

CTSA Program Webinar

May 22, 2024

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	Integration Across the Lifespan Enterprise Committee	Mark Schleiss, M.D. University of Minnesota
2:30 – 2:45 PM	Translational Science Competency-Based Assessment Working Group	Wayne McCormack, Ph.D. University of Florida
2:45 – 3:00 PM	Engaging Individuals with Disabilities in Research Working Group	Daniel Armstrong, Ph.D. University of Miami
3:00 PM	Adjourn	



NCATS/CTSA Program Updates

Erica Rosemond, PhD

Acting Deputy Director, Division of Clinical Innovation
NCATS

May 22, 2024

NCATS Advisory Council

- **Next Meeting:**

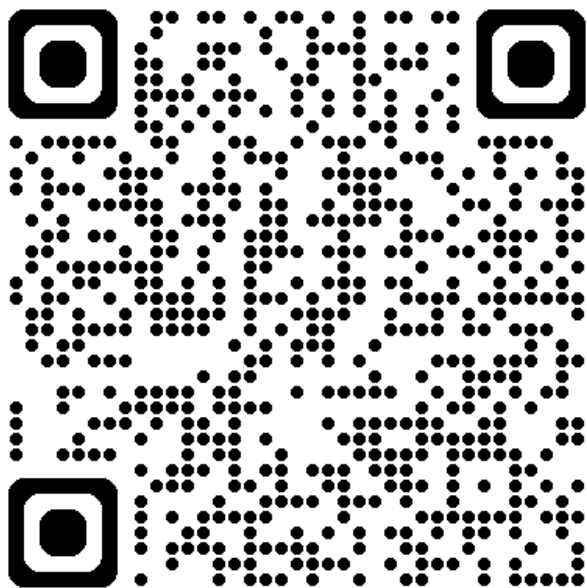
- May 23, 2024 (10:30 a.m. to 4:30 p.m.)
- The NCATS Advisory Council will convene a virtual/in-person meeting on May 23, 2024. The meeting will feature presentations from NCATS Director Joni L. Rutter, Ph.D., and others about the center's initiatives, policies, programs and future direction.
 - Presentation on the draft of the **new NCATS Strategic Plan**

- [Videocast](#)



We Want Your Feedback!

The draft NCATS Strategic Plan for 2024-2029 is now available for input!



We invite you to review the draft strategic plan and email your feedback by June 14:



NCATS2024StrategicPlan@mail.nih.gov

<https://ncats.nih.gov/about/ncats-overview/strategic-plan>



NIH OD Report Language

Women's Health Clinical Research Network.— The Committee directs NIH to expand and more formally coordinate its support women's health clinical research by leveraging the CTSA program. The Committee urges NCATS and CTSA awardees to focus on women's health within its efforts to modernize the translation of research into health benefits across the full spectrum of medical research. The Committee directs NCATS to collaborate with ORWH to evaluate how to better promote research and collaborations that address the distinctive medical and health needs of women and advance the dissemination and implementation of research results. The Committee requests an update on these activities with 120 days of enactment.



NIH-Wide Strategic Plan for Research on the Health of Women 2024-2028

- We invite you to dive into the latest advancements in Women's Health Research with the NIH-Wide Strategic Plan for Research on the Health of Women 2024-2028! This plan highlights the importance of innovative data science methodologies in understanding and addressing the complexities of women's health



- [2024-2028 NIH-Wide Strategic Plan for Research on the Health of Women](#)



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New Opportunity from NIH OD: Clinical Research in Primary Care

- The purpose of this limited competition ROA is to invite applications by organizations currently affiliated with and participating in specific existing clinical research networks --to serve as “Network Research Hubs” to conduct clinical research in primary care settings. This **opportunity is limited to organizations that focus on serving rural communities and are part of or funded by:** NIH Institutional Development Award Clinical and Translational Research (IDeA-CTR) awards, the NIH Clinical and Translational Science Award (CTSA) Program, and/or the Patient-Centered Outcomes Research Institute’s (PCORI) Patient-Centered Clinical Research Network (PCORnet).
- For the purposes of this ROA, organizations with IDeA-CTR and **CTSA awards or sub-awards in no-cost-extensions are eligible to apply.** In addition, applicant organizations must be located in a state/jurisdiction where at least 25% of its census tracts are defined as rural using [the Revised 2010 RUCA Codes](#).
- Applications are due **on June 14, 2024, by 5:00 PM EDT**
- Program landing page: [Clinical Research in Primary Care | NIH Common Fund](#)
- ROA page: [Research Opportunity Announcement | NIH Common Fund](#)
- Do you have questions? Email us at: PrimaryCareResearch@od.nih.gov



Advancing Translational Science through Real-World Data and Real-World Evidence

JCTS Thematic Issue

Journal of Clinical and Translational Science

the Official Journal of ACTS and CR Forum



Theme: This issue highlights research, activities, and processes for the translation of RWD from a range of sources into RWE to enhance the full translational science continuum, and ultimately improve the development, approval, adoption and use of safe and effective medical products.

