CTSA Coordination, Communication, & Operations Support

Steering Committee
Monday, June 10, 2024
2:30pm ET

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Agenda for June 10, 2024

Time	Topic	Speaker(s)
2:30 – 2:35pm ET	Welcome and Announcements	*Michael Kurilla* *Ruth O'Hara*
2:35 – 2:45pm ET	Report Out: TS-CBA Working Group	*Wayne McCormack*
2:45 – 2:55pm ET	Discussion/Q & A	
2:55 – 3:05pm ET	Fall Meeting Logistics Update	*Kerry James*
3:05 – 3:20pm ET	TIN Update	*Daniel Ford*
3:20 – 3:30pm ET	Discussion/Q & A	
3:30pm ET	Adjourn	

Welcome and Announcements

Michael Kurilla

Ruth O’Hara

Development of a Translational Science Competency-Based Mentoring Tool

UF FSU Clinical and Translational Science Institute
UNIVERSITY of FLORIDA FLORIDA STATE UNIVERSITY

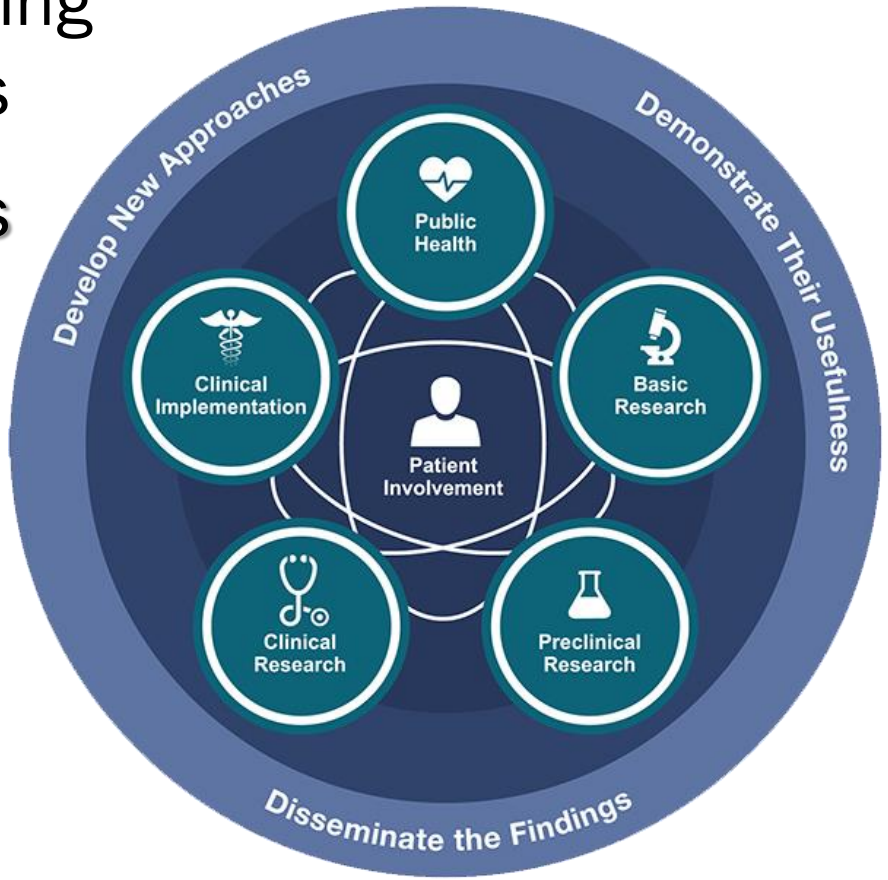
Wayne T. McCormack, PhD
on behalf of the Translational Science Competency-Based Assessment Working Group

CTSA

The UF-FSU hub is supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under University of Florida Clinical and Translational Science Awards UL1TR001427, KL2TR001429 and TL1TR001428.

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



Translational Science Competency-Based Assessment Working Group

- Chair: Wayne T. McCormack, PhD (UF)
- Roster: 54 members from 29 CTSA hubs

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

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

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)**

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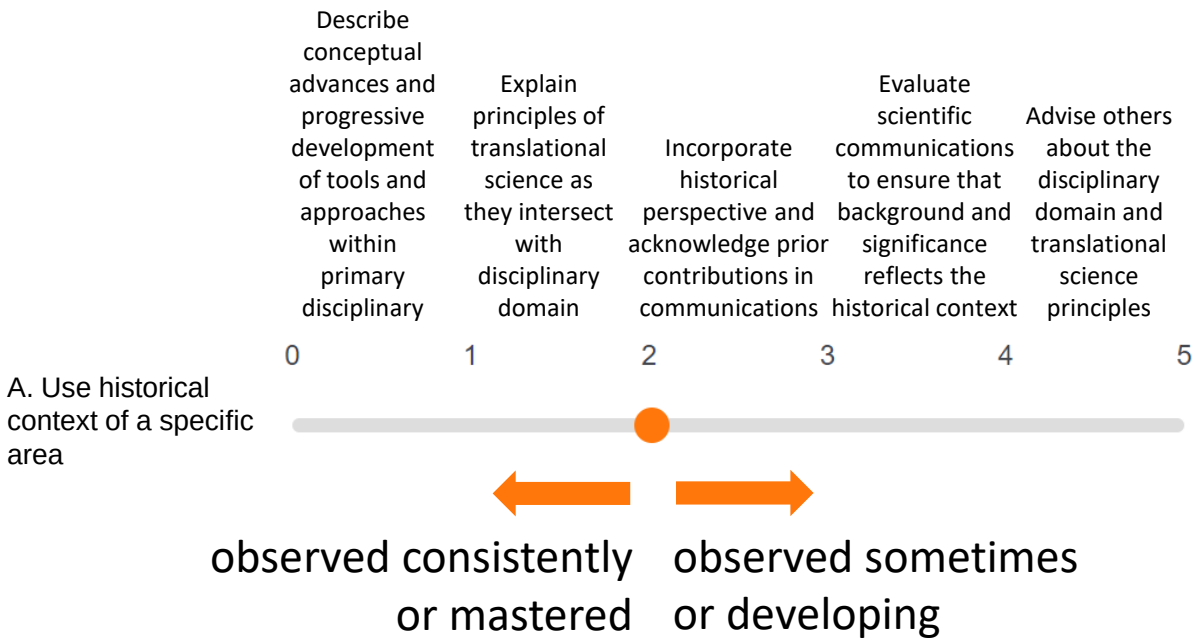
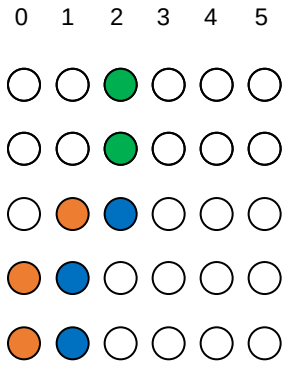
Translational Scientist Training Stages	**Beginning PhD Student / Clinician beginning research training with little or no experience**	**Advanced PhD Student / Clinician Scientist during early research training**	**Defending PhD Student / Beginning Postdoctoral / Clinician Scientist during later research 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

