

Steering Committee Meeting

Monday, September 23, 2024
2:30pm ET

Agenda: September 23, 2024

Time	Topic	Speaker(s)
2:30-2:35pm ET	Welcome and Announcements	Erica Rosemond and Ruth O'Hara
2:35-2:40pm ET	Survey Request from <i>Catalyzing CTSA Hubs as Partners in LHS</i> (an “informal” working group)	Kerry James/Discussion
2:40-2:45pm ET	WG Proposal review/voting process	Cindy Mark
2:45-3:05pm ET	DEIA Update, followed by Discussion	Lori Carter-Edwards, Tung Nguyen, Doriane Miller, Ana Nunez, Mercedes Rubio, Gallya Gannot
3:05-3:10pm ET	Fall Meeting Logistics Update	Kerry James
3:10-3:30pm ET	Pod Feedback	Chris Hartshorn
3:30pm ET	Adjourn	Erica Rosemond and Ruth O'Hara



Welcome and Announcements

Erica Rosemond

Ruth O'Hara



Seeking New CTSA Program Steering Committee Members!

- NCATS is seeking **4UL1/UM1 PIs** to serve on the committee for the next 2-3 years (2025 – 2028).
- If you would like to self-nominate or suggest a fellow PI, please submit the PI name, institution, and brief explanation by **Wednesday, October 16th** ([here](#))

The eligibility criteria for SC appointments:

- A PI must be officially named in the Notice of Grant Award of an active CTSA Program hub.
- The PI's hub award must have at least 3 years remaining during the project period.
- The PI has not served on the SC since December 2018
- Please Review expectations and responsibilities ([linked here](#))



CTSA Survey Request for SC Review

Kerry James



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CTSA Survey Requests for SC Review

Survey Name	Submitted by	Purpose	Target Audience	Timeline	Dissemination Plan
CTSA Hub Partnerships with Learning Health Systems	<p>Lisa Welch, Tufts U</p> <p>on behalf of group that submitted WG proposal <i>Catalyzing CTSA Hubs as Partners in LHS</i></p> <p>WG not approved by SC in Cycle XII – planning to resubmit in Cycle III</p>	<p>To collect information about whether and how CTSA hubs are participating in and/or supporting learning health system (LHS) activities of a health system or healthcare organization.</p> <p>To gain a more comprehensive understanding of whether, and how, the CTSA Consortium is using its unique expertise to directly support improvements in clinical care and healthcare provider organizations</p>	<ul style="list-style-type: none"> • Hub POCs / most knowledgeable about any support of LHS activities • Or Hub Executive Director 	First quarter 2025 with deadline for survey completion by April 2025	<ul style="list-style-type: none"> • Disseminate survey results to NCATS and/or the CTSA Program Steering Committee • Following any discussion with this group, we plan to disseminate results to the CTSA Program hubs and submit a manuscript to foster broader discussion

CTSA Steering Committee (SC) Review of Working Group Proposals

Cindy Mark



CTSA Steering Committee (SC) Review of Working Group Proposals

The purpose of the SC review of Working Group Proposals is to collect feedback about the proposals to inform the discussion and formal voting to be held during the December 9 SC meeting. The review period is open from October 7 to November 11.

All SC members may participate in the discussion on Dec 9; only voting members will be able to vote.

There are three open spots for new working groups to start in January 2025.

It is VERY important that all voting members review the working group proposals!



Current Working Groups

There are currently eleven (11) working groups; two groups are sunsetting in December 2024; three (3) slots open for Cycle XIII.

Working Group	Start Date	Sunset Date
Cycle IX: CTSA Pharmacies and Compounding for Translational Research	1/1/2023	12/31/2024
Cycle IX: Integrating CTS into the Virtual CTSA Visiting Scholar Program	1/1/2023	12/31/2024
Cycle X: Engaging Individuals with Disability in the Research Process	7/1/2023	6/30/2025
Cycle X: 21 CFR Part 11 Compliance for REDCap	7/1/2023	6/30/2025
Cycle X: Translational Science Competency Based Assessment (TS-CBA)	7/1/2023	6/30/2025
Cycle X: TL1 Visiting Scientist Working Group	7/1/2023	6/30/2025



Current Working Groups (Con't)

Working Group	Start Date	Sunset Date
Cycle X: Advancing Dissemination and Implementation Science Working Group	7/1/2023	6/30/2025
Cycle XI: Harnessing CTSA Innovation and Engagement in the Recruitment and Retention of Diverse Populations in Clinical and Translational Research	1/1/2024	12/31/2025
Cycle XI: Learning About the Science of Translation: Identifying Best Practices to Accelerate the Translational Process Through Case Studies	1/1/2024	12/31/2025
Cycle XII: CTSA Translational Impacts	7/1/2024	6/30/2026
Cycle XII: Real World Data Workforce Development Across the Translational Spectrum	7/1/2024	6/30/2026



Working Group Proposal Review Process

Login to the CCOS Website:

- Visit the CTSA CCOS website: <https://ccos-cc.ctsa.io/>
- Log in using your credentials.

