- Developed in response to interest in CTSA Element E Research Programs and Projects at Fall 2025 CTSA Program Meeting
- Hub PIs will select the most appropriate personnel to submit for the Research Program and for the individual Research Projects.
- Each Element E project will be approved by NCATS prior to appearing in the Element E Directory on the CCOS website; a time lag of 2 – 10 business days between submission and its appearance on the CCOS website should be anticipated.
- Please consider that NCATS will only be able to publish on the CCOS website projects that are in line with agency priorities.
- A CCOS account is required for submission and to view the Directory.



Technical issues?

Contact Support@ccos.ctsa.io

Programmatic questions?

Contact Heather Baker @ heather.baker2@nih.gov

CCOS Policy Update

- Starting **September 1**, a CCOS account will be required for CTSA members to join a CTSA Group
 - Enterprise Committees
 - Consortium Groups
 - Working Groups
- Applies to **new group members**
- Current members ***without active CCOS accounts*** will be contacted to complete registration in the coming weeks
- Hub Administrators may see an increase in new user requests for your hub over the coming months
- Please check for new user requests in your **Manage Hub Users** dashboard and review the [Guidance for CTSA User Management](#) if needed

Questions? Please email support@ccos.ctsa.io

Account Access Includes:

- Meeting Materials/Archives
- CTSA Member Directory
- Collaborative Workspaces
- Discussion Forums



To sign up, visit
ccos-cc.ctsa.io/user-account-request

BIDS EC Charter Approval

- The **B**iostatistics, **B**iomedical **I**nformatics, and **D**ata **S**cience (BIDS) EC charter has been approved by the CTSA Steering Committee on Jun 9, 2025.
- For reference, here is the finalized BIDS EC [Charter](#).
- BIDS EC Membership:
 - BIDS EC Meetings are open to any member of CTSA program hubs
 - Participation in the BIDS EC is strongly encouraged among those in BIDS disciplines with institutional leadership roles.
 - Balance is also encouraged between professionals, administrators, and across levels of BIDS faculty and trainees.
- BIDS EC Voting Members:
 - Per approved charter, CTSA Hubs are allowed to have **two voting members on the BIDS EC** due to increase in size and scope of the BIDS EC.
 - Voting members from different disciplines at each CTSA hub are highly encouraged.
 - Hub voting members should reflect institutional authority in a BIDS related discipline.

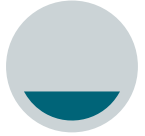
Enterprise Committee (EC) Voting Member Status

- Membership on at least one of the four Enterprise Committees (EC) is required for each CTSA Program hub
- Each hub is allowed to have one voting member on each EC except for the BIDS EC, which is allowed 2 voting members per hub due to increase in size and scope of EC
- The voting members are appointed by the hub PI and serve as primary point of contact for their hub for all matters relating to their specific EC
- Hub administrators are responsible for reviewing and updating the list of voting members for each EC in preparation for EC Lead Team Elections

❖ **More details to come from CCOS regarding confirming voting members on CCOS website**

For more information about Enterprise Committee membership, review the **Guidance for CTSA Program groups** at [Governance and Guidance | CTSA CCOS](#)

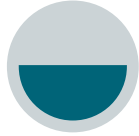
Upcoming Annual EC Lead Team Elections



September
2025

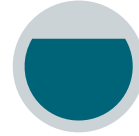
Pls work with
Administrators to
select EC voting
members

Administrators
confirm EC voting
members via
***Manage Hub
Users section*** of
CCOS website



October
2025

EC voting
members submit
Lead Team
nominations



November
2025

Nominees accept
nomination &
provide bio

Ballots circulated
to EC voting
members

EC Lead Team
votes tallied



December
2025

New EC Lead
Team members
notified

Announcements
to CTSA EC
members

CCOS to
schedule meeting
with new Chairs

Fall 2025 CTSA Program Meeting

CTSAs Leading the Way: Resilience, Innovation and Impact

Tentative Date: October 22-24, 2025

Day 1

9:00-1:00 Steering Committee

1:00-2:30 Joint EC Leads Meeting

1:00-7:00 Hub Administrators

2:00-5:00 TIN Meeting

3:00-7:00 Enterprise Committees

- Workforce Development (3-6pm)
- Collaboration and Engagement (3-6pm)
- BIDS (4-7) (***may move to Day 3 afternoon***)
- Integrations Across the Lifespan (4-7)

Day 2

- Welcome
- Opening Keynote (60 min)
- Sessions 3-5 (75 min each)
- UL1/UM1 PI Meeting
- Poster Presentations

Day 3

- Sessions 6-7 (75 min each)
- NCATS Session (75 min)
- Closing

End by 1:00pm

2025 Fall Planning Committee

VOLUNTEERS	
Grace McComsey, Co-Chair	Case Western Reserve University
Andrea Carnegie	UNC Chapel Hill
Jennifer Cieslak	University of Minnesota
Elmer Bernstam	University of Texas Houston
Jason Hatfield	University of Minnesota
Mike Holinstat	University of Michigan
David Ingbar	University of Minnesota
Julie Johnson	The Ohio State University
Jessica Kahn	Albert Einstein College of Medicine
Brittany Martinez	The University of Kansas Medical Center
Jareen Meinzen-Derr	Cincinnati Children's Hospital
Gerry Moeller	VCU Health
Rey Panettieri	Rutgers Health
Kelsey Schweiberger	Children's Hospital of Pittsburgh
Ted Wun	UC Davis

NCATS
Michael Kurilla, Co-chair
Audie Atienza
Kris Bough
Heather Baker
Gallya Gannot
Joan Nagel
Tom Radman
Erica Rosemond

CCOS
Amanda Scott, Planning Lead
Melissa Brady
Kerry James
Lauren Fitzharris

Fall Meeting Logistics Update

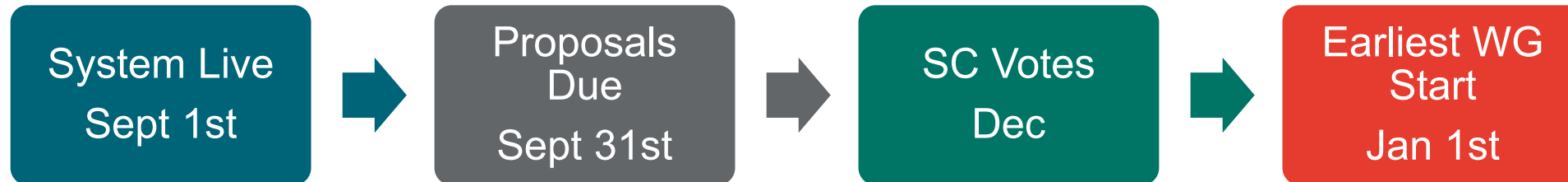
- Reviewing Hotel and AV proposals for October 22-24 meeting; completed site visit.
- Budget to be submitted for NIH approval, required prior to contracting.
- Drafting communication to hubs PIs and Administrators regarding meeting status, attendance limits.
- Fall Planning Committee (FPC) to focus topics, format and structure until outcome of NIH approval is determined.

