Guidance for CTSA Program Groups

V6.0 – March 19, 2025

Revisions of this Document:

V1.0 - October 2019: Initial release
V2.0 - January 2022: Revision to have Community Members as voting members
V3.0 - January 2024: Comprehensive revision due to change from CLIC to CCOS, modified format of document, removed appendices, condensed content, added details throughout document (e.g., EC lead team elections, EC roles and responsibilities) and revisions to report structure for WGs and ECs.
V4.0 – December 2024: Revision to include: (1) the requirement for a lead team member from each EC to serve as a voting member on the CTSA Steering Committee; (2) minor revisions to reporting process details for EC reports to the SC and WG reports to SC; (3) minor content and link updates.
V5.0 – January 2025: Revision to Enterprise Committees.
V6.0 – March 2025: Revision to WG extension process.

General Notes

Questions and comments regarding the governance and operational guidelines for the CTSA Program Groups should be emailed to CCOS Support.

Glossary / Definitions

Abbreviation	Definition
CCOS	Coordination, Communication and Operations Support Center
CG	Consortium Group
Community Member	A member of the community that includes all stakeholders connected to clinical and translational research. Communities may include but are not limited to non-profit or industry entities engaged in translational research, and might include disease advocacy groups, local health providers, community-based organizations, and other national or local communities.
CTSA	Clinical and Translational Science Awards
DCI	Division of Clinical Innovation
DF	Discussion Forum
EC	Enterprise Committee
Hub	A CTSA Program hub is defined as a UL1 or UM1 award with a linked K award and/or T award. CTSA Program hubs can consist of a single institution, plus the possibility of one or more participating partner institutions.
IOM	Institute of Medicine
NCATS	National Center for Advancing Translational Sciences
PI	Principal Investigator as named in the U award
SC	Steering Committee
TIN	Trial Innovation Network
WG	Working Group

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Guidance for CTSA Program Groups

A variety of CTSA Program Groups were established to execute the recommendations of the NCATS Advisory Council Working Group on the IOM Report on the CTSA Program (see report here).

Objectives of CTSA Program Groups:

- Focus on short- and long-term needs (as identified by each group) with the goal of speeding up the translation of research discoveries into improved care.
- Provide a structure where measurable objectives of the strategic goals of the CTSA Program can be implemented.
- Support an inclusive process where all Hubs can participate and access translational science education, training, tools, and resources.
- Foster communication and collaboration at all levels across the consortium.
- Establish discrete objectives, timelines, and deliverables for every CTSA program activity.

Figure 1: Overview of the CTSA Program Groups

1. CTSA Program Steering Committee

The purpose of the Steering Committee (SC) is to enable bidirectional information and idea sharing between the CTSA Program Principal Investigators (PIs), Administrators, and NCATS leadership regarding all aspects of the CTSA Program and the field of clinical and translational science. For more information, please view the Steering Committee Roles & Responsibilities document. **For more information see:** https://ccos-cc.ctsa.io/groups/steering-committee.

2. CTSA Program Groups

The CTSA Program is built upon a robust infrastructure of CTSA Program groups. These groups bring together a broad range of perspectives, expertise, and capabilities from across the hubs – including scientists, research administrators, communicators, evaluators, informaticians, trainees and scholars, patient advocacy organizations, and community members—to tackle system-wide scientific and operational problems in clinical and translational research. Through the CTSA Program Groups, leaders, innovators, and other essential contributors from across the United States research enterprise work collaboratively to accelerate advances in clinical and translational science. The CTSA Program Groups are: **1) Consortium Groups, 2) Enterprise Committees, 3) Working Groups and 4) Discussion Forums.**

2.1. Consortium Groups

The Consortium Groups include individuals from the hubs that have expertise in the subject matter of their group. This includes the Communication Officers, Administrators, KL2 PI/Directors and the TL1 PI/Directors, Evaluators, and QA/QC specialists:

2.1.1. Communicators Group

The purpose of this group is to facilitate communication between Communications staff at the CTSA Program hubs and NCATS regarding communication strategies and approaches. Program Staff from the NCATS Office of Communications interface with this group and CCOS to align communication strategies and goals with local hubs.

Group Membership and Term
- The Communicators are typically those representatives of the CTSA Program hub who perform communication related activities.
- Membership in the CTSA Program Communicators Group is **voluntary.**
- The term of the membership is variable as the membership is voluntary and there is no set limit on the membership.

Meeting Frequency
Virtual meetings are held on a quarterly basis and an annual face-to-face meeting is organized and supported by NCATS and CCOS.

