



Clinical and Translational Science Awards Program

Coordination, Communication, & Operations Support

CTSA Steering Committee Meeting Summary Zoom Conference October 28, 2024; 2:30-3:30 PM ET

Steering Committee Attendees:

Michael Kurilla, Co-Chair
Ruth O'Hara, Co-Chair
Arleen Brown
Andrea Carnegie
Daniel Ford

Mimi Kim
Jen Kraschnewski
Grace McComsey
Jareen Meinzen-Derr
F. Gerald Moeller

Elizabeth Ofili
Kathryn Sandberg
Randy Urban
Rosalind Wright
Ted Wun

SC Regrets: Steven Reis, Vesna Garovic, Duane Mitchell, Stephan Bour, Melissa Haendel, Doris Rubio

NCATS Attendees:

Heather Baker
Kris Bough
Soju Chang
Jennie Conroy
Pablo Cure
Anthony DiBello
Jamie Doyle
Stephanie Ezequiel

Josh Fessel
Stacia Fleisher
Gallya Gannot
Brittany Gibbons
Rashmi Gopal-Srivastava
Chris Hartshorn
Rebecca Katz
Joan Nagel

Thomas Radman
Erica Rosemond
Joni Rutter
Meredith Temple-
O'Connor
Annica Wayman

Invited Guests: Karen Wilson, Mark Schleiss, Meredith Zozus, Thomas Campion, Melissa Brady

CCOS: Cindy Mark, Lauren Fitzharris, Kerry James

Welcome (Slide 2)

Speakers: Michael Kurilla and Ruth O'Hara

M. Kurilla welcomed the members of the Steering Committee (SC), briefly reviewed the agenda, and facilitated the call.

Update: Real-World Data Task Force, followed by discussion (Slides 3-10)

Speaker: Josh Fessel, Ruth O'Hara, and Karen Johnston



Presentation summary:

J. Fessel provided an update for the Real-World Data Task Force, explaining its origins, membership, progress to date, key outputs, and upcoming tasks. The Task Force initially formed at the urging of both NCATS and the SC for the purpose of understanding real-world data needs of CTSA and sharing information across the network about real-world data assets. The focus of the Task Force has since shifted to conducting a needs assessment related to education, democratization of data sciences, and community engagement. The group has determined there is a need for a shared glossary of terms and concepts, accessible set of standard training materials, and space for practicing with datasets when training. It is pursuing opportunities to (1) include a broad array of individuals with different areas of expertise, (2) develop mechanisms for promoting data science similar to clinical trials and the Trial Innovation Network (TIN), and (3) identify and engage multiple communities. The Task Force is currently reviewing its mission and anticipating it might be replaced by other Enterprise Committees (ECs) or Working Groups (WGs) pursuing similar goals or that it might need to refocus on bridging gaps related to community engagement around real-world data. The group would appreciate feedback from the SC related to how it can continue to best serve the CTSA.

Questions and Discussion:

- M. Kim asked how the Task Force defines “data science” since it involves more than real-world data.
 - J. Fessel explained the Task Force focuses on the term only as it applies to real-world data.
 - M. Kurilla commented, the aim is to determine CTSA data and infrastructure needs; real-world data is simply one of the needs.
 - T. Wun noted there are many types of real-world data, including electronic health records (EHRs), clinical data, exposomic data, economic data, and others. The goal should be to improve scientific rigor in harnessing these data to form a robust set of evidence that can be analyzed using computer science, informatics, biostatistics, and other methods.
- R. Wright emphasized the importance of incorporating workforce development experts in the discussion to best leverage data to improve health outcomes.
- E. Ofili noted the difficulty in trying to mimic the TIN model, given the breadth of real-world data and disparate communities to engage, including those who are not health literate.

Report Out: Integration Across Lifespan EC, followed by discussion (Slides 11-17)

Speakers: Karen Wilson and Mark Schleiss

Presentation Summary:

K. Wilson and M. Schleiss provided an update from the Integration Across the Lifespan EC. They noted its Lead Team and non-voting members, goals, recent activities, and anticipated future directions. The goals of the EC are to integrate translational science across all life stages

to improve the health of all individuals. To achieve these aims, the EC focuses on developing initiatives for investigating disparities in disease progression and treatment, and promoting an integrated approach to translational science across all research phases. Highlights for this year include monthly meeting presentations, establishment of Social Determinants of Health and Pediatric Clinical Trials subcommittees, a successful Spring 2024 CTSA Spring meeting, establishment of a new Engaging Individuals with Disabilities in the Research Process WG and a pediatric clinical trials WG proposal, and an accepted submission for a scholarly session at the Pediatric Academic Societies (PAS) meeting. Anticipated future activities include supporting a Social Determinants of Health Subcommittee WG proposal, partnering with other ECs on related programs, and expanding EC membership and participation. Efforts at membership expansion will focus on recruiting non-pediatric experts from underrepresented institutions. The presenters provided their contact information ([Karen Wilson](#), [Mark Schleiss, EC](#)) and invited feedback from the SC regarding (1) the role of lifespan research in the new NCATS Strategic Plan, (2) whether the EC should form additional partnerships with various lifecourse pediatric and geriatric organizations, and (3) how best to intentionally disseminate information related to overcoming barriers to lifespan research.