Guest Editors: Pablo Cure, Joshua P. Fessel, Christopher M. Hartshorn and Scott J. Steele

Editorial: [Advancing Regulatory Science through Real-World Data and Real-World Evidence](#)

Click [here](#) for the full issue.

ACTS
ASSOCIATION FOR CLINICAL
AND TRANSLATIONAL SCIENCE

Clinical Research
FORUM
Analysis. Advocacy. Action.

 **CAMBRIDGE**
UNIVERSITY PRESS



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HOW YOU CAN HELP WITH NIH CLINICAL TRIALS REPORTING COMPLIANCE



- Investigators, submit your results to [ClinicalTrials.gov](https://clinicaltrials.gov) ASAP
- Institutional leaders, develop internal controls to make it easier for faculty to report results efficiently
- If you receive a letter about a non-compliant trial, be responsive

NCATS Guidance for Correcting Human Subjects Submission Validation Errors

- NCATS has developed a guidance document to assist awardees to address RPPR submission system validations for clinical trial registration and results reporting as of October 1, 2021: [NOT-OD-22-008](#) (released on October 29, 2021).
- The requirements for registration and results reporting are:
 - Registration:
 - Recipients must ensure that their NIH-funded clinical trials are registered at ClinicalTrials.gov for public posting no later than 21 days after enrollment of the 1st participant.
 - Results Reporting:
 - Results information must be submitted to ClinicalTrials.gov no later than one year after primary completion date (with limited exceptions).

Links:

- [Guidance for Correcting Human Subjects Submission Validation Errors](#)

Failure to adhere to the guidance presented in
NOT-OD-22-008 will prevent submission of the RPPR



Updates to NIH Training Grant Applications

- Wednesday, June 5, 2024; 1:00 – 2:00 p.m. ET (REGISTRATION REQUIRED!)
- NRSA Training Grant Program application is undergoing changes that take effect for submissions due on or after January 25, 2025. Modifications:
 - the Recruitment Plan to Enhance Diversity will become its own attachment
 - Updates to the NRSA Data Tables to reduce burden on the research community
 - Better-defining expectations for mentor training;
 - Clarifying positive career outcomes within the scope of research and related careers aligned with the NIH mission; and
 - Including "Training in the Responsible Conduct of Research" and the "Recruitment Plan to Enhance Diversity" as items that contribute to the overall impact score.
- Wondering about the implications for your application preparation? Consider participating in this live, virtual event where NIH experts will provide insights and updates on these changes, concluding with a live Q&A session.
- <https://grants.nih.gov/learning-center/nih-training-grant-application-updates-webinar>



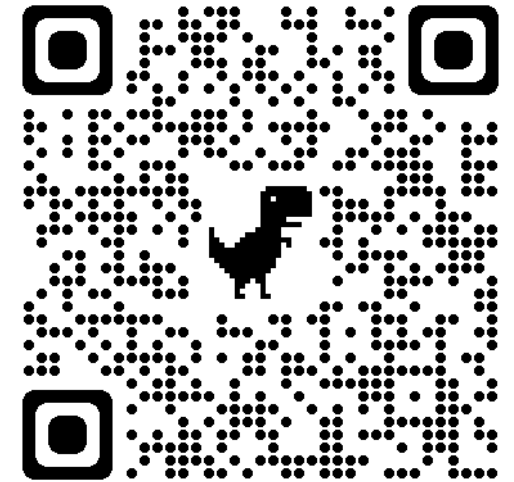
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Public Access Policy Reminders

- Applies to any manuscript that is peer-reviewed, accepted for publication in a journal and arises from any direct federal government grant funding support and/or approved voluntary committed cost share.
- ONLY include publications, along with the PMCID (Pubmed Central ID) found in MyNCBI, that were directly resulting from the award.
- For publications where the UM1/UL1 only contributed shared resources, list and/or summarize these publications in section B2. Publications listed and/or summarized in this section will not count against the section's two-page limit.
- Review publication listings **early** to prevent Public Access Non-Compliance. **NIH cannot issue an award until all publications are compliant.** Repeated submissions of applications with non-compliant publications will result in potential compliance actions.
- For Institutional Training, Career Development, and Related Awards(T32/TL1, R25/RL5, K12/KL2): Trainee, scholar, and participant publications fall under the public access policy if the publication resulted from work conducted while the individual was supported by the award (i.e., receiving a stipend or salary from the award).

To date - 25% of CTSA RPPR submissions for FY 2024 have been non-compliant.

NIH Public Access Policies



Website:

<https://sharing.nih.gov/public-access-policy>



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Upcoming Dates to Remember

Next CTSA Program Webinar

June 26, 2024; 2-3 PM ET. [Register here.](#)



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)



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CCOS Updates

Kerry James
CCOS





Save the Date!