For more information see: [Consortium Groups | Communicators Group](#)

2.1.2. Administrators Group

The purpose of the Administrators Group is to facilitate communication between the Administrators of each hub and NCATS regarding administrative and management issues at the hubs.

Group Membership and Term
- The Administrators Group is comprised of those representatives of the CTSA Program hub who perform administrative related activities.

- Membership of the CTSA Program Administrators Group is **voluntary.**
- The term of the membership is variable as the membership is voluntary and there is no set limit on the membership.
- There is one Administrator on the CTSA Program Steering Committee. [See Steering Committee Roles & Responsibilities document](#) for more information.

Meeting Frequency

CCOS provides support for virtual meetings to occur every other month and one annual face-to-face meeting.

For more information see: [Consortium Groups | Administrators Group](#)

2.1.3. KL2/K12 PI/Directors

The purpose of the KL2/K12 PIs/Directors Group is to serve as an avenue for communication across the CTSA Program consortium and to create a community of individuals with shared goals and responsibilities. Additionally, the goal of this group is to share experiences and best practices, provide a forum to discuss pertinent topics, and offer opportunities to work collaboratively and to address challenges in unison.

Group Membership and Term

- The KL2/K12 PI/Directors Group is comprised of PIs and Directors of CTSA Program KL2/K12 grants.
- Membership in the CTSA Program KL2/KL12 PI/Directors Group is **voluntary.**
- The term of the membership is variable as the membership is voluntary and there is no set limit on the membership.
- There is one KL2/K12 PI on the CTSA Program Steering Committee. See Steering Committee Roles & Responsibilities document for more information.

Meeting Frequency

CCOS provides support for virtual meetings to occur every other month and one annual face-to-face meeting in conjunction with the TL1/T32 PI Directors group (see section 2.1.4) and the Workforce Development Enterprise Committee group (see section 2.2).

For more information see: [Consortium Groups | KL2/K12 PI Directors Group](#)

2.1.4. TL1/T32 PI/Directors

The purpose of the TL1/T32 PIs/Directors Group is to serve as an avenue for communication across the CTSA Program consortium and to create a community of individuals with shared goals and responsibilities. Additionally, the goal of this group is to share experiences and best practices, provide a forum to discuss pertinent topics, and offer opportunities to work collaboratively and to address challenges as a group.

Group Membership and Term

- The TL1/T32 PI/Directors Group is comprised of PIs and Directors of CTSA Program TL1/T32 grants.
- Membership in the CTSA ProgramTL1/TL32 PI/Directors is **voluntary.**

- The term of the membership is variable as the membership is voluntary and there is no set limit on the membership.
- There is one TL1/T32 PI on the CTSA Program Steering Committee. See Steering Committee Roles and Responsibilities for more information.

Meeting Frequency
CCOS provides support for one virtual meeting per month and one annual face-to-face meeting in conjunction with the KL2/K12 PI Directors group (see 2.1.3) and the Workforce Development Enterprise Committee (see 2.2).

For more information see: Consortium Groups | TL1/T32/R25 PI Directors Group

2.1.5. Evaluators Group

The purpose of the Evaluators Group is to encourage cutting edge research on methods and processes relevant to evaluating the impact of translational science. They support the CTSA Program consortium with expertise on common evaluation techniques, promote cross-hub collaborations, and provide valuable insights through focused sub-groups and research efforts. Additionally, there are five affiliated sub-groups listed below. These sub-groups are responsible for managing short-term deliverables that align directly with the group's overarching objectives.

- Evaluation Survey Group
- Retrospective Case Studies Research Group
- Bibliometrics Group
- Translational Science Benefits Model Group
- Data Aggregators Group

Group Membership
- The Evaluators Group is comprised of staff at hubs who are engaged in evaluation research.
- The Evaluators Group is co-chaired by two members elected by a simple majority of the Evaluators Group.
- Membership in the CTSA Program Evaluators Group is **voluntary.**
- The term of the membership is variable as the membership is voluntary and there is no set limit on the membership.

Meeting Frequency
CCOS provides support for virtual meetings every other month. The sub-groups also meet on a regular basis but are not supported by CCOS.

For more information, see: Consortium Groups | Evaluators Group

2.1.6. Quality Assurance / Quality Control Group

The purpose of the QA/QC group is to engage in discussions regarding processes, challenges, and optimal approaches linked to ensuring the successful submission of CTSA-related information packages to NCATS. The group places particular emphasis on submissions involving piloted projects and K projects that encompass research involving human subjects. NCATS has extended an administrative supplement

to UL1 grants to facilitate the presence of a dedicated quality assurance-quality control role. This form of support persists in the latest CTSA funding opportunity.