Questions and Discussion:

- M. Kurilla asked about the date of the PAS meeting and whether it conflicts with the Association for Clinical and Translational Science (ACTS) meeting.
 - M. Schleiss noted it will be the last week of April 2025 in Honolulu, Hawaii, and thus does not conflict with ACTS. He stated one of his goals when joining the EC was to strengthen the relationship with the PAS.
- M. Kurilla suggested TIN might be a helpful resource for membership recruitment.
 - M. Schleiss agreed and proposed the EC dedicate an upcoming monthly meeting to discussing barriers, overlaps, and opportunities for study collaboration with TIN.
- A. Brown asked for further information on the EC's efforts to recruit junior faculty, and specifically their methods of recruitment.
 - M. Schleiss explained intentional recruitment efforts have included arranging several presentations from early-stage investigators at the Spring 2024 meeting in Las Vegas, Nevada, and a few monthly meeting presentations from assistant professors. He noted early-stage investigators will be the future leaders, so it is critical to engage them.
 - K. Wilson agreed, stating that engaging junior faculty is critical since they will help lead and sustain clinical and translational science institutes (CTSIs) into the future.
 - K. Wilson explained the EC recruited presenters for the Spring Las Vegas meeting by asking K and T Directors for suggestions. To boost monthly meeting attendance, EC members were asked to identify potential early-career presenters.
- J. Kraschnewski suggested in the Chat the EC consider establishing additional subcommittees to engage more members across the lifecourse.
- G. McComsey asked whether the EC has any initiatives to promote involvement of seniors in clinical trials and whether EC membership includes geriatricians.
 - K. Wilson confirmed there are geriatricians in the EC, though they are underrepresented.

- M. Schleiss noted inclusion of the elderly and pregnant women in clinical trials remains an issue that the EC is still discussing. He acknowledged engaging such populations in research is highly important.
- K. Wilson acknowledged a comment from R. Gopal-Srivastava in the Chat that noted there was a WG that developed tools and resources for recruiting the elderly in research studies.

Informatics vs. Data Science Discussion (Slides 18-20)

Speakers: Joni Rutter and Michael Kurilla

Presentation Summary:

M. Kurilla provided an overview of NIH activities that led to this discussion. As the opioid epidemic arose and NIH received special funding to address the crisis, effective non-opioid pain management strategies were a primary focus of their approach, and the role of digital resources, including data, science, and informatics, became critical to decision making across the NIH. This has led to a need to clarify terminology so that it is broad and inclusive of various niche research areas.

J. Rutter explained each NIH institute and center has data, science, and information offices that are distinct but are becoming more interwoven as the role of data science becomes increasingly more important. There is a desire to better coordinate and integrate various methods for collecting, processing, and analyzing data to support the NIH Strategic Plan. She asked for suggestions about how (1) better to align and synergize efforts across NIH focusing on the important overlapping roles of data, artificial-intelligence, and machine learning in biomedical research, and (2) to collate these topic areas into an overarching EC to improve scientific research across the CTSA network.

M. Zozus then shared a Venn diagram showing Data Science as the integral topic connecting Computer Science, Math and Statistics, and Domain Expertise. She invited further discussion about the relationship between Data Science and Biomedical Informatics in clinical translational research and science. T. Campion noted although there are many ways to view the overlap between Data Science and Biomedical Informatics, the critical component among the complementary fields is the actual overlap. They invited feedback about the Venn diagram.

Questions and Discussion:

- M. Kurilla noted this will be a lengthy, ongoing process that will evolve and undergo refinement over time as technologies emerge. The most important part of the process will be to ensure inclusivity and an acknowledgment of the key role of the CTSA in translational research.
- G. Moeller noted NCATS was one of the few NIH institutes that has been interested in and actively working with protected health information in EHR data, so the CTSA network is uniquely positioned regarding expertise in this area.
- M. Kim asked about the role of Biostatistics, Epidemiology, and Research Design (BERD) programs in this expansive view of data science. Where is the overlap?

- J. Rutter noted BERD absolutely has a role because those programs will provide useful insight into the infrastructure, systems, and frameworks related to the collection, organization, and analysis of data.
- M. Kurilla stated these discussions will continue at future meetings, but he thought it was important to highlight the issue for the SC members' awareness as the SC works to gather feedback from other experts.

Adjourn (Slide 21)

Speakers: Michael Kurilla

Presentation Summary:

M. Kurilla reminded everyone the November meeting will be held at the CTSA Fall Meeting site in Bethesda, Maryland, before adjourning the meeting. **The final adjournment slide reminded everyone to please review Working Group proposals.**

Next Steering Committee Meeting: Wednesday, November 13, 2024, at 1:30-6:00 pm ET