Navigate to the Steering Committee Landing Page:

- Once logged in, access the [Steering Committee Landing Page](#).

Steering Committee Review SOP available [here](#)



Access Working Group Proposals:

During the review period, a button will be visible to voting members of the Steering Committee on the CCOS website to access the current cycle's Working Group Proposals.



The screenshot displays the CTSA CCOS website interface. At the top, a purple header bar contains the text: "U.S Department of Health & Human Services", "National Institutes of Health", "NCATS", and "CTSA Program". Below this, a secondary navigation bar includes the NIH logo, "National Center for Advancing Translational Sciences", and "CTSA CCOS Coordination, Communication, and Operations Support". A user profile dropdown for "Kerry James" is visible on the right. The main navigation menu includes "Home", "About", "CTSA Groups and Meetings" (highlighted), "Resources", "News", and "Help". The breadcrumb trail shows "CTSA Groups and Meetings > Steering Committee". A "Need Help" button is located in the top right corner of the main content area. The page title is "About the Steering Committee". The introductory text states: "The CTSA Program Steering Committee provides leadership in promoting the exchange of policies, practices, and resources. It also facilitates discussions on various topics such as opportunities, challenges, and broad issues that hinder clinical research. Furthermore, the Steering Committee recommends best practices and policies to support the growth of clinical and translational research as a discipline. It encourages collaboration and sharing among CTSA Program and non-Program institutions, as well as with partners in clinical and translational research such as industries, laboratories, and hospitals." The section "Working Group Proposal for Cycle XII" is highlighted in a purple box. The text within this section reads: "Working Group (WG) Proposals for Cycle XII are now available for review. Please click the button below to navigate to the WG Proposal Review landing page, where you will find an SOP to guide you through the CCOS review process as well as links to review each WG Proposal. You may save a review form and return to edit the form. All forms must be submitted by the end of the review period, which is June 3, 2024. Please note that you will not be able to edit a review form after you submit. Thank you for participating!" A "Review WG Proposals" button is located at the bottom of this section.



View Working Group Proposals:

To view a specific Working Group Proposal, double click on the proposal title hyperlink. This will open the proposal in a new tab, allowing you to have the proposal and the review form open simultaneously. You can also copy and paste text from the proposal into the comments section on the review form.



king-group-proposals

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Working Group Proposals

Proposals are available for review from April 1, 2024 to April 30, 2024


The WG Proposals for Cycle XII are listed below. You can read each proposal by clicking on the hyperlinked proposal title. When you are ready to review it, you can do so by clicking on the "Review" button on the right. Review forms may be saved and returned to later. All forms must be submitted by the end of the review period, which is June 3, 2024. Please note that you will not be able to edit a review form after you submit.


Review Process SOP

Cycle XII WG Proposals

WG Proposal Title	Submitted By	Submitted At	SC Review Status	SC Review
Uncertainty in Artificial Intelligence Working Group	Ram GOURIPEDDI	4/1/2024, 1:04 PM	Not Reviewed	★ Review
Translational Impacts Working Group	Krist Holmes	4/1/2024, 3:00 PM	Not Reviewed	★ Review
Centering Anti-Racism in Community Engagement Program	Linda Ko	3/27/2024, 10:53 PM	Not Reviewed	★ Review
Real World Data workforce development across the translational spectrum	<input checked="" type="checkbox"/> Melissa Haendel	3/31/2024, 8:54 PM	Not Reviewed	★ Review

The proposal will open in a separate tab.


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Need Help

Working Group Proposal

Proposal Title

Submitter First Name, Last Name
Text

Submitter Email address
Text

Submitter Institution
Text

WG Application Cycle
Cycle XI default

Is this working group proposal sponsored by an Enterprise Committee (EC)? ☒ yes

Provide the background or rationale for this Work Group
Text

How does this WG proposal differ from or complement current consortium efforts?
Text



Begin Review:

On the Working Group Proposals page click the "Review" button (with star icon) on the right-hand column. This will open the review form for the proposal in that row.

working-group-proposals

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Conflict of Interest Check:

Determine whether you have a conflict of interest with the proposal. For our purposes, this includes:


- You are part of the team that requested this WG
- You are on the Lead team of the EC that sponsored this WG
- You are part of the Discussion Forum that submitted this WG Proposal

Conflict of Interest Response:


If you have a conflict of interest, select "Yes" from the drop-down box.

