



Clinical and Translational Science Awards Program Coordination, Communication, & Operations Support

CTSA Steering Committee Meeting Summary Zoom Conference January 22, 2024 2:30-3:30 PM ET

Steering Committee Members:

Michael Kurilla, Co-Chair
Ruth O'Hara, Co-Chair
Stephan Bour
Arleen Brown
Daniel Ford
Vesna Garovic

Melissa Haendel
Jessica Kahn
Mimi Kim
Jennifer Kraschnewski
Grace McComsey
Frederick "Gerry" Moeller

Elizabeth Ofili
Steven Reis
Doris Rubio
Kathryn Sandberg
Randy Urban
Ted Wun

NCATS Attendees:

Audie Atienza
Jane Atkinson
Heather Baker
Kristopher Bough
Patrick Brown
Penny Burgoon
Soju Chang
Jennie Conroy
Pablo Cure
Jamie Doyle

Sarah Dunsmore
Stephanie Ezequiel
Josh Fessel
Stacia Fleisher
Gallya Gannot
Ken Gersing
Rashmi Gopal
Chris Hartshorn
Greg Jarosik
Rebecca Katz

Andrew Loudon
Carol Merchant
Joan Nagel
Erica Rosemond
Joni Rutter
Clare Schmitt
Meredith Temple-
O'Connor

Excused: Duane Mitchell, Tesheia Johnson, Rosalind Wright

Guests: Lindsay Eyzaguirre, Robert MacArthur

CCOS: Cindy Mark, Kerry James, Lauren Fitzharris

Welcome and Introduction of Two New Members (Slides 2-3)

Speakers: Michael Kurilla and Ruth O'Hara

M. Kurilla welcomed the members of the Steering Committee (SC) and facilitated the call.

He welcomed Vesna Garovic and Jennifer Kraschnewski, who presented brief bios.

Report Out from CTSA Pharmacies & Compounding for Translational Research Working Group (Slides 4-17)

Speaker: Robert MacArthur

R. MacArthur presented the work of the CTSA Pharmacies & Compounding for Translational Research working group, focusing on translational research and the compounding process in hospitals. The objective was to share initial data findings and outline next steps. He explained the project's aim to document the contributions of research pharmacists to institutional research and the development of FDA-approved drug products. The group has developed a survey, established standard research procedures, and is collaborating with data collaborators. The group's expansion of research pharmacy services was discussed, as well as its connection with early phase clinical trials and FDA approval. The working group also plans to publish its findings and host a webinar on investigational drug compounding for research.

Discussion followed regarding the role of pharmacy programs in clinical trials. Ted Wun highlighted the importance of preparing blister packs and ensuring patient adherence, while also noting the potential for adverse events. Grace McComsey raised concerns about new regulations making it difficult for pharmacists to compound investigation drugs for research. R. MacArthur acknowledged these difficulties and shared his experience of universities often deciding against involvement due to insurance issues and complexities. The team also discussed potential solutions, such as establishing a Residency and Drug Service to address manpower issues, as suggested by Daniel Ford. The challenges faced by research pharmacists due to varying compliance requirements across states were also discussed.

R. MacArthur will follow-up with Ted Wun and Dan Ford to include data from UC Davis and Johns Hopkins. C. Mark provided contact information.

Revision for Guidance of CTSA Program Groups (Slides 18-27)

Speaker: Cindy Mark

Presentation Summary:

Cindy Mark discussed revisions to the report out process for Enterprise Committees and Working Groups to the steering committee groups. She outlined that the enterprise report out will now include more pertinent details and constructive feedback from steering members. EC chairs will create a list of questions to be presented during the feedback session. The presentation slides and questions must be submitted a month prior to the presentation. The working group report outs will also undergo some changes, with a 10-minute pre-recorded presentation, with their goals and deliverables, along with a timeline for completion of the deliverables. Discussion and constructive feedback from steering committee members will be included. These draft slides need to be submitted a month prior to their presentation. These changes will be implemented starting in March 2024.

Two Steering Committee members will be assigned to each EC and Working Group, to act as a liaison. C. Mark stated that if there is a conflict of interest, please let her know and the assignments will be adjusted. An email will be disseminated with the assignments and the slides with the revisions.

Presentation: TIN Needs Assessment Survey (Slides 28-34)

Speakers: Daniel Ford, Lindsay Eyzaguirre

Presentation Summary:

D. Ford presented the purpose of the survey:

- The survey is a training needs assessment that has been developed by TIC to inform the development of our Training Academy.
- The purpose of bringing it here is to seek Steering Committee approval for the distribution to the Clinical and Translational Science Awards (CTSA) Points of Contact (POCs) across our network.
- The survey has 8 questions; estimated time to complete is 10 minutes.
- The collection of identifiers is optional, participants have the option to provide their name and email.
- Following approval of this committee, the survey will be sent to CTSA POCs, preferably Q1 2024.
- POCs will be encouraged to disseminate the survey to as many as possible **active clinical trial PIs** and their **respective project managers/research coordinators** within their institutions. We would also like to send it to all the PIs who went through the TIN consultation process during our first 7 years.
- The survey will:
 - assist us in pinpointing the most significant knowledge gaps and determining their priority.
 - help us tailor the training academy curriculum to emphasize the most essential training requirements.
 - will play a crucial role in identifying the best approach for disseminating the curriculum, ensuring alignment with preferred learning modes.

Daniel Ford and Lindsay Eyzaguirre answered questions from the group; M. Kurilla stated that it appears the Steering Committee is very interested in this survey.

Request for Volunteers (Slide 35)

Speakers: Michael Kurilla, Ted Wun

Presentation Summary:

Ted Wun is leading the planning committee for the 2024 in-person Fall CTSA Meeting and is seeking volunteers to assist. Contact [M. Kurilla](#) or [T. Wun](#) to express interest.

Volunteers to date are:

Grace McComsey
Mimi Kim
Doris Rubio
Kathryn Sandberg
Teshia Johnson
Gelise Thomas
Dan Ford
Jessica Kahn

Adjournment (Slide 49)

Speakers: Michael Kurilla

Presentation Summary:

M. Kurilla shared the date of the next SC meeting and adjourned the meeting.

Next Steering Committee Meeting: Monday, February 12, 2024, at 2:30-3:30 PM ET