

CTSA Program Webinar

February 25, 2026

Agenda

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Lauren Fitzharris, M.P.H., P.M.P. CCOS
2:01 – 2:10 PM	NCATS/CTSA Updates	Michael Kurilla, M.D., Ph.D. DCI/NCATS
2:10 – 2:15 PM	CCOS Updates	Lauren Fitzharris CCOS
2:15 – 2:30 PM	Translational Case Studies in Commercialization CTSA Working Group	Andrew Kant, M.S. University of North Carolina- Chapel Hill
2:30 – 3:00 PM	Update on NCATS National Clinical Cohort Collaborative (N3C)	Michael Kurilla Rebecca Baker, Ph.D., NCATS Kristen Hansen, Ph.D., NCATS Chris Dillon, NCATS
3:00 PM	Adjourn	



NCATS

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NCATS/CTSA Program Updates

Michael G. Kurilla, MD, PhD

Director, Division of Clinical Innovation
NCATS

February 25, 2026



NIH National Center
for Advancing
Translational Sciences

CTSA Program NOFO Updates

- Due to unforeseen circumstances a **Notice to Change the Award Information for [PAR-24-272](#) (the UM1 NOFO)** for receipt dates January 28, May 28 and September 28, 2026 has not been released. This notice was to reflect the update of the “Hub Tiers” with respect to the **5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, PLUS 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s) based on FY2020-FY2024 NIH Funding Data.**
- Because this NOFO suite is part of a required set of companion applications, new UM1s and any companion applications being submitted for the first time will not currently be able to submit applications for the January 28, 2026 receipt date (October 2026 Council cycle). Resubmission of companion applications (K12, T32, R25, RC2s) for the January 28, 2026 receipt date can be submitted to their NOFOs if the UM1 has been awarded or is under consideration.
- **We have released the CTSA partner list for FY25 on our website:** <https://ncats.nih.gov/research/research-activities/ctsa/applicant-information/CPUBRT>
- Please reach out to CTSANOFQQuestions@mail.nih.gov if you have questions.
- We will update the community when we have more information.



2026 Supporting Instructions for the CTSA Program RPPRs

- Supporting Instructions for the CTSA Program are *supplemental* to the NIH RPPR Instructions ([here](#))
 - <https://ncats.nih.gov/research/research-activities/ctsa/ctsa-program-governance-guidelines/rppr-instructions>
- Questions? CTSARPPRQuestions@mail.nih.gov
- Reminder about reporting things in the RPPR: if a budget item / activity has been removed in the past year that you are reporting on THEN DO NOT ADD INFORMATION TO THE RPPR on said activity
 - Unallowable activities that are reported in the RPPR may result in termination of the award (references: [NOT-OD-26-009](#) and [NOT-OD-26-007](#))



NIH Notices and NOFOs

- NIH Requires Use of the eRA Prior Approval Module for the Submission of ALL Prior Approval Requests ([NOT-OD-26-026](#)) (Released Jan 21, 2026)
 - All Prior Approvals must be submitted through eRA starting **2/23/26** (inclusive of JIT materials). **WARNING: VERY LITTLE can now be received by email – plan accordingly.**
 - NCATS is in the process of updating guidance related to pilot project prior approval submissions to align with this new policy requirement.
 - The main change for HSS and VAS prior-approvals is that the AOR will need to submit a prior-approval request to the eRA prior-approval module and NOT to the NCATS PRIOR APPROVAL REQUEST email box (NCATSPRIORAPPROVALREQUEST@mail.nih.gov). The use of the mailbox will not be allowed for most prior approval submissions.
 - **WARNING:** deviations and exceptions to prior approval requests will only be considered in extremely rare circumstances and require NIH prior approval.



NIH Notices and NOFOs

- Basic Experimental Studies in Humans (BESH) Will No Longer Be Considered Clinical Trials by the NIH ([NOT-OD-26-032](#)) (Released Jan 29, 2026)
 - Although BESH research, which produces fundamental information about biology or behavior, might eventually inform advances in health, it is not conducted with the express intent of changing clinical practice or health but rather aims to understand fundamental aspects of phenomena without immediate clinical applications.
 - Therefore, BESH research is no longer considered to meet the NIH definition of a clinical trial.
 - Effective with applications submitted to due dates on or after **May 25, 2026**, BESH will no longer be considered clinical trials by the NIH.
 - Going forward, BESH will not have to follow the requirements for clinical trials, including registration and reporting in ClinicalTrials.gov.