Check the acknowledgement button below.

Click "Submit." This records your response and reports the Conflict of Interest to the Steering Committee.




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 First Last

 Need Help

Working Group Proposal Review Form

Proposal Title

1

Conflict of Interest

2

Evaluation

3

Submit

Conflict of Interest

Before proceeding, please take a moment to determine whether you have a conflict-of-interest with this proposal. For our purposes this means:

1. You requested this Working Group (WG)
2. You are on the lead team of the Enterprise Committee (EC) that is sponsoring this WG proposal.
3. You are part of a discussion forum that submitted this WG Proposal.

If you meet any of these criteria, please select "Yes" in response to the Conflict of Interest question and then click the "submit" button. Your review of this proposal will be considered complete and you may continue to the next proposal. Clicking the "submit" button includes your response in the data summary, giving a more accurate view of the proposal. If you do not have a conflict of interest with this proposal, select "No" and the "next" button and you will be able to access the remaining questions about this proposal. You may edit your response to the Conflict of interest question up until the close of the review period.

Conflict of Interest

Yes

Acknowledgment ☒

You have selected that you have a Conflict of Interest with this proposal. Please select "Submit" to record this result and complete your review. You may edit this response up until November 20, 2023. Thank you!

Save

Submit



Working Group Proposal Review Form

✓ Conflict of Interest — Evaluation — 3 Submit

Thank you for your submission.

CCOS will review the submission and reach out with any questions or clarifications in preparation for the Steering Committee Review. If you have any questions, please email support@ccos.ctsa.io

Back To Working Group Proposals

Confirmation of Submission:

You should see a "Thank you for your submission" screen.

Your review of this proposal is complete; proceed to the next proposal.


Note: You may edit your response to the conflict of interest statement until the close of the review period.


No Conflict of Interest:

If you do not have a conflict of interest with this proposal, select "No" from the dropdown menu.

Click "Save" if you wish to return to the review later or click "Next" to continue to the proposal evaluation.



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Conflict of Interest

No

Save

Next



Evaluate the Proposal:

Evaluate the proposal based on the following 5 questions by determining whether each meets expectations or needs improvement:

Importance of Purpose: This criterion evaluates the significance and relevance of the proposed Working Group's objectives. Reviewers assess whether the purpose is crucial to the organization's goals and mission.


Feasibility: Reviewers consider the practicality and likelihood of the Working Group achieving its stated goals. This assessment examines whether the proposal is realistic and attainable.


Value of Deliverables: This criterion examines the quality and impact of the outcomes the Working Group aims to produce. Reviewers evaluate whether the proposed deliverables hold substantial value for the organization.

Expertise: Reviewers assess the competence and qualifications of the individuals involved in the proposed Working Group. The focus is on determining whether the team possesses the necessary expertise and/or recruitment strategy to successfully execute the plan.

Alignment with Steering Committee Areas of Interest: This criterion gauges how closely the proposal aligns with the specific interests and priorities of the Steering Committee. Reviewers evaluate if the Working Group's objectives match the committee's focus areas.

- | | |
|---|---|
| a. Learning Health and Research Systems | e. National Training Curricula in CTS |
| b. Best Practices for Navigating the Science of Translation | f. Diversity, Equity, Inclusion and Accessibility |
| c. Causes of Midlife Mortality in America | g. Enhancing the Impact of Clinical Trials |
| d. Climate Change and Health | h. Artificial Intelligence |

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Conflict of Interest

Evaluation

Submit

1. Importance of Purpose

Rating *
Select

Additional comments, if any

Characters Remaining: 1000

2. Feasibility

Rating *
Select

Additional comments, if any

Characters Remaining: 1000



Additional Comments:

If you have additional comments to add, please do so in the comments box below each question. Be aware that these comments will be de-identified but presented verbatim to the Steering Committee at large.

Scoring:

Score the Working Group Proposal on a 1-5 point scale, where:

1=Superior- A "Superior" rating signifies that the Working Group Proposal is exceptionally well-crafted, demonstrating outstanding quality and alignment with the working group's goals. It reflects an extraordinary level of excellence, and potential for significant impact.

2=Excellent- An "Excellent" rating indicates a high-quality proposal that exhibits a strong potential to contribute significantly to the CTSA's overarching goals. It represents well-thought-out ideas, thorough planning, and substantial promise.