Fall 2024 CTSA Program Meeting

DATE: November 13-15th

LOCATION: Bethesda North Marriott

Day 1:

- TIN Meeting
- CTSA Administrators Meeting
- CTSA Steering Committee Meeting

Days 2-3:

- CTSA Program Meeting

More details and
online registration to
come!

Questions?

Contact FallMtg@ccos.ctsa.io

2024 Fall Planning Committee (FPC)

VOLUNTEERS

Theodore Wun, FPC Co-chair, UC Davis

Daniel Ford, Johns Hopkins University

Daniel Foster, University of Colorado Anschutz Medical Campus

Tesheia Johnson, Yale University

Jessica Kahn, University of Cincinnati – Cincinnati's Children's

Mimi Kim, Albert Einstein School of Medicine

Grace McComsey, Case Western University

Jareen Meinzen-Derr, University of Cincinnati - Cincinnati Children's

Andriana Morales Gomez, Mayo Clinic

Doris Rubio, University of Pittsburgh

Kathryn Sandberg, Georgetown University

Ronald Sokol, Children's Hospital Colorado

Gelise Thomas, Case Western University

NCATS

Michael Kurilla, FPC Co-chair

Erica Rosemond

Robin Wagner

Jennie Conroy

CCOS

Lauren Fitzharris, Logistics Lead

Kerry James, Project Manager

Cindy Mark, Senior Meeting Coordinator

***Amanda Scott, Lead Meeting Planner**

****Questions for FPC?***

Contact FallMtg@ccos.ctsa.io

Registration now closed

Learning Health Systems Collaborative Workshop



Co-sponsored by:

- **The Coordination, Communication, and Operations Support (CCOS) Center**
- **Wake Forest CTSI and Wake Forest University School of Medicine**

Registration Closed May 9th

What's Our Focus?

Bringing together:

- CTSA Program representatives
- Researchers
- Clinicians
- Policymakers
- Healthcare innovators
- Opinion leaders
- Other healthcare professionals

Why Attend?

This is an opportunity for CTSA's to:

- Form teams around LHS
- Learn about the ways the CTSA's have and can support LHS
- Research implementation science and operations to address translational science barriers

Wednesday, May 22, 2024
8:00 am – 4:30 pm ET
In-Person Meeting

Sanger Heart & Vascular Institute
Kenilworth Medical Office Building 1
1237 Harding Place
Charlotte, NC 28204

Stay Updated on Collaborative Workshops!
Visit ccos-cc.ctsa.io/groups/collaborative-workshops
Email collaborative_workshop@ccos.ctsa.io



**SCAN ME TO
REGISTER**



CCOS Website Account

Getting Started

Get step-by-step guidance on getting started including how to create a CCOS account and how to log in can be found here:

Getting Started Page

Account Access Includes:

- Meeting Materials/Archives
- Collaborative Spaces
- Discussion Forums
- CTSA Hub Directory

Questions? Please email support@ccos.ctsa.io.

Want to stay up to date on the CTSA Program?

Follow this link or scan the QR code to join the CCOS All Communications Email List to receive CTSA Program communications and updates:

<http://eepurl.com/iw9nZA>



Remember to add communications@ccos.ctsa.io to your contacts list to prevent important CCOS emails from ending up in your spam folder!

CTSA Integration Across the Lifespan Enterprise Committee

CTSA Steering Program Webinar

May 22, 2024



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Integration Across the Lifespan Co-Chairs



Mark R. Schleiss, MD

University of Minnesota Medical School

American Legion and Auxiliary Research Foundation Chair in
Pediatric Infectious Diseases

Minnesota American Academy of Pediatrics, Executive Counsel

American Pediatric Society Advocacy Committee

Child Health Champion, University of Minnesota CTSI



Karen Wilson, MD, MPH

University of Rochester School of Medicine

Ruth A. Lawrence Professor of Pediatrics

Co-Director, URM C Clinical and Translational Science Institute

Vice-Chair for Clinical and Translational Research, Department
of Pediatrics

Chief Research Officer, UR Medicine Golisano Children's
Hospital



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Lead Team Members

Voting Members

- **Mark R. Schleiss**, University of Minnesota (Co-Lead)
- **Karen Wilson**, University of Rochester (Co-Lead)
- **Amanda Dettmer**, Yale University
- **Elisabeth Borsheim**, University of Arkansas
- **Susan McColly**, Northwestern University
- **Mark Supiano**, University of Utah



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Non-Voting Members

- **Rashmi Gopal-Srivastava**, NIH/NCATS Representative
- **Megan Stewart**, CCOS Coordinator
- **Daniel Hanley**, TIN Representative



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Presentation Goals and Expected Outcomes

- Disseminate prior working groups' products
- Request participation in current and planned working group activities: recent survey completed
- Generate nominations for members from across the life course/lifespan to generate goals and plan future work products



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Integration Across the Lifespan Enterprise Committee Goals

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

Its goals are to:

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



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IAL Working Group Deliverables