Group Membership and Terms
- The QA/QC group is comprised of quality assurance staff working in clinical research and pilot projects.
- Membership in the CTSA Program QA/QC Group is **voluntary.**
- The term of the membership is variable as the membership is voluntary and there is no set limit on the membership.

Meeting Frequency
CCOS provides support for meetings to occur every other month.

For more information, see: Consortium Group QA/QC Group

Figure 2: Enterprise Committees, Working Groups and Discussion Forums
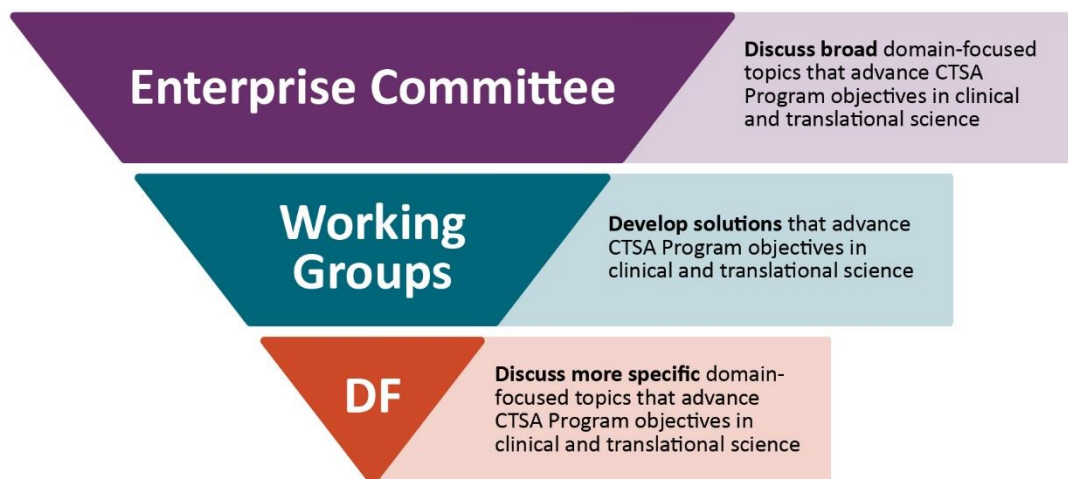
2.2. Enterprise Committees

The Enterprise Committees (EC) advance CTSA Program objectives in high priority areas in clinical and translational science through the following activities:

- Promote collaboration and innovation across key areas
- Provide an open forum for broad, domain-focused discussions
- Discuss and disseminate best practices
- May develop plans for projects that fill identified gaps and/or further the program objectives through a working group proposal

The CTSA Enterprise Committees include:

- Collaboration & Engagement EC
- Biostatistics, Biomedical Informatics & Data Science (BIDS) EC (Note: name change effective December 2024 from Informatics EC)
- Integration Across the Lifespan EC
- Workforce Development EC

For more information about each EC, see Enterprise Committees | CTSA CCOS

EC Group Membership

- Membership on a minimum of one EC is **required** for each CTSA Program hub.[1]
- **EC Voting Members:** Each CTSA Program hub is allowed to have **one voting member** on each EC. This member is appointed by the hub PI and is the primary point of contact for their hub for all matters relating to their specific EC.
- **EC Non-voting members**: Membership (non-voting) is also open to any personnel of CTSA Program hubs. Personnel of CTSA Program hubs and/or partnering institutions are encouraged to attend regularly scheduled EC calls and participate in EC activities.
- **Community Members (voting):** It is recommended that three community representatives, or four with justification, are part of each EC. ECs may decide on a nominating process for Community members. Community members should register with CCOS website when they become a member of the EC.
- **NCATS Program Staff Member (non-voting):** one appointed by DCI Leadership will serve as the NCATS representative on the EC.
- **Other Members (non-voting):** FDA, PCORI, CDC, etc., are appointed and approved by DCI Leadership.

EC Lead Teams

The governance of each EC is conducted by a **Lead Team** who are elected annually from the voting membership of each EC. The Lead Teams are charged with conducting the specific goals of their EC as well as the overall goal of providing a platform to engage in scientific conversation and collaboration at the national level.

- A **minimum of three and a maximum of seven** individuals from the eligible voting membership of an EC serve on the Lead Team. Members are nominated to fill open seats and, if necessary, elected by voting members of the EC to serve on the EC Lead Team.
- Voting members may nominate up to two eligible candidates per open seat.
- Lead team members will elect an EC Chair. If necessary, the Lead Team may appoint a Co-Chair to assist the Chair in the management of the EC.