3=Good- A "Good" rating suggests that the proposal meets the basic standards and expectations of a Working Group. While it may lack the exceptional qualities of higher ratings, it still demonstrates value and feasibility.

4=Fair- A "Fair" rating implies that the proposal has notable weaknesses or lacks certain critical elements. It may require improvements or adjustments to fully align with the goals of a Working Group.

5=Poor- A "Poor" rating indicates that the Working Group Proposal does not meet the standards of a Working Group. It may lack essential details, expertise, or alignment with the CTSA's objectives. It requires substantial revisions for reconsideration.





Please provide your Final Working Group Recommendation and score.

Score

Select ▼

Recommendation

Select ▼

If you have any additional comments that you would like to add, please do so below.

Additional comments, if any

Characters Remaining: 1000

Acknowledgment ☒

By submitting this form I understand that my responses will be deidentified and presented to the Steering Committee discussion. I can edit my responses including my Conflict of Interest statement up until the close of the review period on November 20, 2023.

[Clear all fields](#)

[Back](#)

[Save](#)

[Submit](#)



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Recommendation for the Working Group:

Provide your final recommendation for the Working Group by selecting one of the following options from the drop-down menu:

- I support this as a Working Group
- I cannot support
- I recommend as a Discussion Forum
- I Cannot support; Recommend Revision and Resubmission

Overarching Comments:

If you have any overarching comments about the proposal, add them to the comments box.

Submission Acknowledgment:

Click the acknowledgment box to confirm that you are submitting your response to the proposal, with the option to edit it until the close of the review period.

Save Your Response; At any time, you may save your responses and return to your evaluation at a later date. See save button at the bottom of the page.



Submit Your Response:

To submit and record your responses, click the "Submit" button. This will trigger a "Thank you for your Submission" page.

Move to the next Proposal

To review the next proposal click “Back to the WG Proposals” at the bottom of the submission page.



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Working Group Proposal Review Form

✓ Conflict of Interest ————— ✓ Evaluation ————— 3 Submit

Thank you for your submission.

CCOS will review the submission and reach out with any questions or clarifications in preparation for the Steering Committee Review. If you have any questions, please email support@ccos.ctsa.io

[Back To Working Group Proposals](#)



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Edit Your Review:

If you wish to edit your review form **prior** to submission, click on the Edit button in the table to return to edit your form. This feature is available until the close of the review period.




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Centering Anti-Racism in Community Engagement Program 	Linda Ko	3/27/2024, 10:53 PM	Not Reviewed	Review



View Your Submitted Review:

If you would like to view your review form (read only) after submission to prepare for the SC meeting, click the view button. This feature will be available until the SC meeting during which SC members vote on WG proposals.

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Thank you for participating in this process! If you have any questions, please reach out to CCOS support at Support@ccos.ctsa.io.

Diversity, Equity, Inclusion, and Accessibility (DEIA) Enterprise Committee: Update to CTSA Steering Committee and Next Steps

Lori Carter-Edwards, PhD, MPH

DEIA Faculty Liaison, University of North Carolina at Chapel Hill
Associate Dean for Community Engagement and Government Affairs
Professor of Health Systems Science and Interim Co-Director, Health Equity Research Core
Kaiser Permanente Bernard J. Tyson School of Medicine

Tung Nguyen, MD

Stephen J. McPhee, MD Endowed Chair in General Internal Medicine and Professor of Medicine, UCSF
Associate Vice Chancellor for Research Inclusion, Diversity, Equity, and Anti-Racism (IDEA), UCSF
Associate Director for DEIA, UCSF Helen Diller Family Comprehensive Cancer Center
Multiple Principal Investigator, UCSF Clinical and Translational Sciences Institute

CTSA Steering Committee Meeting
September 23, 2024



Objectives

1. Provide an update on the overall membership status (decline) for the DEIA EC.
2. Share what has been done by the EC to help support the hubs (particularly those facing challenges in conducting their work) given the current climate.
3. Ask the Steering Committee next steps in collectively successfully supporting DEIA in translational research given the current, and projected climate.

Membership and Participation

- **88** members on the distribution list (not including 5 CCOS Support Staff)
- **57** hubs on the distribution list (not including CCOS and NCATS)
- **78** registered meeting participants from **51** hubs
- **3** who stated they had to leave the EC due to university/state DEIA mandates
- Some have not contacted us but are not present, which may be related to the current climate

Poll Question: Spring 2024 CTSA Meeting

What do you perceive is the ***greatest need*** for your CTSA hub to advance DEIA efforts in translational research?

