

CLINICAL AND TRANSLATIONAL SCIENCE AWARD (CTSA) PROGRAM STEERING COMMITTEE ROLES AND RESPONSIBILITIES

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1. Steering Committee Overview

The purpose of the Steering Committee (SC) is to enable bidirectional information and idea sharing between and among the CTSA Program Principal Investigators (PIs), Administrators, Enterprise Committees (ECs) and NCATS leadership regarding aspects of the CTSA Program and the field of clinical and translational science.

Virtual and in-person meeting support for the SC is provided by the Coordination, Communication and Operations Support (CCOS) Center, the CTSA Program Coordinating Center.

1.1. Membership, Nominations, and Eligibility Criteria

The CTSA Program SC is comprised of 24 members: 11 UL1/UM1 PIs, 1 KL2/K12 PI/Director, 1 TL1/T32 PI/Director, 1 Administrator, 1 member of each of the Enterprise Committee Lead Teams, one member PI of each funded national collaborative activity [e.g. Trial Innovation Network (TIN) and ENACT: Translating Health Informatics Tools to Research and Clinical Decision Making], the NCATS Division of Clinical Innovation (DCI) Director and the NCATS Director (ex officio). All members are considered voting members of the SC. See Table 1 below for SC constituents and their representative groups.

Table 1. CTSA Steering Committee Members and Group representation

SC Member (Voting)	CTSA Group	Meetings Organized By
1 UL1/UM1 PI Co-Chair	UL1/UM1 PIs	CCOS
1 NCATS Co-Chair	NCATS	N/A
11 UL1/UM1 PIs	Pod group comprised of UL1/UM1 PIs	SC Pod leader
1 KL2/K12 PI	KL2/K12 PI/Directors Group	CCOS
1 TL1/T32/R25 PI	TL1/T32/R25 PI/Directors Group	CCOS
1 Administrator	Administrators Group	CCOS
1 Trial Innovation Network PI	Trial Innovation Centers (TICs) Recruitment Innovation Center (RIC)	TIN / CCOS
1 ENACT PI	ENACT Network	ENACT
4 Enterprise Committee Lead Team Members	CTSA Program Enterprise Committees	CCOS
1 NCATS Director (ex officio)	NCATS	N/A

NCATS solicits new **UL1/UM1 SC member nominations** annually in the Fall in an open call to the CTSA Program consortium. The solicitation is advertised widely through communication channels for the CTSA Program (e.g. newsletter, distribution lists, webinars). Members of the consortium may nominate another PI, and PIs may submit self-nominations.

UL1 / UM1 PIs selected to fill open Steering Committee seats will receive a formal invitation from the NCATS DCI Director in late November / Early December.

Please see **Table 2** below for details about each SC role including nomination / appointment, eligibility criteria and membership terms.

Table 2. CTSA Steering Committee Membership Details

SC Role	Nomination / Appointment	Eligibility	Term
UL1/UM1 PIs and	<ul style="list-style-type: none"> CTSA members nominate PIs Call for nominations annually in the Fall 	<ul style="list-style-type: none"> Must have at least 2 years remaining on their award Must not be in a No-Cost Extension¹ Must be officially named in the Notice of Award (NoA) of an active CTSA Program grant/award (includes the “contact” PI and all PIs listed as a “multiple PI”) The PI has not served on the SC since December 2020.² 	<ul style="list-style-type: none"> Minimum 2 year term³, max of 3 years Beginning Jan 1st and ending Dec 31st of the appointee’s 2nd term
KL2/K12 PI	<ul style="list-style-type: none"> Member of KL2/K12 PI / Directors Consortium Group Selected by Leads or Chair(s) 	<ul style="list-style-type: none"> Must have at least 2 years remaining on their award Must not be in a No-Cost Extension The PI has not served on the SC in last 4 years 	<ul style="list-style-type: none"> 2 year term Beginning Jan 1st and ending Dec 31st of the appointee’s 2nd term
TL1/T32/R25	<ul style="list-style-type: none"> Past Chair of the TL1/T32/R25 Directors Consortium Group 	<ul style="list-style-type: none"> Must have at least 2 years remaining on their award Must not be in a No-Cost Extension The PI has not served on the SC in last 4 years 	<ul style="list-style-type: none"> 2 year term Beginning Jan 1st and ending Dec 31st of the appointee’s 2nd term Start 2 yrs after they complete their 2 yr term as TL1/T32 Director’s Consortium Group
Administrator representative	<ul style="list-style-type: none"> Selected by the co-chair(s) of the Administrator’s Group Annual in the Fall as needed 	<ul style="list-style-type: none"> Must be the key point of contact between their institution’s CTSA Program leadership and PI and NCATS personnel 	<ul style="list-style-type: none"> 2 year term Beginning Jan 1st and ending Dec 31st of the appointee’s 2nd term