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[1] A CTSA Program hub is defined as a UL1 award with a linked KL2 award and an optional TL1 award or a UM1 award. Refer to the NCATS CTSA Program Funding Table and/or the Notice of Grant Award to determine voting member eligibility. Note that hubs in a *No Cost Extension* are eligible to participate. CTSA Program hubs can consist of a single institution, plus the possibility of one or more participating partner institutions. Participation in the ECs by those personnel from partnering institutions is allowed.

- One NCATS Program Staff Member (non-voting) appointed by DCI Leadership will serve on the EC Lead Team.
- One liaison from the Trial Innovation Network (non-voting) may serve on the EC Lead Team.
- One liaison from the N3C (non-voting) may also serve on the EC Lead Team.

EC Lead Team Elections

- As per timeline below, elections for the Lead Team will take place during **November-December** of every year, as needed. Elections must be completed by **December 31st** and appointments begin **January 1st**.
  - ➢ Before this process begins, CCOS will work with Hub Administrators to confirm the current EC voting members in Sept-October.
- Individuals are elected by a simple majority vote by EC voting members.
- Elections may occur on an ad-hoc basis as needed to ensure continuity in the membership of the Lead Team (e.g., if a lead team member leaves their hub for another position outside of the CTSA consortium prior to the end of their term).
- Election processes are supported by CCOS.
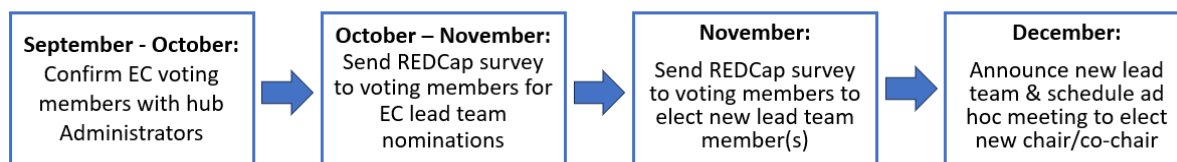
Figure 3. EC Election Timeline

September - October: Confirm EC voting members with hub Administrators	→	**October – November:** Send REDCap survey to voting members for EC lead team nominations	→	**November:** Send REDCap survey to voting members to elect new lead team member(s)	→	**December:** Announce new lead team & schedule ad hoc meeting to elect new chair/co-chair

Table 1: Eligibility for EC Lead Team Member and Chair

EC Lead Team Member: Eligible candidates include CTSA Program hub members (voting). They may be nominated or self-nominate. If more individuals are nominated than open lead team "seats," an election will take place.

EC Chair: Eligible candidates include the EC Lead Hub Members for the upcoming term. They may be nominated or nominate themselves.

- If more than one individual is nominated, an election will take place among the incoming Lead Team (voting) members.
- If no existing EC Lead Team Member is nominated, self-nominated or accepts the nomination, an EC Member (voting) may be nominated or self-nominated. If more than one individual is nominated, an election will take place among the incoming Lead Team (voting) members.

EC Co-Chair: If necessary, the Lead Team may appoint a Co-Chair to assist the Chair in the management of the EC.

Table 2. EC Membership Terms and Responsibilities

EC Member Type	Term	Responsibilities
Chair (and Co-Chair If applicable)	- One year starting January 1st - Renewable for an additional year by a majority of Lead Team Members	- Lead the virtual meetings for EC Lead and Full Team - Lead strategic planning to work towards goals of EC - Work closely with CCOS coordinator and lead team to develop agendas for virtual and in person EC meetings - Identify potential presenters for meetings - Review / approve meeting summaries - Vet and review WG proposals; provide endorsement for sponsored WG application for the SC review - Oversee/monitor working groups - Advise CCOS coordinator regarding communications and website content as needed - Present to the SC on an annual basis - Present to the CTSA Program consortium on a CTSA Program webinar on an annual basis
Lead Team Member	- One year starting January 1st - Renewable for an additional year by a majority of Lead Team Members - An individual that has formerly held the EC Chair position may be on the Lead Team for up to one additional year	- Assist in preparing agendas for virtual full membership meetings as well as in person meetings - Identify and moderate topics of discussions for the group - If proposing a WG, vet and review WG, provide feedback as necessary - Contribute to presentation to SC and or webinar on an annual basis as needed - One lead team member to serve on Steering Committee as voting member (see SC Roles and Responsibilities for more details). The term on Steering Committee will be up to 24 months or equal to the remainder of the term to be served on the EC.
Lead Team – NCATS Representative	- Two years starting January 1st - Renewable at the discretion of DCI Leadership - Transitions of staff between terms must include an overlap of 3 months	- Facilitate relevant discussions and encourage consistency with CTSA Program objectives in high priority areas in clinical and translational science - Coordinate with and/or disseminate to DCI Leadership issues, questions, or other items of relevance to the EC Lead Team
Lead Team – TIN representative, N3C representative	At the discretion of TIN or N3C	Facilitate synergies and coordination between EC activities and relevant TIN or N3C activities.
Community Member (Voting)	Each EC may choose the length of term. However, a term of at least two years is preferable from an organizational/logistical standpoint	- Attend meetings, contribute to discussions, agenda setting, priorities, and strategic planning from community perspective - Participate in annual EC Lead elections - Other responsibilities as determined by EC
Member (Voting)	At the discretion of the CTSA Program Hub PI	- Attend meetings, contribute to discussions, agenda setting, priorities, and strategic planning from hub perspective - Participate in annual EC Lead Team elections
Member (Non-Voting)	Voluntary	Attend meetings and contribute to discussions as able