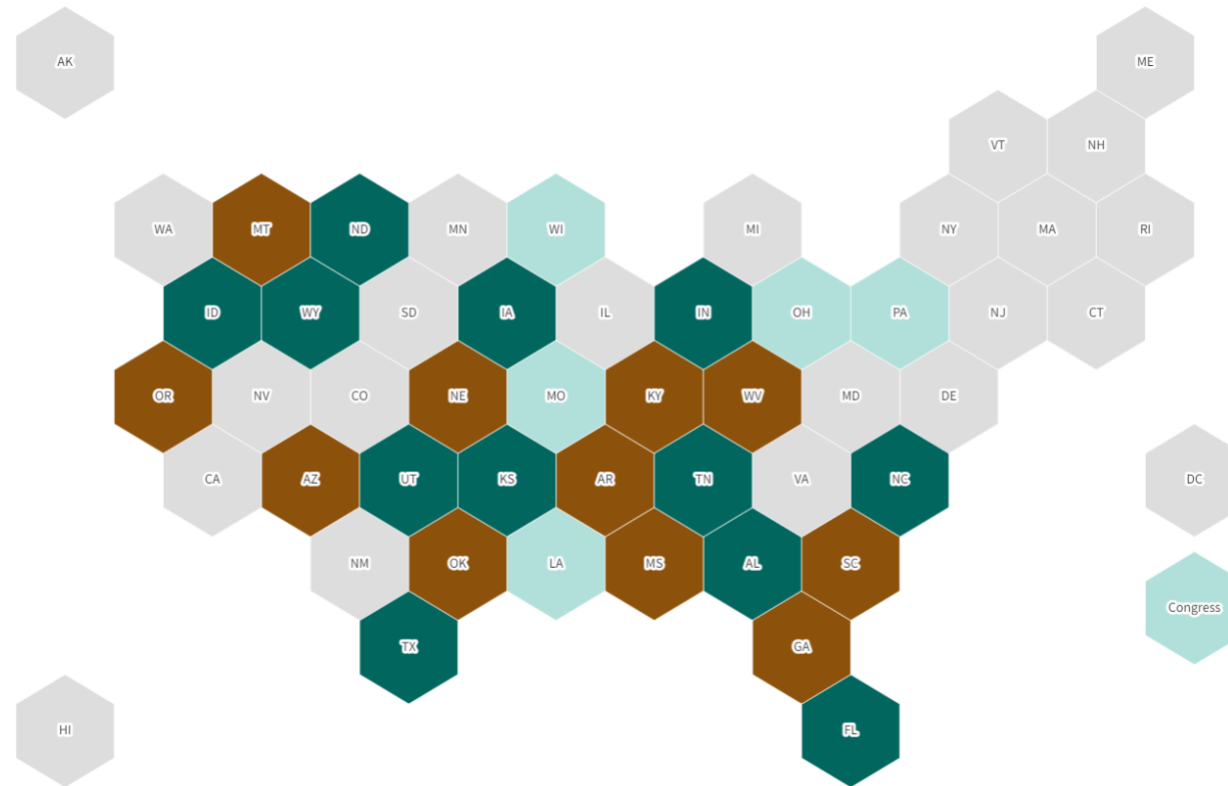
Most common responses bolded in purple.

1. Hub leadership's understanding the value of DEIA research.
2. Developing innovative ways to have within-hub conversations about DEIA research.
3. Identifying ways to support DEIA workforce development within the hub.
4. **Identifying ways to improve the hub's support for DEIA research. *****
5. **Identifying ways to partner across the institution to develop collaborative research opportunities.**
6. **Improve partnerships with the local communities to better conduct DEIA research.**
7. How to continue CTSA DEIA research efforts in a transitional climate.

National Map – DEI Legislation Status

Where Anti-DEI Legislation Has Been Proposed

■ No bill ■ Introduced ■ Final legislative approval ■ Signed into law ■ Tabled, failed to pass, or vetoed



Note: Florida and North Carolina also have bills introduced, which their colors do not reflect.