¹ Hubs in a [No-Cost Extension \(NCE\)](#) are ineligible for SC appointments. During a NCE a hub does not receive funding from NCATS in a fiscal year. A hub award in a NCE is not considered eligible as there is insufficient time remaining in the award project period for initiation of an appointment.

² At the time the SC was reorganized in 2014, NCATS made a commitment to the consortium that all funded and eligible PIs will have the opportunity to serve 1 term before making second-term appointments.

³ SC members are appointed for 2 year terms; however, this may be fewer than 2 years depending on the number of years remaining in the hub grant. Term may extend 1 year for Co-Chairs; Co-Chair Designates and Past Co-Chairs.

TIN / ENACT PIs	<ul style="list-style-type: none"> PI from TIN or ENACT 	<ul style="list-style-type: none"> Must be a PI on Notice of Award from TIN or ENACT 	<ul style="list-style-type: none"> Duration of award May rotate an appointment to another PI on Notice of Award during the grant period
EC Lead Team Members (one per EC)	<ul style="list-style-type: none"> Selected by EC Chair(s) or lead teams 	<ul style="list-style-type: none"> Current EC Lead Team member 	<ul style="list-style-type: none"> Duration of term on EC Lead Team Up to 2 years

SC Member Replacements and Extensions

- Replacement of a SC member may be considered in certain situations (e.g., when members step down from their position) and requires prior approval by NCATS.
- Extensions of membership may be required for co-chairs to complete a full calendar year of service.

See **Appendix A** for a current list of members of the CTSA Program Steering Committee.

A list of past Steering Committee members is available on the [CCOS Steering Committee Webpage](#).

1.2. Steering Committee Co-Chair Role and Appointment

The SC Co-Chairs lead the SC by identifying priority topics for discussion, provide an asynchronous structure for items that require administrative approvals or voting, and if applicable and when appropriate, creating SC-driven projects that realize opportunities identified by the SC.

The SC Co-Chairs are:

- The NCATS Director for the Division of Clinical Innovation
- A current UL1/UM1 PI member serving on the SC

Effective January 2021, the **Co-Chair** serves a 1-year term. Upon completion of a Co-Chair's 1-year term, the **Co-Chair Designate** assumes the Co-Chair position and NCATS appoints a new Co-Chair Designate. Each year, NCATS selects a Co-Chair Designate from the current SC roster. The Co-Chair Designate will co-lead the Fall Planning Committee during the year they serve as the designate.

The **Past Co-Chair** is the preceding year's Co-Chair and has this role for 1 year. The Past Co-Chair supports the present SC Co-Chair by providing historical information on past committee work and other information as needed. If the Past Co-Chair has completed their 2-3-year SC appointment, the Past Co-Chair is invited by the current Co-Chair to attend SC meetings during this 1-year term as a non-voting member.

The SC will always have a Past Co-Chair, Co-Chair, and Co-Chair Designate serving simultaneously. This is designed to allow more PIs to serve in the Co-Chair role while also providing the current SC Co-Chair with adequate support and assistance, if needed.

2. Steering Committee Meetings

2.1. NCATS Staff Attendees at SC Meetings

The following NCATS staff members support the SC Co-Chairs in preparation for upcoming meetings. These attendees may attend SC calls and provide their area of expertise during the discussion.