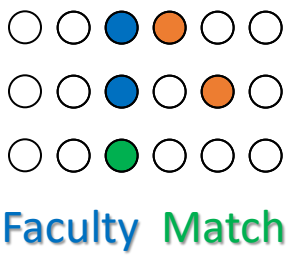
Proposed Process for Mentor & Self-Assessment



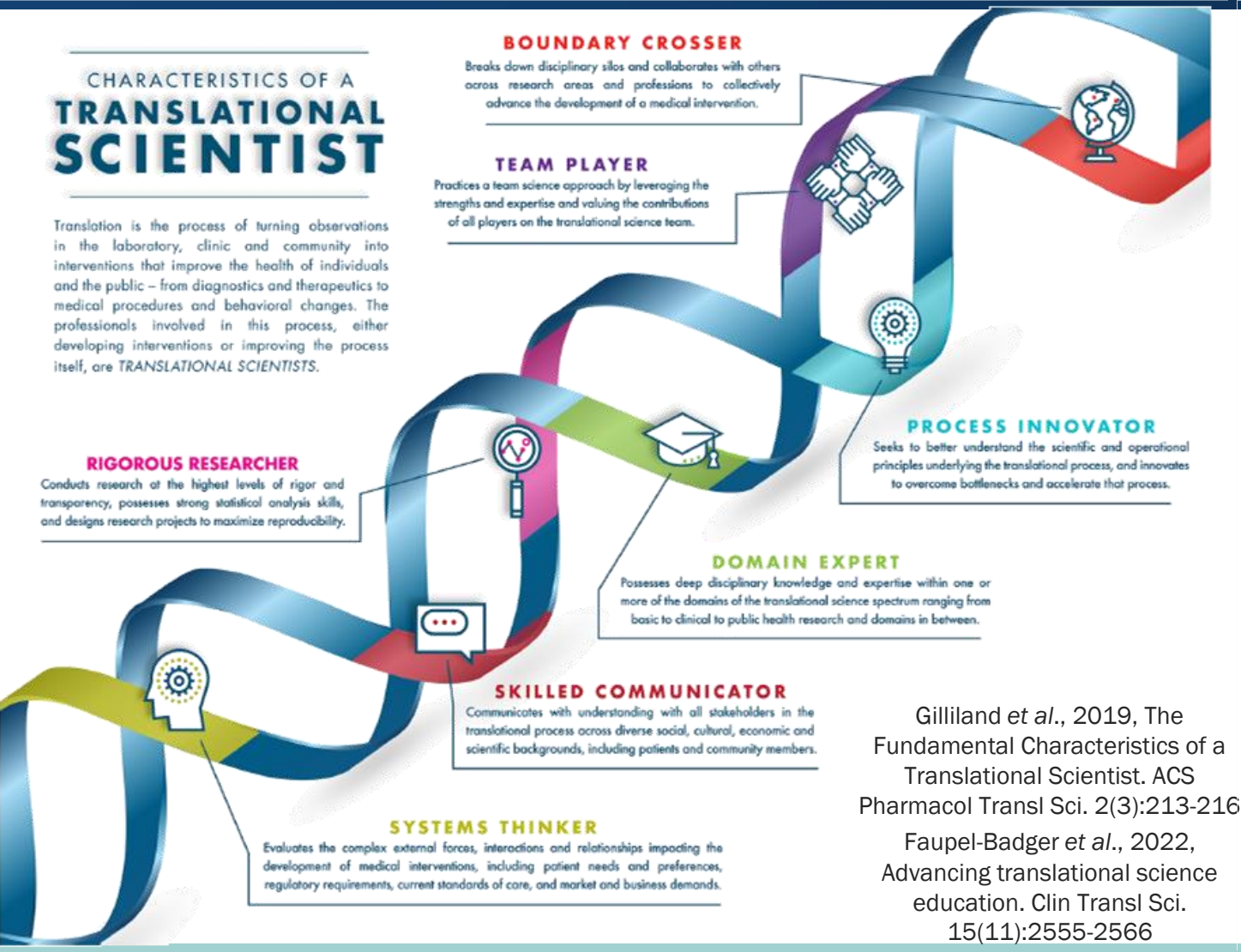
BOUNDARY CROSSER



DOMAIN EXPERT



Characteristics of a Translational Scientist



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

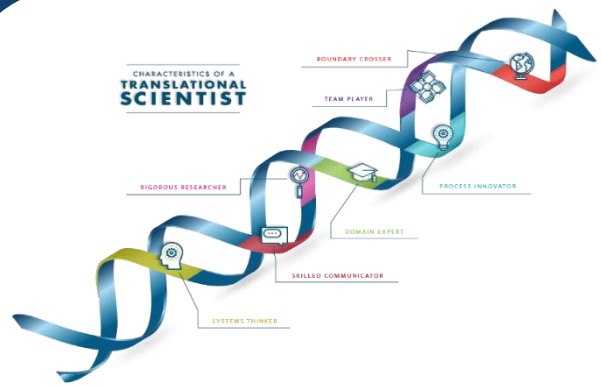
TS CBA WG Goals

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



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

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

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

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

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

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

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

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

- 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%

TS CBA WG Goals

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Use feedback from trainees and mentors (via survey) 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