As of August 30, 2024
86 bills in 28 states and the US
Congress since 2023

86	Introduced
14	Have final legislative approval
14	Have become law
54	Have been tabled, failed to pass, or vetoed

Source: The Chronicle of Higher Education;
https://www.chronicle.com/article/here-are-the-states-where-lawmakers-are-seeking-to-ban-colleges-dei-efforts?bc_nonce=4eq9otkzjukascxjhgvqy6&cid=reg_wall_sign-up

Support through DEIA EC

- Survey questions to gauge climate, concerns, and needs
- Continued conversation by the EC Lead Team
- Presentations at the full DEIA EC meetings
 - **Jeanette Pritchett-Clay (NCATS)** – DEIA alignment and driving pillars
 - **Doris Rubio (ACTS)** – Nomenclature change to “Inclusive Excellence”
- Seeking to:
 - Change name – e.g., *Inclusive Excellence EC*
 - Provide safe spaces for sharing
 - Identify resources and practices to share so the work can continue
 - Identify areas for EC cross-collaboration (e.g., Collaboration & Engagement EC)

Support through DEIA EC: *Next Steps*

- **Activate the Learning System Accountability Framework**
 - Increase understanding of the framework
 - Foster cross-hub sharing of DEIA promising practices, facilitators, and barriers
- **Priority activities and timelines for 2024**
 - Leadership diversity follow-up survey
 - Equity, inclusion, and accessibility assessment plan
 - Initiate catalogue of DEIA best practices throughout the CTSA Consortium
 - Other activities identified by the full team (DEIA logic model)
 - Ad hoc operational structure to accomplish activities

Ask of the CTSA Steering Committee

- What should be next steps for the EC to support the hubs?
 - What can we collectively communicate to the hubs from the CTSA Program?
 - What roles can the Hubs' PIs have to support faculty, staff, and communities:
 - At your own institutions?
 - Collectively?
- Are there resources we should share with hubs during the current climate?
 - How can hubs continue to conduct translational science from a DEIA lens in light of the current climate?
- Other thoughts or ideas?

lori.c.edwards@kp.org
tung.nguyen@ucsf.edu

THANK YOU!

Fall Meeting Logistics Update

Kerry James and Ted Wun



National Center
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Translational Sciences

Fall 2024 CTSA Program Meeting

Theme: Building CTSA Program
Impact through Innovation,
Collaboration and Equity

Date: November 13-15

Location: Bethesda North Marriott



- Registration is open through **November 1st**
- Poster Submission portal is open through **Oct 25**

See more details on the
[CCOS Website](https://ccos.ctsa.io)

Questions? Contact
FallMtg@ccos.ctsa.io

Agenda- November 13-14

November 13		
8:30am – 11:30am	TIN Meeting	
10:00am – 6:00pm	Hub Administrators Meeting	
1:30pm – 6:00pm	Steering Committee Meeting	
November 14		
8:30am – 9:00am	Session1: Welcome	Mike Kurilla, NCATS Ruth O’Hara, Stanford
9:00am – 10:30am	Session 2: CTSA Collaborations with Primary Care Practice-Based Research Networks (PBRNs)	Invitations pending Moderator: Cynthia Morris, Oregon Health & Science U
10:30am- 11:15am	Session 3: Keynote	Monica Bertagnolli, NIH (Invited)
11:30am - 12:15pm	Poster Session A	
12:15pm -1:45pm	Break	
1:45pm - 3:15pm	Session 4: PCORnet / TIN / ENACT / N3C Engagement	Dan Hanley, Johns Hopkins Emily Pfaff, UNC School of Medicine Steven Reis, U of Pittsburgh Elizabeth Shenkman, U of Florida
3:30pm- 4:15pm	Poster Session B	
4:15pm- 5:45pm	Session 5: Equity in Focus: Advancing Women’s Health Research through Diversity Action Plans	Janine Clayton, NIH (Invited) Jenica Patterson, ARPA-H Tiffany Whitlow, Acclinate Moderator: Gelise Thomas, Case Western Reserve
6:00pm-7:00pm	UPI Meeting	Networking Session Facilitators TBD

Agenda- November 15

November 15		
8:00am- 9:15am	Session 6: CTSA Experiences with Transition from Translational Research to Translational Science	Patricia Wimokur, U Iowa Julie Johnson, Ohio State Julie Lumberg, U Michigan Moderator: Ted Wun, UC Davis
9:30am- 10:45am	Session 7: Application of Generative AI and Large Language Models in Translational Science	Matthew DeCamp, U of Colorado Menisha Desai, Stanford Eneida Mendonca, U Cincinnati (Invited)
11:00am – 12:30pm	Session 8: Element E/RC2/303 Approaches	Ange-Therese Akono, NC State Geoff Curran, U of Arkansas Thomas Houston, Wake Forest Ruth O'Hara, Stanford Olena Taratula, Oregon State Moderator: Mike Kurilla
12:30pm – 1:00pm	Closing: Poster Awards, Top Ten Takeaways	Mike Kurilla, NCATS Ruth O'Hara, Stanford