NIH Notices and NOFOs

- NIH No Longer Requires Advanced Permission for Conference Grant Applications ([NOT-OD-26-040](#)) (Released Feb 10, 2026)
 - As a reminder, applications can communicate specific assignment preferences to the Division of Receipt and Referral using the [PHS Assignment Request Form](#).
 - Conference grant applications that buttress CTSA Program goals will be considered for support by the CTSA Program. Please email Gallya Gannot (Gallya.Gannot@nih.gov) if you have interest in submitting
 - Conference grants supported with funding from the CTSA Program must:
 - be from a primary CTSA institution or a CTSA partnering institution,
 - address the CTSA Program goals, and
 - have consortium-wide impact and/or are intended for participation by multiple CTSA.
 - <https://ncats.nih.gov/funding/conference-grant-information>



Compliance with Publications

- **Revision: Notice of Updated Effective Date for the 2024 NIH Public Access Policy ([NOT-OD-25-101](#)) (Released April 30, 2025)**
 - This notice alerts the community that the 2024 NIH Public Access Policy goes into effect July 1, 2025 instead of December 1, 2024.

The 2024 NIH Public Access Policy requires:

- Submission of an electronic version of the Author Accepted Manuscript to PubMed Central upon its acceptance for publication for public availability **without embargo upon the Official Date of Publication**;
- An acknowledgment in the Author Accepted Manuscript and Final Published Article that satisfies the requirements in the NIH Grants Policy Statement (GPS) regarding communicating and acknowledging federal funding ([GPS 4.2.1](#) and [GPS 8.2.1](#)), as well as analogous requirements for acknowledging federal funding as incorporated into the terms of Other Transaction agreements and applicable contracts; and
- When an Author Accepted Manuscript is submitted to NIH¹, agreeing to a standard license that mirrors that of the Government Use License at [2 CFR 200.315](#), or its successor regulation, explicitly granting NIH the right to make the Author Accepted Manuscript publicly available through PubMed Central without embargo upon the Official Date of Publication.



Compliance with Publication Reporting in RPPRs

- Publications resulting from grant support must be reported in the RPPR per the NIH Public Access Policy in order to advance science and improve human health. NIH makes the peer-reviewed articles it funds publicly available on PubMed Central.
- It is entirely possible that RPPRs will contain a publication involving grant activity that occurred prior to Fiscal Year 2025 and do not align with agency priorities.
- The recipient cannot remove said publication. All publications supported by the grant must be reported.
- The recipient cannot change the past and must report activity accordingly.



Compliance with Common Forms for Biographical Sketch and Current and Pending (Other) Support

- **NIH's Implementation of Common Forms for Biographical Sketch and Current and Pending (Other) Support for Due Dates on or after January 25, 2026 ([NOT-OD-26-018](#)) (Released December 2, 2025)**
 - **Purpose:** NIH is adopting the Common Forms for Biographical Sketch and Current and Pending (Other) Support as per the White House Office of Science and Technology Policy (OSTP) memorandum on [Policy Regarding Use of Common Disclosure Forms](#).
- **An important reminder:** institutions must maintain internal controls (e.g., policies and procedures) for disclosure, which must include training on these policies and procedures for senior/key personnel.
- **Adjusted Timeline for NIH's Implementation of Common Forms ([NOT-OD-26-033](#)) (Released February 4, 2026)**
 - **Effective Date:** Use of the Common Forms for Biographical Sketch, Current and Pending (Other) Support and NIH Biographical Sketch Supplement will be required for application due dates and all JIT, RPPR, and Prior Approval submissions:
 - NIH will be extending the **current leniency period through May 2026**
 - During this leniency period, NIH will provide a warning when the Common Forms are not used but will not withdraw applications that don't comply with the use of the Common Forms
- You will be required to use [SciENcv](#) to complete Common Forms (i.e., Biographical Sketch, Current and Pending (Other) Support) and the NIH Biographical Sketch Supplement to produce digitally certified PDF(s) for use in application submission.
- **Incomplete, outdated and/or inaccurate Common Form submissions will be returned and will result in award delays and/or compliance action.**

<https://grants.nih.gov/policy-and-compliance/implementation-of-new-initiatives-and-policies/common-forms-for-biosketch>



Reminder: Pilot Programs supported with the UM1

- Pilot projects on the UM1 can ONLY be conducted under Element D/Module D2 and must align with the NOFO requirements
- No other pilot project programs will be approved
- Any other pilot programs requested will be deem unallowable
- RPPR note:
 - NIH assumes no responsibility for those projects and **should not receive any reports related to those projects**
- **WARNING:**
 - NCATS Grants Management Branch will allow the recipients one opportunity to clarify and if they are still describing a pilot program outside Element D/Module D2, it will be removed