- NCATS Director
- NCATS Deputy Director
- NCATS Chief Medical Officer
- NCATS Division of Clinical Innovation (DCI) Deputy Director
- NCATS DCI CTSA Program Branch Chief
- NCATS DCI Education and Training Section Chief, CTSA Program Branch
- NCATS DCI Initiatives & Consortium-Wide Activities Section Chief, CTSA Program Branch
- NCATS DCI Digital & Mobile Technologies Section Chief, CTSA Program Branch
- NCATS DCI Director of Informatics
- NCATS DCI Clinical Affairs Branch Chief
- NCATS DCI Trial Innovation Network Section Chief, Clinical Affairs Branch
- NCATS DCI Clinical Research Resources Section Chief, Clinical Affairs Branch
- NCATS DCI Officer of Program, Evaluation Analysis and Reporting Director (OPEAR)
- Steering Committee Executive Secretary

2.2. Ad-Hoc Attendees of SC Meetings

The following “ad-hoc” members usually attend SC meetings and provide their area of expertise during the discussion:

NCATS Division of Clinical Innovation (DCI) Program Officers

- NCATS Director, Division of Extramural Activities
- NCATS Deputy Director, Division of Extramural Activities
- NCATS Director, Scientific Review Branch
- NCATS Deputy Director, Scientific Review Branch
- NCATS Director for the Office of Communications, Policy, and Education
- NCATS Chief, Policy Branch
- NCATS Chief, Education Branch
- NCATS Chief, Communications Branch
- NCATS Chief, Grants Management Branch
- NCATS Deputy Director, Grants Management Branch

2.3. Administrative Support

The Executive Secretary is an NCATS employee who supports the SC Co-Chairs in preparing for upcoming meetings. A CTSA Program Coordinating Center (CCOS) meeting coordinator provides logistics and administrative support for all SC and co-chair meetings.

2.4. SC Meetings

The CTSA Program SC meets at least twice monthly via zoom and 1-2 times per year either in person or virtually for an extended meeting and communicates as needed via email. Meetings are attended by the SC members, NCATS Staff and Ad-Hoc attendees. Meeting summaries are prepared by the CCOS coordinator and the Executive Secretary, disseminated to the consortium, and posted to the calendar entry available via the archive on the [Steering Committee](#) webpage.

3. Steering Committee Roles and Responsibilities

The CTSA Program Steering Committee (SC) serves multiple important functions, including strategic and logistical functions.

1. The SC identifies major systemic, scientific, and operational problems in clinical translational science that the CTSA consortium should work to solve via collective action. It may create subgroups of the SC or charter formal Task Forces to address these problems.
2. The SC serves a broad coordinating function, selecting and monitoring the activities of the Working Groups, and ensuring that all parts of the large and diverse CTSA Program have the opportunity to be included in consortium efforts.
3. The SC serves as a conduit for bidirectional communication and transparency between NCATS and the CTSA consortium.

The required roles and responsibilities of SC members are described below.

3.1. CTSA Program Pod Leadership

To facilitate bidirectional communication between the SC, NCATS, and CTSA program hubs, the CTSA Program has set up Pods led by the eleven UL1/UM1 representatives on the SC.

A concise list of pod leader responsibilities is available [here](#).

3.1.1. What is a Pod?

A “Pod” is a subgroup representing five to six CTSA Program hubs which is led by the “Pod Lead,” a current member of the CTSA Steering Committee. Together each Pod Lead and their assigned CTSA Program hub representative(s) (“Pod Member”) form a Pod.

3.1.2. Pod Composition

- (1) Pod Lead: CTSA Program Steering Committee principal investigator
- (5-6) Pod Members: CTSA Program UL1/UM1 principal investigator
- (5-6) Administrators (Optional)

Pod members are strongly encouraged to include their hub's Administrator on Pod calls and emails. CTSA Program hubs that are no longer considered to be "active" (i.e., hubs that are beyond No Cost Extension and whose grants are or being closed out) are removed from the Pod structure.