Fall 2024

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

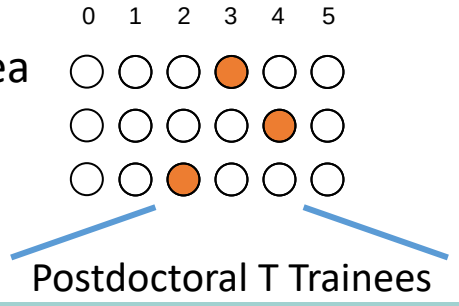
Predoctoral T Trainees | K Scholars

DOMAIN EXPERT

A. Use historical context of a specific area

B. Use current content expertise …

C. Use tools and approaches …



TS CBA WG Goals

Phase 1: Develop list of competency domains & competencies

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→ **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)**

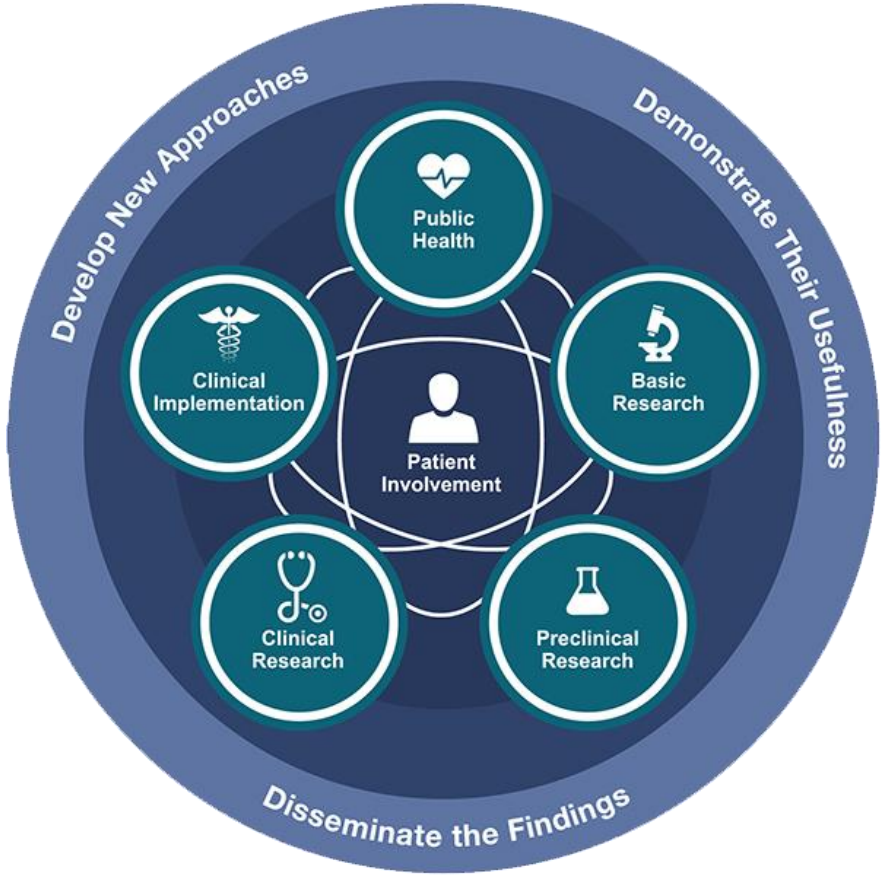
Spring 2025

→ **Final revisions**

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?



Fall Meeting Logistics

Kerry James

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
Heather Baker
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

Fall Planning Committee

- Started meeting on April 23, 2024
- Meeting on the 2nd and 4th Tues at 1-2pm ET

2024 Fall CTSA Program Meeting Goals

Meeting Goals: To provide Hub leadership with an opportunity to:

- Network with their peers
- Share best practices for practical applications
- Gain knowledge through resource updates

Fall 2024 CTSA Program Meeting

Building CTSA Program Impact through Innovation, Collaboration and Equity

More details and online registration to come!

Questions?

Contact FallMtg@ccos.ctsa.io

DATE: November 13-15th

LOCATION: Bethesda North Marriott

Day 1:

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

Days 2 (full day) and 3 (half day):

- CTSA Program Meeting

2024 Fall Program Meeting – Session Topic Ideas

Broad Topic	Ideas from Steering Committee, Pods, DCI

Translational Science	• Translational scientist competencies, continuity, and next steps (a panel presentation)
	• Careers in translational science
	  • Senior investigators describe what it is like to have funding, continue their research, and make meaningful contributions
	  • PI succession planning (Have senior PI talk about success)
	  • Accomplishments of new investigators could be celebrated
	  • Early career scholars (rather than more senior investigators) talk about their journeys toward promotion, the resources they used, and how the CTSA program supported them
	  • Outcomes of scholars trained with new programs that focused on translational science
	• Funding for translational science outside of NCATS
	• Catalyzing translational science innovations at hubs and engaging commercial entities and business schools
	• NIH and hub experience re: new FOA

NCATS Strategic Plan	• Session could be interactive and include ideas for implementing the plan • Provide opportunity for hubs to provide input • **Session with the new NIH Director to hear her vision for CTSAs**
Clinical Trials	• Enhancing diversity in clinical trials • Enhancing the impact of clinical trials • Novel and adaptive trial designs that could accelerate clinical trial research

2024 Fall Program Meeting – Session Topic Ideas

Broad Topic	Ideas from Steering Committee, Pods, DCI
CTSA Program Updates / Issues	• Revisit the updates from TIN, WGs, ENACT, Enterprise Committees, Collaboration grants to ensure hub engagement • Opportunities for collaboration across the networks • Onboarding of new PIs (Targeted programming for “new” CTSA Directors and Associate Directors (i.e. 1-3 years)) • Retaining research staff (e.g., biostatisticians, technicians, research administrators) • Issues related to the cost/expense of clinical and translational research • R03 session
Emerging Health Threats	• Climate Change and Health
Dissemination and Implementation Science	• Advancing D&I science • Plan for the CTSA consortium? Opportunity to provide hub feedback
Data Platforms	• N3C present and future
2023 Fall Meeting Topics (e.g., AI, RWD/RWE)	• Revisit topics from 2023 with focus on how CTSAs contribute (e.g., Discuss AI and ARPA-H next steps with a greater CTSA focus) • Rigor and reproducibility in RWD/RWE
New network for research and primary care	• Network is in development, but more information will be available in the Fall • Could include lessons learned from the primary care practice-based research networks (PBRNs)
Evaluation	• Consortium Level Evaluation • The future of Metrics with the TSBM model

