

CTSA Program Webinar

May 27th, 2026

 Attendees are muted  Ask questions using Q & A  Webinar is recorded  Materials posted to [CCOS](#)

Agenda CTSA Program Webinar May 27th, 2026

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Kerry James, MPH, PMP, Project Director CCOS
2:01 – 2:10 PM	NCATS/CTSA Updates	Michael Kurilla, MD, PhD DCI/NCATS
2:10 – 2:15 PM	CCOS Updates	Kerry James, MPH, PMP, Project Director CCOS
2:15 – 2:45 PM	FDA's CDER Center for Clinical Trial Innovation	Meghana Chalasani, MHA, Associate Director for Clinical Trial Innovation in the Office of New Drugs (OND) in U.S. FDA's Center for Drug Evaluation and Research (CDER)
2:45 – 3:00 PM	Publication Compliance Strategies	Pamela Shaw, Pamela L. Shaw, MSLIS, MS, Northwestern Karen Wilson, MD, MPH University of Rochester Kristi Holmes, PhD, Northwestern
3:00 PM	Adjourn	Kerry James, MPH, PMP, Project Director CCOS



NCATS

COLLABORATE. INNOVATE. ACCELERATE.

NCATS/CTSA Program Updates

Michael G. Kurilla, MD, PhD

Director, Division of Clinical Innovation
NCATS

May 27, 2026



NIH National Center
for Advancing
Translational Sciences

NCATS Advisory Council (May 21-22): CTSA Concepts

- **Renewed Concepts Approved:**

- CTSA Suite:

- Clinical and Translational Science Award: UM1
 - Institutional Career Development: K12
 - Institutional Training: T32 (post-doc), T32 (pre-doc)
 - Education Research: R25 (short-term research experiences)
 - Specialized Innovation Programs: RC2

- CTSA Consortium Activities:

- Trial Innovation Network: Trial Innovation & Recruitment Innovation Centers
 - CTSA Collaborative & Innovative Acceleration Awards

- **New Concept Approved:**

- Real-world Evidence Innovation Challenge

- [Watch the VideoCast \(Day 2\)](#) (available in a few days after the event)



T32 NOFO Update: Combining Predoctoral and Postdoctoral Programs into a Single NOFO

What is changing:

- NCATS intends to reissue the T32 NOFOs
- The two current T32 NOFOs — one predoctoral (PAR-25-194) and one postdoctoral (PAR-25-195) — **will be combined into a single new NOFO**
- This is part of NIH-wide efforts to streamline the NOFO landscape

What this means for you:

- Institutions applying for both predoctoral and postdoctoral programs must submit two separate applications
- Each application must describe one training program — either predoctoral or postdoctoral, not both
- Combined pre/postdoctoral applications will not be accepted



Collaborative Workshop on Real-World Data (RWD) & Real-World Evidence (RWE): Stanford Medicine, NCATS, and CCOS

- A multidisciplinary workshop bringing together researchers, patients, industry, and government leaders to advance the future of RWD/RWE research.
- Discussions emphasized:
 - Transparency, adaptability, and reproducibility in data-driven research
 - The importance of governance, interoperability, metadata standards, and data quality
 - Meaningful patient and community engagement throughout the research lifecycle
 - Workforce development, team science, mentorship, and sustainable collaborative research models
- Participants highlighted the need for:
 - Shared governance frameworks and common data models
 - Cross-disciplinary collaboration and “research navigator” support systems
 - Rigorous validation of analytic methods across diverse health systems and clinical settings



CTSA Program – Clarifications

Scholar Appointment Policy:

Pending Independent K Awards CTSA KL2/K12 Program

THE POLICY

- NIH standard K policy and PAR-25-196 (CTSA K12 NOFO) prohibit appointing scholars with a pending independent K award (e.g., K08, K23)
- The CTSA K12 program is designed for late-stage postdocs or early-career faculty who are not yet ready for independent funding
- Scholars should be selected who can complete the full career development program (2- to 5- year)

WE HEAR YOUR CONCERN

- Programs worry that scholars who do not apply early may face a funding gap after their appointment ends
- NCATS wants to avoid early terminations due to the duplicate provisions of mentored, career development components
- Historically, early departures and their causes have not been systematically tracked — we are working to understand this better



CTSA Program – Clarifications

Scholar Appointment Policy:

Pending Independent K Awards CTSA KL2/K12 Program

PRACTICAL GUIDANCE: WHEN SHOULD SCHOLARS BEGIN APPLYING FOR INDEPENDENT K AWARDS?

- 2-year program design → Begin applying in Year 2 (after completing Year 1 of K support)
- 3-year program design → Begin applying in Year 3 (after completing Year 2 of K support)
- 4-year program design → Begin applying in Year 4 (after completing Year 3 of K support)

**Note: The large majority of CTSA K12 programs use a 2-year design. Very few use a design longer than 3 years. These guidelines are intended to balance scholar readiness with funding continuity*

WHAT THIS MEANS FOR APPOINTMENT APPROVALS GOING FORWARD

- Appointment forms submitted for candidates with a pending independent K application will not be approved by NCATS
- Programs should review candidate readiness against the program's career development timeline before submitting appointment forms
- If you have questions about a specific candidate's situation, please reach out to your NCATS program official before submission



CTSA Program - Clarifications

Text within the CTSA NOFOs:

- UM1: "For our CTSA, NCATS has tiered thresholds that range from \$2,600,000 to \$6,500,000. CTSA UL1 award recipients funded previously under PAR-18-940, PAR-18-464, or PAR-15-304 may request the appropriate tiered UM1 threshold shown on Table B but will not receive more than a 5% reduction in DC annual support for the core hub responsibilities (UM1) relative to the last budget period of the previous competitive project period of their UL1 award, exclusive of administrative supplements/competitive revisions and subaward F&A. Thus, those CTSA UL1 award recipients whose UM1 DC Tier calculation is more than a 5% reduction in DC annual support **may submit a budget request at 95% of the DC level of the last budget period of the previous competitive project period of their UL1 award**, exclusive of administrative supplements/competitive revisions and subaward F&A."
- K12: Budget tier requests (A, C, G, or T) of a companion K12 application submitted in response to the reissued NOFOs **must be the same budget tier of the respective UM1**.
- T32: Budget tier requests (A, C, G, or T) of the optional T32 application submitted **must be the same budget tier of the respective UM1**.

Clarification:

- Companion K12 / T32 applications must be submitted using the same **budget tier designation** as the UM1.
- **Therefore, the K12 / T32 applications must be submitted at the corresponding Tier level**, irrespective of the higher protected UM1 direct cost amount permitted under the 95% transition provision.

Please reach out to CTSANOFOQuestions@mail.nih.gov if you have questions



Reminders

NIH Grants Policy Statement:

- Reference: [4.2.5 Lobbying-Appropriation Prohibition](#)
 - “NIH appropriated funds may not be used for the preparation, . . . , distribution, or use of a kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body...”,
- Reference: [4.1.18 Lobbying Prohibition](#)
 - “Recipients of Federal grants, . . . are prohibited . . . from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments.”

With respect to the CTSA Program, recipients should pay special attention to reporting / describing activities focused on reporting Policy & Legislative impacts under the Translational Science Benefits Model or any other aspect of a NIH funded CTSA grant. CSAAs are encouraged to generate scientific evidence. CSAAs are also required to disseminate findings and evidence resulting from NIH funded research. However, no grant funds including personnel costs may be used for activities as stated above. All grant application and RPPR submissions must clearly indicate what activity was paid for directly with NIH funding support. This clarification is greatly appreciated particularly when reporting on impactful science that has had more broad-scale changes that would benefit all.



