CTSA Steering Committee Meeting Summary
Zoom Conference
September 9, 2024; 2:30-3:30 PM ET

Steering Committee Attendees:

Michael Kurilla, Co-Chair	Jen Kraschnewski	Doris Rubio
Ruth O'Hara, Co-Chair	Grace McComsey	Kathryn Sandberg
Stephan Bour	Jareen Meinzen-Derr	Rosalind Wright
Arleen Brown	Duane Mitchell	Randy Urban
Andrea Carnegie	F. Gerald Moeller	Ted Wun
Daniel Ford	Elizabeth Ofili	
Vesna Garovic	Steven Reis	

SC Regrets: Melissa Haendel,

NCATS Attendees:

Audie Atienza	Stephanie Ezequiel	Erica Rosemond
Jane Atkinson	Stacia Fleisher	Joni Rutter
Heather Baker	Ken Gersing	Meredith Temple-O'Connor
Kris Bough	Brittany Gibbons	
Patrick Brown	Rashmi Gopal-Srivastava	Salina Waddy
Jennie Conroy	Chris Hartshorn	Robin Wagner
Pablo Cure	Greg Jarosik	Annica Wayman
Anthony DiBello	Rebecca Katz	Ken Wiley
Jamie Doyle	Carol Merchant	
Sarah Dunsmore	Thomas Radman	

Invited Guests: Alex Cheng, Meredith Zozus, Thomas Campion

Support Center: CCOS: Lauren Fitzharris, Kerry James, Cindy Mark

Welcome, Announcements and Introduction of Jareen Meinzen-Derr (Slides 3-6)

Speakers: Michael Kurilla and Ruth O'Hara

M. Kurilla and R. O'Hara welcomed the members of the Steering Committee and facilitated the Steering Committee call.

They welcomed Jareen Meinzen-Derr as a new member of the Steering Committee. She will replace Jessica Kahn, whose job is changing. Dr. Meinzen-Derr expressed her excitement about working with other members.

They also shared a call for new members to serve on the Steering Committee for a period of 2-3 years from 2025-2028. Please submit nominations using this form: NCATS is seeking nominations for New CTSA Program Steering Committee (SC) members! (office.com)

Two new CTSAs (Dartmouth and Baylor) are joining Pods.

NCATS Director Roundtable Series (Slides 7-8)

Speakers: Joni Rutter

Presentation Summary:

J. Rutter announced a series of upcoming CTSA roundtable meetings with Principal Investigators (PIs) and Deans, community advisors, and the public to discuss the new NCATS Strategic Plan and future program plans and to receive feedback from the CTSAs that can help bolster the impact of Working Groups (WGs) and Enterprise Committees (ECs) and improve NIH data science initiatives.

- CTSA Roundtable with Public: September 30, 2024, 3:00 PM ET
- CTSA Roundtable with Community Advisors: October 2, 2024, 3:00 PM ET
- CTSA Roundtable with PIs and Deans: October 4, 2024, 1:00 PM ET

Questions and Discussion:

- M. Kurilla noted the CTSAs should be major contributors to discussions.

21 CFR Part 11 Compliance WG Report Out, followed by Discussion (Slides 9-23)

Speaker: Alex Cheng and Theresa Baker

Presentation summary:

A. Cheng provided updates from the 21 CFR Par 11 Compliance for REDCap Working Group, including statistics related to the Co-Chairs, member institutions, membership, engagement with stakeholders, purpose, goals, and deliverables (see below). He also shared numerous WG questions requesting feedback from the Steering Committee pertaining to dissemination strategies, goals, deliverbles, and stakeholder engagement.

- **Purpose**: Provide Part 11 software validation documentation and a standard operating procedure (SOP) template to assist CTSAs in achieving 21 CFR Part 11 compliance for their REDCap instances with minimal external consulting.
- **Goals**:
    - Implement a rapid 21 CFR Part 11 software validation process for REDCap.

- o Produce Part 11 validation documentation within 4 weeks for each 6-month REDCap release.
- o Develop an Implementation Guide to help institutions document study processes for Part 11 compliance.
- **Deliverables**:
  - o Software Validation: There have been several REDCap validation package releases since Setember 2023, with another expected September 2024.
  - o Implementation Guide: Components include a stakeholder document, configuration document, and conformance document, as well as organization infrastructure documentation, all expected to be completed by Novermber 2024.
  - o Dissemination and Impact Measurement: There will be a CTSA program webinar in January 2025, a Trial Innovation Network (TIN) webinar in February 2025, and an expected manuscript in April 2025 detailing challenges and lessons learned in the development process.