- <https://ccos-cc.ctsa.io/groups/enterprise-committees/integrations-across-the-lifespan>

Sunsetted Groups

Inclusion of Older Adults as a Model for Special Populations

Life Course Visual Toolkit Development



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Full Membership Meeting Overview

Past and Future

Date	Presenter	Presentation Title
September 26, 2023	Amanda Dettmer	Integration/Harmonization of Lifespan Datasets Across CTSAs
October 24, 2023	Jessica Woo	Harnessing the Power of Life course Cohorts in Cardiovascular Epidemiology
November 28, 2023	David Haas	Maternal Heart Health Study
November 28, 2023	CHAP Team	Chronic Hypertension and Pregnancy Studies
January 23, 2024	Edith Williams	Health Equity
February 27, 2024	Susanna McColley	Discovery, Diagnosis and Disparities: Translational Approaches Towards Health Equity in Cystic Fibrosis
March 26, 2024	Neal Halfon	Advancing Research, Policy & Innovations Within Pediatrics
May 28, 2024	Chairs	Overview of Group Progress
June 25, 2024	Heather Whitson	A Life-course Perspective on Cognitive Impairment
August 27, 2024	Ashley Jenkins	Transitional Populations (adolescent/young adult)



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Current Working Group

Engaging Individuals with Disabilities in the Research Process

Chair, Dr. Daniel Armstrong

University of Miami School of Medicine



Other EC Goals

Submission of Additional WGs

- Pediatric Clinical Trials
- SDOH Research Toolkit

Expansion of membership

- Goal to have representatives from all CTSA sites
- Encourage representatives from all life stages



Engaging Individuals with Disability in the Research Process Working Group

Led by Dr. Daniel Armstrong, University of Miami School of Medicine

Goals

- Provide the research community with knowledge, resources, and tools that will facilitate engagement of individuals with 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.

Deliverables

- Toolkit of resources providing practical and meaningful strategies to include and fully engage individuals in the research process. Toolkit will include guidelines, information materials, recorded webinars, and successful examples of engagement
- Publication of at least one paper addressing process and context of research participation by individuals with lived experience, including lessons learned about challenges and benefits, and a recommended curriculum for investigators.



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SDOH Working Group Application Planning

- Social determinants of health (SDOH) are the conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of-life outcomes. They:
- Must be understood across the life course but pose measurement challenges.
- Must be addressed in all phases of research to ensure interventions and applications are both effective and equitable.
- Require interdisciplinary collaboration and a collective vision.

Potential project: SDOH Research Toolkit

- Draft Objective: Create a comprehensive toolkit for researchers at all translational stages to seamlessly integrate SDOH into their work across the lifespan.

SDOH Working Group

Draft Deliverables:

- A digital compendium of validated and harmonized measures to assess SDOH across the lifespan ensuring consistent and comparable data collection.
- Guidelines on how to incorporate SDOH in study designs.
- Case studies demonstrating the integration of SDOH in diverse research contexts.
- Online training modules to familiarize researchers with the toolkit and the importance of SDOH.
- An open-access database compiling datasets with these measures, fostering collaboration.
- User-friendly data visualization tools allowing researchers to quickly analyze and interpret SDOH trends across the lifespan

Team:

Susy Stark, PhD, Elizabeth Eckstrom, MD, Jareen Meeinzen-Derr, PhD and Alan Tita, MD, PhD



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Membership

EC Membership Stats

- Need to encompass the entire lifespan/lifecourse
- **125** active members
- **57/65** Hubs represented
- Recent survey of membership to gauge IAC meeting attendance, engagement, representation from CTSA hubs (Megan Stewart) → responses being analyzed

Agenda

Time	Presentation Title	Speaker(s)
1:00 – 1:15 PM	Welcome & Introduction	Karen Wilson, University of Rochester Mark Schleiss, University of Minnesota
1:15 – 1:20 PM	NCATS Updates	Rashmi Gopal-Srivastava, NCATS Representative
1:20 – 1:40 PM	Targeting the Emotional-Behavioral Impacts of Food Insecurity in School-Aged Children	Lauren Ciszak, Tufts University Boston Merelise Ametti, Maine Medical Center
1:40 – 2:00 PM	Unmet sexual health & resource needs among female partners of patients with prostate cancer	Natasha Gupta, NYU Grossman School of Medicine
2:00 – 2:20 PM	Advances in Determining Maternal, Fetal, and Infant Exposure to Medications	Kathleen Job, University of Utah School of Medicine
2:20 – 2:40 PM	Early-life Injury and Chronic Pain: Understanding the Lifelong Impact	Morika Williams, University of North Carolina at Chapel Hill
2:40 – 2:55 PM	Break	
2:55 – 3:25 PM	“Long Cytomegalovirus”: How Acquisition of CMV Infection in Childhood Exerts a Profound Impact on Health Over the Life Course	Mark Schleiss
3:25 – 3:45 PM	IAL & Working Group Updates	Karen Wilson Daniel Armstrong, University of Miami
3:45 – 4:00 PM	Wrap-up & Adjourn	Karen Wilson Mark Schleiss