9 attendees per hub *(not including TIN, Steering Committee or FPC members)*

- 5 representatives of Hub leadership per NOFO
- 1 representative per EC (4 total)

New Working Groups

- 4 proposals submitted in Cycle XIV
- Steering Committee approved two proposals
 - Notifications will be sent the week of June 30th
- Next WG proposal cycle opens in September



Webinar Series: Engaging Individuals with Disability in the Research Process WG

- The CTSA Engaging Individuals with Disability in the Research Process Working Group will hold their third and final webinar **on Friday, June 27th, 2025, from 2:00 – 3:00 pm ET**
- This webinar will cover “**Leveraging Your Lived Experience on a Research Team.**”
- The session is designed to support individuals with lived experience of disability and/or chronic health conditions in contributing meaningfully to research collaborations. Presenters will share tools and strategies for building research teams that recognize and incorporate lived experience, identify common barriers and facilitators to participation, and offer practical recommendations for individuals, mentors, and research teams. This interactive webinar will include real-world examples, audience polling, and a live Q&A to support learning, implementation, and translation into practice.
- **Please register for the webinar using the Zoom link [here](#) and save the calendar invitation sent via email.**



Kara B. Ayers, Ph.D.
University of Cincinnati



Emily Hotez, Ph.D.
University of California Los Angeles



Robin Lanzi, Ph.D., M.P.H.
University of Alabama at Birmingham

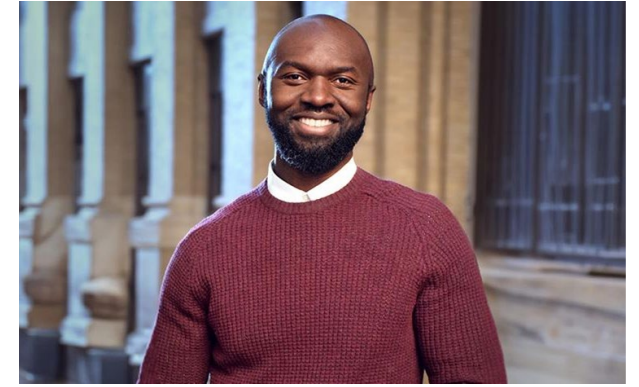
Thank you!

CTSA Translational Impacts Working Group

Report Out to CTSA Program

June 25, 2025

TI-WG co-leads:



Emmanuel Tetteh, MD
Washington University



Institute of Clinical and
Translational Sciences



Kristi Holmes, PhD
Northwestern University

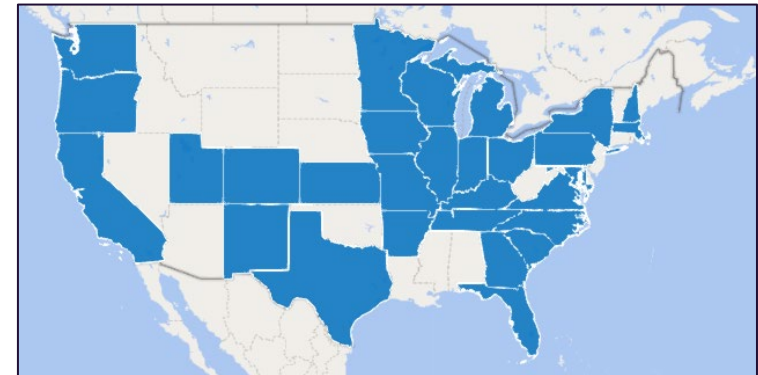
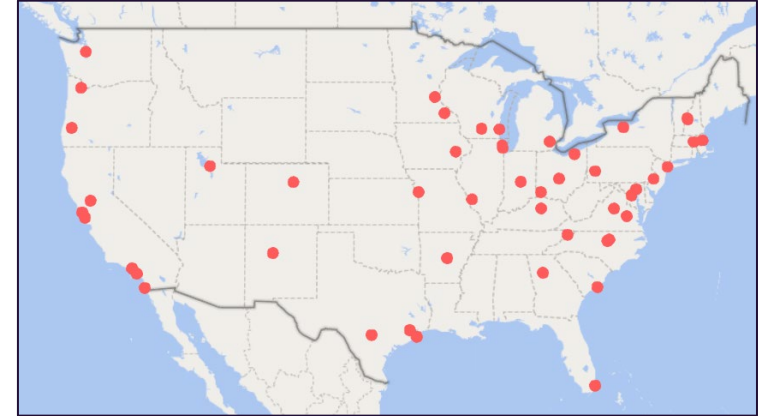
Translational Impacts Working Group

139 members from 62 CTSA Institutions

Boston University Medical Campus
Case Western Reserve University
Cincinnati Children's Hosp Med Ctr
Columbia University Health Sciences
Dartmouth
Dartmouth College
Duke University
East Tennessee State University
Emory University
Harvard Medical School
Howard University
Indiana University
Johns Hopkins University
Mayo Clinic Rochester
Medical College of Wisconsin
Medical University of South Carolina

Medical College of Wisconsin
Medical University of South Carolina
New York University School of Medicine
Northwestern University
Ohio State University
Oregon Health & Science University
Pennsylvania State University
Stanford University
Tufts University Boston
University of Arkansas For Med Scis
University of California
University of California At Davis
University of California Irvine
University of California Los Angeles
University of California San Diego
University of California, San Francisco

University of Cincinnati
University of Colorado Denver
University of Houston
University of Illinois At Chicago
University of Iowa
University of Kansas Medical Center
University of Kentucky
University of Massachusetts Med Sch Worcester
University of Miami School of Medicine
University of Michigan At Ann Arbor
University of Minnesota
University of New Mexico Health Scis Ctr
University of North Carolina Chapel Hill
University of North Carolina Chapel Hill
University of Pennsylvania
University of Pittsburgh At Pittsburgh



Translational Impacts WG Meetings

8 working group
meetings

139 members
(and counting!)

49 average
attendees

Typical Agenda:

- Report-outs about WG activities
- Informational updates
- CTSA presentations and sharing
- Impact community presentations

The Translational Science Benefits Model, a new training tool for demonstrating implementation science impact: A pilot study

Dr. Enola K. Proctor & Stephanie Andersen, MPH, Brown School at Washington University St Louis; ICTS

Integrating knowledge mobilization and implementation science along the pathways to impact.

Dr. Kathryn Graham, PhD, Research Impact Assessment Lab at University of Calgary

Working Group Goals

- **Establish a Community of Practice** to support CTSA hubs on their efforts to enable Translational Impact (TI) and foster ongoing connection and collaboration across the consortium.
- **Develop and disseminate resources and tools** to assess, communicate, and advance TI across hubs.
- **Address key challenges in translation** through shared strategies, open dialogue, and knowledge exchange.
- **Drive future innovation and collaboration** to strengthen the field and promote continuous improvement in TI.

A dynamic and motivated working group with several areas of work underway!

Accomplishments to date

**Establish the WG
resources and tools**

**Set up a regular meeting
cadence**

**Establish the three task
groups, recruit leaders,
build teams, start work**

**Recruit speakers for
monthly meetings**

**Presentations to the
CTSA Evaluators**

**Presentation & group
discussion on
Translational Impact at
2025 ACTS meeting**

TI-WG Outputs

1. **Impact Instrument***: A standard question set to assess TSI activities and methods across CTSA Hubs;
2. **TSI Repository***: A publicly available, searchable, and curated “toolkit” collection of TSI resources. This “community collection” can include instruments, templates, frameworks, visualizations, protocols, and case studies, as well as collaborative outputs by the TSI-WG and CTSAAs more broadly;
3. **Translational Impact Summit***: A forum for learning, sharing best practices, collaboration, and identifying standard cross-hub TSI metrics – target spring 2026;
4. and a **Community of Practice** focused on maturing TSI evaluation

Translational Impacts Working Group Deliverables

1. Impact Instrument Task Group

Leads: Joe Hunt (Indiana U); Alyson Eggleston (Penn State); Lixin Zhang (Case Western)

Collaborative development of resources to support assessment of Translational Science Impact activities and methods across the CTSAs, including impact metrics/plans across hubs and frameworks used to identify impact; survey, logic model, manuscript and other other resources expected

- **Develop definitions for key terms related to impact assessment.**
- **identify develop and validate impact instruments, tools, and processes.**
- **Promote consistency and comparability.**
- **Empower stakeholders with actionable insights.**
- **Facilitate knowledge sharing and best practices.**

A logic model guides the group's work

Inputs

Activities

Outputs

Outcomes

Impact

Translational Impacts Working Group Deliverables

2. Impact Summit Task Group

Leads: Amelia Bucek (Northwestern); Emmanuel Tetteh (WashU)

Forum for learning, sharing best practices, collaboration, and identifying standard cross-hub TI metrics.

