



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

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## CTSA Steering Committee Meeting Summary Zoom Conference March 27, 2023; 2:30-3:30pm ET

### Steering Committee Attendees:

Stephan Bour	Karen Johnston	Duane Mitchell	Randy Urban
Arleen Brown	Jessica Kahn	Ruth O'Hara	Rosalind Wright
Daniel Ford	Michael Kurilla	Muredach Reilly	Ted Wun
Melissa Haendel	Don McClain	Steven Reis	Martin Zand
Laura James	David McPherson	Lawrence Sinoway	

### SC Regrets:

Tesheia Johnson, Deborah Ossip, Doris Rubio, Kathryn Sandberg

### NCATS Attendees:

Audie Atienza	Stephanie Ezequiel	Rebecca Katz	Erica Rosemond
Mathew Arnegard	Josh Fessel	Ken Gersing	Joni Rutter
Heather Baker	Stacia Fleisher	Andrew Loudon	Meredith Temple-
Patrick Brown	Gallya Gannot	Carol Merchant	O'Connor
Soju Chang	Brittany Gibbons	Leonie Misquitta	Salina Waddy
Elaine Collier	Rashmi Gopal-Srivastava	Marilyn Moore-Hoon	Ken Wiley
Jennie Conroy	Chris Hartshorn	Anna Ramsey-Ewing	
Pablo Cure	Greg Jarosik	Thomas Radman	

### Support Center:

CLIC: Rebecca Laird, Julie Schwan  
CCOS: Kerry James

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### Welcome (Slide 1-3)

Speakers: Mike Kurilla and Co-chair Duane Mitchell

Drs. Kurilla and Mitchell welcomed the members of the Steering Committee and facilitated the Steering Committee call. Dr. Kurilla also reminded the group that Working Group proposals for Cycle 10 are due on March 31<sup>st</sup>.

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### NIH Data Management and Sharing Policy (Slides 4-18)

Speaker: Josh Fessel, NCATS



Presentation summary: Dr. Fessel provided an overview of the new NIH Data Management and Sharing Policy (DMSP), highlighting specific points for consideration, unique aspects of CTSA Hub Award applications as well as current thinking within DCI as to how DMSPs will be handled moving forward.

- The policy went live on January 25<sup>th</sup>. The policy, as well as multiple supplemental notices (as of March 19, 2023) linked to the parent notice, are available on the NIH website (<https://sharing.nih.gov/data-management-and-sharing-policy>). He recommends reviewing all of them, particularly the notice regarding what constitutes scientific data.
- The DMSP applies to applications submitted on or after January 25, 2023. In short, the policy requires that you have a plan for management of data, that you adhere to the plan, and then report on what you did. Not all data must be shared, but all data must be managed. Scientific data still counts as data regardless of publication status.
- Dr. Fessel reviewed the elements / components of a Data Management Plan, DMS Plan Submission process as well as how to submit DMS budgets.
- The first receipt date for UM1 and RC2 applications that will include a DMSP is May 12, 2023. The DMSP for the UM1 applies to all pilots supported by the UM1. For Administrative supplements, if the awarded supplement changes the parent award's approach to data management and sharing, then the parent award's DMSP must be updated.
- He noted unique features of CTSA hub awards – in particular, that supported projects and associated types of data are not necessarily defined at the time of DMSP submission. A key point is that the DMSP for any parent award that supports pilot studies (or similar activities) applies to ALL pilots supported by the parent award.
- DCI will have a group of program staff assess the DMSPs for UM1s. DCI encourages hubs to share their DMSPs with one another and share best practices and effective approaches.

#### **Questions and Discussion:**

- Dr. Mitchell suggested that examples of DMSP be shared across the CTSA.
- Dr. Collier suggested that folks think about this from the perspective of, *How am I going to manage the data at my institution?*, to streamline the processes for your investigators locally.

#### **Crowd Sourced Topic: Considering NCATS supported data platforms: What do the hubs need? (Slides 19-22)**

Facilitator: Karen Johnston, University of Virginia

Presenters: Steven Reis, ENACT, Melissa Haendel, N3C

Presentation summary: This is the first of the crowd sourced topics to be discussed at the Steering Committee meeting. Summaries of the strengths and purpose of ENACT and N3C were presented followed by a discussion regarding how to leverage and synergize these platforms as well as determining what the hubs may need to engage and maximize the utilization of these platforms.

- Dr. Reis stated that the aim of ENACT is to address unmet researcher needs. The investigator is at the center of ENACT, not data. Working with a dissemination and implementation science team, the ENACT team has been trying to figure out what investigators need; they have completed over 100 interviews of investigators, administrators, CTSA PIs. From Dr. Fessel's perspective, this boils down to:
  - Investigators need easy access to a lot of data;
  - And, they need to be able to do their research without having informatics skills or requiring collaboration with an informatician (too few available).
- Dr. Haendel presented a summary of N3C, highlighting that it is the largest publicly available, free, centralized, and linked EHR dataset in US history, represents all 50 states, is demographically representative, with 18 million patient records from 4 different data models, integrates a variety of different data types into single warehouse, supports a robust machine learning and AI analytical environment. She also highlighted the impact to date, scientific productivity, and collaboration. With that foundation, N3C recently launched the National Clinical Cohort Collaborative as a disease agnostic, community driven, institutionally governed, forward thinking version of N3C based on the same infrastructure platform but allowing longitudinal phenotype to be utilized to do disease agnostic research.

**Questions posed by Dr. Johnston for group discussion:**

N3C and ENACT are two very different platforms that represent a centralized network and a distributed network. Each does different things.

- How do we leverage the potential of both and identify synergies across the systems?
- What additional resources do the hubs need to maximize utilization?

**Discussion resulted in the following action items:**

1. Draft and circulate a list of benefits of each platform (including others beyond N3C and ENACT). Include what types of research might utilize each.
2. Provide direct support to sites to pay for preparing and pulling the data from the EHR into the enclave where it could be used for research. Preparing data may include mapping to different data models used by different platforms. This would help both platforms to maximize engagement and would facilitate local data enhancement to accelerate all hubs improving data quality and process. Nearly every data warehouse is different so the data prep support would improve utilization and quality of both platforms and others.
3. Improve communication about specifics to hubs so they can participate in ongoing projects. Make the list public of those at each hub that are actively involved in projects and leaders at hubs. Will allow the hubs to maximize the expertise present at their hub.
4. Improve communication by having each platform team offer to meet with every pod. A formal and systematic approach to answer questions and provide specific information on how to get involved and/or what support is available for those that want it.
5. Improve communication by sending documents out to every hub with specifics of what projects are ongoing, who is participating at each hub, and how to get involved. These would be updated

and redistributed at least annually. Report on the state of the data but also usage by hubs and offer support to those that want to participate at a higher level.

6. Improve communication and collaboration with the Steering Committee by creating a SC subcommittee that would include experts from N3C, ENACT, and other platforms as appropriate. This group would link directly to the Steering Committee to ensure more robust information exchange.
7. Improve communication and collaboration with the K and T Directors. Bring the general principles of using these types of platforms in rigorous research to the training program directors and consider how to infuse into training the next generation of researchers. Teach this skill set and/or a general understanding of how to do this type of research and the strengths and limitations of such research. Offer these platforms to the trainees as resources for them to do research and to learn.
8. Improve our understanding of the different approaches and possible synergies by distributing the CTSA paper on centralized plus distributed data models.

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**Next Steering Committee Meeting: Thursday, April 20, 2023, at 1:30-6pm ET**

***In-Person* at the Washington Hilton, Washington DC**