NIH Notices

- **Announcement of Upcoming System Enforcement of Common Forms and End of NIH's Leniency Period ([NOT-OD-26-079](#)) (Released April 21, 2026)**
 - May 7, 2026 – leniency period for implementation of Common Forms for Biographical Sketch and Current and Pending (Other) Support **ENDS**
 - Use of the Common Forms for Biographical Sketch, Current and Pending (Other) Support, and NIH Biographical Sketch Supplement will be required for all application due dates and Just-In-Time (JIT), Research Performance Progress Report (RPPR), and Prior Approval submissions on or after May 8, 2026.
- **Prior Approval Requirement for Changes to Domestic Subawards ([NOT-OD-26-062](#)) (Released March 25, 2026)**
 - Effective June 1, 2026, all prime recipients are required to obtain NIH prior approval when adding a new domestic subaward to a project post-award, when the arrangement was not originally a part of the peer-reviewed and approved application.



NIH Funding Opportunities

- INCLUDE Project: Transformative Research Awards for Down syndrome (R01 Clinical Trial Not Allowed) ([RFA-OD-27-004](#)) (Released May 12, 2026)
- INCLUDE Project: Clinical Trials Phased Awards for Down syndrome Research (R61/R33 Clinical Trial Required) ([RFA-OD-27-005](#)) (Released May 13, 2026)
- Questions/Inquiries: DownSyndromeINCLUDE@mail.nih.gov



N3C - Updates



National
Clinical
Cohort
Collaborative

Where Are We Today?

Reopening

- Access to the COVID Enclave data restored
- Analytic tools available for continued research
- Stood up the Strategic Partners Committee (March)

Transitional Phase

- Bridging to the Next Phase
- All clinical data
- Governance and review processes evolve
- Architectural decoupling
 - future proof of the environment and reliance on one contractors/vendors

Looking Ahead

- Dynamic Workspaces
- Piloting data sharing models
- Scalable infrastructure to support broader research

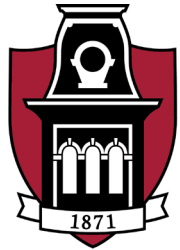


National Center
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Strategic Partner Organizations



UNIVERSITY OF
ARKANSAS

EMORY



The University
of North Carolina
at Chapel Hill

VANDERBILT
UNIVERSITY



Regenstrief
Institute

UTHealth
Houston



UT San Antonio®
The University of Texas at San Antonio



Cincinnati
Children's®

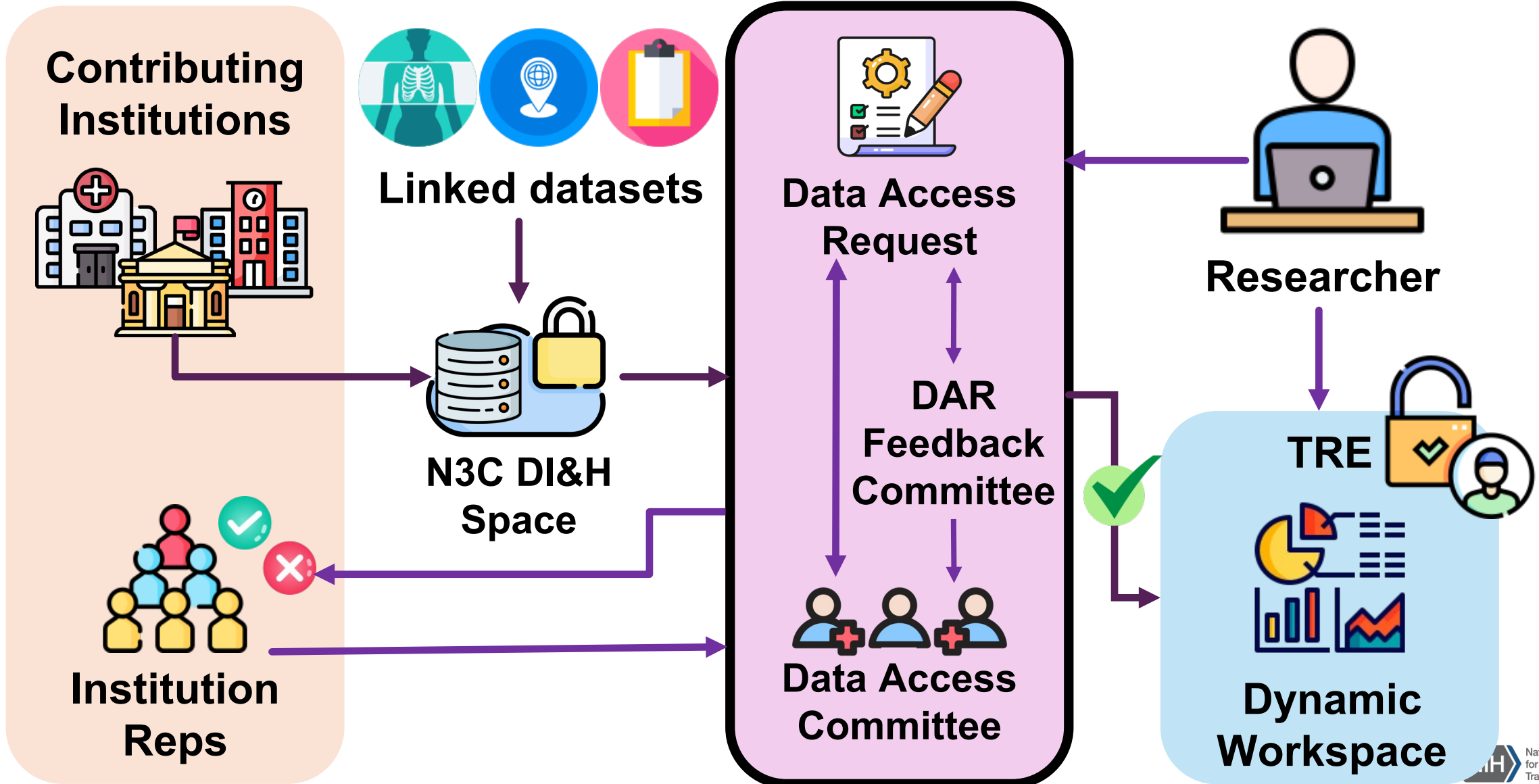


JOHNS HOPKINS
UNIVERSITY



NIH National Center
for Advancing
Translational Sciences

Co-Governed Data



Scaling CT Innovations is an HHS Priority

CTSAs in Action

The CTSA Opportunity: Scaling Clinical Trial Innovation

The CTSA consortium serves as a national "operational innovation infrastructure" designed to identify, test, and scale solutions for clinical trial barriers. By moving from local experimentation to national standardization, the consortium aims to reduce administrative burden and accelerate evidence generation.

The Collective Mission

Operational Innovation Infrastructure

Identifying and scaling approaches that reduce unnecessary burden and improve participant access.



Local Experimentation

“ Solving the “Impossible” Independently:
Addressing friction points in ways that no single institution could accomplish alone. ”

National Standardization

“ Moving to National Standardization
Transitioning from local experimentation to shared, collective solutions for the entire research ecosystem.

Priority Barriers for Innovation

Participant & Administrative Burdens



Streamlining compensation, reducing paperwork, and solving recruitment/retention as efficiency problems.

Systems & Infrastructure Innovation



Advancing alternative IRB review models and supporting decentralized or hybrid trial delivery.

Workforce & Data Interoperability



Supporting clinical research professionals and ensuring research data can be reused across systems.