A highly interactive virtual event, with a mix of sessions, submitted and invited sessions, likely over 2 half-days

- **CTSA impact** – highlight the terrific work happening across our network (TSBM, training, etc.)
- **Broader impact** - Lessons learned and ideas for the future



Translational Impacts Working Group Deliverables

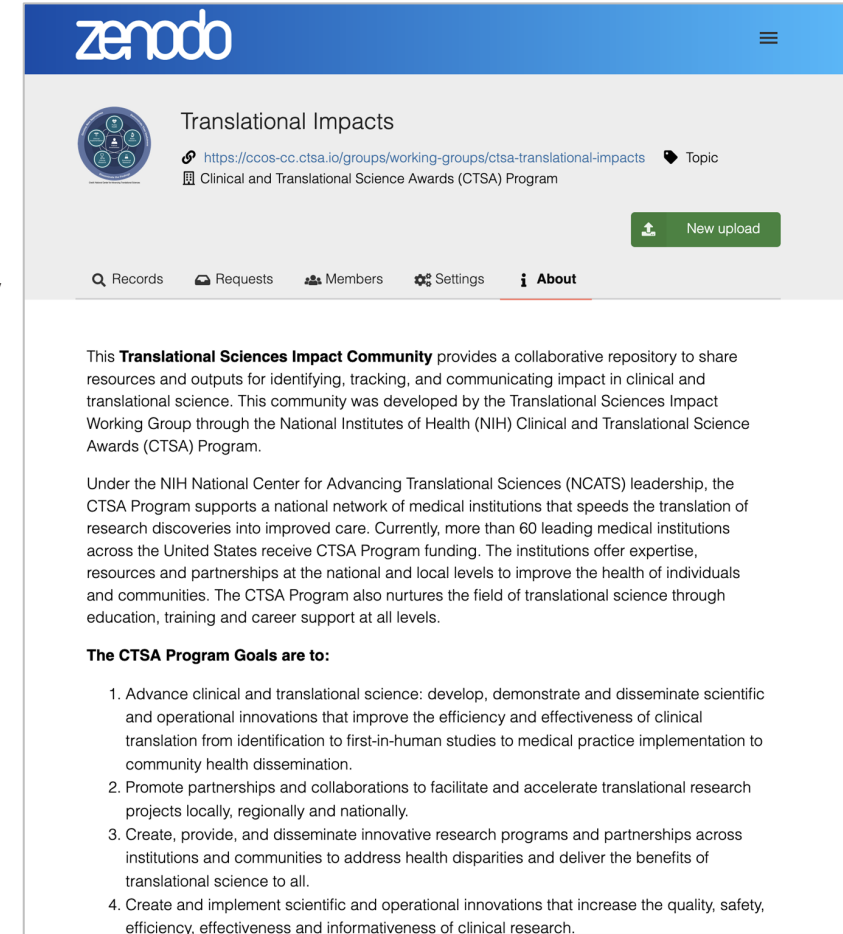
3. Impact Repository Task Group

Leads: Bart Ragon (U. Virginia iThriv), Shannon Casey (UW - Madison), Veronica Hoyo (Northwestern U);

Searchable, curated collection of TI resources (e.g., instruments, templates, frameworks, visualizations, protocols, collaborative outputs) openly available as a Zenodo Community to support a sustainable and FAIR resource. Regular calls for deposits and use of this resource will be introduced.

A Zenodo Community makes materials searchable and accessible

- Records are FAIR and discoverable by people and machines
- Materials assigned DOIs, making them citable and trackable
- Metrics available on the item and collection level
- Accepting deposits now
- Next actions: **guidebook** for deposits and office hours
- Let us know if you have items you'd like to share!





The GREI Zenodo community is home to our collection of project outputs.

All results indicate unique views and downloads of each output/record from the start of the project in 2022 until the present.

GREI's Zenodo Community has:

31
Digital Records

40,316
Total Unique Views

23,804
Total Unique Downloads

Top 5 Most Viewed GREI Resource	
Data updated on: 12/3/2024 8:39:37 PM	
Generalist Repository Selection Flowchart	1,973
GREI Collaborative Webinar: Use Cases in Generalist Repositories and Community Feedback	1,817
GREI Metadata and Search Subcommittee Recommendations_V01_2023-06-29	1,574
GREI Data Citation Best Practices for Repositories	1,267
Generalist Repository Ecosystem Initiative Introductory Brochure	1,003

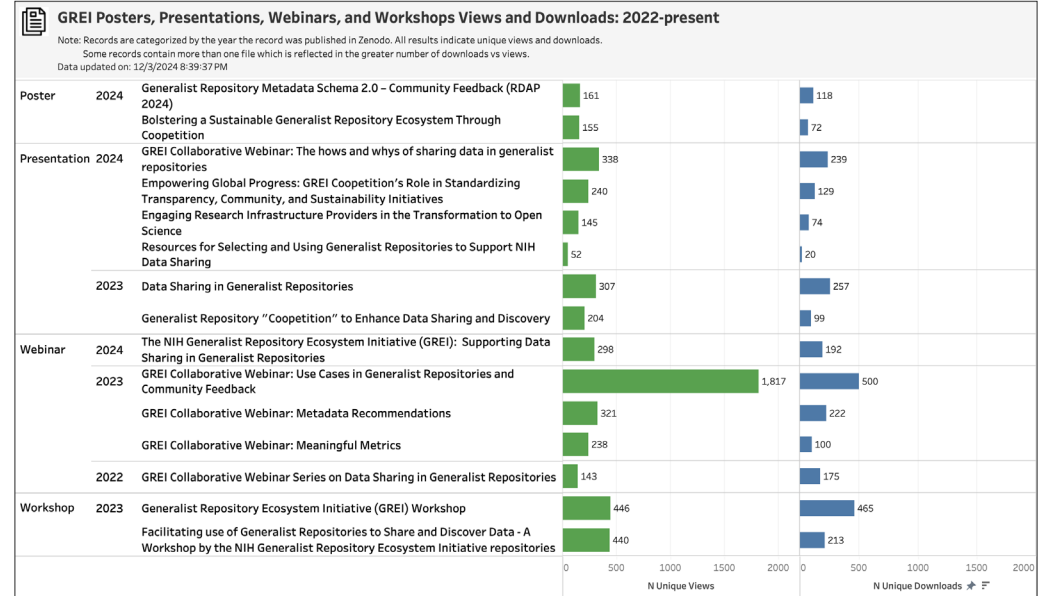
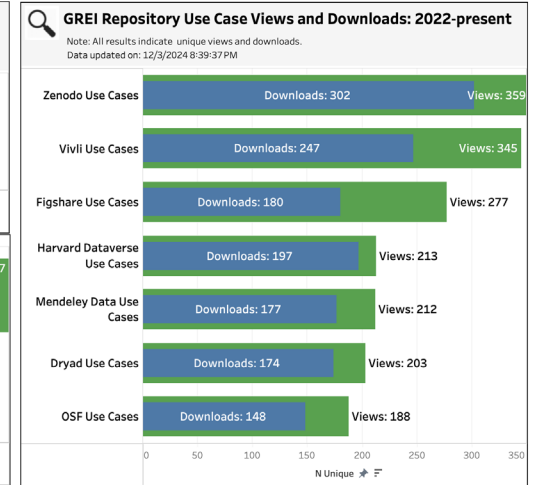
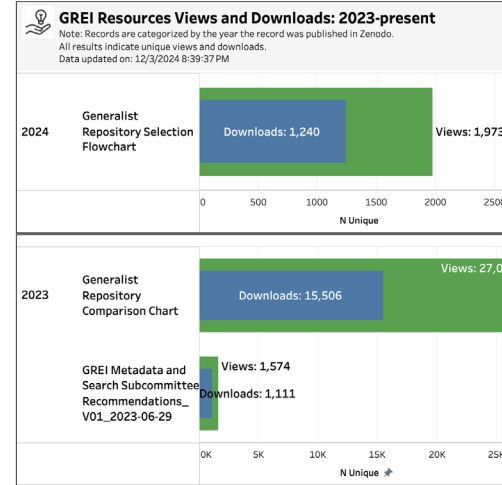
Top 5 Most Downloaded GREI Resource	
Data updated on: 12/3/2024 8:39:37 PM	
Generalist Repository Selection Flowchart	1,240
GREI Metadata and Search Subcommittee Recommendations_V01_2023-06-29	1,111
Generalist Repository Ecosystem Initiative Introductory Brochure	870
GREI Data Citation Best Practices for Repositories	511
GREI Collaborative Webinar: Use Cases in Generalist Repositories and Community Feedback	500