- **One lead team member per EC to serve on Steering Committee:** Starting in January 2025, the EC lead teams will send a representative to serve as a voting member on the CTSA Steering Committee.
- **SC Responsibilities include:**
    - Attend the Steering Committee meetings on the 2nd and 4th Monday of the month from 2:30-3:30pm ET
    - Attend the Steering Committee meetings during the Fall and Spring CTSA Program meetings
    - Review and vote on working group proposals (2x per year)
    - Review and provide feedback on WG progress reports
    - Contribute to discussions and vote on issues posed to the Steering Committee
- For more detailed information, please review [Steering Committee Roles and Responsibilities](.).

EC Required Reports

- **Annual presentation to the SC:** The purpose of this **10-minute, live presentation** is to provide updates to the SC about annual EC goals and highlights of EC activities. This presentation will be followed by 10 minutes of discussion to solicit constructive feedback from the SC regarding EC activities. *Each presentation should follow the structure below*:

    a) Intro slide
        - List EC Lead team members, Chair(s)
        - # EC members (by hub) who participated in EC this year (CCOS coordinator will provide)
    b) Highlights of what the EC has accomplished in the past year
        - What specifically have you achieved related to EC goals?
        - Work product (e.g., publication, guidance document, etc.) (if any)
        - Sponsorship of WGs (if any)
        - Cross EC initiatives or other CTSA collaborations (if any)
        - Other highlights
    c) Upcoming goals for the next year
        - What will the EC work towards in the next year?
    d) Discussion / constructive feedback from SC members (directed questions)
        - EC Chairs should develop a set of questions for the SC to provide feedback on and to serve as a primer for the discussion. Examples below:
            - Is the EC's progress satisfactory to date?
            - Are there short-term goals that this EC should prioritize in the next year?
            - Are there any additional suggestions as to how to enhance the work of this EC?
        - SC members (at least 2) will review content and lead discussion. (*The SC members will be assigned by CCOS*).

    The SC meeting coordinator will reach out to EC Chairs to schedule their presentation at least 2 months in advance of the presentation.

    - The EC will prepare a presentation (.ppt) to include the above-mentioned components and will send to the CCOS coordinator **one month prior to the live presentation**.

- ➢ The CCOS coordinator will share the presentation and questions with the Steering Committee liaisons, who will review and respond to questions if applicable and offer suggestions.
- ➢ The SC Liaison's response will be shared with the EC leads, who will then prepare a live 10-minute presentation consisting of **no more than five slides** and submit to the CCOS coordinator approximately **two weeks prior to the Steering Committee meeting**.

- **Annual Presentation on the CTSA Program Webinar:** The EC presentation to the webinar will take place after the SC presentation – typically within 2 months. The purpose of this presentation is to provide a high-level status report to the CTSA consortium about EC goals and highlights of the EC activities. The presentation should be tailored for the larger CTSA-wide audience and include a *summary* of the SC constructive feedback.

  A CCOS meeting coordinator will reach out to EC Chairs to schedule their webinar presentation at least 2 months in advance of the presentation.

  - The presentation should be 10 minutes in length followed by 4-5 minutes of discussion. **Note:** While live presentations are preferred, there is an option to pre-record the presentation.
  - Draft slides should be provided to the CCOS coordinator **at least 3 business days prior** to their scheduled presentation.

For more information, see [Enterprise Committees | CTSA CCOS](#).