3.1.3. Pod Objectives

- Pod Leads relay pertinent information and updates from previous CTSA SC meetings and other communications to Pod Members on a regular and timely basis.
- Pod Leads gather ideas, agenda topics for SC meetings, questions, concerns, and other feedback from Pod Members.
- Pod Leads act on behalf of Pod Members by reporting ideas, questions, concerns, and other feedback to the CTSA Steering Committee and NCATS on a regular basis. This helps ensure CTSA Program leadership is responsive to the needs of local hubs and prepared to prioritize emerging topics in translational science.
- From time to time, NCATS will solicit the views and opinions from the SC on a variety of topics, projects, and NIH/NCATS activities related to clinical and translational science. CTSA Program hub representatives are expected to meet with their respective Pod, highlighting any specific concerns, challenges, questions, and feedback to relay to NCATS. The Pod Lead should submit a summary of the discussion points to NCATS following the meeting.
 - For example, in the event NCATS launches a new consortium-wide program/initiative, the SC will be asked to provide feedback on planned implementation activities and strategic direction of the program/initiative. During this period, Pods would include targeted discussion about the program/initiative during the next scheduled Pod meeting.
 - Further, the SC and the Pods should continue to provide feedback during the lifecycle of a program. Examples where the SC has provided substantive feedback to ensure CTSA Program success includes, but is not limited to the Trial Innovation Network, the Common Metrics Initiative, and the National COVID Cohort Collaborative (N3C).

3.1.4. Pod Meeting Conduct

Pods meet at least once every two months via teleconference and at the direction of the group to gather perspectives and allow for small group discussions. In general, the agenda topics are determined by the Pod Lead and Pod Members. There may be instances where NCATS or the SC will solicit feedback from Pods on a topic of special interest. In these cases, Pods are required to meet and discuss the topic, prepare a summary of the discussion, and submit an

aggregate report back to NCATS via the Pod Submission Form.

3.1.5. Pod Reporting

The Pod Lead prepares meeting notes using a standardized Pod meeting summary template⁴ following each Pod meeting and submits the notes to NCATS via the Pod Submission Form on the [SC Pod webpage](#) within three days of hosting the call. CCOS will provide each Pod lead with a meeting summary template specific to their Pod. Once reviewed by CCOS, the Pod meeting summaries become publicly available on the Pod [Archive](#).

Meeting notes should include a summary of topics reviewed and/or discussed with the Pod. The option to submit questions, agenda topics for SC meetings, share ideas, respond to requests for information, and provide other feedback is also available via the [Pod Submission Form](#).

Submissions from the Pods including meeting summary reports and pod feedback are posted (unedited) under [Pod section](#) of the SC page of the CCOS website and are made available to the CTSA consortium and broader public community. Where applicable, additional materials, such as program webinar or meeting notes referencing relevant SC discussions, may be appended to Pod submissions.

Feedback aggregated at a national consortium level help inform the SC and NCATS of specific challenges experienced by the consortium on a local level. Pod submissions also help CTSA Program leadership identify emerging topics and innovative approaches that address and/or solve translational science problems. Further, these notes help NCATS formulate productive and engaging agenda topics for upcoming SC and Program meetings.

3.1.6. Review of Pod Submissions

The SC reviews Pod submissions during the second monthly CTSA Program SC meeting of the month. Pod submissions must be received no later than one week prior to the second SC Meeting to be included in that month's review. Submissions received less than one week prior to the second scheduled SC Meeting of the month will be reviewed at the next month's review of Pod submissions.

See the [SC section](#) of the CCOS Website for a current list of CTSA Program Pods.

3.2. Enterprise Committee (EC) Activities

The SC ensures alignment of EC activities with those of the SC, and the mission and goals of the CTSA Program. The full SC promotes synergies among the ECs; provides input on proposed EC Working Groups (WGs) including avoidance of redundancy among ECs/WGs; provides advice on relevant experts for WGs (including from other ECs); and provides final

⁴ CCOS will provide a customized template for each Pod at the beginning of SC member / Pod Lead tenure.

approval of new WGs. The SC receives yearly status reports from the ECs. The SC also reviews and approves EC surveys, as appropriate (see Appendix D).

Starting in 2025, each EC lead team will select a lead team member to sit on the Steering Committee. The time commitment is up to two years or when the lead team member ends their term on the EC lead team. EC representatives will be voting members and will attend all SC meetings.

3.3. Working Group (WG) Activities

The SC oversees the CTSA Program Working Group (WG) process and is required to participate in the review and approval of all WG proposals and to provide constructive feedback on the progress of WGs upon presentation of oral and written reports to the SC.