Draft Agenda

Thursday, November 14, 2024		
8:30 AM	9:45 AM	**Session 1:** Welcome & Keynote
9:45 AM	*10:00 AM*	*Break*
10:00 AM	11:30 AM	**Session 2:** CTSA Collaborations with Primary Care Practice-Based Research Networks (PBRNs)
11:30 AM	12:15 PM	**Poster Session A**
12:15 PM	*1:45 PM*	*Lunch Break*
1:45 PM	3:15 PM	**Session 3:** PCORNnet/CTSA Collaborations | Innovations from TIN, ENACT, N3C to Ensure Hub Engagement
3:15 PM	*3:30 PM*	*Break*
3:30 PM	4:15 PM	**Poster Session B**
4:15 PM	5:45 PM	**Session 4:** Women's Health Initiative | DEI in Clinical Trials
Friday, November 15, 2024		
8:00 AM	9:15 AM	**Session 5:** CTSA Experiences with Transition from Translational Research to Translational Science | Engagement across Communities
9:15 AM	*9:30 AM*	*Break*
9:30 AM	10:45 AM	**Session 6:** Application of Generative AI and Large Language Models in Translational Science: Best Practices for Clinical Decision Making and Equity
10:45 AM	*11:00 AM*	*Break*
11:00 AM	12:30 PM	**Session 7:** NCATS Session
12:30 PM	1:00 PM	Closing

Session Leader Responsibilities

Session Leader(s)
• Design 90-minute session structure • Provide updates on session development during these calls • Identify and invite speakers • Submit initial session agenda including proposed speakers and contact information • Confirm speakers by deadline • Submit final session agenda • Facilitate session including speaker introductions, panel discussions, audience interactions and/or additional incorporated session activities. • Have the expertise and equipment on-hand to successfully perform/troubleshoot any demonstrations that you plan

Planning Timeline for Fall Meeting – Nov 13-15, 2024

By May 31

- Finalize Fall Meeting theme and topics
- Begin promotional activities

By Jun 30

- Confirm Session Leads
- Initial session agendas due
- Determine Poster Session theme and structure
- Discuss suggested speakers
- **Registration opens**

By Jul 31

- Confirm and promote speakers

By Aug 31

- Finalize Fall Program flow and agenda

By Sep 30

- Final session agendas due
- Poster submissions due

By Oct 15

- **Registration closes**

Trial Innovation Network (TIN)

TRIAL **INNOVATION** NETWORK

CTSA Clinical & Translational Science Awards Program

TIN Update

- Current TIN activity with consultations
- Expansion of CTSA Hubs in TIN
- Steering Committee support for TIN surveys
- TIN CTSA PIs “Advisory Committee”
- TIN Role in “Care for Health” NIH Primary Care Research Initiative

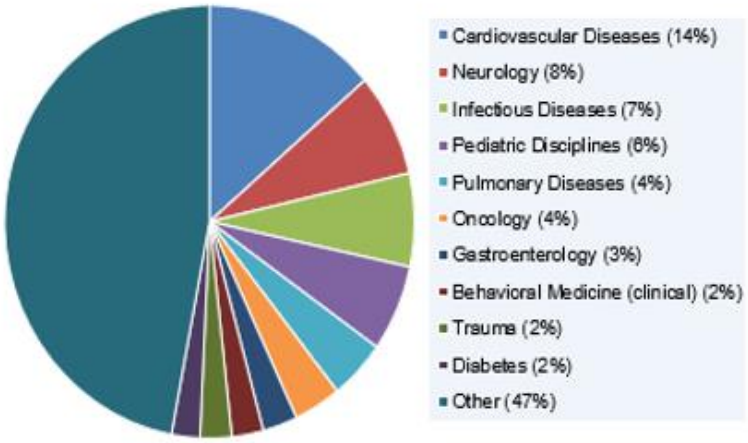
Reporting of the TIN efforts to date

NETWORK PROPOSALS

445	76	62 (94%)	31	20
REQUESTED NETWORK SUPPORT	THERAPUETIC AREAS REPRESENTED	NUMBER (%) OF CTSA SUBMITTED PROPOSALS	NUMBER OF NON-CTSA SUBMITTED PROPOSALS	NIH I/Cs ENGAGED

- NHLBI
- NINDS
- NIDDK
- NCATS
- NICHD
- NIA
- NCI
- NIAMS
- NIAID
- NIDCD
- NEI
- NIAAA
- NIMH
- NIDA
- NIDCR
- NIBIB
- NCCIH
- NINR
- NIMHD
- NHGRI

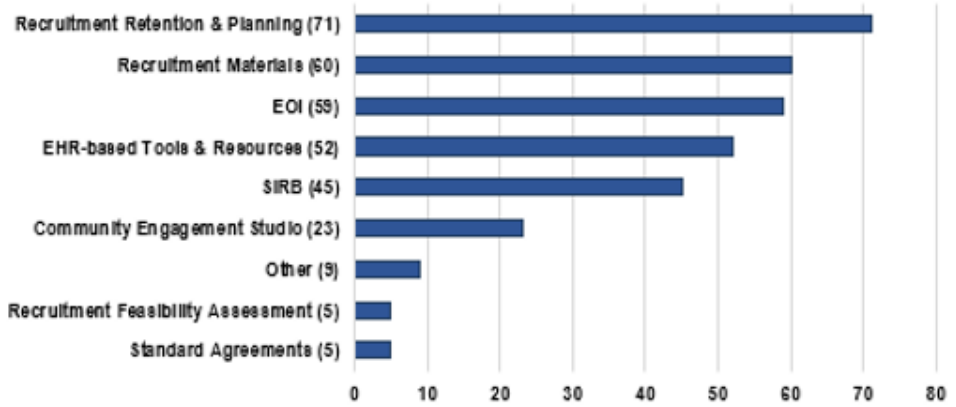
Top 10 Therapeutic Areas Represented (%)