CTSA Collaborative & Innovative Acceleration (CCIA) Award Initiative

Alternative testing models (NAMs) – *call for applications*

- NCATS and NIAID are soliciting CCIA applications for the development, validation, and scale up of the use of human-biology-based **new approach methodologies (NAMs)** to complement animal models
- This could include new or improved *in silico*-, *in chemico*, *ex vivo*, or *in vitro* platforms (e.g., microphysiological systems) to complement and/or reduce the use of animal models



PAR-25-296

Limited Competition: Clinical and Translational Science Award
(CTSA) Program: Collaborative and Innovative Acceleration Award
(UG3/UH3 Clinical Trial Optional)

Please contact Kristopher Bough (kristopher.bough@nih.gov)



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Upcoming Dates to Remember

Next CTSA Program Webinar

March 25, 2026



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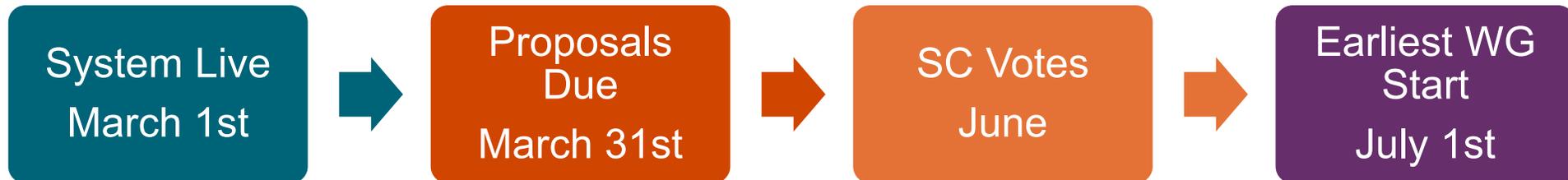
Cycle XVI Working Group Proposals Open March 1

Key topic areas of interest

- Translational science methods & best practices
- Artificial intelligence
- Clinical and health research innovation
- Solution-oriented approaches in health disparities research
- National training curricula in CTS

Details available on the Working Group Proposal [page](#)

Timeline



Translational Impact Summit

Driving Translational Science Toward Measurable Impact

Sponsored by CTSA Translational Impacts Working Group



March 2nd & March 3rd



Virtual



11:00am – 4:00pm Eastern



[Full Agenda](#)

Audience: CTSA-affiliated faculty, staff, trainees and community partners

Summit objectives:

- **Highlight the Broader Landscape of Translational Impact** - Showcase key collaborations and successful examples of translating science into policy and population health, with insights from other sectors.
- **Equip Attendees with Tools and Strategies to Enhance Impact** - Share practical methods to evaluate, communicate, and embed impact using health and economic indicators
- **Strengthen Shared Capacity Across the CTSA Network** - Foster collaboration by sharing effective strategies for planning, implementing, and disseminating impact-driven research.

Translational Impact Summit
Registration Form



Virtual poster session hosted on the FAIR-aligned Translational Impacts Repository



Interactive sessions & networking opportunities

[Questions? Email the Translational Impacts Working group](#)



Rigor and Reproducibility of Real-World Data (RWD) Platforms Collaborative Workshop Tuesday, May 12, 2026

In-Person Meeting
The National Cancer Institute (NCI)
Shady Grove campus is located at
9609 Medical Center Drive, Rockville, MD 20850

**Scan Me to
Register**



Stay updated on Collaborative Workshops!
Visit: <https://ccos-cc.ctsa.io/groups/working-groups>
Email: collaborative_workshop@ccos.ctsai.io

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CCOS is now on Bluesky!

Follow us for CTSA Program
news, events, and updates!

@ccos-ctsa.bsky.social

CTSA Program Webinar

CCOS is switching back to Zoom starting in March

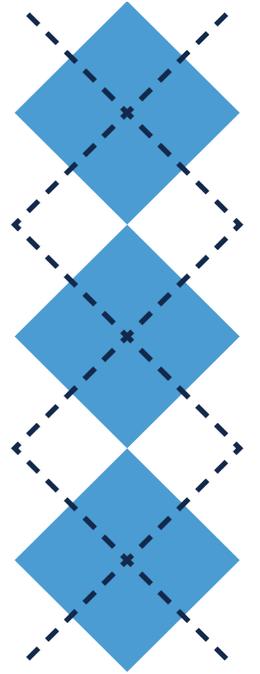
The next webinar is **March 25, 2026**; 2-3 PM ET

A new registration link will be sent via email next week

Translational Case Studies in Commercialization (TCSC)

CTSA Program Update

North Carolina Translational and Clinical Sciences (NC TraCS) Institute



Discovery Does Not Equal Impact



Adoption, access, scale, and sustainability determine impact.