2.3. Working Groups

Upon CTSA Steering Committee (SC) approval, Working Groups (WGs) are formed to address specific gaps in translational research and achieve the CTSA Program's objectives in key areas of clinical and translational science. The timeline for WGs ranges from 12 months to 24 months, with an option to extend for one additional year. WG outputs may include consensus papers, white papers, publications, and plans for workshops, symposiums, meetings, or conferences.[2]

Groups/Individuals interested in forming a WG are required to submit a proposal for SC review and approval during one of two open cycles per year (September and March). High priority areas of interest are reviewed by the SC on an annual basis and updated accordingly.

Working Groups are often sponsored by CTSA Enterprise Committees (EC). While EC sponsorship is not required, it is highly encouraged by the SC and offers an opportunity for more input and review by Consortium leaders as well as providing a venue for promotion and recruitment of WG volunteers. An EC may sponsor more than one proposal during a proposal cycle.

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[2] Consortium members may choose to pursue potential funding for activities stemming from those through CCIAs or supplements; development of applications must take place outside of supported CTSA Program Groups.

Membership and Eligibility

- Membership is **open** to all personnel of CTSA Program hubs. CTSA Program hubs can consist of a single institution, plus the possibility of one or more participating partner institutions. Note that hubs in a no cost extension are eligible to participate.
- Community members may participate, and each WG may decide on a nominating process for community members. WG chairs will need to notify CCOS of community members joining their WG; these members should register with the CCOS website when they join the WG.
- Members of the CTSA Program with an active CCOS account are eligible to submit a proposal. WG proposals may be submitted by any hub or pod member, EC, or consortium group member.

WG Composition and Size

- The WG will have a Chair (from CTSA Program hubs) and a Co-Chair (appointed Program Staff from NCATS). No Lead Team is required.
- There is no required minimum or maximum number of members for a WG; the roster will be dependent on the project timeline and deliverables.
- WGs have the option to request liaisons from other relevant CTSA Program groups and include outside advisors and community members as the project requires. The SC review may also provide feedback on additional liaisons and outside advisors.

WG Terms and Timelines

- The timelines for WGs range from 12 months to 24 months (maximum).
- The end of the period of approved WG term or completion of WG deliverables, whichever comes first, will determine the date of a WG sunset.
- **Requesting an extension:** If a WG requires an extension to complete its deliverables, a WG co-chair must submit a written request on institutional letterhead as soon as the need is identified. The letter should detail the reason for the delay, the additional time required, and the strategy to ensure the deliverables are met within the extended timeline. Refer to Table 3 below for guidance on the review process. Upon reviewing the letter, a decision will be made to either extend the WG, phase it out, or convert it to a Discussion Forum. If an extension of 12 months or more is needed, a new proposal should be submitted during the next WG submission cycle.

Table 3. WG Extension Request Process

Length of Extension	Request to:	Reviewed by:
3 month extension	CCOS meeting coordinator, copy NCATS liaison	NCATS
6 month extension	CCOS meeting coordinator, copy NCATS liaison	CTSA Steering Commitee
12 months or greater	New proposal during next WG cycle	CTSA Steering Commitee

WG Required Reports

- **Written reports** are submitted to the SC at: 6-months, 12-months, 18-months, and 24-months. These reports should cover: the purpose of the WG, goals and deliverables, timeline and progress towards those goals and deliverables, and a summary of community member involvement in the WG. The CCOS coordinator will share a **report template** with WG chair(s).

- **Annual presentation to the SC:** The purpose of this **10-minute, live presentation** is to provide updates to the SC about annual WG goals and deliverables. This presentation will be followed by 5-10 minutes of discussion between WG chair(s) and SC to solicit constructive feedback regarding WG activities. ***Each presentation should follow the structure below***:

  a) Introductory slide (WG title, chair(s), and membership)
  b) WG goals and deliverables, along with a timeline
  c) Progress towards goals and deliverables
  d) Discussion / constructive feedback from SC members (directed questions)
     - WG Chairs should develop a set of questions for the SC to provide feedback on and to serve as a primer for the discussion. Examples below:
       - Is the progress satisfactory to date?
       - In your opinion, are we on the right track to make an impact with this WG?
       - Are we engaging the appropriate stakeholders/participants or are there others we are missing to date?
       - Are there other goals or deliverables that we missed in the conception of this WG that you think we need to incorporate now to enhance the significance? (This could be future facing or as an additional follow-on WG)
       - Are there any additional suggestions as to how to enhance implementation and dissemination of the deliverables of this WG?
     - SC members (at least 2) will review content and lead discussion. (The SC members will be assigned by CCOS).

