CTSA Steering Committee Meeting Summary
Zoom Conference
June 10, 2024
2:30-3:30 PM ET

Steering Committee Members:

Ruth O'Hara, Co-Chair	Tesheia Johnson	Elizabeth Ofili
Stephan Bour	Jessica Kahn	Steven Reis
Arleen Brown	Mimi Kim	Doris Rubio
Daniel Ford	Grace McComsey	Kathryn Sandberg
Vesna Garovic	Duane Mitchell	Randy Urban
Melissa Haendel	Frederick "Gerry" Moeller	Rosalind Wright

NCATS Attendees:

Audie Atienza	Jamie Doyle	Rashmi Gopal
Heather Baker	Sarah Dunsmore	Francisco Leyva
Kris Bough	Stephanie Ezequiel	Joan Nagel
Patrick Brown	Josh Fessel	Erica Rosemond
Soju Chang	Stacia Fleisher	Meredith Temple
Jennie Conroy	Gallya Gannot	O'Connor
Pablo Cure	Ken Gersing	Salina Waddy
Anthony DiBello	Brittany Gibbons	Robin Wagner

Regrets: Jennifer Kraschnewski, Michael Kurilla, Ted Wun

Guests: Wayne McCormack

CCOS: Lauren Fitzharris, Kerry James, Cindy Mark

Welcome and Announcements (Slides 2-3)

Speakers: Ruth O'Hara

R. O'Hara welcomed everyone, briefly reviewed the agenda, and facilitated the call.

Report Out: TS-CBA Working Group / Q & A (Slides 4-17)

Speaker: Wayne McCormack

Presentation Summary:

W. McCormack shared an update from the Translational Science Competency-Based Assessment Working Group (WG) on its progress in developing a mentoring tool to help

trainees and scholars understand expectations, perform self-assessments of competencies, and take self-directed learning courses. The tool will use a milestone approach based on skills appropriate for different career levels and include a clear process for evaluating progress and knowledge of translational science principles. It will allow mentors to assess trainee progress and engage in meaningful conversations with mentees.

He began by describing the membership of the WG, which includes 54 members from 29 CTSA Hubs. He noted the WG meets the 1st and 3rd Mondays of every month at 1:00 PM ET. He then described the goals of the WG by phase.

Phase I includes developing a list of competency domains and competencies for the training tool. To date, 10 domains and 46 competencies have been identified. To evaluate the list, the WG surveyed trainees and mentors across the CTSA consortium and plans to use their feedback to finalize the list. Survey responses totaled 181 from representatives of 58 CTSA Hubs. Finalization of the list as a deliverable is expected by end of Summer 2024.

Phase 2 has begun and involves defining and calibrating milestones for competency levels according to training stages and making revisions after a pilot test planned for Fall 2024. In the test, trainees and scholars will be invited to use the tool as a self-assessment, and that data will help with finalization of the milestones and tool components.

Phase 3, planned for Spring 2025, will include a pilot test of the final proposed tool, focus group discussions to assess the mentoring value of the tool, and publication of the final tool and results outcomes.

He concluded by inviting comments related to progress and discussion of proposed stakeholders, goals, impact, deliverables, implementation, and dissemination.

Questions and Discussion:

- D. Rubio commended the WG for its progress, involvement of so many CTSA members in development of the tool, and adherence to an ambitious timeline. She asserted the tool will be useful and wondered whether the Steering Committee (SC) could help issue an extension if all deliverables are not met by the intended deadline.
- D. Ford asked how the WG plans to assess whether the tool improves training.
    - W. McCormack noted this is beyond the scope of the WG but hopes the CTSA would approve a follow-up survey of Hubs in several years to determine usefulness of the tool and its full impact.

Fall Meeting Logistics Update (Slides 18-28)

Speaker: Kerry James

K. James shared preliminary information about the Fall 2024 CTSA Program Meeting, which will be held November 13-15 at the Bethesda, Maryland, North Marriott Hotel. The SC, CTSA Administrators, and Trial Information Network (TIN) will meet on Day 1, and the program meeting will follow on Days 2 and 3. The goal of the Fall meeting is to provide Hub leadership the opportunity to network with peers, share best practices, and obtain knowledge through

shared resource updates. The meeting theme is "Building CTSA Program Impact through Innovation, Collaboration and Equity."