Cohesive Research Ecosystem



National clinical research network
with accelerated outcomes and improved patient access



National Center for Advancing Translational Sciences

Upcoming Dates to Remember

Next CTSA Program Webinar

June 24, 2026



NCATS

COLLABORATE. INNOVATE. ACCELERATE.


 ncats.nih.gov

 [@ncats_nih_gov](https://twitter.com/ncats_nih_gov)

 [@ncats.nih.gov](https://www.facebook.com/ncats.nih.gov)

 [NIH-NCATS](https://www.linkedin.com/company/NIH-NCATS)



 National Center
for Advancing
Translational Sciences

CCOS Slide Updates

Week of May 26, 2026

K & T Visiting Scientists Consortium Group (KTVS-CG)

New CTSA Consortium Group

A Unified Model for Trainee & Scholar Engagement

- ✓ Charter approved by Steering Committee (May 11, 2026)
- ✓ Establishes a permanent Consortium Group structure
- ✓ Builds on two successful programs:
 - TL1 Visiting Scientist Working Group
 - KL2 Virtual Visiting Scholar Working Group



Purpose

- Create a **coordinated, scalable, and sustainable model** for cross-hub collaboration
- Support a **nationally connected community** of trainees and scholars

K & T Visiting Scientists Consortium Group (KTVS-CG)

Leadership Opportunities & Engagement

Now Forming Leadership Team

- Co-Chairs (K & T representation)
- Leadership Team Members (3–6)
- Activity Leads (4 program areas)



- ➔ Strategic roles guiding direction and annual priorities
- ➔ CCOS provides coordination, communications, and survey support

Get Involved

- 📣 Recruitment underway (Spring–Summer 2026)

🔗 [Leadership Interest Form](#)



Welcome to the New CCOS Homepage!

- A refreshed design
- Improved search functionality
- Hub and member directories
- Upcoming events
- Information on committees, groups, and meetings
- Featured impact story
- Latest CCOS news
- Browsable CTSA resources

Clinical and Translational Science Awards (CTSA) Program

Coordination, Communication, and Operations Support (CCOS)

Connecting translational science teams nationwide!

[Explore Hubs \(69\)](#) [Find Members \(2000+\)](#)

[Search](#)

About Us
Powering the CTSA
[About CCOS](#) [CTSA Program](#)
ncats.nih.gov

CCOS contributes to bringing the National Center for Advancing Translational Sciences (NCATS) CTSA Program together as one network. When the consortium moves in sync, ideas travel farther and patients benefit faster.

Across hubs, we align people, data, and day-to-day operations. We coordinate groups and meetings, communicate program updates and CTSA impact clearly, and streamline logistics. Program data turns into insights, and shared tools and training help teams act with confidence.

Calendar
Upcoming Events [View Calendar](#)

- Other Events**
[What Biomedicine Can Learn about Reproducibility from Social & Behavioral Research: The SCORE Project](#)
med.stanford.edu
May 26, 2025 at 5:00 AM
- CTSA Program Webinars**
[CTSA Program Webinar - May 2026](#)
us06web.zoom.us
May 27, 2025 at 1:00 PM
- Other Events**
[Research Impact Series: Evaluating Your Research Impact with Emily Zimmerman, Ph.D. and Maria Thomson, Ph.D.](#)
vcu.zoom.us
May 27, 2025 at 12:00 PM

Have an event to share?

Access the **homepage**, click **“View Calendar”** and then use the **“Pitch an Event”** button to open the event submission form.

Calendar

Have an event to share?
Feature your upcoming event in our community calendar!

[Pitch an Event](#)

CTSA Program Impact Now on the CCOS Website

New CTSA Program Impact Section

- Describes what CTSA Impact is
- Highlights high-level impact indicators
- Includes an Impact Story Directory

Future releases to include:

- CTSA publications repository
- Communities of practice
- Best practices, tools, and other resources

Have an Impact Story that you'd like posted?

- Follow the Impact Story Guidance Document: <https://ccos-cc.ctsa.io/help/help-topics#share-content>
- Use the Impact Story Submission Form: <https://forms.gle/VCD8T3xZuq949Q4C9>

CTSA Program Impact

How CTSA grants accelerate clinical research, improve patient outcomes, and serve communities.



709	35.4K	513	5590	145.3K
Clinical Trials	Health-Policy Citations	Medical Patents	Grants Funded	Scientific Publications

Updated April 9, 2026

Share Your Work with the CTSA Community

Events

News Articles

Impact Stories

Examples:

Meetings, symposia, webinars, trainings, workshops

Event recaps, notable publications, awards, profiles, new resources

Success stories, case studies, or comparative analyses with **clear & measurable outcomes** across TSBM domains

How to Submit:

[CCOS Calendar](#) -> **Pitch an Event** button

[CCOS News](#) -> **Pitch an Article** button

[Impact Story submission form](#) (direct link)

For more info:

[CCOS Events Guidance Document](#) (in development)

[CCOS News Article Guidance Document](#)

[CCOS Impact Story Guidance Document](#)

All submissions can be promoted in *The Ansible* and/or on CCOS social media platforms (X, LinkedIn, and Bluesky), by checking a box during submission.

*All Impact Stories posted in the first release will be shared via CCOS social media over the next few weeks.

CTSA Meetings Snapshot: June 2026

Enterprise Committees

June 1 | Collaboration & Engagement | 1:00 PM

June 5 | Biostatistics, Biomedical Informatics, & Data Science | 1:00 PM

June 24 | Integration Across the Lifespan | 1:00 PM

Working Groups

June 2 | Pediatric Clinical Trials | 12:00 PM

June 3 | Learning Health Systems | 12:00 PM

June 3 | Translational Science Competency-Based Assessment | 1:00 PM

June 8 | Engaging Individuals with Disability | 1:00 PM

June 10 | Principles for AI Translation in Healthcare | 3:00 PM

June 11 | Real World Data Workforce Development | 12:00 PM

June 15 | Translational Impacts | 3:00 PM

June 18 | Translational Case Studies in Commercialization | 4:00 PM

June 25 | Translational Science Case Studies | 2:00 PM

June 26 | Overcoming Barriers to Women's Health Research | 11:00 AM



CTSA Program

June 24 | CTSA Program Webinar | 2:00 PM

Consortium Groups

June 9 | KL2/K12 PI Directors | 1:00 PM

June 17 | Administrators | 1:00 PM

[CCOS Calendar](#)



CCOS Reminders

Join CTSA Groups on the CCOS Website:

- Step by step instructions [here](#) to join CTSA groups from your CCOS member account.

Need a CCOS Account?

- [Getting Started Page](#) has detailed information or click [here](#) to get started.
- Questions? Please email support@ccos.ctsa.io

CCOS All Communications Email List:

- Click here: <http://eepurl.com/iw9nZA> to join the list and receive CTSA Program communications and updates.
- Add communications@ccos.ctsa.io to your contacts list to prevent important CCOS emails from ending up in your spam folder



COORDINATION



CCOS Feedback Form

We want to hear from you!

Share your feedback and suggestions about:

- Meeting Content
- Technical Issues
- Communication Before and After the Meeting
- Group Webpage on CCOS Website
- Group Collaborative Space
- Anything else that's on your mind



Use this [Link](#) or Scan the QR Code to Provide Feedback on this Group

**Feedback will be reviewed by CCOS Logistics Lead and CCOS Project Manager*

CDER Center for Clinical Trial Innovation

Meghana Chalasani, MHA

Associate Director for Clinical Trial Innovation
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

CTSA Program Webinar 2026
May 27, 2026

For years, CDER has championed clinical trial innovation



These efforts have enhanced the design and conduct of clinical trials intended to generate evidence of safety and effectiveness of therapies.