NETWORK SUPPORT

411	83	37
INITIAL CONSULTATIONS	COMPREHENSIVE CONSULTATIONS	FUNDED TRIALS

Types of TIN Support



Select NIH ICs Engaged with the TIN

- NHLBI-80 studies — National Heart, Lung, and Blood Institute
- NINDS-35 studies — National Institute of Neurological Disorders and Stroke
- NIDDK-31 studies — National Institute of Diabetes and Digestive and Kidney Diseases
- NCATS-30 studies — National Center for Advancing Translational Sciences
- NICHD-26 studies — *Eunice Kennedy Shriver* National Institute of Child Health and Human Development
- NIA-19- studies — National Institute on Aging

Use Cases from the RIC

TARGET: Initial consultation + Resources

- **Overview:** Treatments Against RA and Effect on FDG PET-CT (TARGET) examined the effect of RA disease modifying drugs on vascular inflammation; recruitment goals of 400 participants across 40 sites

  Resources included
  - recruitment materials,
  - recruitment feasibility assessment
  - Clinician Study App (CSA)
  - Competing Studies Tool (CTT)
  - Social Media guidance
- **Outcomes**:
  - Completed enrollment within timeframe
  - Became a repeat customer for a new grant submission

TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards Program

LUNA: Initial consultation + Resources

- **Overview:** Smoking cessation study within a lung cancer screening program; actively recruiting but looking for more effective and sustainable methods
- Received recommendations report + 2 resources: 1) Social Media campaign, and 2) Community Engagement Studio
- **Outcomes:** Uptick in enrollment after social media campaign; successful completion of enrollment; published manuscript

ELSEVIER

Contemporary Clinical Trials

Volume 107, August 2021, 106461

Short Communication

Engaging smokers in research: Utility of Facebook in facilitating recruitment to a smoking cessation study

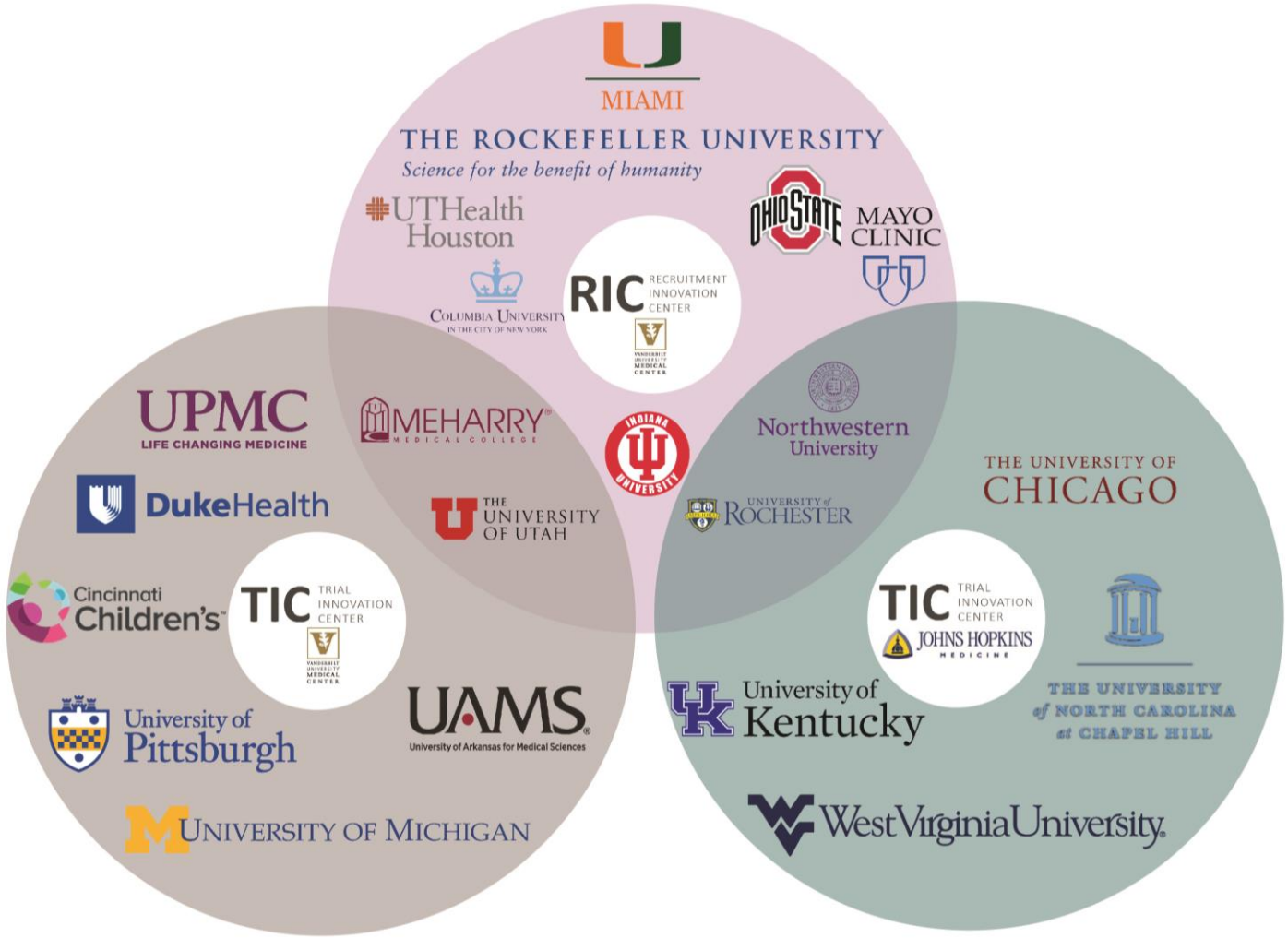
Sarah K. Cook [a], Rebecca N. Jerome [a], Julia Dunagan [a], Nan Kennedy [a], Terri Edwards [a], Jennifer A. Minnix [b], Leann Witmer [b], Jennifer Ferguson [b], Paul Cinciripini [b], Consuelo Wilkins [a, c, d, f], Paul Harris [a, e]

Conclusions

The social media campaign was successful at increasing outreach and interest in the LUNA study. However, the price-per-participant enrolled was higher than in comparable tobacco cessation studies. These results and lessons learned may be beneficial to others considering social media as a recruitment method for their clinical research trial.