Action Items

- Support Social Determinants of Health Subcommittee Working Group proposal submission
- Consideration of subcommittee to explore a creating a working group proposal on pediatric clinical trials
- Explore partnerships/programs with other ECs:
 - Workforce
 - Informatics (Harmonizing longitudinal datasets across the lifespan)
 - DEIA
 - Community Engagement
- Expanding EC membership and participation
- Contact: integrationacrosslifespan@ccos.ctsa.io

Other Potential
Initiatives and
Collaborations



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Dr. Schleiss and Dr. Wilson

Please put your questions in the Q and A box

Or reach out at: integrationacrosslifespan@ccos.ctsa.io



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Development of a Translational Science Competency-Based Mentoring Tool



Wayne T. McCormack, PhD
on behalf of the Translational Science
Competency-Based Assessment Working Group



Translational Science Competency-Based Assessment Working Group

- Chair: Wayne T. McCormack, PhD (UF)
- Roster: 51 members from 28 CTSA hubs



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 State U	U Massachusetts	

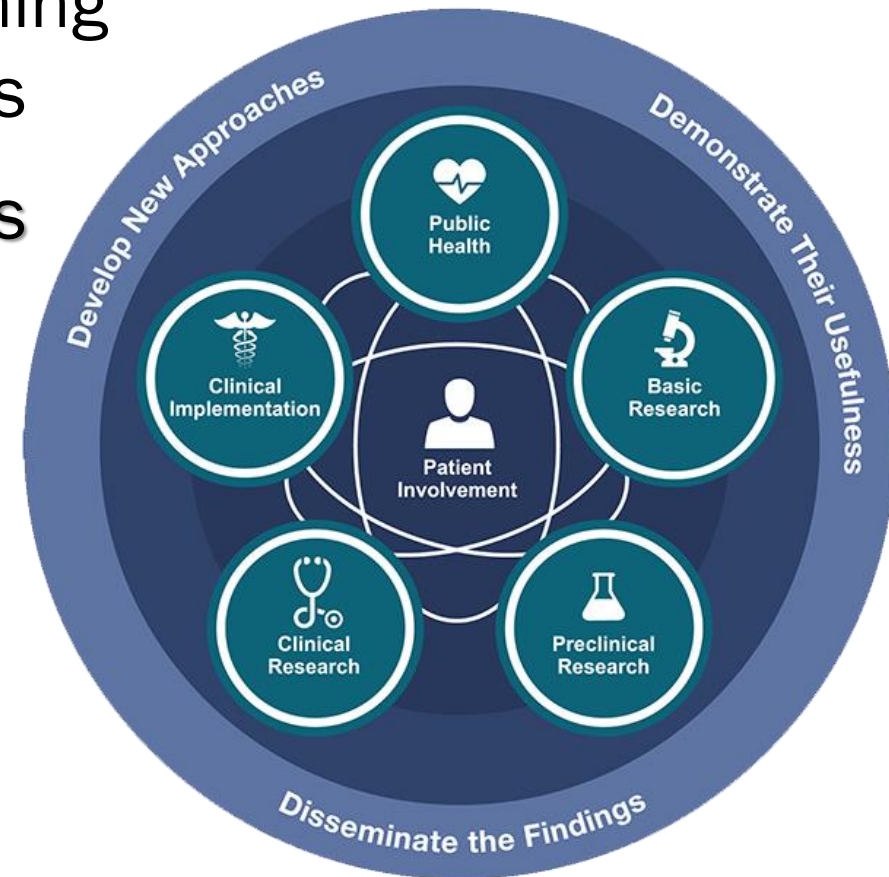
- CTSA Roles: K, T, WD, Evaluation, Team Science, Pilot Studies
- Meetings: 1st and 3rd Wednesday at 1:00 pm (ET)

Why Competencies?

- PROBLEM
 - PhD scientist training has traditionally been an apprenticeship
 - When is a grad student or postdoc ready to finish?
 - “I know it when I 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 bring more treatments to all people more quickly
- A LIST OF COMPETENCIES IS NOT ENOUGH
 - Must be linked to formative assessment

Value of Using a Translational Science Competency-Based Mentoring Tool

- Inform Trainees & Scholars about expectations
- Tool for self-assessment and self-directed learning throughout training and future research careers
- Tool for mentor assessment of training progress
- Support productive mentoring conversations
- Combined with curricular mapping and program enhancement plans, provide a framework for continuous improvement of learning objectives, training, and assessment



Milestone Approach: Learning Is a Developmental Process

- **Milestones:** expectations for the knowledge, skills and attitudes at stages of development, demonstrated by observable behaviors
 - Verderame *et al.*, 2018. Competency-based assessment for the training of PhD students and early-career scientists. *eLife* 7:e34801