Key Programs

- > Complex Innovative Trial Designs
- > Digital Health Technologies
- > Drug Development Tool Qualification
- > Model-Informed Drug Development
- > Patient-Focused Drug Development
- > Rare Disease Endpoint Advancement
- > Real-World Evidence

Additional Focus Areas

- > Artificial intelligence and machine learning
- > Decentralized clinical trial designs
- > Enrollment of participants from underrepresented populations
- > International harmonization
- > Public-private partnerships and external collaborations
- > Simpler trials that could more easily be integrated into clinical practice

Drug development landscape has been changing dramatically in recent years, which requires innovation



Key Drivers:

- **Multiple approved drugs for many chronic diseases** – reduced investment and development in future drugs
- **Rapidly expanding understanding of diseases'** genetics, genomics, molecular defects and molecular disease “drivers”
- **New drug platforms** enabling targeting of previously “undruggable” targets
- Increased focus on the **need for clinical trial participant diversity**
- Increased focus on **health equity and inclusion of underserved populations** in clinical trials

Leading to:

- More drug development programs targeting **rare diseases**
- More programs targeting **molecular subtypes** of diseases (both rare and common), or targeting patients with **resistant or late-stage disease**
- **Innovative trial approaches** – point of care trials, pragmatic trials, master protocols, adaptive designs, use of Bayesian statistics, real-world evidence, decentralized trial practices
- **Greater collaboration** across government, industry, academia and other interested parties
- **Increased cross-discipline coordination** within FDA

C3TI aims to improve the efficiency of drug development through innovative clinical trial approaches.

Stakeholder Feedback

Perception of Internal Siloes

External stakeholders seek assurance that FDA pilot programs and review teams are aligned and sharing lessons learned.

Gap Between Guidance and Implementation

Stakeholders seek examples and resources that help bridge the gap between FDA guidance and real-world implementation.

Desire for Enhanced Communication Pathways

Stakeholders seek additional opportunities for communication with FDA about product-specific innovative approaches.

C3TI Goals

Facilitate Collaboration

across CDER's innovation programs.

Share Knowledge

with FDA staff, industry, academia, advocates, and others.

Expand Opportunities

for drug developers to engage with CDER experts.

C3TI collaborates with and is supported by a team of leaders and experts from across CDER



Innovation Forum

C3TI's Innovation Forum **brings together CDER innovation programs** quarterly to share updates and encourage alignment. Through the forum, C3TI also **creates an internal newsletter**.

C3TI Compass

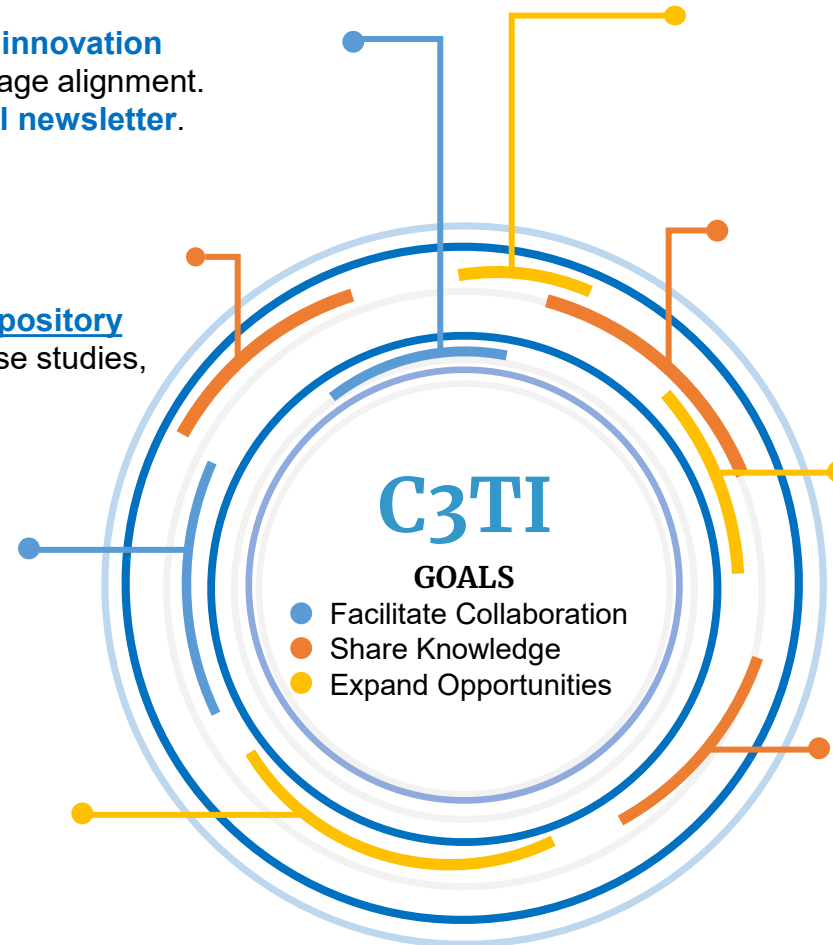
The [C3TI Compass knowledge management repository](#) connects parties to FDA guidance documents, case studies, and related resources.

Internal Outreach

Engage with CDER staff through internal outlets, including Office newsletters, SharePoint pages, and staff meetings.

C3TI Champions

CDER staff who partner with C3TI to help promote and nurture a culture of innovation.



C3TI Demonstration Program

Expand structured engagement opportunities between CDER experts and drug developers.

C3TI Rounds

A speaker series to **discuss case studies** and experiences with clinical trial innovation.

C3TI Listening Sessions

Provide **opportunities to hear directly from external organizations** about emerging trends, challenges, and innovations in clinical trials.

External Engagement

Leverage multiple channels, including the [FDA webpage](#), [quarterly newsletters](#), presentations, and public workshops, to **disseminate knowledge and updates** to industry, academia, patient groups, and others.

C3TI leads a demonstration program to expand structured engagement opportunities between CDER experts and drug developers.

Enhance Communication

- ✓ Offer **early, direct engagement** between drug developers and CDER review teams and subject matter experts
- ✓ Provide **timely, focused feedback** on innovative trial elements, reducing uncertainty

Prioritize Speed

- ✓ Accept project proposals on a **rolling basis**
- ✓ Provide **preliminary comments** on innovative trial elements with program acceptance correspondence
- ✓ Design **tailored engagement plans** to support critical milestones such as protocol development and study start-up

Share Lessons Learned

- ✓ Share insights from implementation experiences to **advance understanding and promote broader adoption** of innovative trial approaches
- ✓ Develop and disseminate case studies to **support drug developers and reviewers** in applying innovative approaches

Current
Project
Areas:

Bayesian Statistical
Analysis (BSA)

Selective Safety Data
Collection (SSDC)

Streamlined Trials
Embedded in clinical
Practice (STEP)

Overview

Bayesian methods can enhance trial design and conduct by:

- ✓ Providing probability statements about treatment effects
- ✓ Supporting trial monitoring
- ✓ Unifying evidence across multiple endpoints
- ✓ Formally incorporating credible prior data into the primary analysis
- ✓ Leveraging all relevant trial data in subgroup analyses

Eligibility Criteria for C3TI Demonstration Project

- Trial must be a phase 3 efficacy or safety trial with a simple design, such as a trial with a non-adaptive or straightforward sequential design (e.g., a trial with the potential for stopping early for efficacy or futility).
- The Bayesian analysis may be used for one of the following:
 - Pre-specified primary analysis
 - Supplemental analysis of the primary endpoint in the overall study population and/or in relevant subgroups (i.e., for subgroup analysis).
 - Trial monitoring

Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products

Guidance Overview

The intent is to provide guidance on the information needed to support decisions at various stages of drug development.