TRIAL INNOVATION NETWORK

TIN Cycle 2-Expanded Partnerships



TRIAL **INNOVATION** NETWORK

CTSA Clinical & Translational Science Awards Program

TIN Cycle 2

40 new submissions → **20** different Organization/ Institutions → **3** New Organizations/ Institutions

Boston University	Stanford University	University of Michigan	Weill Cornell Medical College/ Hunter College
Columbia University	University of Utah	University of Minnesota	**University of Missouri**
Duke University	Ohio State University	University of Rochester	**University of Arizona**
Icahn School of Medicine at Mount Sinai	University of Pittsburgh	University of Wisconsin-Madison	The Alzheimer's Association
Johns Hopkins University	University of Colorado	Vanderbilt University Medical Center/ Meharry Medical Center	**Neurona Therapuetics (UC collaboration)**

TIN Survey Process

TRIAL INNOVATION NETWORK

NCATS CTSA Program Policy and Procedures for Surveys

A Federal agency cannot collect ***or sponsor a collection of information*** from 10 or more public respondents without obtaining approval from the Office of Management and Budget *(Paperwork Reduction Act (PRA) 1995)*

When making determinations to assess whether the project, in question, is subject to PRA clearance, NIH needs an answer to the following questions:

1. Will the program analyze the project outcomes in a systematic way?
2. Will the program publicize the results of your systematic analyses?

If the answer to both questions is yes, then the program is conducting NIH research and will be considered exempt from the PRA approval requirements as outlined by the 21st Century Cures Act.

An example of an item that is exempt from PRA approval includes the following:

- Customer Satisfaction / Feedback Surveys if outcomes are analyzed in a systematic way and the results are publicized.