GREI Outputs

GREI Zenodo Community Top 10 Most Viewed and Downloaded Resources: 2024			
Note: Records are categorized by the year the record was published in Zenodo. Data updated on: 12/3/2024 8:39:37 PM			
	Output Title	N Unique Views	N Unique Downloads
2024	GREI Data Citation Best Practices for Repositories	1,267	511
	Zenodo Use Cases	359	302
	Vivli Use Cases	345	247
	GREI Collaborative Webinar: The hows and whys of sharing data in generalist repositories	338	239
	The NIH Generalist Repository Ecosystem Initiative (GREI): Supporting Data Sharing in Generalist Repositories	298	192
	Figshare Use Cases	277	180
	Empowering Global Progress: GREI Coopetition's Role in Standardizing Transparency, Community, and Sustainability Initiatives	240	129
	Harvard Dataverse Use Cases	213	197
	Mendeley Data Use Cases	212	177
	Dryad Use Cases	203	174
	OSF Use Cases	188	148

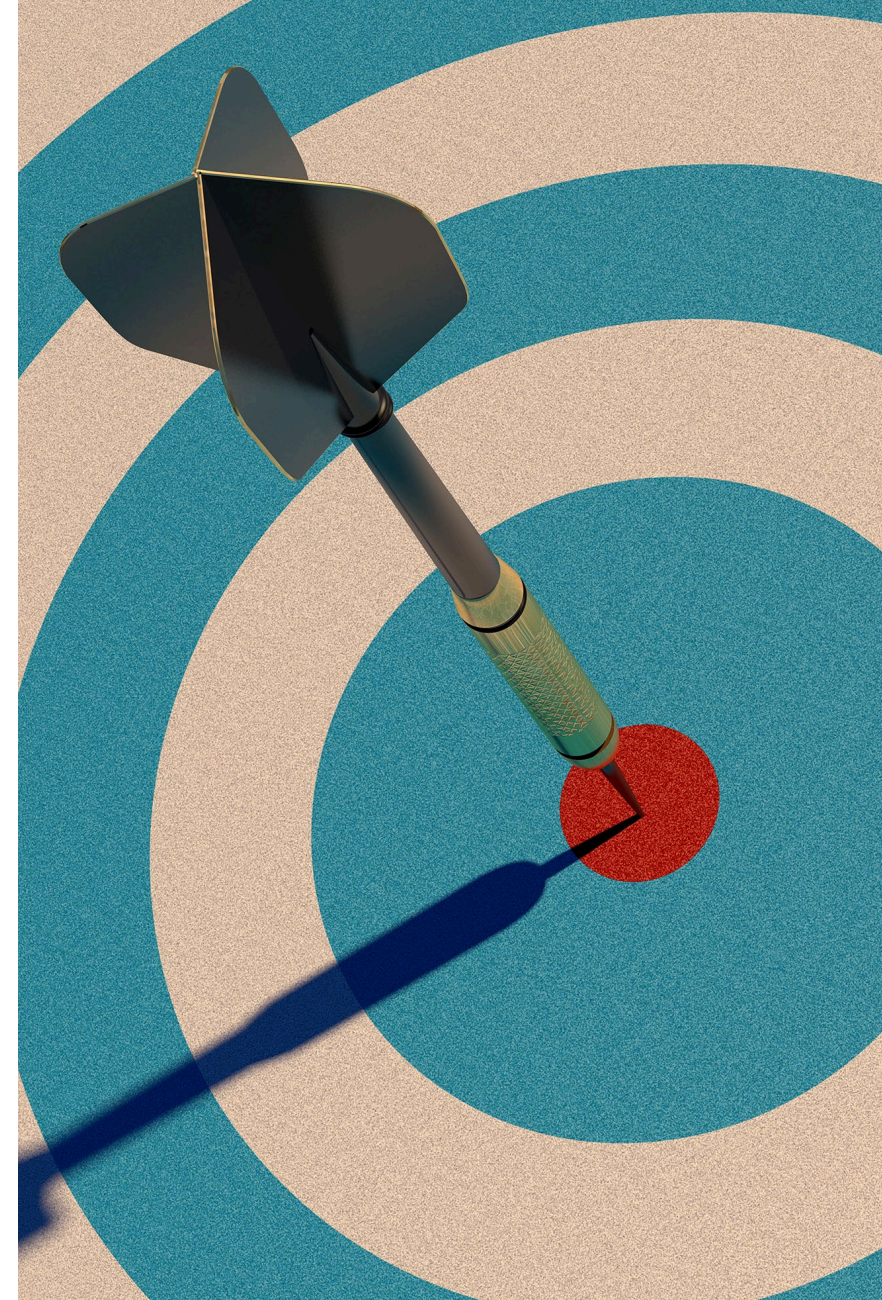
GREI Output Types

■ N Unique Downloads ■ N Unique Views



Plans for the upcoming year

1. Make progress on working group deliverables
2. Identify opportunities to present more openly about our work
3. Continue engagement – other CTSA WG, different hub roles
4. Speakers for our WG meetings – facilitate ongoing learning and sharing
5. Impact Summit
6. Build our Community of Practice!



Teamwork makes the dream work

Current “asks”

- Nominate speakers for upcoming WG meetings
- Let us know if you have materials to share (instruments, reports, data visualizations, logic models, case studies, white papers, dissemination materials, etc.)

Translational Impacts WG

WG Mailbox: Translational.Impacts@ccos.ctsa.io

WG Webpage: [Translational Impacts WG](#)

Sign up: <https://forms.office.com/r/tMzjk2UrNX>



Questions we posed to the Steering Committee

1. What are the strategic priorities we should keep front and center as we design and execute our work?
2. Are there any specific collaborations with external partners, funders, or policymakers we should pursue? If so, can you assist us with making these connections?
3. How would you like us to report progress and share findings with the broader CTSA community?
4. What input do you have for us about the sustainability of efforts post-project?

Thank you!