- Situations Where Bayesian Methods Have Been Used
- Success Criteria and Operating Characteristics
- Prior Distributions
- Estimands and Missing Data
- Software and Computation
- Documenting and Reporting Bayesian Analyses

Link to Guidance: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-bayesian-methodology-clinical-trials-drug-and-biological-products>

Overview

Selective Safety Data Collection (SSDC) refers to a planned reduction in the collection of certain types of data in a clinical investigation for drugs when:

- ✓ The drug has a well-characterized safety profile
- ✓ Continued collection of common, non-serious adverse events or routine laboratory assessment is unlikely to provide additional clinically important knowledge

Eligibility Criteria for C3TI Demonstration Project

A late-stage pre- or post-marketing trial for a drug where the safety profile, with respect to commonly occurring adverse events, is well understood and documented. This may include:

- Trial for an approved drug, seeking a new indication in a similar population or seeking to expand the label to include additional endpoints in the same patient population
- Safety trial investigating a very specific safety concern (e.g., a postmarketing requirement under the 2007 Food and Drug Administration Amendments Act (FDAAA))
- Trial designed to provide additional evidence of efficacy when current data support a well-characterized safety profile

E19 A Selective Approach to Safety Data Collection in Specific Late-Stage Preapproval or Post-Approval Clinical Trials Guidance Overview

The intent is to provide internationally harmonized guidance on the use of SSDC that may be applied in specific pre-approval or post-approval late-stage clinical trials.

- Introduction
- General Principles
- Implementation of SSDC
- Practical Considerations for SSDC
- Relationship with Other Guidances/Regulations
- Glossary
- References

Link to Guidance: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e19-selective-approach-safety-data-collection-specific-late-stage-pre-approval-or-post-approval>

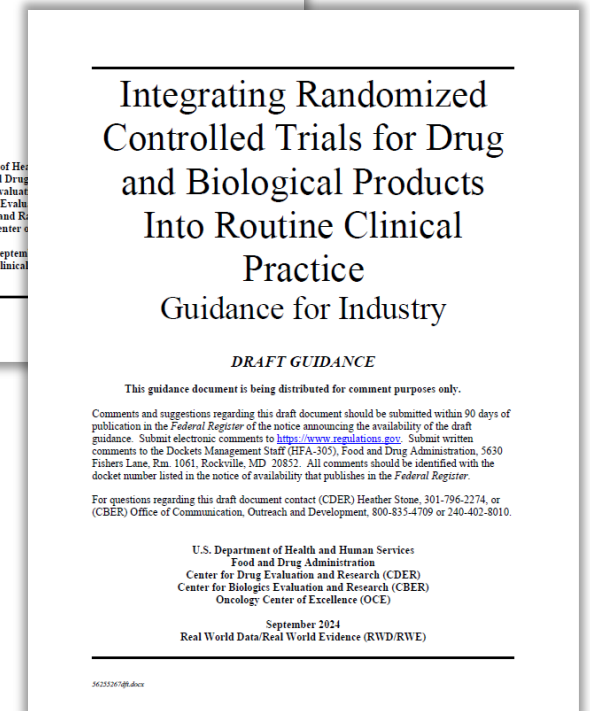
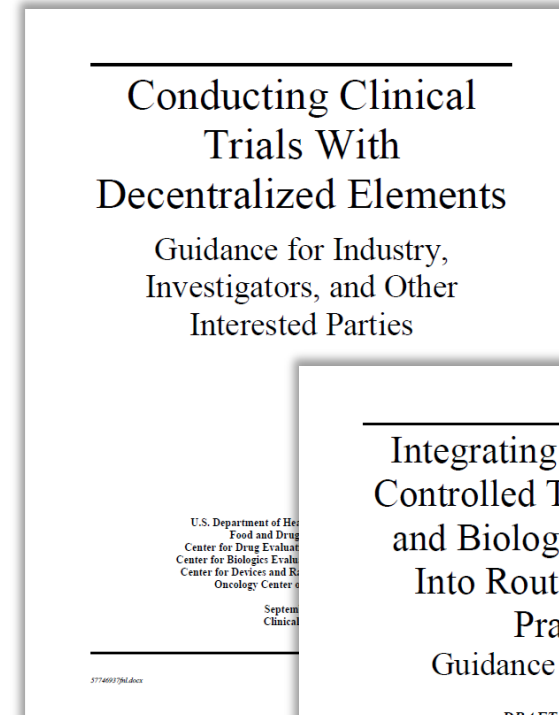
Overview

Streamlined Trials Embedded in clinical Practice (STEP) may include:

- ✓ Broad eligibility criteria
- ✓ Limited visits and procedures outside of routine clinical care
- ✓ Decentralization of procedures that can be done outside of designated research sites
- ✓ Use of real-world data to obtain outcomes

Eligibility Criteria for C3TI Demonstration Project

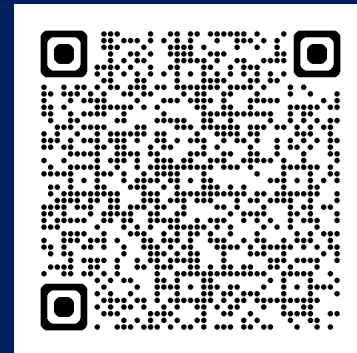
- The trial incorporates design elements that reflect clinical practice to improve trial efficiency and enhance patient centricity while maintaining patient safety and data integrity.
- The trial fits one of the following criteria:
 - In pre-market development, when the safety profile is reasonably well-defined.
 - A post-approval trial (either that the sponsor initiated or in response to a post-marketing requirement), wherein the population, trial procedures, and endpoints can all be appropriately incorporated into a large simple trial.



Proposal Content

- **Product and application information:** Product name, pre-IND or IND application number, proposed indication(s), context of product development, background on the development program, timeline for trial conduct, and whether the trial will be subject to review by other regulatory agencies.
- **Discussion topics:** A list of topics/questions for discussion with CDER staff regarding elements related to the applicable demonstration project.
- **Trial design overview:** High-level summary of trial design, conduct, and analysis methods, including study design, data sources, and/or proposed analyses most relevant to the applicable demonstration project.
- **Disclosure:** If the proposal is accepted, details provided in the proposal will be considered for disclosure unless specified otherwise. Shared details would aim to reflect general principles and innovative aspects, while maintaining the necessary confidentiality of proprietary or sensitive information.

To learn more about the proposal submission process for the C3TI Demonstration Program, visit www.fda.gov/C3TI.



C3TI in Action | Enhancing Engagement and Knowledge Sharing



C3TI facilitates a speaker series that provides an internal forum for experts to discuss case studies and their experiences with clinical trial innovation.

C3TI Rounds

There are two types of C3TI Rounds: Briefs and Conversations. Briefs feature internal experts, including review staff, while Conversations welcome external experts from academia and industry.