The Fall Planning Committee (FPC) began meeting on April 23 and will continue to meet on the 2nd and 4th Tuesdays of every month from 1:00 to 2:00 PM ET. K. James shared a list of FPC members, session topic areas under consideration, a draft agenda, responsibilities of session leaders, and a planning timeline of milestones to achieve from May through early October.. Email questions to the FPC at FallMtg@ccos.ctsa.io.

Questions and Discussion:

- R. O'Hara asked for confirmation that the proposed agenda does not include breakout sessions.
  - K. James confirmed the current plan does not include breakout sessions, which should allow for a longer panel presentation and discussion. She noted there likely will be interactive tabletop discussions built into some sessions.

Trial Innovation Network (TIN) Update (Slides 29-48)

Speaker: Daniel Ford

Presentation Summary:

D. Ford provided an update on TIN activities, including an overview of network proposal metrics, associated therapeutic areas, the overall number and types of TIN support, and the numerous NIH institutes actively engaged with TIN. He then shared brief use case information for the Treatments Against RA and Effect on FDG PET-CT (TARGET) study and the Project LUNA smoking cessation study, both of which used either social media campaigns or TIN tools to support recruitment and study operations. He discussed outcomes, lessons learned, and efforts to continue publication production and growth of the knowledge base. He explained TIN is growing, noting submissions under Cycle 2 have included collaborations with twenty institutions and several new CTSA Hubs.

Next, he reviewed the CTSA survey request process, asserted TIN's attempt to follow the rules, and requested the SC proactively support TIN plans for multiple surveys, perhaps by granting global approval for particular types of surveys, given TIN conducts myriad surveys of similar design related to different topics. He then described a TIN Training Academy survey recently approved by the SC as an example of the type of work conducted by TIN. The Training Academy aims to address gaps in critical competencies necessary for engaging in and managing multicenter clinical trial activities. Survey respondents include investigators and clinical research managers working on multicenter clinical trials, and survey questions ask respondents to rank needs associated with trial activities associated with five phases of a trial. He noted there was a good response rate, but certain CTSA sites were more responsive while others did not participate, which might be a concern for the SC.

He stated TIN is restarting a CTSA Principal Investigator (PI) Advisory Committee. Pending decisions include committee composition, how to effectively communicate committee activities to CTSA Hubs, and determining the best advice needed by Hubs that should drive committee

activities. He concluded by discussing the NIH CARE for Health Initiative, which aims to connect research to rural and underserved populations primary care sites to expand enrollment diversity. He asked about the extent to which TIN and the CTSA should be involved in the initiative and urged quick action if CTSA desires representation.

Questions and Discussion:

- J. Fessel posted in the Chat a link to a site listing the dates and deadlines associated with the CARE for Health initiative.
- E. Rosemond explained the survey policy was implemented due to a proliferation of random surveys as an effort to organize and approve important surveys and minimize the overall burden on the consortium and Hub resources. T. Johnson also noted some surveys collecting significant data only benefitted a single Hub, which did not share results across the consortium, and that is something to be avoided if possible.
- D. Ford stated his hope that SC approval would not be required for administrative and customer service type survey assessments.
  - E. Rosemond noted administrators likely would approve such surveys local to a particular space/group. T. Johnson agreed administrative leaders could approve such surveys without SC approval.
  - R. O'Hara stated her understanding an initial survey would require SC approval, but subsequent follow-up customer surveys likely would not require SC approval.
- K. James noted any surveys to be distributed by CCOS must follow the CCOS request process because the University of Rochester team must program the survey and CCOS has limited support available.
- K. James noted any surveys that are WG deliverables have built-in approval that do not require SC approval. E. Rosemond also noted this is true for grants.
- D. Ford suggested having a list of all surveys conducted that could be consulted would be useful in terms of avoiding duplication.
  - K. James posted a link in the Chat to a non-exhaustive archive of more recently completed surveys maintained by the coordinating center. She will investigate options for building out the archive to be more inclusive.
- M. Haendel commented via the Chat that repeating surveys should be expected of groups within the CTSA and suggested they could be considered a TIN deliverable.
  - R. O'Hara agreed that is a possibility and is something to discuss further.

Adjournment (Slides 49-50)

Speakers:

Presentation Summary:

C. Mark reminded everyone of the date of the next SC meeting. R. O'Hara adjourned the meeting.

Next Steering Committee Meeting: Monday, June 24, 2024, 2:30-3:30pm ET