CTSA Translational Science Competency-Based Assessment (TS-CBA) Working Group

**CTSA Program Webinar
Wednesday, June 25, 2025**

Wayne T. McCormack, PhD
mccormac@ufl.edu

Translational Science Competency-Based Assessment Working Group

- Chair: Wayne T. McCormack, PhD (UF)
- Roster: 58 members from 29 CTSA institutions



Boston U	Oregon HSU	U Michigan
Clemson U	Penn State U	U Minnesota
Duke U	Rutgers U	U North Carolina
Einstein	U Arkansas Med Sci	U Rochester
Georgetown U	U Buffalo	U Texas Austin
Howard U	U Cincinnati	U Texas HSC San Antonio
Mayo Clinic	U Colorado	U Washington
Med Coll Wisconsin	U Florida	U Wisconsin
NYU	U Kansas	Virginia Commonwealth U
Ohio St U	U Mass	

- CTSA Roles: K, T, WD, Evaluation, Team Science, Pilot Studies
- Meetings: 1st and 3rd Wednesday at 1:00 pm (ET)

Why Competencies?

■ PROBLEM

- Research training has traditionally been an apprenticeship
- When is a postdoc ready to lead their own research group?
- When is a student ready to graduate? Do you “know it when you see it?”

■ COMPETENCY

- The ability to do something successfully or efficiently (Oxford Dictionary)

■ GOAL

- To define the knowledge, skills and attitudes required for a translational scientist to lead a successful translational research team

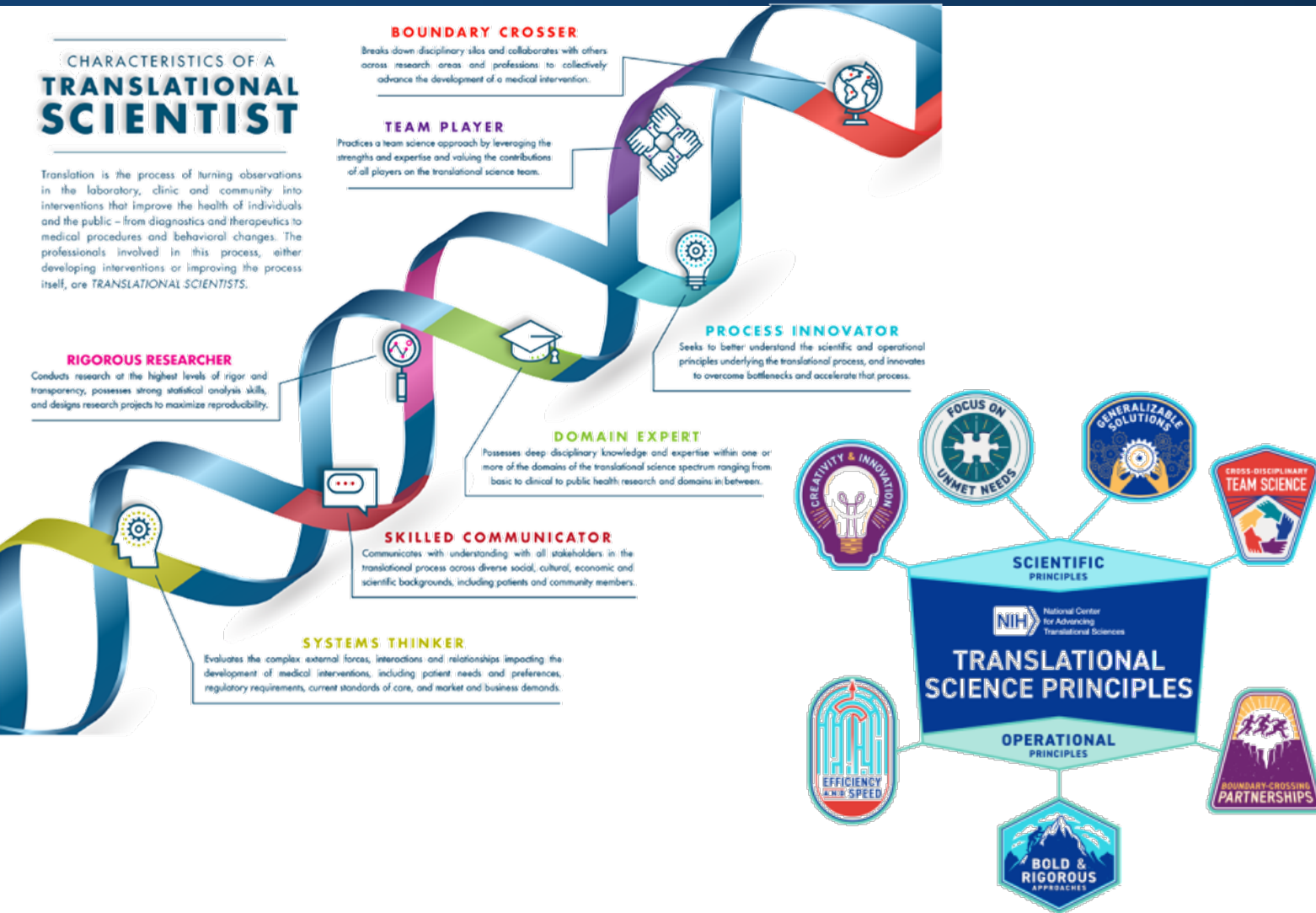
■ A LIST OF COMPETENCIES IS NOT ENOUGH

- Link to formative assessment → Mentoring Tool

Goals

- Identify key translational science competency domains & competencies
- Develop a competency-based assessment tool that supports productive mentoring conversations for CTSA trainees and scholars
- Pilot-test and assess the mentoring value of this CTSA mentoring tool

We Focused on the Characteristics of a Translational Scientist



- Embedded in T32 & K12 NOFOs
- If these are the characteristics of a Translational Scientist, what should a Translational Scientist be able to do?
- What are the competencies?

Approach Based on Previous Work on Science PhD Core Competencies

POINT OF VIEW



Competency-based assessment for the training of PhD students and early-career scientists

Abstract The training of PhD students and early-career scientists is largely an apprenticeship in which the trainee associates with an expert to become an independent scientist. But when is a PhD student ready to graduate, a postdoctoral scholar ready for an independent position, or an early-career scientist ready for advanced responsibilities? Research training by apprenticeship does not uniformly include a framework to assess if the trainee is equipped with the complex knowledge, skills and attitudes required to be a successful scientist in the 21st century. To address this problem, we propose competency-based assessment throughout the continuum of training to evaluate more objectively the development of PhD students and early-career scientists.

DOI: <https://doi.org/10.7554/eLife.34801.001>

MICHAEL F VERDERAME^{†*}, VICTORIA H FREEDMAN[†], LISA M KOZLOWSKI[†]
AND WAYNE T MCCORMACK[†]



In the top 5% of all research outputs scored by Altmetric

High Attention Score compared to outputs of the same age (97th percentile)

44 competencies in 10 domains:

1. Broad Conceptual Knowledge
2. Deep Knowledge of Specific Field
3. Critical Thinking Skills & the Scientific Method
4. Experimental Skills for Conducting Research
5. Computational Skills
6. Collaboration & Team Science
7. RCR & Research Ethics
8. Communication Skills
9. Leadership Skills
10. Survival Skills

A list of competencies
is not enough...

Decided to use milestone approach instead of ratings

WG Phase 1: Competency Domains & Competencies

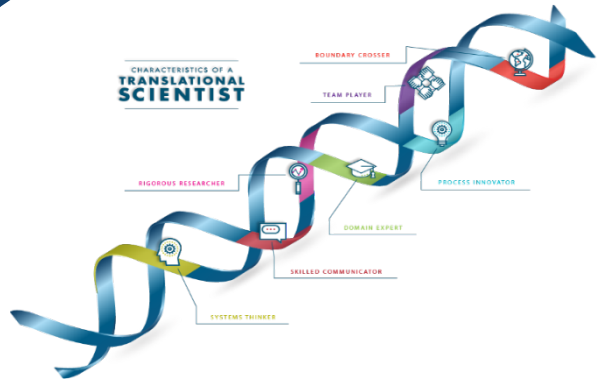
Fall 2023 – Spring 2024

Phase 1: Develop
list of competency
domains &
competencies

Finalize the list of
domains and
competencies

Do we have the
right list of
competencies? Is
anything important
missing?