Survey request and approval process

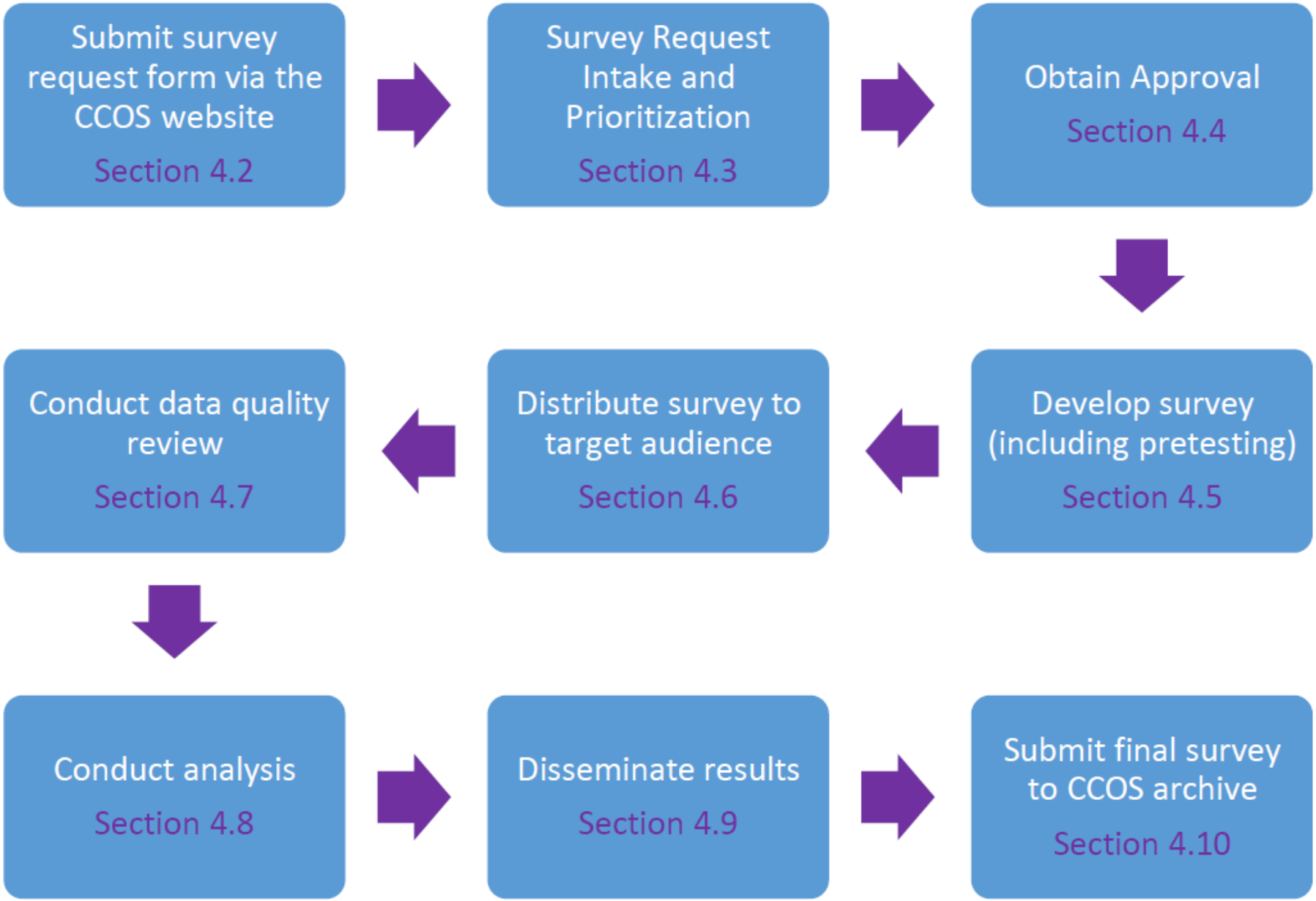


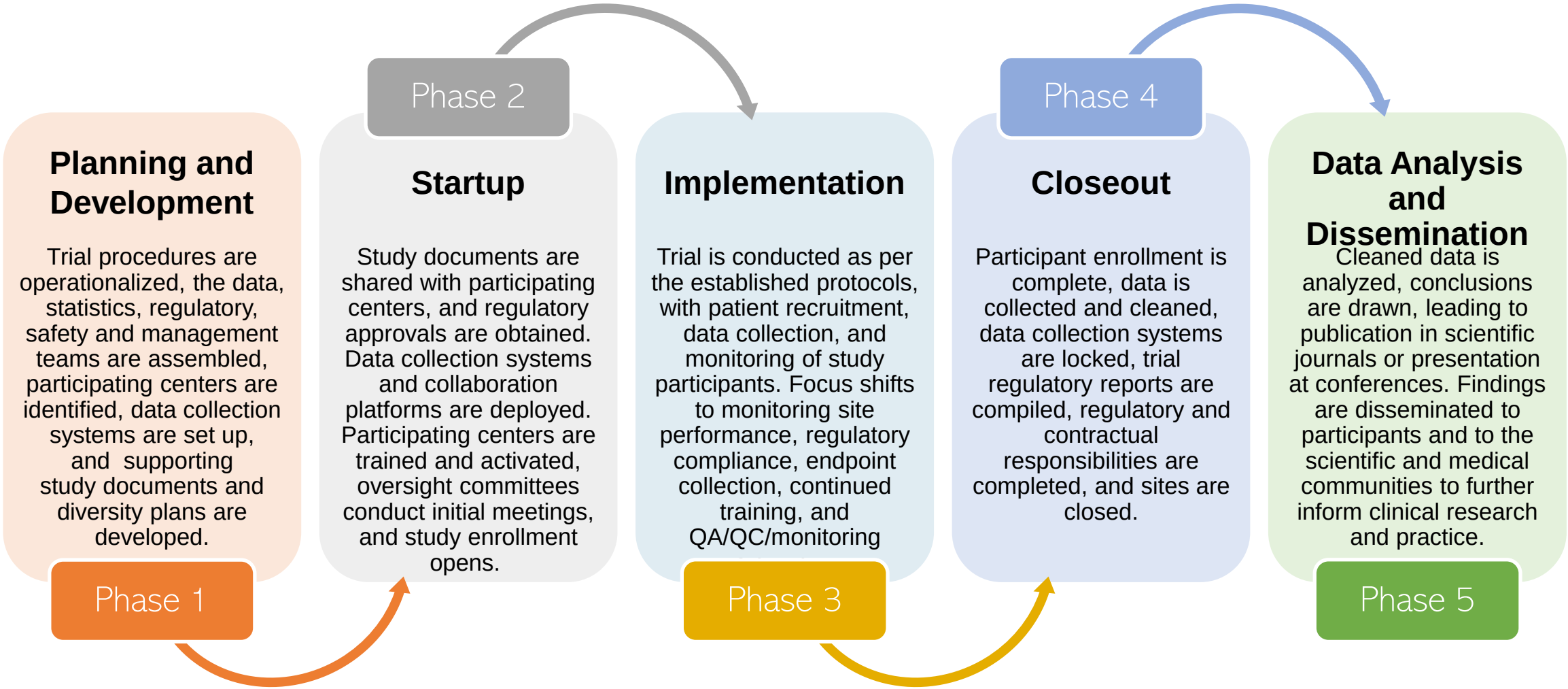
Table 1. CTSA Survey Approval Process by Survey Type

Survey Source	Target	Reviewed by	Approved by	Distribution
A. EC Survey	EC (Including those developed by work groups)	Lead Team of the EC & NCATS Program COR	EC NCATS Program Officer	CCOS Survey Team (will support up to 3 surveys, per EC, per year)
	Other ECs	Lead Team of the Other ECs & NCATS Program COR	EC NCATS Program Officer	
	CTSA Program PIs	CTSA Program Steering Committee & NCATS Program COR	Leadership of the Division of Clinical Innovation, NCATS	
B. CTSA Program Consortium Grantee (not Hub) Survey	CTSA Program (Described in Grant Application)	CTSA Program Steering Committee & NCATS Program COR	N/A	CCOS Survey Team
	CTSA Program (Not Described in Grant Application)	CTSA Program Steering Committee & NCATS Program COR	Leadership of the Division of Clinical Innovation, NCATS	CCOS Survey Team
C. CTSA Program Hub or Partner Survey	CTSA Program Hubs	CTSA Program Steering Committee & NCATS Program COR	Leadership of the Division of Clinical Innovation, NCATS	CCOS Survey Team
D. Other CTSA groups (Admin, Communicators,	Within CTSA Program groups (e.g., Administrators,	Self-reviewed &	Self-approved	The group specific to the