WGs consider and develop solutions around a specific clinical and translational science issue. A maximum of 12 active WGs will be supported by CCOS across the consortium at any given time with a target of ≤ 2 sponsored by specific EC. A WG will propose and deliver well-defined projects or deliverables that fill identified translational gaps and/or further the CTSA Program objectives in high priority areas in clinical and translational science. Projects may result in outputs such as consensus papers, white papers, publications, and/or plans for workshops, symposiums, meetings, and/or a conference. Consortium members may choose to pursue potential funding for activities stemming from the WGs through CTSA Collaborative Innovation and Acceleration Awards (CCIAs) or supplements; development of applications must take place outside of supported CTSA Program Groups.

3.3.1. Working Group Proposal Review and Voting

Pending WG resource availability, open calls for Working Group Proposal cycles occur two times per year – in March and September. Utilizing a rubric, each SC member provides an individual review of a WG proposal on the following areas:

- importance of purpose
- value of deliverables to the consortium and to the field of clinical and translational science
- project feasibility
- expertise
- group composition

SC members with a conflict of interest on a WG proposal will abstain from participating in that specific application review. SC members will review WG proposals and submit their reviews through a private portal on the SC webpage. See the [Getting Started section](#) of the CCOS website for information about registering for a CCOS account.

CCOS aggregates and presents the results to the full SC. The SC will then formally vote, hold a discussion, and/or may request for additional information/clarification, or suggested revisions. If

50% of voting SC members cannot support a proposed WG then we will not bring it to vote at SC meeting. Possible SC decisions are that a WG is approved, denied, deferred, combined with a similar proposal, or approved with a delayed start. NCATS reviews the aggregate data and prepares a summary statement back to the WG proposers with the SC's decision.

3.3.2. Working Group Oversight

Working Groups are required to submit written progress reports to the Steering Committee at 6-, 12-, 18- and 24-months (sunset report). These reports cover: the purpose of the WG, goals and deliverables, timeline and progress towards those goals and deliverables, changes made to deliverables, any challenges or lessons learned while completing deliverables, and a summary of community member involvement in the WG. Steering Committee members will receive these reports and provide any critical feedback about their progress to the CCOS coordinator for the Steering Committee, who will then share this feedback with the WG Chairs. Additionally, the Steering Committee is responsible for considering WG timeline extension requests submitted in writing by WG co-chairs at least 3 months prior to their sunset date; a formal vote to approve or reject the request will be held during the next available SC meeting.

Additionally, Working Groups are also required to make an annual presentation to the SC about WG goals and deliverables. This 10-minute live presentation will be followed by 5-10 minutes of discussion between WG chair(s) and SC to solicit constructive feedback regarding WG activities.

For more information about Working Group reports, please visit the CCOS [Working Group webpage](#) and review the *Guidance for CTSA Program Groups*, found on the [Governance and Guidance page](#).

3.4. Planning Committee for Fall CTSA Program Meeting

The SC is the official planning committee for the Annual CTSA Program Meeting. This meeting is typically held in person during the Fall in the Washington, D.C. metro area and is attended by up to 5 representatives from each hub in the CTSA Program consortium. If an in-person meeting is determined to be not feasible, such as during the COVID-19 pandemic, the meeting may be held virtually, in which case the number of participants per hub will be determined by the platform used for the meeting.

The planning committee is led by the Co-Chair Designate and the NCATS Co-chair and comprised of other SC members. Additional members are identified in response to the agenda. Support for the planning committee is provided by the CTSA Program Coordinating Center (CCOS). Planning for the meeting should be initiated by February, starting with identifying Fall Planning Committee members.

The SC does not serve as the planning committee for the spring CTSA meeting, where CTSA Program Groups will meet (inclusive of the Workforce Enterprise Committee / KL2/K12 PI/Directors / TL1/T32/R25 PI/Directors, Communicators, and other Enterprise Committees). The individual group meetings are planned by the leads of those groups.

3.5. Planning Committee for the Meeting of UL1/UM1 PIs

The purpose of the UL1/UM1 PI meeting is to create a forum for communication for the UL1/UM1s PIs across the consortium. These meetings typically are held in person once per year during the Fall CTSA Program Meeting. The Planning Committee for this meeting will be comprised of the Co-Chair Designate and the Co-Chair and 2-3 volunteer UPIs, who will work with CCOS to develop the goals, agenda topics, and format of the meeting. As part of agenda development, topics of interest for the in person meeting will be solicited from the broader group of CTSA UPIs.