Use feedback from
trainees and
mentors (via
survey) to finalize
the competencies



Process Innovator
Systems Thinker

Domain Expert
Boundary Crosser
Team Player
Skilled Communicator
Rigorous Researcher

Ethical Researcher
Resilient Scientist
Research Leader

Point of View: Competency-based
assessment for the training of PhD
students and early-career scientists

Michael F Verderame, Victoria H Freedman, Lisa M Kozlowski, Wayne T McCormack

WG Phase 1: Competency Domains & Competencies

Summer – Fall 2024

Phase 1: Develop
list of competency
domains &
competencies

Finalize the list of
domains and
competencies

Do we have the
right list of
competencies? Is
anything important
missing?

Use feedback from
trainees and
mentors (via
survey) to finalize
the competencies

National Survey 1

- For competencies in each domain:
 - include the competency as written
 - revise as suggested in comments
 - omit the competency because it does not fit the domain
- Are any competencies missing?
- 181 responses
 - 58 CTSA hubs represented
 - T Trainees & K Scholars 34%
 - T/K Program Directors 25%
 - Other WD Roles 24%
 - Other 18%

44 Translational Science Competencies

PROCESS INNOVATOR

- A. Identify unmet needs requiring innovative approaches
- B. Seek efficiency and/or speed in research processes
- C. Find generalizable solutions

SYSTEMS THINKER

- A. Use systems thinking to improve research
- B. Operate within a system of health innovation
- C. Integrate patient perspectives

RIGOROUS RESEARCHER

- A. Recognize important questions
- B. Design and execute study protocols
- C. Design & manage a research program
- D. Apply basic statistical analysis methods
- E. Use appropriate informatics methods
- F. Manage research data
- G. Conduct research according to safety & regulatory policies

DOMAIN EXPERT

- A. Use historical context of a specific area
- B. Use current content expertise in the specific area
- C. Use techniques and approaches for the specific area

BOUNDARY CROSSER

- A. Integrate knowledge from multiple disciplines
- B. Engage partners across health professions
- C. Engage partners across research sectors
- D. Build relationships with communities
- E. Engage in research across translational phases

TEAM PLAYER

- A. Demonstrate a collaborative research approach
- B. Demonstrate self-awareness in a team environment
- C. Apply strategies to work effectively in teams

SKILLED COMMUNICATOR

- A. Demonstrate effective oral presentation skills
- B. Prepare and submit scientific manuscripts for publication
- C. Prepare research grant proposals
- D. Communicate effectively with research participants and communities
- E. Communicate effectively with funders
- F. Communicate effectively with policy-makers

ETHICAL RESEARCHER

- A. Practice responsible conduct of research (RCR)
- B. Apply ethical decision-making in RCR
- C. Display moral courage and research integrity

RESILIENT SCIENTIST

- A. Motivate self and others
- B. Demonstrate perseverance
- C. Adapt to new situations & challenges
- D. Engage in career planning & professional development
- E. Build professional network
- F. Practice wellness and self-care behaviors

RESEARCH LEADER

- A. Develop a shared vision
- B. Foster integration and a collaborative environment
- C. Practice effective organization and planning skills
- D. Make decisions and delegate decision-making when appropriate
- E. Facilitate collaborative problem-solving

Milestones: Observable Behaviors That Reveal Level of Competency

Dreyfus & Dreyfus Levels of Skill Acquisition	Novice	Advanced Beginner	Competent	Proficient	Expert
	Rule-based behavior, limited, inflexible	Incorporates aspects of the situation	Acts consciously from long-term goals and plans	Sees situation as a whole and acts from personal conviction	Has intuitive understanding of situations, zooms in on central aspects
Translational Scientist Training Stages	Beginning PhD Student Clinician beginning research training with little/no experience	Advanced PhD Student Clinician Scientist during early research training	Defending PhD Student Beginning Postdoc Clinician Scientist during research training	Early Career Scientists Postdocs in/out of academia Clinician Scientist near end of research training	Science Professional Principal Investigator Research Team Leader in/out of academia (may be aspirational)

←

→

Predoc TL1/T32 Trainee

←

→

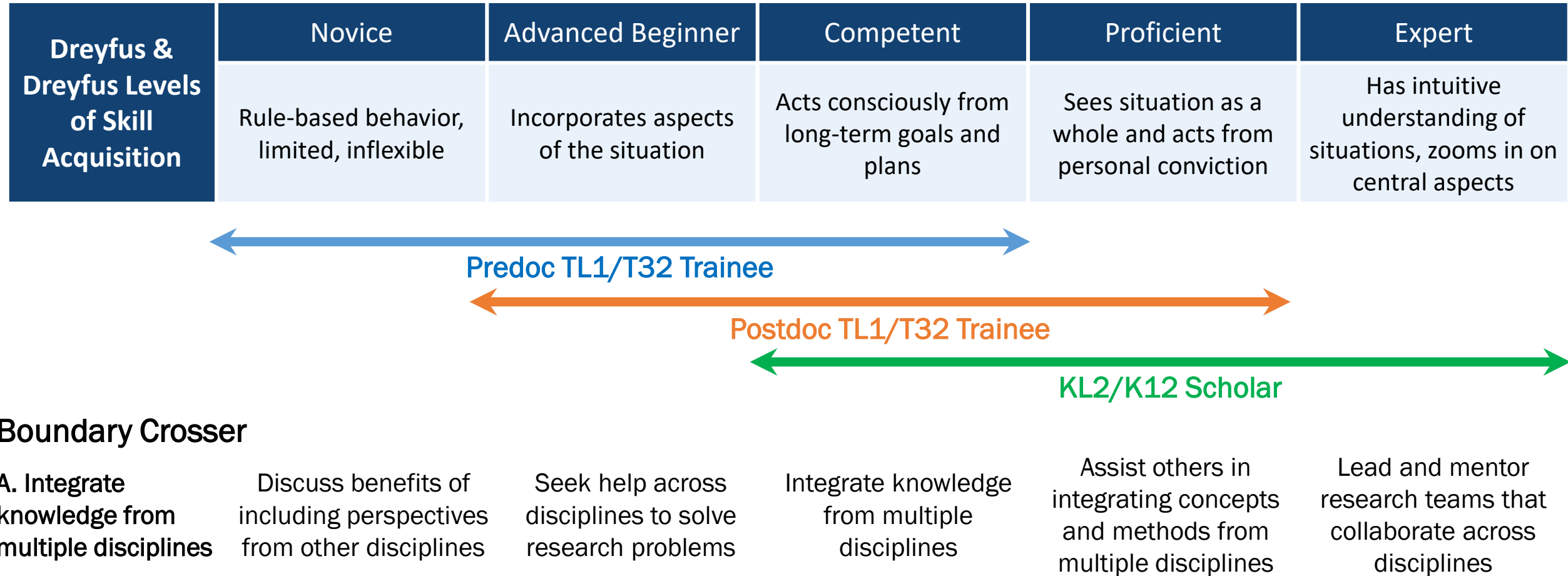
Postdoc TL1/T32 Trainee

←

→

KL2/K12 Scholar

Milestones: Observable Behaviors That Reveal Level of Competency



WG Phase 2: Identify and Calibrate Milestones

Phase 2: Calibrate milestones for competency levels

Summer – Fall 2024

Write milestones for each competency at five levels of skill acquisition, aligned with training stages