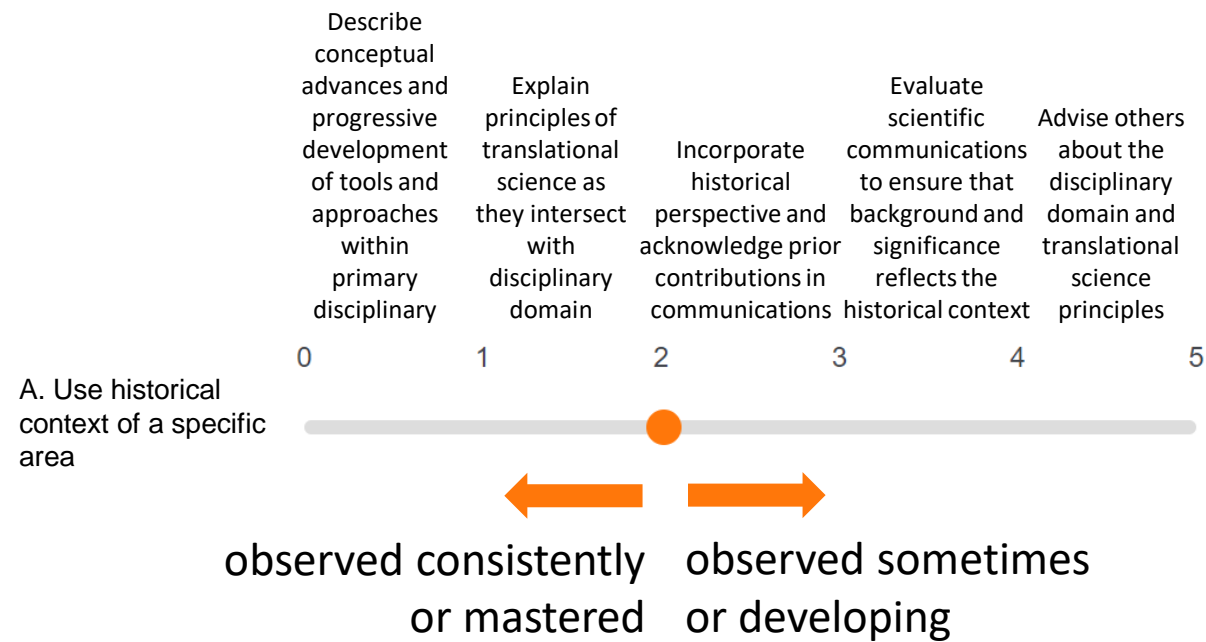
Dreyfus & Dreyfus Levels of Skill Acquisition	Novice	Advanced Beginner	Competent	Proficient	Expert
	Rule-based behavior, limited, inflexible	Incorporates aspects of the situation	Acts consciously from long-term goals and plans	Sees situation as a whole and acts from personal conviction	Has intuitive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

Milestone Approach: Learning Is a Developmental Process

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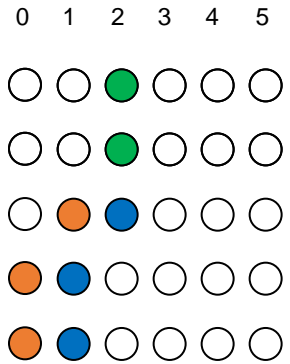
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Translational Scientist Training Stages	Beginning PhD Student / Clinician beginning research training with little or no experience	Advanced PhD Student / Clinician Scientist during early research training	Defending PhD Student / Beginning Postdoctoral / Clinician Scientist during later research training	Postdoctoral Trainee / Early Career Scientist / Clin Sci near end of research training / Residents/Fellows	Science Professional / Research Team Leaders (may be Aspirational)
Observable Behaviors	MILESTONES				
	discuss, describe, follow	identify, use, explain	design, develop, evaluate	plan, adjust, teach	lead, review, mentor

Proposed Process for Mentor & Self-Assessment



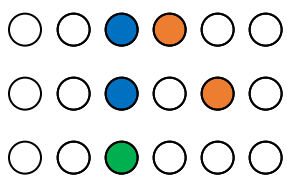
BOUNDARY CROSSER

- A. Use knowledge from multiple disciplines
- B. Use broad scientific approaches
- C. Participate across translational phases
- D. Engage stakeholders across professions
- E. Engage with communities



DOMAIN EXPERT

- A. Use historical context of a specific area
- B. Use current content expertise ...
- C. Use tools and approaches ...



Trainee Faculty Match

Characteristics of a Translational Scientist

CHARACTERISTICS OF A TRANSLATIONAL SCIENTIST

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public – from diagnostics and therapeutics to medical procedures and behavioral changes. The professionals involved in this process, either developing interventions or improving the process itself, are **TRANSLATIONAL SCIENTISTS**.

RIGOROUS RESEARCHER

Conducts research at the highest levels of rigor and transparency, possesses strong statistical analysis skills, and designs research projects to maximize reproducibility.