3.6. SC Task Forces

The SC can tackle clinical research and translational science barriers through the creation of up to three task forces supported by the CTSA Program Coordinating Center (CCOS). These task forces are created by the SC and approved by the SC Co-Chairs. These task forces are deliverable-focused with milestones and should not exceed 1 year in duration. Further, they can include non-SC members with relevant subject matter expertise. One or more NCATS representatives are assigned to these task forces at the discretion of the NCATS SC Co-Chair.

Oral reports / presentations will be provided at the in-person SC meetings and on the CTSA Program webinar on an annual basis. A final written report will be provided that summarizes the Taskforce activities at the completion of the Taskforce.

The SC oversees the SC task force(s) and provides constructive feedback on the progress of task force(s) upon presentation of oral and written reports to the SC.

3.7. Survey Review and Approval

The SC reviews and approves survey requests submitted by members of the consortium. For further information, including detailed processes and procedures, see the [Survey](#) section of the CCOS website and *CCOS Guidance for CTSA Surveys*, found on the [Governance and Guidance page](#).

3.8. Communication among the KL2/K12 PIs/Directors, TL1/T32/R25 PIs/Directors, and Administrators

The KL2/K12, TL1/T32/R25 and Administrator SC members have regular meetings with their respective groups. During these meetings, the groups will have the opportunity to disseminate and share information. Meeting summaries are prepared by the CCOS coordinator and posted to the respective group pages.

For more information, visit the [Groups and Meetings](#) page on the CCOS website.

Appendix A: Membership of the CTSA Program Steering Committee (2025)

Member	Last Name	First Name	Affiliation	Term
Co-Chair	Kurilla	Michael	National Center for Advancing Translational Sciences (NCATS)	No term limit
Co-Chair	Wun	Theodore	University of California Davis	2023-'24 2024-'25 2025-'26
Past Co-Chair (non-voting member)	O'Hara	Ruth	Stanford University	2022-'23 2023-'24 2024-'25
NCATS Director	Rutter	Joni	NCATS	No term limit
Co-Chair Designate	McComsey	Grace	Case Western	2024-'25 2025-'26
UL1/UM1 Member	Brown	Arleen	University of California Los Angeles	2023-'24 2024-'25 2025-'26
UL1/UM1 Member	Wright	Rosalind	Icahn School of Medicine at Mount Sinai	2023-'24 2024-'25 2025-'26
UL1/UM1 Member	Ofili	Elizabeth	Morehouse School of Medicine	2024-'25 2025-'26
UL1/UM1 Member	Moeller	Frederick "Gerry"	Virginia Commonwealth University	2024-'25 2025-'26
UL1/UM1 Member	Kim	Mimi	Albert Einstein College of Medicine	2024-'25 2025-'26
UL1/UM1 Member	Garovic	Vesna	Mayo Clinic	2024-'25 2025-'26
UL1/UM1 Member	Lumeng	Julie	University of Michigan	2025-'26 2026-'27
UL1/UM1 Member	Bernstein	Steve	Dartmouth Hitchcock Medical Center	2025-'26 2026-'27
UL1/UM1 Member	Panettieri, Jr.	Reynold A.	Rutgers University	2025-'26 2026-'27
UL1/UM1 Member	Vilain	Eric	University of California Irvine	2025-'26 2026-'27
KL2/K12 PI	Rubio	Doris	University of Pittsburg	2023-'24 2024-'25 2025-'26
T32/TL1/R25 PI	Holinstat	Michael	University of Michigan	2025-'26 2026-'27
Administrator	Carnegie	Andrea	University of North Carolina	2024-'25 2025-'26
BIDS EC	Bernstam	Elmer	UT Health Houston	2025-'26
Collaboration & Engagement EC	Wiehe	Sarah	Indiana University	2025-'26
Integration Across the Lifespan EC	Schleiss	Mark	University of Minnesota	2025-'26
WFD EC	Ingbar	David	University of Minnesota	2025-'26
Trial Innovation Network Member	Ford	Dan	Johns Hopkins University	Length of award
ENACT	Reis	Steven	University of Pittsburgh	Length of award