Commercialization is not “downstream” of translation; it is the infrastructure that makes translation durable.

Commercialization journeys (5–15 years) involve many steps, yet early-stage barriers and leverage points are under-described in the literature.

Goal: Identify generalizable bottlenecks and better practices across CTSA hubs.

TCSC Goals & Deliverables



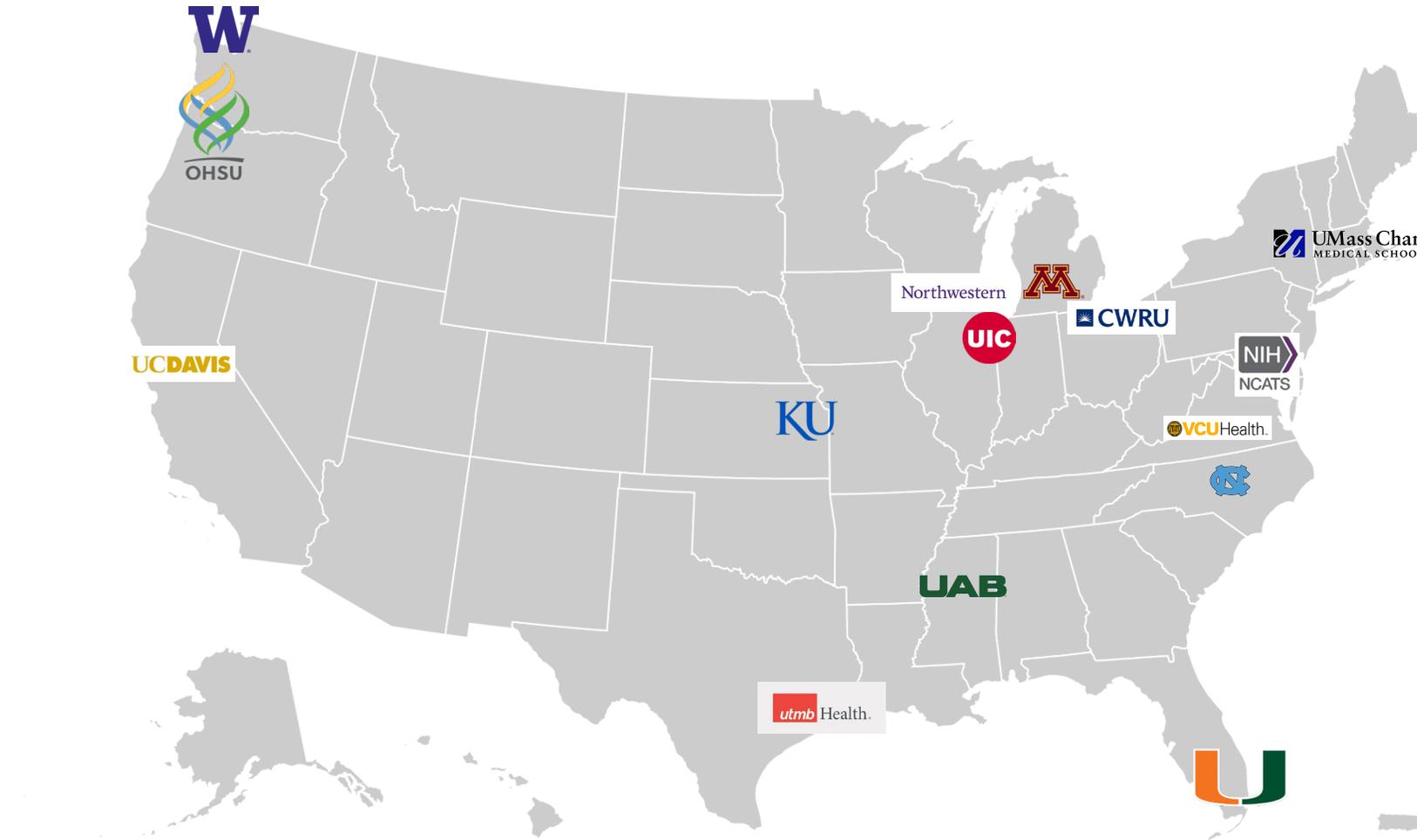
Goals

- Detail lifecycle of biomedical commercialization
- Compare success and challenged efforts
- Identify better practices

Deliverables

- Standardized Case Study Framework
- Case Repository (2 per hub)
- Cross-case Comparative Analysis
- JCTS manuscript

