CTSA Steering Committee Webinar Summary
May 2025, 2025; 2:30-3:30 PM ET

Steering Committee Attendees:

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

SC Regrets: Elizabeth Ofili

NCATS Attendees:

Heather Baker
Kris Bough
Patrick Brown
Jennie Conroy
Pablo Cure
Anthony DiBello
Stephanie Ezequiel
Rashmi Gopal-Srivastava
Gallya Gannot
Brittany Gibbons
Cynthia Gonzalez
Chris Hartshorn
Rebecca Katz
Irina Krasnova
Joan Nagel
Katie Patel
Thomas Radman
Erica Rosemond
Joni Rutter
Yolana Vallejo
Andie Vaught
Annica Wayman

Invited Guests: Kristi Holmes

CCOS: Lauren Fitzharris, Kerry James, Amanda Scott, Cindy Mark

Welcome (Slides 2-3)

Speakers: Michael Kurilla and Ted Wun

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

CTSA Translational Science Impacts Working Group (Slides 4-10)

Speaker: Kristi Holmes, Northwestern University

Presentation summary: K. Holmes provided an on the Translational Science Impacts Working Group starting with an acknowledgement of the hubs and partners who are participating in the

group. The group consists of 62 CTSA institutions and one community member from East Tennessee State University.

The goals of the working group are to:

- Establish a Community of Practice to unite CTSA stakeholders around Translational Science Impact (TSI) and foster ongoing connection and collaboration.
- Develop and disseminate resources and tools to assess, communicate, and advance TSI across hubs.
- Address key challenges in translation through shared strategies, open dialogue, and knowledge exchange.
- Drive future innovation and collaboration to strengthen the field and promote continuous improvement in TSI.

K. Holmes described the status of the working group's three main deliverables and supported by subgroups. The first deliverable is the Impact Instrument. This instrument focuses on developing resources to support the assessment of Translational Science Impact activities and methods across the CTSAs. This includes impact metrics/plans across hubs and frameworks used to identify impact. The group aims to develop definitions for key terms related to impact assessment, identify, develop, and validate impact instruments, tools, and processes, promote consistency and comparability, empower stakeholders with actionable insights, and facilitate knowledge sharing and best practices

The second deliverable is the Impact Summit which aims to organize a forum for learning, sharing best practices, collaboration, and identifying standard cross-hub TSI metrics. The Translational Impact Summit will be modeled after the highly successful CTSA "Collaborative Workshops", with WG members creating the agenda to establish a strong and highly interactive event and engage participation from the learning health system, industry, community, and government

K. Holmes described the third deliverable is the Impact Repository which creates a searchable, curated collection of TSI resources (e.g., instruments, templates, frameworks, visualizations, protocols, and case studies, as well as collaborative outputs by the larger group) made openly available as a Zenodo Community to support a sustainable and FAIR resource. Regular calls for deposits and use of this resource will be reinforced. Zenodo is operated by CERN and was established 10 years ago. The Zenodo makes materials searchable and accessible, records are FAIR and discoverable by people and machines, materials are assigned DOIs, making them citable and trackable, and metrics are available on the item and collection level

Questions and Discussion:

- M. Kim discussed the distinction between translational research and translational science, noting that while translational research impacts clinical, community, economic, and policy areas, translational science focuses on improving the research process. She raised a question about the impact of translational science, suggesting that its success should be measured by deliverables useful to other researchers.
    - K. Holmes acknowledged the overlap between translational research and translational science and emphasizes the need to explore both concepts to understand their impacts better. She also noted that the CTSA program is well-

positioned to guide the conversation on translational science impact, highlighting the importance of operational resources and the potential for broader collaboration.

- T. Wun emphasized the importance of tailoring the value proposition to different audiences, noting that their institution receives more funding from internal sources than from grants. They must justify the value of their resources annually. He noted that they make different value statements to various regions and leadership levels, highlighting the importance of using different instruments and perspectives depending on the audience
    - K. Holmes appreciated the comment and acknowledges the complexity of having impact conversations with various partners across different translational stages and roles.
    - Both T. Wun and K. Holmes express enthusiasm about the ongoing discussions and the importance of these conversations
- S. Bernstein asks about the possibility of surveying or cataloging the various electronic platforms used to capture impact information, such as REDCap.
    - K. Holmes acknowledged the question and mentions that extensive work has been done by the Informatics Enterprise Committee (now the BIDS Enterprise Committee) to understand how these resources are being used. She highlighted the synergy and overlap between evaluation and informatics work, suggesting that this could be an opportunity for collaboration on a project to better understand and utilize these tools.
- M. Kurilla emphasizes the importance of demonstrating impact, as it is what people outside the academic research community pay attention to. He notes that impact is often long-term and difficult to track, especially when individuals change institutions. He suggested that tools that make it easier to track and follow the long-term effects of work would be very helpful.
    - K. Holmes agreed and highlighted the challenge of finding time to accomplish everything. She suggested leveraging data and tools to make it easier for people to tell impactful stories. She emphasized the importance of starting conversations at the local hub level and introduced a book titled "Creating Meaningful Impact: The Essential Guide to Developing an Impact Literate Mindset" as a useful tool to support local-level conversations.
- A. Carnegie asked about the possibility of helping people look retrospectively at the impacts of their past work, noting that it can be challenging for long-standing CTSA programs to track and build on previous efforts.
    - K. Holmes referred to this retrospective tracking as following "digital breadcrumbs" and emphasized the importance of best practices for persistent identifiers, such as DOIs for objects, ORCID IDs for people, and RORs for institutions. She highlighted the need for local hubs to adopt best practices, mentioning that at Northwestern, they have implemented ORCID IDs and