Briefs

4 Sessions with
FDA Speakers



Conversations

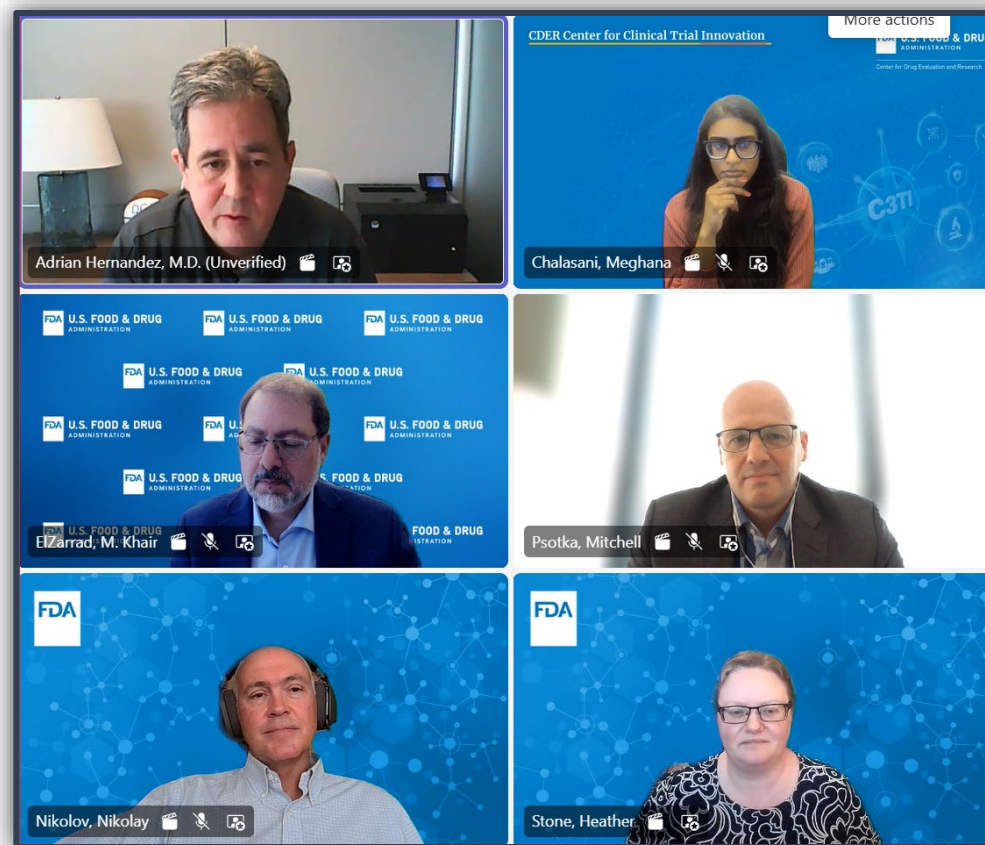
5 Sessions with
External Speakers

Topics include:

- Specific Reviews of Innovative Clinical Development Programs
- Registry-based Randomized Controlled Trials
- Quality by Design/Critical to Quality Assessment

650

Average Attendees per Session



A C3TI Rounds Conversation with Dr. Adrian Hernandez (top left) on Integrating Trials into Routine Clinical Care

C3TI in Action | Enhancing Engagement and Knowledge Sharing



C3TI presents at events, hosts listening sessions, and convenes public workshops to improve transparency and strengthen engagement with external stakeholders.

External Presentations

C3TI leverages a variety of forums to disseminate knowledge and updates to industry, academia, patient groups, and others.

Since 2024, C3TI has conducted **65+** external presentations.

C3TI Listening Sessions

Listening sessions provide C3TI with the opportunity to hear directly from external organizations about emerging trends, challenges, and innovations in clinical trials.

Since 2024, C3TI has hosted **6** listening sessions.

Public Workshops

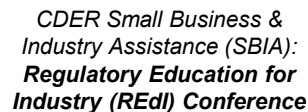
Public workshops **foster dialogue that informs C3TI's priorities** and ensures initiatives incorporate stakeholder feedback.

March 19, 2024

Enhancing Adoption of Innovative Clinical Trial Approaches

April 14, 2026

Scaling Innovative Clinical Trial Approaches: Challenges, Progress, and Opportunities



C3TI in Action | April 2026 Public Workshop



On April 14, 2026, C3TI and the Duke-Margolis Institute for Health Policy hosted a public workshop titled [Scaling Innovative Clinical Trial Approaches: Challenges, Progress, and Opportunities](#).

Key Themes Heard at the Workshop

Clinical Trials are at an Inflection Point

Trial design and conduct are evolving, with progress seen as dependent on execution and systemic change. Early cross-stakeholder collaboration and embedding research into routine care were highlighted as priorities for advancing accessibility and scalability.

Rationale for Streamlined Trial Designs is Growing

Prior experience (e.g., pandemic-era) supports movement toward simpler, more adaptive designs. Rigorous upfront planning, regulatory alignment, and risk-mitigation strategies were identified as critical to maintaining data quality while reducing patient burden.

Global Alignment Needed to Support Broader Adoption of Innovations

Coordinating across multiple regulatory authorities and managing operational complexity present ongoing challenges to adopting innovative trial approaches. Clearer, more aligned international expectations and quality-by-design principles were identified as important enablers.

Need for Consistent and Clear Communications

Meaningful progress requires clear problem definitions, committed leadership, and a shared sense of urgency across the ecosystem. Pilots designed as scalable pathways were discussed as one mechanism for driving broader, lasting change.



C3TI centralizes CDER's clinical trial innovation resources, improving communication and access through its webpage, newsletter, and knowledge repository.

Webpage and Newsletter

C3TI maintains a dedicated FDA webpage that serves as a **one-stop shop** for CDER's clinical trial innovation information.

Quarterly C3TI newsletters provide **updates on initiatives, resources, and upcoming events**, helping stakeholders stay informed.

21,000+

Webpage Visitors

18,700+

Newsletter Subscribers

Scan to learn more



www.fda.gov/C3TI

C3TI Compass

The C3TI Compass knowledge management repository **connects parties to FDA guidance documents, case studies, and related resources**. C3TI Compass features tailored user experiences for FDA staff and external stakeholders.

C3TI Compass has 60+ resources related to:

AI / Machine Learning

Good Clinical Practice

Bayesian Approaches

Master Protocols

Clinical Trials with Decentralized Elements

Integrating Trials into Routine Clinical Practice

Complex Innovative Trial Designs

Real-World Evidence/Data

Digital Health Technologies

Selective Safety Data Collection

C3TI Goals

Facilitate Collaboration

across CDER's innovation programs.

Share Knowledge

with FDA staff, industry, academia, advocates, and others.

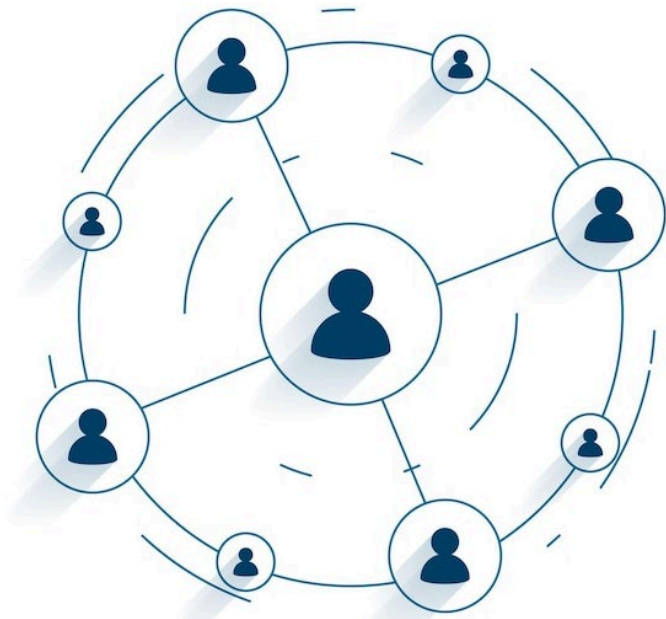
Expand Opportunities

for drug developers to engage with CDER experts.