  The SC meeting coordinator will reach out to WG Chair(s) to schedule their presentation at least 2 months in advance of the presentation.
  - The WG chair(s) will prepare a presentation (.ppt) to include the above mentioned components and will send to the CCOS coordinator **one month prior to the live presentation**.
  - The CCOS coordinator will share the presentation and questions with the Steering Committee liaisons, who will review and respond to questions if applicable and offer suggestions.
  - The SC Liaison's response will be shared with the WG Chair(s), who will then prepare a live 10-minute presentation consisting of **no more than five slides** and submit to the CCOS coordinator approximately **two weeks prior to the Steering Committee meeting**.

- **Annual Presentation on the CTSA Program Webinar:** The annual presentation to the webinar will be scheduled after the SC presentation – typically within 1-2 months. The purpose of this presentation is to provide a high-level status report to the CTSA consortium about WG goals and deliverables, with a focus on the value and impact of the WG. The presentation should be tailored for the larger CTSA-wide audience and include a summary of the SC constructive feedback.
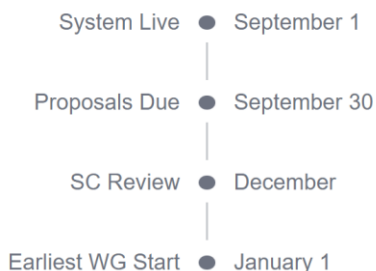
A CCOS meeting coordinator will reach out to WG Chairs to schedule their webinar presentation at least 2 months in advance of the presentation.

- The presentation should be 10 minutes in length followed by 4-5 minutes of discussion. **Note:** While live presentations are preferred, due to time constraints, there is an option to pre-record the presentation.
- Draft slides should be provided to the CCOS coordinator **at least 3 business days prior** to their scheduled presentation.

- **A final written report** is required summarizing the outcomes of the project and/or deliverable(s) no later than 3 months after the proposed end date of the WG. The report should also outline any efforts that may continue after the working group sunsets as well as a point of contact for the WG who will provide updates about ongoing efforts or deliverables. The CCOS coordinator will share a report template with WG chair(s).

Annual WG Proposal Cycles

Pending WG resource availability, open Working Group proposal cycles occur two times per year (see schedule below). To have your working group idea considered by the CTSA Program SC for either round, you must complete and submit a proposal (see Proposal Cycle Information | CTSA CCOS) no later than 3:00 PM ET on the day listed below.

Fall Submission Timeline		Spring Submission Timeline	
System Live	September 1	System Live	March 1
Proposals Due	September 30	Proposals Due	March 31
SC Review	December	SC Review	June
Earliest WG Start	January 1	Earliest WG Start	July 1

Criteria for the WG proposal form include:

- Submitter's name(s), email address(es) and institution(s)
- EC Sponsorship
- If the proposal is a resubmission and what the revised proposal addresses
- How WG differs from or complements current consortium efforts
- Purpose of the Working Group
- Deliverable(s)
- Proposed Metrics (if applicable)
- Workgroup Membership
- Needed Expertise
- Type of support requested
- Timeline / Milestones (including proposed start and end date)

- Sunset criteria
- Options to obtain additional CTSA Program (CCOS) resources

Working Group Proposals will be evaluated by the SC based on the criteria below:

- Importance of purpose
- Value of deliverables to the Consortium and Clinical and Translational Science
- Feasibility
- Proposed expertise
- Alignment with CTSA/NCATS goals

The Steering Committee may request additional information or clarification or suggest revisions prior to determining whether they will approve the proposal, or deny, defer, approve with a delayed start, or recommend as a discussion forum. Working Groups which are approved by CTSA Program Steering Committee will be supported.

WG Support and Funding Guidance

- Although no direct funding is provided, monthly meetings of the WGs are supported by CCOS. (See **Section 3 - CCOS Support for CTSA Program Groups**).
- A maximum of 12 active WGs will be supported by CCOS across the consortium at any given time with a target of ≤2 from a specific EC.
- *WGs may not use CTSA Program WG organized meeting time or CCOS provided resources to develop a grant application.*
- *If WG members determine that funding is necessary for project completion or product development, discussion of a proposal for funding may not use meeting time or resources supported by CCOS.*

For more information, see [Working Groups](#).

2.4. Discussion Forums

The Discussion Forums (DF) advance CTSA Program objectives in high priority areas in clinical and translational science through the following activities:

- Discuss more specific, focused topics in depth
- Develop plans for projects that fill identified gaps and/or further the program objectives through a working group proposal, as desired
- Collaborate, share knowledge, and engage via Google drive and listserv (hosted on NCATS G Suite) on an ad hoc / as needed basis

DF Membership

- Membership within a Discussion Forum is self-selected and is open to all personnel of the CTSA Program.
- Community Members may participate in a DF; they will need to register with the CCOS website prior to joining.