BOUNDARY CROSSER

Breaks down disciplinary silos and collaborates with others across research areas and professions to collectively advance the development of a medical intervention.

TEAM PLAYER

Practices a team science approach by leveraging the strengths and expertise and valuing the contributions of all players on the translational science team.

PROCESS INNOVATOR

Seeks to better understand the scientific and operational principles underlying the translational process, and innovates to overcome bottlenecks and accelerate that process.

DOMAIN EXPERT

Possesses deep disciplinary knowledge and expertise within one or more of the domains of the translational science spectrum ranging from basic to clinical to public health research and domains in between.

SKILLED COMMUNICATOR

Communicates with understanding with all stakeholders in the translational process across diverse social, cultural, economic and scientific backgrounds, including patients and community members.

SYSTEMS THINKER

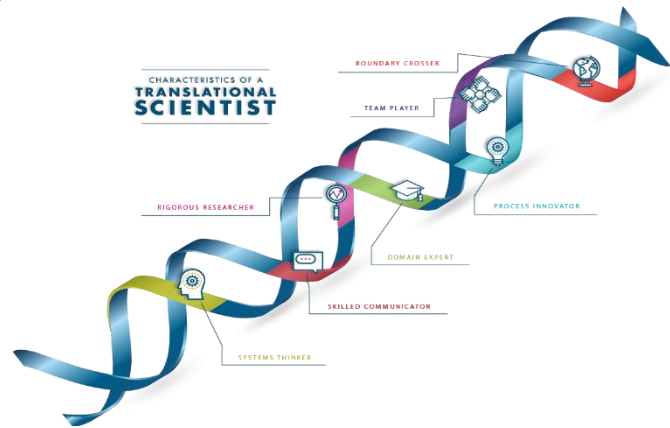
Evaluates the complex external forces, interactions and relationships impacting the development of medical interventions, including patient needs and preferences, regulatory requirements, current standards of care, and market and business demands.

Gilliland et al., 2019, The Fundamental Characteristics of a Translational Scientist. *ACS Pharmacol Transl Sci.* 2(3):213-216

Faupel-Badger et al., 2022, Advancing translational science education. *Clin Transl Sci.* 15(11):2555-2566



Ten Translational Science Competency Domains




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

46 Translational Science Competencies

BOUNDARY CROSSER

- A. Use knowledge from multiple disciplines
- B. Use broad scientific approaches
- C. Participate across translational phases
- D. Engage stakeholders across professions
- E. Engage with communities

DOMAIN EXPERT

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

TEAM PLAYER

- A. Demonstrate a cross-disciplinary, collaborative mindset
- B. Demonstrate reflective awareness in a team environment
- C. Apply strategies to work effectively within diverse teams

SKILLED COMMUNICATOR

- A. Practice effective oral presentation skills
- B. Write and review scientific manuscripts for publication
- C. Write and submit research grant proposals
- D. Communicate effectively with patients & community members
- E. Communicate effectively with funders
- F. Communicate effectively with policy-makers

PROCESS INNOVATOR

- A. Focus on unmet needs
- B. Use creativity & innovation
- C. Seek efficiency & speed
- D. Find generalizable & impactful solutions

46 Translational Science Competencies

SYSTEMS THINKER

- A. Operate within a system of therapeutic innovation
- B. Leverage interconnections of translational research
- C. Integrate patient perspectives

RIGOROUS RESEARCHER

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

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. Seek professional growth opportunities
- E. Build professional network

RESEARCH LEADER

- A. Develop an Inclusive and Shared Vision
- B. Foster integration and a collaborative environment
- C. Practices effective organization and planning skills
- D. Empower progressive decision making
- E. Facilitate collaborative problem-solving
- F. Promote a culture of trust and psychological safety

TS CBA WG Goals

**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**

- 181 responses
 - 58 CTSA hubs represented
 - T Trainees & K Scholars 34%
 - T/K Program Directors 25%
 - Other WD Roles 24%
 - Other 18%
- 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
- Deliverable #1: TS Competency Framework

TS CBA WG Goals

**Phase 1: Develop
list of competency
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**Finalize the list of
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**Do we have the right
list of competencies?
Is anything
important missing?**

**Use feedback from
trainees and
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to finalize the
competencies**

Deliverable 1: TS Competency Framework

**Phase 2: Calibrate
the milestones for
competency levels**

**Write milestones for
each competency at
five levels of skill
acquisition, 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 & mentors**