Training Academy Vision

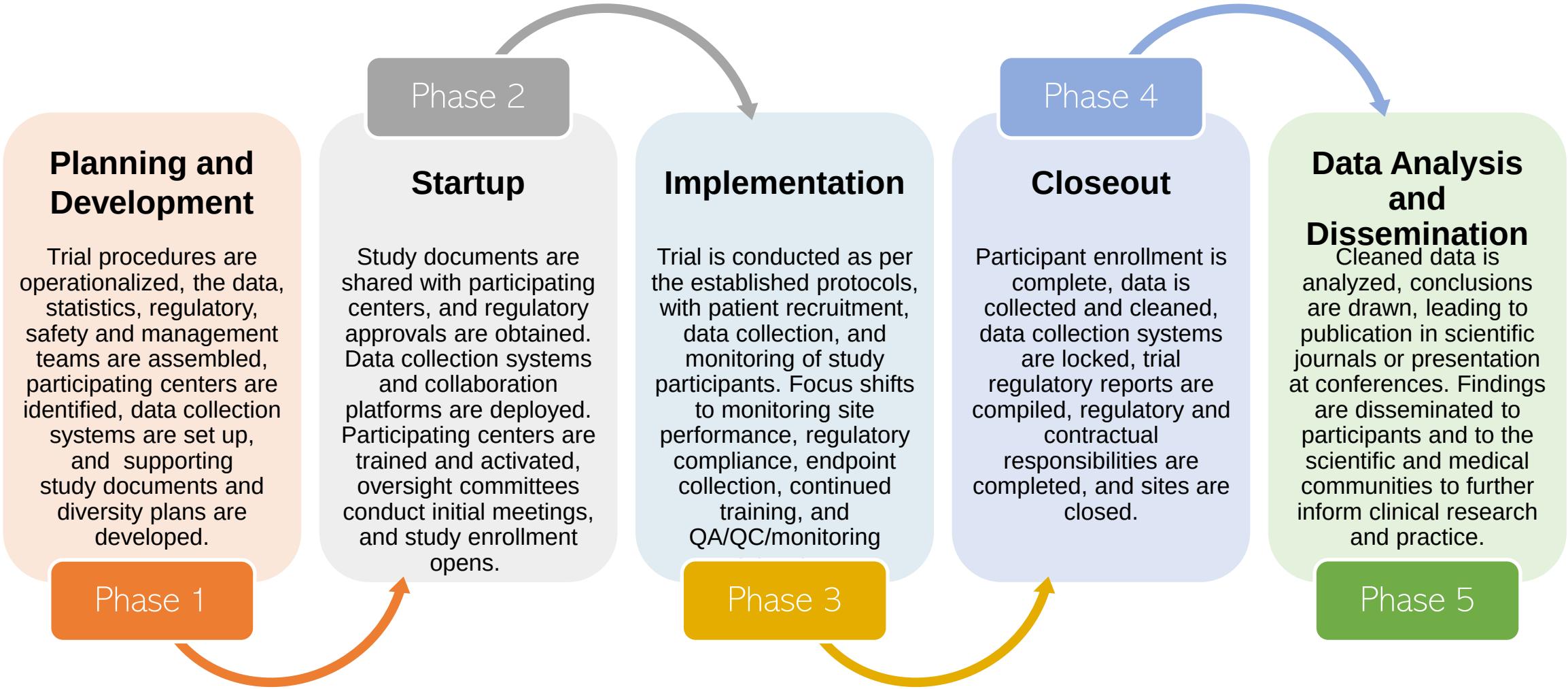
- The TIN is developing a training program designed to address these gaps in critical competencies necessary for engaging in and managing multicenter clinical trial activities.
- We envision a program that extends beyond the mandatory training in institutional Human Subjects Research (HSR) and Good Clinical Practice (GCP).
- Our target audience will be investigators and clinical research managers transitioning from single-site to multicenter clinical trials.

The Five Phases of a Multicenter Clinical Trial



Fashioned from original art by Caroline Foley, University of Utah, for Lane, K., Palm, M., Marion, E., Kay, M., Thompson, D., Stroud, M.,… Ford, D. (2023). Approaches for enhancing the informativeness and quality of clinical trials: Innovations and principles for implementing multicenter trials from the Trial Innovation Network. Journal of Clinical and Translational Science, 7(1), E131. doi:10.1017/cts.2023.560

The Five Phases of a Multicenter Clinical Trial



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Survey Respondent Profile

- 283 respondents partially or fully completed the survey
- 77% (n=218) identified themselves as PIs/Clinical research managers
- Other roles 23%

#	Field		Choice Count
1	Research Coordinator	28.13%	18
2	Clinical Research Manager (CRM)/Trial Manager/Project Manager	4.69%	3
3	CTSA PI	4.69%	3
4	CTSA Medical Director	0.00%	0
5	CTSA Point of Contact	15.63%	10
6	CTSA Biostatistician	0.00%	0
7	Other	46.88%	30
			64

TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards Program

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TRIAL INNOVATION NETWORK

CTSA Clinical & Translational Science Awards Program

Ranking & Comparison

1 No need | 2 Low priority | 3 Moderate Need | 4 High Priority

#	Training Academy Module	Overall	PIs & RMs	Other Roles	Top 5 Sites	All Other Sites
		N=283 (100%)	N=218 (77.03%)	N=65 (22.97%)	N=5	N=29
1	Multicenter Clinical Trial - Planning and Development	3.26	3.21	3.44	3.15	3.38
2	Accelerated Site Start-up	3.19	3.22	3.11	3.06	3.32
3	Managing Sites in a Multisite Clinical Trial	3.14	3.12	3.2	3.04	3.25
4	Multicenter Clinical Trial Management - Bringing It All Together	3.14	3.17	3.05	3.06	3.22
5	Multicenter sIRB Procedures and Coordination	3.12	3.12	3.14	3.03	3.21
6	Recruitment and Retention in Clinical Trials	3.09	3.08	3.11	3.04	3.14
7	Diversity in Clinical Trials	3.05	3.04	3.11	2.97	3.14
8	Enhancing Clinical Trial Quality through Monitoring Plans and Quality Assurance	3.03	3.02	3.09	2.87	3.2
9	Understanding Clinical Trial FDA Submissions and Navigating FDA Oversight in Clinical Trials	3.01	3.02	2.96	2.9	3.13
10	Developing Electronic Data Capturing (EDC) Systems	2.91	2.94	2.78	2.9	2.92
11	Adverse Event (AE) Documentation and Reporting	2.89	2.85	3.07	2.84	2.94
12	Developing Electronic Trial Master Files (eTMF)	2.86	2.89	2.73	2.83	2.89
13	Data and Safety Monitoring Board (DSMB) Management	2.8	2.8	2.82	2.74	2.86
14	Multisite Study Closure Procedures	2.77	2.77	2.74	2.69	2.86
15	Statistical Analysis Plan Development and Compliance	2.65	2.63	2.69	2.61	2.7
16	Data Analysis and Dissemination	2.58	2.59	2.59	2.47	2.7
17	Science Communication and Public Relations	2.55	2.57	2.48	2.45	2.65

TIN CTSA Hub PI Advisory Committee

- PIs or TIN Medical Directors or Designee?
- Communication back to your CTSA Hub?
- Most helpful advice?

NIH Director Care for Health Initiative

- Connecting Research to Primary Care Sites to Expand Diversity
- Network of Networks Concept
- Initial goal is expanding enrollment of existing NIH studies into rural areas
  - Sally Hodder Mountaineer Health Initiative with Johns Hopkins TIC
- Programs in Network Research Hub
  - Clinical Science Center – study design?
  - Operations Center
  - Independent Review and Monitoring Boards
  - Community Engagement
  - Industry Partnership

June 24, 2024
2:30-3:30pm ET
We will be discussing and voting on new working groups.

National Center for Advancing Translational Sciences

Adjourn