Looking Ahead

- Integrate insights from April 14 public workshop
- Strengthen the demonstration program
- Develop training programs informed by recent training needs assessment
- Continue and enhance current portfolio of activities to drive collaboration across CDER
- Expand internal and external outreach efforts

- C3TI provides a single CDER point of contact for non-product-specific questions related to clinical trial innovation.
- Serves as a “switchboard,” triaging inquiries and connecting individuals to the relevant CDER program or expert.
- If you are unsure where to start or who to contact, C3TI is a helpful starting point.



Contact Us:



Website:
www.fda.gov/C3TI



Email: CDERclinicaltrialinnovation@fda.hhs.gov



Subscribe to Newsletter: <https://public.govdelivery.com/accounts/USFDA/subscribers/qualify>

Where and how to acknowledge CTS award funding in progress reports

*Under the 2024
NIH Public Access Policy*



National Center
for Advancing
Translational Sciences

HOW TO DEFINE A
"SHARED RESOURCE"
Under Management of
a CTSA?

CAN PUBLICATIONS
BE MOVED FROM
SECTION C.1 TO
SECTION B.2 PRIOR TO
RPPR SUBMISSION?

If so, who is responsible?

**NORTHWESTERN
TEAM**

Kristi Holmes
Pamela Shaw
Karen Gutzman
Richard D'Aquila

NCATS TEAM

Erica Rosemond
Michael Kurilla

ROCHESTER TEAM

Karen Wilson

THE QUESTIONS

The team

The team began discussions by email, then met via Zoom to clarify, consolidate and discuss the best way to convey the information

RPPR

Products

(Section C.1)

Must include

ALWAYS INCLUDE IN C.1:

Any publication resulting from research receiving direct funding support (including salary) from the CTSA award must be reported in section C.1 of the RPPR.

Even if the primary funding is from elsewhere, if CTSA funds are used, the publication must be reported in C.1.

HOW DO PAPERS GET LISTED IN C.1?

When a manuscript is linked to an NCATS award in any user's NCBI My Bibliography or during upload to NIHMS, that record is also imported into the CTSA PI's My Bibliography. In eRA Commons, the RPPR pulls records from the PI's My bibliography into section C.1

SHARED Resources

NOT-OD-16-079

Resources developed through an NIH award that are made available to others, where the award’s only contribution to a publication is the resource itself (not intellectual input, design, analysis, or authorship)

NIH’s Research Tools Policy

NIH’s long-standing Research Tools Policy uses a broad definition of “research tools,” including materials, methods, equipment, protocols, software, and similar products, which are commonly treated as “shared resources” in CTSA contexts when centrally managed

In a CTSA Context

A centrally managed service, facility, platform, dataset, tool, or workforce capability developed or maintained with CTSA support, made available to multiple investigators, where CTSA personnel do not/may not meet authorship criteria on resulting publications.



- Recruitment services, registries, and cohort feasibility tools
- Clinical research units, labs, or regulatory support services
- Data platforms, analytic pipelines, or software tools
- Biostatistics or informatics consultation cores
- Pilot infrastructure that enables others’ science but does not shape hypotheses or analysis

CONSIDER NIH Public Access Compliance

RPPR

Products (C.1)?

Or

Accomplishments (B.2)?

All publications listed in Section C.1 are subject to NIH Public Access Policy compliance

Must have PMCID and be available in PMC upon date of publication

Publications reported in section C.1 are non-compliant if they do not cite the award in-text

[2024 NIH Public Access Policy](#) (last paragraph)

If:

- The only contribution from the NIH award is a shared resource, &
- Award personnel are not authors

Then:

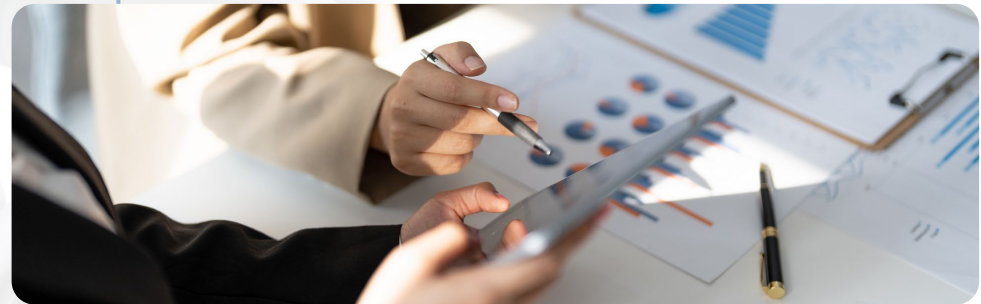
- Publications should be reported in the narrative in section B.2

In other words

A publication that would otherwise appear in C.1 is appropriately reported in B.2 instead, provided it meets the shared resource criteria.

WHO IS RESPONSIBLE FOR THIS DECISION?

- The Authorized Organization Representative (AOR) and
- The PD/PI(s) for the CTSA award



This is not retroactive “movement” after RPPR submission; it is a classification decision made prior to RPPR submission.

NOTE

If a manuscript has been associated with an award during deposit to PMC via the NIH Manuscript Submission system, it will be locked into section C.1 of the RPPR – see slide #8

MANY CTSA_s HANDLE THIS BY:

1. Maintaining an internal review step where cores or pilot administrators flag publications as:
 - “Shared resource only” vs.
 - “CTSA intellectual contribution”
2. Having final determination made by the CTSA PI or designated RPPR lead
3. Documenting the rationale internally (not required by NIH, but helpful for consistency and audits)



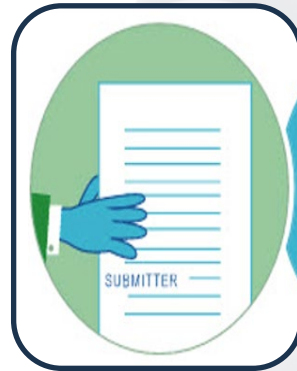
PRACTICAL CTSA GOVERNANCE (Best practice)

Otherwise

How else do papers get into RPPR C.1?

Author (or occasionally publisher) deposits to PMC via NIHMS

At the time of deposit, the CTS award number is associated with the manuscript record



01

02



Manuscript record is automatically pulled from NIHMS into CTSA PI's NCBI My Bibliography

Because of award association in NIHMS

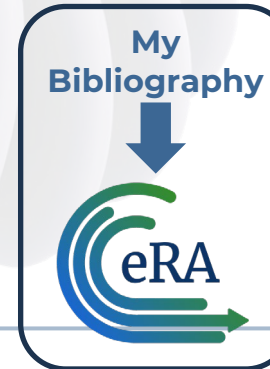
Award is locked to manuscript's My Bibliography record

The award will have a gold (yellow) lock in the My Bibliography award panel



03

04



Manuscript record is automatically pulled from the PI's My Bibliography into section C.1 of the RPPR