Questions and Discussion:

- G. McComsey asked in the Chat about the proportion of CTSAs that have already implemented Part 11-compliant REDCap.
  - o A. Cheng replied, noting although they do not have exact metrics, there are at least 10 institutions currently using Part 11-compliant REDCap software.
- D. Ford asked how often changes to CFR Par 11 are anticipated.
  - o A. Cheng reported significant changes are not anticipated.
- M. Kurilla asked how burdensome the need is to regularly test and update documentation with each new REDCap release.
  - o A. Cheng noted validating each new feature can be challenging, but members of the WG help with that task. He reported they are working on developing automated testing.
- T. Wun asked whether those using the compliant REDCap also use other systems.
  - o A. Cheng noted sometimes users have trials involving more than one system, but generally those who have adopted the compliant REDCap are using it exclusively.
- M. Kurilla asked whether the validation methods used for the compliant version are more efficient.
  - o A. Cheng clarified the methodology documentation has not yet been released for adoption by others, so he has no metric data.
- M. Kurilla asked whether any European countries are using REDCap.
  - o A. Cheng noted he is unsure of compliance rules in Europe, but his understanding is that CFR Part 11 is stricter, so the system should be positioned well to achieve compliance with European rules.

Informatics EC Report Out, followed by Discussion (Slides 24-33)

Speakers: Thomas Campion and Meredith Zozus

Presentation Summary:

ECOS

T. Campion shared statistics about the EC, including Lead Team and committee members, Hub representation, average attendance at virtual meetings, accomplishments, and goals (see below). He also asked if progress is satisfactory, requested feedback, and invited questions.

- **Accomplishments:**
  - Shareware talks at monthly virtual community meetings on such topics as research reproducibility, patient portals for research participation, data and artificial intelligence (AI) platforms, computable phenotypes and electronic health record (EHR) analytics, and clinical and translational research self-service tools.
  - Surveys on clinical trials management and LOINC approach for clinical and research uses.
  - In-person meetings: 2024 with AMIA and in 2025 with AMIA and ACTS
  - WG activities and cross-EC initiatives related to real world data (RWD) education, sustainability, AI, and use of informatics
    - Enterprise data warehouse for research (EDW4R) Working Group activities, including a publication
- **Goals:**
  - Supporting NCATS Strategic Plan goals by contributing to computational drug discovery, warehousing clinical data, providing clinical decision support via EHR and genomics, using RWD for clinical trials post-market surveillance, providing eConsent opportunities to engage patients in clinical trials, and collaborating at a national level
  - Upcoming activities related to AI, digital health technologies, social determinants of health, data sharing, sustainability, dissemination, and the Informatics workforce

Questions and Discussion:

- E. Ofili asked for clarification about where electronic consent (eConsent) is covered in the EC's publication.
  - T. Campion stated this publication did not discuss eConsent but noted members have published widely on eConsent elsewhere.
- M. Kurilla announced one topic at an upcoming Steering Committee meeting will be to consider changing the name of the "Informatics" EC to the "Data Science" EC to better reflect the NIH holistic approach to research. He asked the presenter about his thoughts about a potential name change.
  - T. Campion noted the EC has had similar discussions, and the consensus has been Informatics is very distinct from Data Science. For example, the concept of eConsent falls within the domain of Informatics, not Data Science.
  - M. Zozus clarified the EC membership believes the current definition of Data Science omits critical aspects of Informatics related to RWD, workflow analysis, process, and architecture design, all of which are necessary for efficient throughput in clinical translational research.
  - T. Wun and J. Kraschnewski noted in the Chat they have seen similar pushback from Informatics professionals.

- J. Rutter suggested in the Chat simply adding "Data Science" to the EC name rather than removing "Informatics."
- M. Kurilla noted he has heard some people perceive Informatics is included within Data Science and others perceive Data Science is a subset of Informatics, so there are conflicting views, all of which will need to be considered carefully as NCATS attempts to better align with NIH approaches.

Fall Meeting Logistics Update (Slides 34-48)

Speakers: Kerry James and Ted Wun

Presentation Summary:

K. James and T. Wun shared the theme, agenda, poster logistics, and other information for the upcoming 2024 Fall Program Meeting:

- November 13-15, 2024, at Bethesda North Marriott
- Theme: Building CTSA Program Impact through Innovation, Collaboration and Equity
- Agenda is available on CCOS website
- Registration is now open! As of September 3, there are 212 registrants (180 in-person and 32 virtual)
- Poster Submission Portal is open.
  - One poster allowed per Hub, to be selected by the Hub Administrator and Hub PIs and submitted by the Hub Administrator.
  - Poster presentations will be randomized, with half presented in the morning and half in the evening.
  - A jury of 26 will score posters according to scales related to overall quality and impact. Eight posters will receive awards.
- A dedicated conference website and mobile Cvent application (app) for viewing it will be available soon.
- There will be opportunities for networking via tabletop discussions during sessions, discussion groups in the mobile app, and interactive graphic recording.
- Send questions to FallMtg@ccos.ctsa.io

Adjourn

Speakers: Michael Kurilla and Ruth O'Hara

Presentation Summary:

M. Kurilla adjourned the meeting.

Next Steering Committee Meeting: Monday, September 23, 2024, at 2:30-3:30 PM ET