CTSA Steering Committee Meeting Summary
Zoom Conference
January 13, 2025; 2:30-3:30 PM ET

Steering Committee Attendees:

Michael Kurilla, Co-Chair
Ted Wun, Co-Chair
Elmer Bernstam
Steven Bernstein
Arleen Brown
Andrea Carnegie
Daniel Ford
Vesna Garovic
Mike Holinstat
David Ingbar
Mimi Kim
Julie Lumeng
Grace McComsey
F. Gerald Moeller
Elizabeth Ofili
Reynold Panettieri
Steven Reis
Doris Rubio
Mark Schleiss
Eric Vilain
Sarah Wiehe
Rosalind Wright

SC Regrets: Ruth O'Hara

NCATS Attendees:

Audie Atienza
Heather Baker
Kris Bough
Patrick Brown
Dale Burwen
Soju Chang
Jennie Conroy
Pablo Cure
Anthony DiBello
Jamie Doyle
Sarah Dunsmore
Stephanie Ezequiel
Josh Fessel
Stacia Fleisher
Gallya Gannot
Rashmi Gopal-Srivastava
Chris Hartshorn
Greg Jarosik
Rebecca Katz
Irina Krasnova
Francisco Leyva
Joan Nagel
Anna Ramsey-Ewing
Erica Rosemond
Joni Rutter
Meredith Temple-O'Connor
Salina Waddy
Robin Wagner

Invited Guests: Robert MacArthur, Melissa Brady

CCOS: Lauren Fitzharris, Kerry James, Cindy Mark

Welcome and Announcements (Slides 2-6)

Speakers: Michael Kurilla and Ted Wun

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

He announced two NIH UM1 grant-funded Clinical and Translational Science Research Program (Element E) opportunities (PAR-21-293 and PAR-24-272), reviewed similar Fiscal

Year 2023-funded UM1 projects, and requested CTSAs report UM1-funded projects to CCOS so the information can be shared with other CTSAs via the CCOS website. Standard information to report includes title, purpose, abstract, point of contact, funding period, budget, and expected outcomes and deliverables. Sharing this information may help promote collaboration within the consortium.

Survey: 2024 Standard Agreements Proposed Revisions (Slides 7-12)

Speaker: Daniel Ford

Presentation summary:

D. Ford announced two recently developed surveys requiring SC approval, neither of which will require signficiant data collection or effort to complete. The first relates to standard agreements and associated revisions needed. Staff at Hubs working on standard agreements would complete this survey to provide input about their use of standard agreements, including perceptions about possible updates needed. The second survey will collect information from CTSA Hubs about experiences serving as a reviewing Instituttional Review Board (IRB) or relying institution and the tools and resources used to support single IRB (sIRB) review at Hub sites. He explained the aims of the survey are to use data collected to foster understading of working cultures within the sIRB community, aid the development of new tools and resources supporting sIRB review, direct plans for optimizing processes, and ehance national capacity for sIRB review. IRB and Human Research Protection Program (HRPP) contacts, Smart IRB points of contact, and IRB Reliance Specialists and others working in similar roles at Hubs should complete the survey so the Trial Innovation Network (TIN) can understand what training tools are needed to support sIRB review.

Introduction of New Steering Committee Members (Slides 13-22)

Speaker: Michael Kurilla

Presentation summary:

M. Kurilla invited new members beginning their terms on the Committee as of January 2025 to introduce themselves to current SC members. Each new member briefly shared about their educational, employment history and research background. C. Mark then listed the current SC members and their affiliations.

Introduction of New Pods (Slides 23-28)

Speaker: Cindy Mark

Presentation summary:

C. Mark announced the Pods have been updated for 2025, as previously shared via email. She directed members to email CCOS with questions and to review information on the presentation

slides, which list the new 2025 CTSA Pods, Pod Leaders' names and contact information, and associated participating institutions. Pods are:

- Michigan Institute for Clinical and Health Research
- New Jersey Alliance for Clinical Translational Sciance (NJ ACTS)
- Mount Sinai Health System Translational Science Hub
- Wright Regional Center for Clinical and Translational Science
- Einstein-Montefiore Clinical and Translational Science Award Hub
- Clinical and Translational Science Collabortive at Case Western Reserve University
- Institute for Clinical and Translational Science at the University of Calfiornia-Irvine
- Mayo Clinic Center for Clinical and Translational Science
- Dartmouth Clinical and Translational Science Institute
- Georgia Clinical and Translational Science Alliance
- University of California Los Angeles Clinical and Translational Science Institute

---

WG Report Out: CTSA Pharmacies and Compounding for Translational Research (Slides 29-35)

Speakers: Ribert MacArther

Presentation Summary:

R. MacArthur provided an overview of the Research Pharmacy Working Group (WG). He listed the ten participating CTSAs and shared statistics about mention of research pharmacy products and services in clinical trial publications, typical staffing roles at research pharmacies, and the scope of research pharmacy services performed. He noted the WG's deliverables include documenting research pharmacy dispensing practices in literature, evaluating costs and time performed on such practices, and comparing research pharmacy dispensing to drug manufacturer experiences. He shared results of a survey of research pharmacists within the WG that documents their practices, procedures, and staffing. He then shared brief information about multiple early phase CTSA studies whose research pharmacy work directly relates to FDA-approved study products, including the funding vehicles, study populations, drug names, study start dates, FDA approval dates, and purpose of the drugs. He concluded by noting research pharmacies actively support CTSA site clinical trials, help lower costs, speed drug development, and provide a wide array of specialized services. CTSA sites with participating research pharmacies are key contributors to the development of FDA-approved drugs.

Questions and Discussion:

- E. Ofili asked whether there is an opportunity to partner with institutions with pharmacy school programs, regardless of whether they are focused on research.
    - R. MacArther acknowledged there are pharmacy schools that conduct excellent commercial grade research, and there is an opportunity for those schools to potentially provide part-time staffing support to research pharmacies.
- D. Ford asked whether compounded drugs produced at an institution are shareable to other institutions.

    - R. MacArthur noted the data includes multiple examples of research pharmacies that dispensed, packaged, and shipped drugs to patients or other institutions or clinics.
- R. Wagner asked in the Chat for clarification about whether the shared information relates to clinical trials supported by CTSA-funded infrastructure at sites or trials specifically conducted by institutions that had CTSA awards.
    - R. MacArther noted they searched clinicaltrials.gov for institutional name and did not dig too deeply to determine further details related to this distinction. He offered to discuss the issue offline.
- D. Ingbar noted via the Chat that shipping drugs across state lines is sometimes an issue.
    - V. Garovic agreed, commenting that it is a significant barrier for decentralized trials.

Instruction for Pod Feedback Site (Slides 36-41)

Speakers: Lauren Fitzharris

Presentation Summary:

L. Fitzharris defined Pods as representing five to six CTSA Hubs and explained the role of Pod leaders, which includes serving as a liaison between Pods and the SC. In that capacity, Pod leaders will share information from the SC with Pods and collect ideas, questions, concerns, and feedback from Pod members to share with the SC and NCATS leadership. In an effort to collect and share information more standardly, CCOS will provide a Pod meeting summary template for Pods to attach to summary reports, which Pod leaders should submit online via the CCOS website after each Pod meeting. The template will include a section for Pods to provide dedicated feedback to the SC. All summaries will be open to the public once posted online. She explained how to access the Pod meeting summary form on the CCOS website, attach the completed template, and submit the report via the portal. Previous Pod submissions are available to view on the website by selecting the “Archive” button. She directed SC members to refer to the Governance section of the CCOS website for further details.

Adjourn

Speakers: Michael Kurilla

Presentation Summary:

M. Kurilla thanked everyone and adjourned the meeting.

Questions and Discussion:

- Prior to adjournment, G. Moeller asked via the Chat if the Spring CTSA meeting dates have been finalized.

- C. Mark replied to note the meeting is scheduled for April 14-17, 2025, and the SC will meet on April 17.
- T. Wun noted in the Chat the meeting will be concurrent with the Association for Clinical and Translational Science (ACTS) meeting in Washington, DC.
- E. Rosemond stated NCATS is working with ACTS to minimize overlap in attendance requirements between the two groups.

Next Steering Committee Meeting: Monday, January 27, 2025, at 2:30-3:30 pm ET