Fall 2024

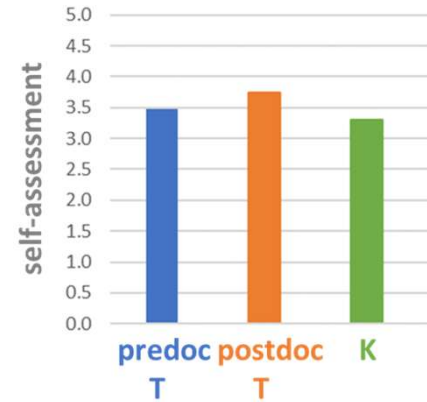
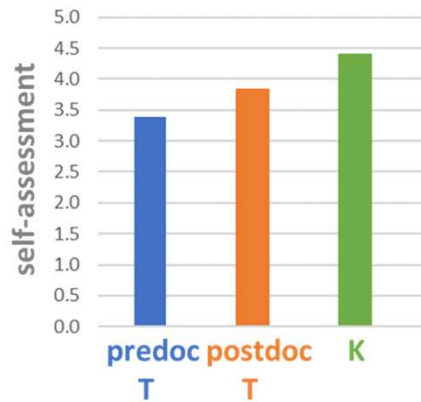
Are the milestones calibrated correctly?
Pilot-test with trainees all levels

Spring 2025

Revise based on pilot-test results and feedback from trainees & scholars

133 usable responses

Some competencies reveal trends of higher self-assessment, suggesting good calibration



Competencies without such trends were revised

Phase 3: Pilot-Testing TS-CBA Tool

Phase 1: Develop list of competency domains & competencies

Finalize the list of domains and competencies

Do we have the right list of competencies?
Is anything important missing?

Use feedback from trainees and mentors (via survey) to finalize the competencies

Phase 2: Calibrate milestones for competency levels

Write milestones for each competency aligned with training stages

Are the milestones calibrated correctly?
Pilot-test with trainees all levels

Revise based on pilot-test results and feedback from trainees & scholars

Phase 3: Pilot-test the final TS-CBA tool

Compare self/mentor assessment; Survey users about usability, feasibility; Focus groups with trainees, scholars & mentors (mentoring value) (Spring-Fall 2025)

Complete data collection by December 2025

WG Phase 3: “Real-World” Pilot-Testing

Phase 3: “Real-world” pilot-test

Self & Mentor
Assessment

Combine into
Report

Mentoring
Meeting

Focus Groups
& Survey

Boundary Crosser

A. Integrate knowledge from multiple disciplines	Working on skills to the right	Discuss benefits of including perspectives from other disciplines	Seek help across disciplines to solve research problems	Integrate knowledge from multiple disciplines into research program	Assist others in integrating multiple disciplines into their research programs	Lead and mentor research teams that collaborate across disciplines	Not applicable
B. Engage in research across translational phases	Working on skills to the right	Discuss and describe research across the translational research continuum (T0-T4)	Identify opportunities to collaborate across the translational research continuum	Collaborate with others working across the translational research continuum	Resolve barriers to collaboration across the translational research continuum	Lead research that facilitates movement along the translational research continuum	Not applicable
C. Engage partners across health professions	Working on skills to the right	Identify relevant partners across health professions (e.g., medicine, public health, nursing, pharmacy)	Seek perspectives from other health professions	Modify research plans based on input from other health professions	Collaborate across health professions (e.g., co-lead manuscripts, grants)	Lead a research team that facilitates collaboration across health professions	Not applicable
D. Build relationships with communities	Working on skills to the right	Define characteristics that bind people together as a community	Consult with community members for feedback and information sharing	Involve community to identify research issues, implement research and disseminate findings	Share leadership and decision-making with community partners	Mentor research teams to build relationships with communities	Not applicable
		Match	Self	Mentor			

Phase 4: Final Analysis

Phase 1: Develop list of competency domains & competencies

Finalize the list of domains and competencies

Do we have the right list of competencies?
Is anything important missing?

Use feedback from trainees and mentors (via survey) to finalize the competencies

Phase 2: Calibrate milestones for competency levels

Write milestones for each competency aligned with training stages

Are the milestones calibrated correctly?
Pilot-test with trainees all levels

Revise based on pilot-test results and feedback from trainees & scholars

Phase 3: Pilot-test the final TS-CBA tool

Compare self/mentor assessment; Survey users about usability, feasibility, utility; Focus groups with trainees, scholars & mentors (mentoring value) (Summer-Fall 2025)

Complete data collection by December 2025

Phase 4: Final Analysis

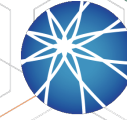
Complete data analysis, final revisions to CBA mentoring tool

Submit manuscript to JCTS

Disseminate TS-CBA tool and outcomes to WD EC and Consortium Group

Questions or comments? Feedback is welcome!

mccormac@ufl.edu



AUCD

ASSOCIATION OF UNIVERSITY CENTERS ON DISABILITIES
RESEARCH, EDUCATION, SERVICE

Engaging Individuals with Disability in the Research Process Working Group

A Collaboration between the CTSA Integration Across the Lifespan Enterprise Committee and the Association of University Centers on Disability

Daniel Armstrong, PhD.

Working Group Lead

University of Miami CTSI

Conflicts and Acknowledgements

- ❖ Dr. Armstrong has no Conflicts of Interests or Financial Relationships to disclose.
- ❖ A portion of Dr. Armstrong's effort related to this project is funded by a grant from the Agency on Community Living, Award Number 90DDUC0126, The Mailman Center UCEDD: Building Capacity at the Intersection of Disability and Disparity through Innovation and Connection and by the Miami Clinical and Translational Science Institute, NCATS Award UM1TR004556.

Presentation Goal and Expected Outcomes

- ❖ Goal: Inform CTSA network about the Ongoing Working Group on Engaging Individuals with Lived Disability Experience in the Research Process
- ❖ Expected Outcomes
 - At the conclusion of this presentation, participants will be able to:
 - Identify the anticipated components of the Toolkit being developed by the Working Group and how these can contribute to improved science
 - Understand the potential for generalization of the model across other disease and condition research programs

Working Group Purpose

- ❖ This Working Group's overarching purpose is to provide the context and strategies for investigators to actively engage with the disability lived experience community in the conduct of research.
- ❖ To accomplish this, we are focusing 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 meaningfulness such as equity, social stigma, accessibility, and resources.
- ❖ We anticipate that this model will be generalizable to research on almost all diseases and conditions.

Goals

- Provide the research community with knowledge, resources, and tools that will facilitate engagement of individuals with disability lived experience in the conduct of research.
- 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.