integrated them into institutional systems to facilitate data management and reporting. K. Holmes stressed the importance of setting up digital aspects for new early career investigators quickly to reduce the burden of tracking and reporting impact, acknowledging that while there are challenges, proactive measures can help manage them.

Working Group Proposal Reviews (Slides 11)

Speaker: Cindy Mark

Presentation summary:

C. Mark reminded SC members to complete their reviews of working group proposals from Cycle XIV. Reviews are due by Monday, May 19. Anyone with questions on how to access can reach out to CCOS.

Best Models for Building Clinical and Translational Research Infrastructure to Ensure Efficient Financial Support (Slides 12-18)

Speaker: Dan Ford, Johns Hopkins University

Presentation summary: D. Ford presented on the best models for building clinical and translational research infrastructure to ensure efficient financial support. He started by expressing his appreciation for the opportunity to discuss his thoughts on the IDC (indirect costs) model and its implications for clinical research core services. He noted that recent discussions have focused more on labs, buildings, and high-cost lab tests, potentially neglecting clinical research core services. He emphasized the need for a proactive approach to defining a preferred model for these services, considering both qualitative and quantitative assessments.

He outlined several assumptions for evaluating different models, aiming to maximize clinical research output. He highlighted the importance of producing high-impact clinical trials and acknowledges the challenges in defining and funding these trials, especially for vulnerable populations. He suggested that NIH and academic centers should jointly fund clinical research, and administrative costs associated with transferring grant funds should not be overlooked

D. Ford described the components of clinical research infrastructure, including physical space, research staff, databases like REDCap, IRB and regulatory support, and community engagement services. He points out the complexities and costs associated with these components, particularly in the context of single IRB policies and clinicaltrials.gov registration. He emphasized the need to clearly define what falls under clinical research infrastructure and how these services are funded.

Lastly, D. Ford presented several options for funding clinical research services, ranging from including all costs in NIH grants to providing block grants to universities. He discussed the pros and cons of each approach, including administrative complexity and the balance between simplicity and oversight. Ford concludes by seeking feedback on whether these models are feasible and if they adequately address the implications for clinical research.

Questions and Discussion:

- E. Bernstam highlighted the importance of considering the informatics side of the discussion and mentions that their institution's service center is partially funded by the CTSA, partially by chargebacks, and the rest by the university, which is ill-defined.
    - Daniel Ford agrees with Elmer Bernstam's point and notes that while service centers have advantages in terms of real costs and charges, the subsidies allowed by universities can undermine the purpose of these centers. He suggested that moving some costs from the IDC bucket to the direct cost bucket could be beneficial, but the subsidies complicate this process.
- R. Panettieri raises the question of whether the discussion on service centers and IDCs should be expanded to all federal funding, noting that service centers serve everyone and are subsidized because IDC does not cover all needs. He supported the idea of billing service centers into direct costs for better transparency and accountability, and questions why agencies like NSF and the Department of Defense should be treated differently.
    - D. Ford agreed and mentioned that PCORI (Patient-Centered Outcomes Research Institute) has a different approach to IDCs, providing a flat 40% rate without negotiation and allowing higher salaries for investigators. He continued to discuss the challenges of accurately accounting for what is covered under the 40% PCORI IDC rate and suggests that institutions could charge lower rates for clinical research, similar to NIH rates for clinical trials.
- T. Wun mentioned that clinical research services often used the same research units for both federal and industry-sponsored studies but had different structures for recharging costs. He noted that institutions typically had multiple revenue funding sources for clinical research, and the level of subsidy required for these resources varied significantly. Additionally, T. Wun shared that a task force before the pandemic found that the industry standard for institutional subsidy of core resources ranged from 10% to 80%, with a target of 30%.
    - D. Ford added that the IDC for commercial partners reflected real costs, while the lower IDC for federal grants indicated institutional subsidy, emphasizing that institutions should not subsidize commercial partners.
- M. Kurilla suggested forming a task force with a 6 to 9 month timeframe to develop recommendations due to the diverse and historical legacies of institutions. T. Wun noted experiencing mission creep, where tasks not funded by the grant are being added to their responsibilities, leading to institutionally funded oversight.
    - The discussion included focusing on what falls within the CTSA scope and its role in supporting clinical research infrastructure at universities.
    - The group considered refining the mission and charge of the task force and scheduling the next meeting, noting that the typical meeting date falls on a Federal holiday.

Adjourn (Slide 19)

M. Kurilla adjourned the meeting.

Next Steering Committee Webinar Monday, June 9, 2025, at 2:30-3:30 PM ET