- Discussion Forums are housed in the NCATS Google Suite. DFs may be accessed via the CCOS website, but a login will be required to access the pages.
- To request a new Discussion Forum, the leader or co-leader submits a request to CCOS Support Team.
  - In the email, please include the proposed DF title, a short description of the DF, Lead Team Member Name, Email, Organization and Funded Institution, as well as a Co-Lead Name, Email and Organization, along with the name, email, and organization of the Forum Manager (if different that Lead or Co-Lead).
  - Each DF requires a designated 'Forum Manager' or leader- please be sure to indicate who this individual will be when submitting your request. (The designated Forum Manager may change as the DF evolves.) The Forum Manager is responsible for tasks like coordinating forum activities, membership, and access rights, and managing a group calendar. Non-managerial members of a DF also assist with tasks related to the DF, but only managers control the group's membership and access rights.

NOTE: As with other program activities, you cannot use a DF to develop a grant application or for discussion of funding.

For more information about active Discussion Forums, see Discussion Forums.

3. CCOS Support for CTSA Program Groups

Support for CTSA Group Meetings

Each of the CTSA Program Groups including Enterprise Committees, Working Groups, Consortium Groups are supported by a CCOS meeting coordinator (and a back-up coordinator). CCOS Coordinator assignments, along with the meeting schedules, are found on the group page on the CCOS website. CCOS coordinators will provide support for virtual CTSA Program Group meetings. CCOS coordinators will also support one in-person meeting annually for Enterprise Committees and for the Communicators Consortium group. Details are below.

Virtual meeting support includes:

- Scheduling recurring group meetings
- Setting up and hosting virtual (Zoom) calls
- Coordination of agenda development
- Speaker invitations and coordination
- Preparation of meeting materials (.ppt slide decks)
- Creation of meeting summary
- Maintenance of membership and distribution lists
- Maintenance of website calendar and meeting artifacts
- Use of virtual polling software
- Facilitation of survey request process
- Coordination of annual Lead Team elections and onboarding (ECs and Evaluators group only)

In person meeting support includes:

- Development of agenda with Lead Team and / or Co-Chair(s)
- Speaker invitations and coordination
- Preparation of meeting materials (ppt. slide decks)
- Integration of polling software as needed
- Coordination with meeting planning team re: room set up, AV needs
- Setting up the Zoom meeting for virtual participants
- Onsite meeting support
- Creation of meeting summary
- Posting materials to website (post-meeting)

Set up of Collaborative Space (Shared Drive in NCATS G Suite)

In addition to meeting support, the CCOS coordinator can facilitate the set-up of a collaborative space, which includes a shared drive for file storage and sharing for group members using the NCATS G Suite. If requested by the Lead Team, a google group can also be set up within NCATS G Suite infrastructure (also used for Discussion Forums).

NOTE: The G Suite Shared Drive and/or google groups require two group member(s) (e.g., Lead Team members or Chair(s)) to serve as owner/primary point of contact and folder managers. NCATS ITRB maintains these drives; CCOS role is strictly to facilitate the set up.

Survey Support

CCOS also provides support for survey development, dissemination, implementation, and analysis through the CCOS Survey Team at the University of Rochester. CCOS Survey Support may include survey design and analytic consultation, configuring survey in REDCap, survey dissemination, REDCap technical support, data delivery, and descriptive analytics of survey results. The CCOS Survey Team support will depend on priorities and UR Survey team resources.

Additional guidance for surveys may be found in the [CCOS Guidance for CTSA Surveys](#). For a copy of this guidance or for any questions regarding surveys, you may reach out directly to the survey team at surveys@ccos.ctsa.io.

Table 4. CCOS Support Quick Reference Table

CTSA Group	Virtual Meeting Support	In Person Meeting	Survey Support	CCOS Webpage	G-Suite Shared Drive	Google Group
Enterprise Committees	Monthly full team meetings (Maximum of 12/year) and monthly Lead Team meetings (maximum of 12/year)	One annual in person meeting (Spring)	Yes, as available	Yes	Yes, upon request	Yes, upon request
Consortium Groups	Monthly meetings (Maximum of 12/year)	One annual in-person meeting (only Comm and Admin Groups)	Yes, as available	Yes	Yes, upon request	Yes, upon request
Working Groups	Monthly meetings (Maximum of 12/year)	N/A	Yes, as available	Yes	Yes, upon request	Yes, upon request
Discussion Forum	N/A	N/A	N/A	Yes	Yes	Yes

For any questions about CTSA Program groups or CCOS support, please email the CCOS Support Team.