Alignment with CTSA Priorities

National training curriculum in
clinical and translational science



Enhancing the impact of
clinical trials

Collaboration with the Association of University Centers on Disability



- University Centers for Excellence in Developmental Disabilities (UCEDD)
 - N=67
 - Funded by the Agency for Community Living
- Leadership Education in Neurodevelopmental Disabilities (LEND)
 - N=60
 - Funded by the HRSA/Maternal Child Health Bureau
- Intellectual and Developmental Disabilities Research Centers (IDDRC)
 - N=16
 - Funded by NICHD
- Developmental Behavioral Pediatrics Training Programs
 - N=12
 - Funded by HRSA
- Autism Intervention Research Network on Physical Health (AIR-P)
 - N=16
 - Funded by HRSA



CTSA-AUCD Alignment

9 universities with CTSAAs also have a UCEDD, LEND, & IDDRC

18 universities have a CTSA and two of the three AUCD programs

4 universities have a CTSA and one of the three AUCD programs

Founding Working Group Core Members

CTSA Network

- Daniel Armstrong, University of Miami. (Lead)
- Susy Stark, Washington University in St. Louis
- Nora Singer, MetroHealth System and Case Western University
- Jareen Meinzen-Derr, Cincinnati Children's Hospital
- Kimiko Domoto-Reilly, University of Washington
- Mark Schleiss, University of Minnesota Medical School
- Elizabeth Eckstrom-Oregon Health and Science University

AUCD Network

- Kara Ayers, Cincinnati Children's Hospital
- Rodney Samaco, AUCD
- Kathleen Angkustsiri, UC Davis Mind Institute
- Jeffrey Neul, Vanderbilt Kennedy Center
- Emily Hotez, UCLA Geffen School of Medicine

AIR-P Network

- Heather Brown, University of Alberta

- Includes representatives from:
 - CTSA Hubs
 - LEND Programs
 - UCEDDs
 - IDDRCs
 - AIR-P
 - Individuals with disabilities and family members of individuals with disabilities

Deliverables

- ❖ **Deliverable 1:** A toolkit of resources that provide practical and meaningful strategies to include and fully engage individuals with disabilities in the research process. This toolkit will include guidelines, information materials, recorded webinars, and successful examples that facilitate engagement of individuals with lived disability experience.
 - (1) development of study questions,
 - (2) determination of study hypotheses,
 - (3) selection of an appropriate research design,
 - (4) selection of measures that are scientifically important and meaningful to the community being studied,
 - (5) participation in the informed consent process and enrollment of participants,
 - (6) participation in data collection,
 - (7) participation in data analysis and interpretation, and
 - (8) participation in outcome dissemination, including authorship of publications.
- ❖ The toolkit will include an appropriate guideline, webinar, and/or web-based resource for each of these eight elements.

Deliverables

- ❖ **Deliverable 2:** At least one publication that addresses the process and context of research participation by individuals with disability lived experience, including lessons learned about challenges and benefits, and a recommended curriculum for investigators

Toolkit Components

Content	Leads (* = Additional support or co-lead needed)
Developing Aims and Hypotheses that are scientifically interesting and meaningful and relevant to the disability population of interest.	Emily Hotez, Kimiko Domoto-Reilly
Adapting measures and interventions that can be accessed by individuals with disability lived experience.	Heather Risser, Heather Brown, Rebecca Fischbein
Selecting study designs that are practical and ensure relevance.	Mark Schleiss, Rodney Samaco*
Understanding disability specific ethical considerations.	TBA
Understanding context and impact of data analysis and interpretation.	Jareen Meinzen-Derr
Recruiting and sustaining participation in research.	Heather Risser, Cathy Bodine, Rebecca Fischbein
Writing and publishing together.	Kara Ayers, Robin Lanzi
Structuring the research environment (bench and clinical trials) for ILDE participation.	Robin Lanzi, Cathy Bodine
How to's of funding ILDE participation on grants (and administrative supplement possibilities).	TBA

Webinar Series: Engaging Individuals with Disability in the Research Process WG

- The CTSA Engaging Individuals with Disability in the Research Process Working Group will be hosting a three-part webinar series starting on **Friday, May 9th, 2025, from 2:00 – 3:00 pm ET**
- The first webinar will cover “**Adding Meaningfulness to Research – Engaging Individuals with Lived Disability Experience on Research Teams.**”
- This webinar is intended for investigators, individuals with lived disability experience, research administrators, journal editors, and NIH or foundation staff. The objective of the webinar is to inform and inspire participants to include individuals with lived experience as part of investigative research teams, specifically focusing on how this can improve the science and meaningfulness of the research for the populations being studied.
- **Please register for the webinar using the Zoom link here and save the calendar invitation sent via email:**
https://zoom.us/webinar/register/WN_rox7D5WIReOAVh3Ybuz_1A



Daniel Armstrong, Ph.D.,
University of Miami Mailman Center for
Child Development and Miami CTSI



Rodney Samaco, Ph.D.,
Association of University Centers on
Disability (AUCD)

Webinar Series: CTSA Engaging Individuals with Disability in the Research Process WG

- **"Building Investigator Capacity to Engage Individuals with Disability in the Research Process"**
- Friday, June 13th, 2025, from 2:00 – 3:00 pm ET
- Please register for the webinar using the Zoom link here and save the calendar invitation sent via email:
https://zoom.us/webinar/register/WN_b14r56RST8mf4LF54-kYqA



Heather J. Risser, Ph.D.
Northwestern University



Mark R. Schleiss, M.D.
University of Minnesota

Webinar Series: Engaging Individuals with Disability in the Research Process WG

- The CTSA Engaging Individuals with Disability in the Research Process Working Group will hold their third and final webinar **on Friday, June 27th, 2025, from 2:00 – 3:00 pm ET**
- This webinar will cover “**Leveraging Your Lived Experience on a Research Team.**”
- The session is designed to support individuals with lived experience of disability and/or chronic health conditions in contributing meaningfully to research collaborations. Presenters will share tools and strategies for building research teams that recognize and incorporate lived experience, identify common barriers and facilitators to participation, and offer practical recommendations for individuals, mentors, and research teams. This interactive webinar will include real-world examples, audience polling, and a live Q&A to support learning, implementation, and translation into practice.
- **Please register for the webinar using the Zoom link [here](#) and save the calendar invitation sent via email.**



Kara B. Ayers, Ph.D.
University of Cincinnati



Emily Hotez, Ph.D.
University of California Los Angeles



Robin Lanzi, Ph.D., M.P.H.
University of Alabama at Birmingham

White Paper

- Writing team will produce a white paper highlighting challenges and potential solutions for active engagement in research for investigators and individuals with lived disability experience
- Writing Committee (Paper ready for submission by November 2025)
 - Daniel Armstrong
 - Jareen Meinzen-Derr
 - Heather Risser
 - Emily Hotez
 - Kara Ayers
 - Jareen Meinzen-Derr
 - Karen Bonuck
 - Deborah DiazGranados
 - Rodney Samaco
 - Rebecca Fischbein
 - Jamie Doyle
- Special Issue
 - Broad invitation for papers for a special issue on this topic.
 - Pediatrics and Journal of Clinical and Translational Science have both expressed strong interest
 - Current roadblock is funding. Funding proposals have been shared with potential donors and other options are being explored.

COORDINATION



Survey

- Survey has been prepared to address:
 - Barriers to engaging individuals with lived disability experience in research
 - Benefits of engaging individuals with lived disability experience in research
 - Recommendations for toolkit components and content
 - Recommendations for toolkit format
- Each survey question includes multiple responses and an opportunity for narrative additions or clarifications
- For each question, participants indicate items they have personally encountered and then rank order all items by importance
- Survey participants will be recruited from investigators and individuals with lived experience across the CTSA and AUCD networks
- Data will be used to inform next steps as well as data for White Paper

Working Group Timeline and Next Action Steps

(Working Group extended until 12/31/2025)

Workplan for Upcoming Months

- April 2025-June 2025: Host 3 webinars (2 have been completed and archived)
- July 2025: Distributed Survey and begin data collection and analysis
- July 2025-November 2025: Writing group prepares White Paper for submission and dissemination
- May 2025-November 2025: Toolkit Component Working Teams prepare, edit, and finalize Toolkit Components for dissemination
- August 2025 -September 2025: Working Group prepares submission for Working Group 2.0
- August 2025 -December 2025: Negotiate funding and agreement for Special Issue
- December 2025: Complete all deliverables, submit final WG report

Questions?

Reminder: July 2025 CTSA Webinar

The next webinar is **July 23, 2025; 2-3 PM ET**