These associations are difficult to break

NIH PA Compliance Concerns

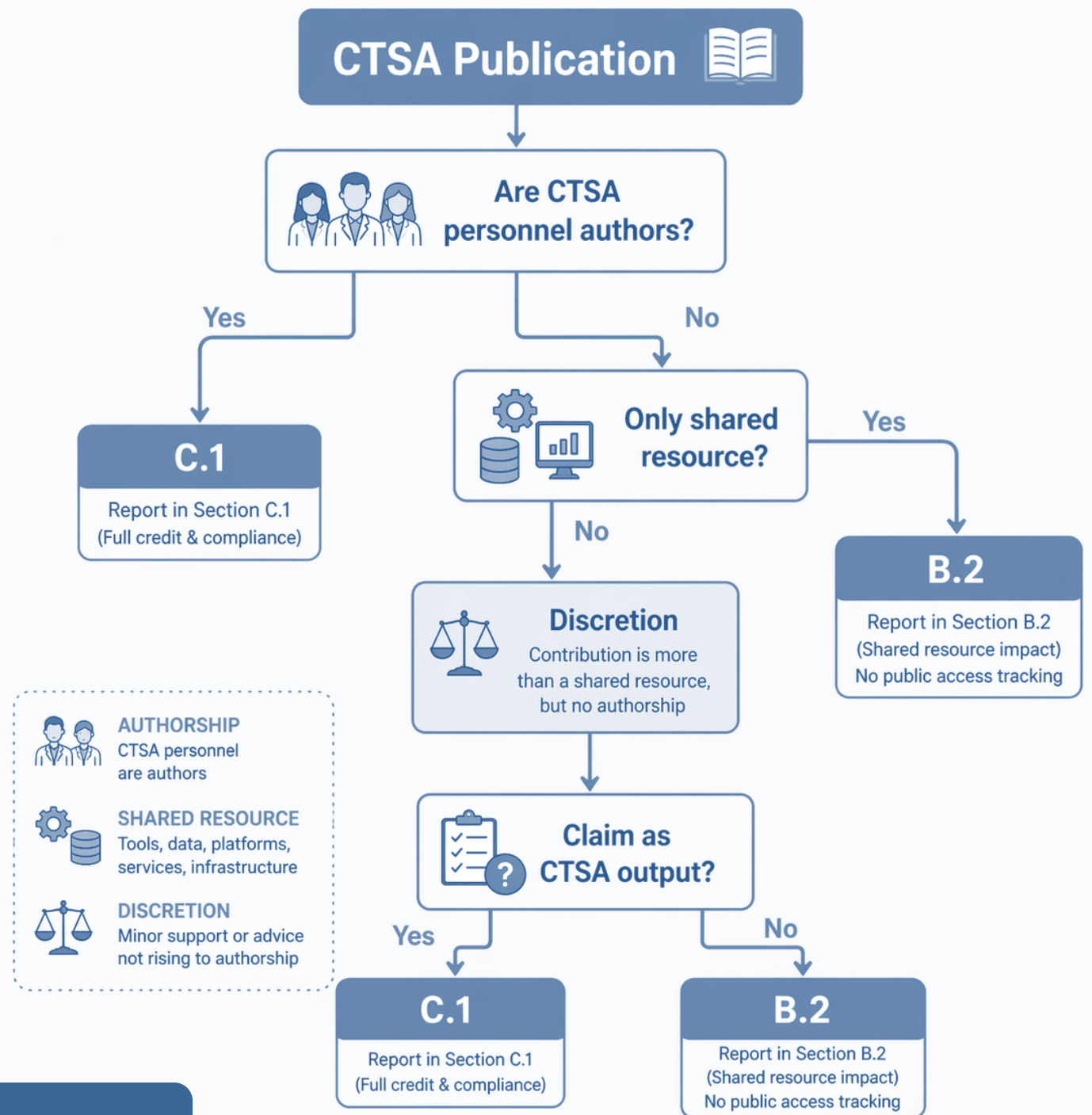
If a publisher deposits a manuscript to PMC via NIHMS and places it under an embargo, **the “Reviewer” named for the record can reset the embargo to 0 months.**

If publisher deposits a manuscript to PMC *directly* and places an embargo on it, this embargo can only be removed by the publisher (after the author pays OA fees or convinces the publisher to lift the embargo)

Decision Tree



Key Principle: Classification is based on the nature of the CTSA contribution, not on public access compliance.



Made by Karen Gutzman,
Head of Research Impact and
Communications,
Galter Health Sciences Library,
Northwestern University Feinberg
School of Medicine and NUCATS
Using ChatGPT

OPTIONS for open access

Resources: (And check your library!)

- Some libraries have subscriptions
- <https://libguides.urmc.rochester.edu/OA>
- <https://libguides.galter.northwestern.edu/NIH-public-access/green-oa-publishers>

Types of Open Access

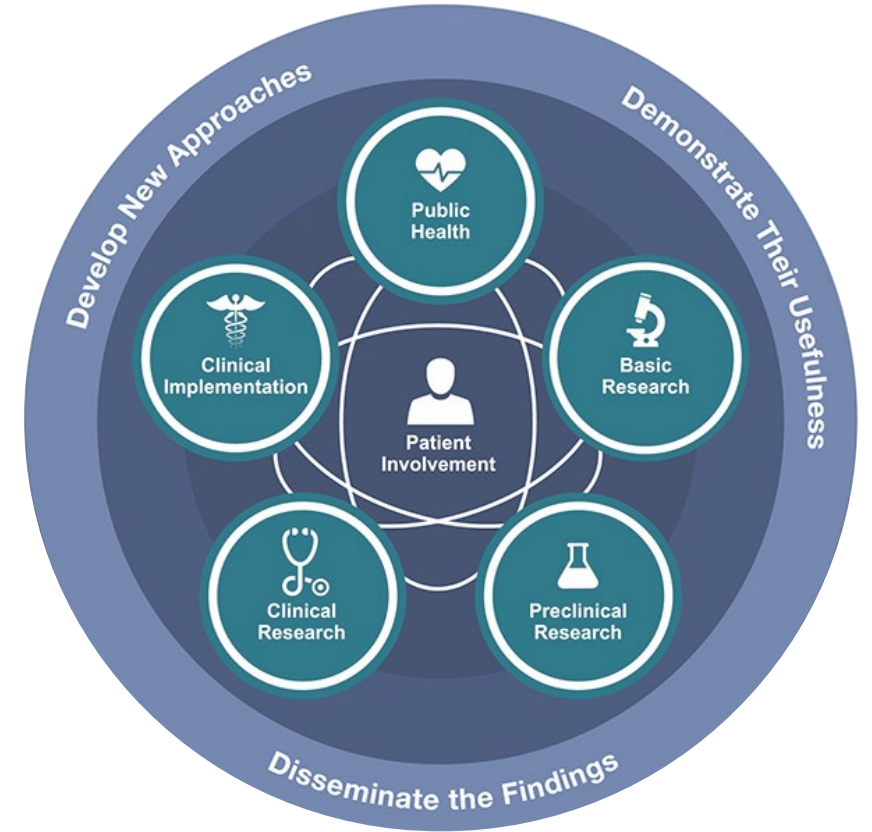
Gold OA	Published immediately OA on journal website; author or funder pays an article processing charge (APC). Permanent, unrestricted access · CC license · common in STEM · APC typically \$1,000–\$5,000+
Diamond OA	Published immediately OA with no cost to authors or readers; funded by institutions, societies, or grants. No APC · community-run or subsidized · often smaller/society journals · growing in humanities & social sciences
Green OA	Author deposits a manuscript version in a repository; journal article itself may remain paywalled. No APC · preprint, accepted MS, or VOR deposited · embargo periods may apply (6–24 months) · e.g. PubMed Central, arXiv
Bronze OA	Publisher makes article freely available on its site but without an explicit open license. Free to read but reuse rights are restricted · access can be revoked · not considered fully 'open'
Hybrid OA	Subscription journal that allows individual articles to be made OA upon payment of an APC. Rest of journal remains paywalled · criticized for 'double dipping' · common via Read & Publish funder deals

Figure generated by Claude.ai

Taxonomy based on SPARC, DOAJ, and Sherpa/RoMEO definitions

*THANK
YOU!*

Questions?



Next CTSA Program Webinar



June 24th, 2026 at 2:00pm Eastern



Register [here](#)



Updates on the CCOS [Webinar Page](#)