Registration Updates

As of 9/18/2024

	In Person	Virtual	Total
Nov 13, 2024			
Administrators meeting	66	7	73
Steering Cmte meeting	39	1	40
PI meeting	70		70
TIN meeting	30	3	33
Nov 14-15, 2024			
Total registration	232	35	267

Pod Feedback

Christopher Hartshorn, PhD

Section Chief

Clinical and Translational Science Awards Program Branch

Division of Clinical Innovation

Digital & Mobile Technologies Section



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Date Received: July 1, 2024 and August 5, 2024

Pod Lead: Jennifer Kraschnewski, Pennsylvania State University

Pod Membership: Cornell, Johns Hopkins, U Pittsburgh, State University NY Buffalo, U Pennsylvania

July 1 Pod Meeting Summary:

- The Pod discussed updates from the June 10th Steering Committee Meeting
- Group Discussion, topics included:
 - Fall Meeting Agenda
 - TIN updates and the opportunities for the proposed Training Academy to upskill clinical research staff and faculty in multi-site studies. Opportunities for collaboration with companies engaged in multi-site trials in better understanding best practices and how these might be adapted for academics
 - Seven-year timeframe under new NOFO and best practices for managing the flat budget.

August 5 Pod Meeting Summary:

- The Pod discussed updates from recent Steering Committee Meetings (6/24, 7/8, 7/22)
- Group Discussion, topics included:
 - Presentation from the Real-World Data Training Hub
 - Approaches, experiences, and resources to submitting RC2
 - Possible concerns about sustainability of future funding to support CTSAs
 - Collaborative Pitt/Penn/Penn State CTSAs OHRP Forum, September 9-10 virtually
 - REDCap CON, hosted by JHU in September 8-11 in Florida



Date Received: July 18, 2024 and August 15, 2024

Pod Lead: Randy Urban, University of Texas Medical Branch-Galveston

Pod Membership: U Michigan, UT-San Antonio, U Kansas, U Arkansas, UT-Houston

July 18 Pod Summary:

Meeting topics included:

- Randy Urban shared updates from recent Steering Committee meetings (6/24 and 7/8).
- Houston hub discussed Translational Science in Training Programs (TL1/T32 Co-Director, Dr. Joya Chandra)
 - Presented findings from the National T Directors group related to the importance of offering training in TS.
 - Houston program has lab-based mentor and a clinical mentor, trainees are required go to clinics and see some of the roadblocks in doing clinical research
 - Dr. Wayne McCormick and Dr. Amanda Vogel's efforts to provide training and resources in translational science were shared.
- Updates from each hub.

August 15 Pod Summary:

Meeting Topics included

- Updates from 7/22 SC meeting and the Fall Meeting session on successful RC2s, Element Es, and R03s
- TL1 Award Challenges
 - Late notice creates challenges for getting stipends to TL1 trainees.
 - There is increasing scrutiny on reporting from the HHS and OMB level, which slows down NIH GM. E.g., greater scrutiny on Other Support. In May 2025, training will become available.
- Discussion with Dr. Kurilla
 - Topics included: RPPR Burden with new funding suite, challenge of flat budget over 7 years, Financial challenges for partnering with MSIs, How can CTSA's tackle pending big issues?, and Phase III clinical trials.



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Date Received: July 25, 2024 and August 22, 2024

Pod Lead: Vesna Garovic, Mayo Clinic

Pod Membership: University of Southern California, Ohio State University, Medical College of Wisconsin, Tufts University, University California - Irvine

July 25 Pod Feedback:

It would be beneficial to receive the Steering Committee slides earlier to have time to formulate questions and feedback.
*It would be helpful to receive one bulleted slide to bring back to the POD. This would include main points.

July 25 Pod Meeting Summary:

- CTSA Fall Program Meeting Planning
 - The Pod discussed the draft agenda and topics that will be covered at the Fall Meeting.
 - Dan Cooper will reach out to Ted Wun on the concern for decreased breakout opportunities at the Fall Meeting
- Survey for Mentors/Mentees
 - Dr. Felicity Enders is conducting an anonymous survey from mentors and mentees on their competencies. Pod members are encouraged to participate.
- CTSA Steering Committee Meeting (7/22) and Discussion
 - Dr. Ken Gersing and Dr. Aubri Hoffman presented on RWD and domain analysis models in 7/22 meeting

August 22 Pod Meeting Summary:

- Dr. Garovic shared the request for SC slides to be sent earlier with Dr. Kurilla. They will consider that moving forward.
- Dr. Cooper connected with Dr. Wun who explained the Fall Planning Committee is exploring options for more collaboration opportunities among PIs.
- Recap of the July 22nd SC meeting: Presenters include Jeanita Pritchett-Clay on NIH TS initiatives and Ken Gersing and Abri Hoffman on the shortage of AI & machine learning expertise.
- Translational Science Pilots discussion: Grant funding and the difference between CTS and CTR



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Date Received: July 11, 2024

Pod Lead: Mimi Kim, Albert Einstein College of Medicine

Pod Membership: Columbia, Harvard, U Chicago, U Rochester, Washington University

Pod Summary:

- The Pod discussed updates from the June 24th and July 8th Steering Committee meetings including working group proposals.
- The Fall CTSA meeting and the proposed PI meeting were also discussed.

Pod Feedback:

- The pod suggests improved communication about WGs to CTSA PIs for better engagement and awareness in WG activities. Some PIs were unaware their hub members had submitted a proposal, and others requested more information about joining WGs.
- The pod recommends the PI meeting address one or two “big” themes for discussion, e.g., vision and direction of NIH from NCATS CTSA perspective; biggest threat to clinical and translational research (e.g., diminishing interest in CTR careers in younger generation)



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Date Received: June 4, 2024 and July 2, 2024

Pod Lead: Theodore Wun, UC Davis

Pod Membership: UNM Health Sciences Center, UC San Francisco, Colorado CTSI, Utah CTSI, U Washington

June 4 Pod Meeting Summary:

- Guest speakers presented on N3C and discussed N3C Covid vs upcoming clinical participation requirements and expectations in future iterations of N3C. Slide presentation was distributed to Pod members. List of external databases for N3C Covid <https://discovery.biothings.io/dataset?template=n3c>
- The Pod briefly reviewed the proposed CTSA fall meeting agenda

July 2 Pod Meeting Summary:

- Colorado will continue to participate in N3C (one of initial 12 in pilot) Utah requested additional information for participation in N3C. New Mexico not in the right timing as they await their UM1 scores. Washington uncertain. UCD and UCSF uploaded through consolidated data warehouse. Potential back door to CMS data
- Colorado to hold on ENACT participation due to funding. Utah has participated in ENACT but did not find much use. They would be interesting to know actual users. UCD checking funds status for ENACT
- The Pod discussed updates from the June 25th SC meeting. The SC accepted two WG proposals.
- The Pod discussed the CTSA Fall Meeting (November 13 – 15th in Bethesda, MD)

Action Items:

- **6/4:** Next month's agenda: biostatistics support, domain assistance, analyze/prioritize requests, feasibility, efficiency, etc.
- **7/2:** T. Wun to follow up with Mike Kurilla about having a PI session at the CTSA Fall Meeting



Date Received: May 28, 2024, and July 23, 2024, and August 27, 2024

Pod Lead: Gerry Moeller, Wright Regional Center for Clinical & Translational Science

Pod Membership: VCU, NYU Langone, Translational Science Institute, U Mass, Georgetown/Howard University, Yale, UVA

May 28 Pod Meeting Summary:

The Pod held a Q&A session with Dr. Michael Kurilla (NCATS). Questions and discussion points included:

- **Question 1:** When there is an MPI plan that involves two institutions, will each institution be able apply for other NCATS opportunities on their own or will all future applications have to be routed through the prime/lead institution?
- **Question 2:** AI/ML and Real-World Data (RWD) – There is a collaboration between NCATS and AIM AHEAD to develop training modules for AI/ML and RWD for use by the CTSA consortium. How can (a) hubs apply to be part of working groups, (b) apply to be part of the advisory team and (c) when will RFAs become available so hubs can apply to contribute to module development?

July 23 Pod Meeting Summary:

- **Internal Advisory Boards:** The Pod discussed how hubs are utilizing Internal Advisory Committees and reporting meeting details in the annual RPPR.
- One topic that the group thought would be interesting for the steering committee to discuss is the internal advisory committees and how they differ from hub to hub. Putting too much pressure from the CTSA program on hubs to have uniformity in the internal advisory committees was not a good idea considering the hubs differ substantially in their partners, collaborators, etc.

August 27 Pod Meeting Summary:

- New NIH directive (NOT-OD-23-182) and different implementation approaches for international subawards.
- 2024 Fall CTSA Meeting and ACTS Spring 2025 Meeting



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NEXT MEETING

October 28, 2024
2:30-3:30pm ET

*The October 14 meeting has been
cancelled due to Columbus Day.*



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