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

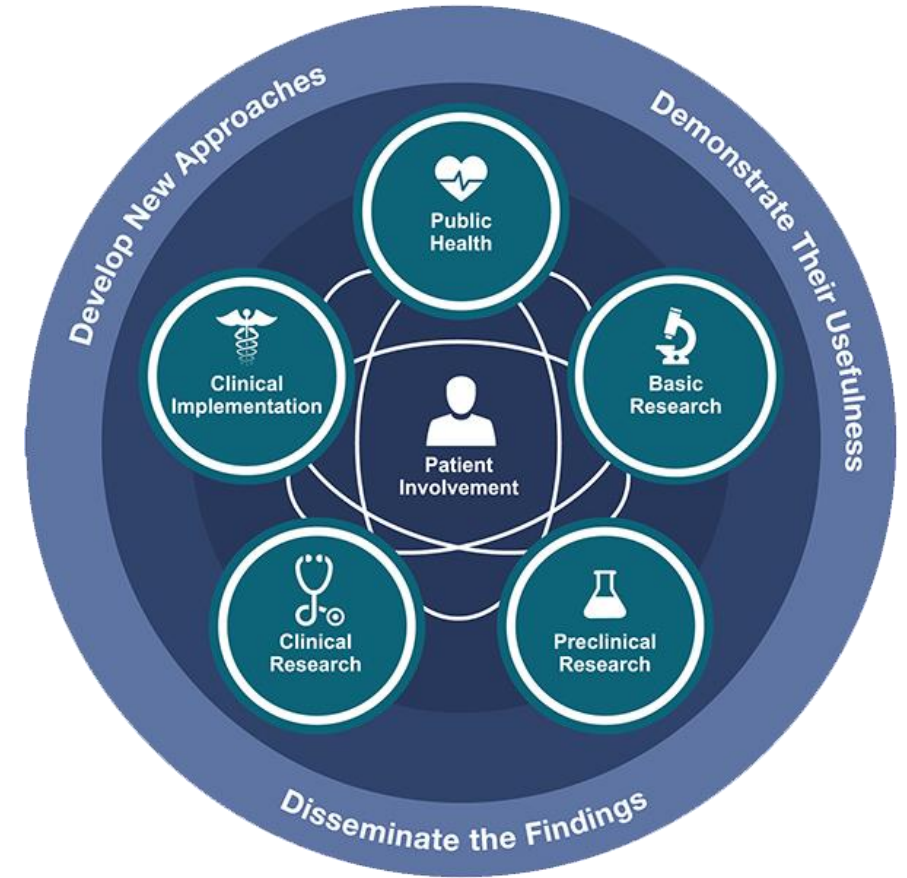
**Compare self/mentor
assessment. Focus
groups with trainees
& mentors
(mentoring value)**

**Survey users about
usability, feasibility,
utility**

**Deliverable 2:
Publish TS-CBA tool
and outcomes**

Discussion

- Is the progress satisfactory to date?
- Are we on the right track to make an impact with this WG?
- Are we engaging appropriate stakeholders/participants?
- Are there other desirable goals or deliverables that may enhance impact?
- Suggestions about enhancing implementation and dissemination?





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 CTSA

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.

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:
 - Understand the rationale for the establishment of the Working Group
 - Identify collaborative partners in the Working Group efforts and opportunities for additional collaborations
 - 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 proposal'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 will 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 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.

What Does Active Research Participation by Individuals with Disability Lived Experience Mean?

- Active Engagement in:
 - Development of research questions
 - Hypothesis generation
 - Decisions about study design
 - Selection of measures
 - Data collection
 - Informed consent process
 - Determination of meaningful analyses
 - Interpretation of analysis and context of analyses
 - Manuscript writing and publication as author

Alignment with CTSA Priorities

Diversity, equity, inclusion, and accessibility



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 (IDDRRC)
 - 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 CTSAs 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

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
- John Tschida, Executive Director, AUCD (Senior Advisor)

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 in:
 - (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

Working Group Timeline and Action Steps

Workplan for Upcoming Months

- Apr-June: 2024: Distribute survey, review survey results, prioritize Toolkit components
- May-June, 2024: Assign Toolkit component sub-groups; Contact JCTS and other Journals about possibility of special issue on WG topics
- June-September, 2024: Design Toolkit components, First Webinar: Overview of topic for professionals and ILDEs (inspire, inform); expand participation outside core WG to include collaborators on toolkit components
- October-December, 2024: initiate additional specific webinars for targeting professionals, institutional research leaders, ILDEs, and journal editors; post Toolkit components
- December, 2024-May, 2025: Complete toolkit components; Prepare manuscript(s) or special issue
- June-August, 2025: Submit and respond to journal reviews for revisions if needed
- August, 2025: Toolkit completed and paper/special issue accepted/published

Survey Questions

- 5 questions
 - Barriers to integration of ILDEs in research
 - Benefits of integration of ILDEs in research
 - Topics of toolkit components
 - Formats of toolkit components
 - Audience for toolkit components





Getting Involved

- Contact CCOS at Engaging_Individuals@ccos.ctsa.io and Daniel Armstrong, PhD, Working Group Chair: darmstrong@miami.edu if interested in contributing to a Toolkit Component
- Next Steps: Distribute Survey and Initial Webinar (June-September)

Questions?



Thank you!

Next webinar is **June 26, 2024; 2-3 PM ET.**