TCSC Working Group



**27 members
across 16
CTSA
institutions**

Comparative Case Study Approach



- Two cases per CTSA hub (success + challenged effort)
- Multi-stakeholder perspective per case
- Standardized coding enabling cross-site comparability



Pilot Phase Completed

- Case Study Framework completed
- 3 pilot cases: device, diagnostic and therapeutic
- 12 pilot interviews completed
- Interview guide developed and refined
- External qualitative coding support engaged

Early Themes Emerging



Institutional Misalignment

- COI complexity / anxiety
- Licensing rigidity at inflection points
- Institutional Partner or Adversary
- Return-on-Investment measurement & Impact challenges

Human Capital

- Trainee-driven entrepreneurship
- Protected time as catalyzer
- Early mentor/investor alignment



Now Scaling Across CTSA Hubs

- ≥ 2 cases per participating CTSA
- 6–10 interviews per site
- 8–10 week completion window
- Structured cross-site analysis

Additional CTSA hubs invited to participate

Translational Science



- Moves beyond “what to do” → examines how commercialization actually unfolds
- Identifies leverage points within institutional ecosystems
- Surfaces policy-level variables influencing speed of translation
- Produces generalizable insights aligned with NCATS principles



Invitation to Engage

- Contribute a success and challenged case
- Share commercialization metrics
- Participate in cross-case learning
- Help define commercialization as a core translational science competency



The University
of North Carolina
at Chapel Hill

Andrew Kant: akant@email.unc.edu
WG Email: casestudiescommercializationwg@ccos.ctsa.io



Update on NCATS National Clinical Cohort Collaborative (N3C)

February 25, 2026



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Michael G. Kurilla, M.D.-Ph.D.
Director, Division of Clinical Innovation, NCATS



N3C 2025-2026 Notable Moments

- Late January 2025 - Communications Moratorium
- February 14 2025 – Communications staff (among others) RIF'd
- May 2025 - Communications moratorium lifted and centralized
- June 2nd 2025 - N3C Community Forum
- September 27th 2025 - N3C platform goes offline
- October 1st 2025 - Government shutdown
- October 22nd 2025 – Special Allowance to Update CTSA SC
- November 12th 2025 - Shutdown ends
- December 1st to 12th 2025 - N3C platform re-opens temporarily
- December 10th 2025 - HHS Provides path forward for N3C platform
- January 12th 2026 - N3C platform online for rebuild
- March 2nd, 2026 - N3C platform will open to public



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Rebecca Baker, Ph.D.
Senior Advisor to the NCATS Director



N3C Engagement Goals

- Establish trust for the expanded N3C platform through transparent governance and communication
- Drive adoption across research communities
- Demonstrate value through showcasing platform capabilities, efficiencies, and research outcomes
- Build sustainable community of researchers, institutions, and community partners committed to collaborative science

N3C Strategic Partners Committee

- 15–20 thoughtful, experienced voices to help guide N3C
- Data contributors and users, future federal and community partners
- Transparent forum for information exchange
- Shaping the future direction of N3C across a broad range of disease domains

N3C Strategic Partners Committee

- Ongoing, frequent communication about platform status, evolution
- Resources for data contributors and users to maximize value
- Collaborations with technical and scientific partners
- Storytelling to build sense of shared mission
- Email us: ncats_n3c@mail.nih.gov



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Kristen Hansen, Ph.D.

Lead, Data and Geospatial Engineering





Where we are today?

Reopening

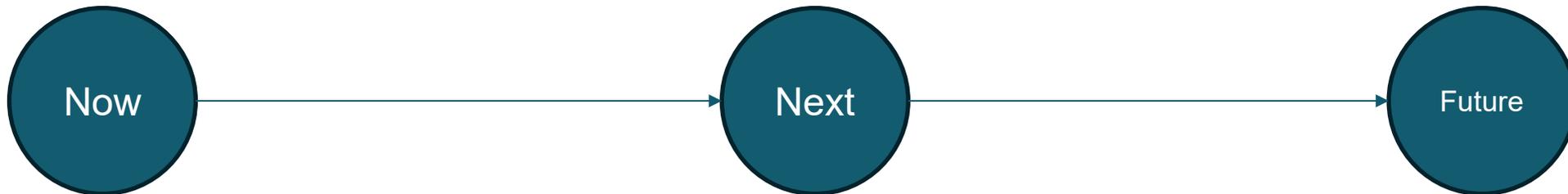
- **Access to the COVID Enclave data restored**
- **Analytic tools available for continued research**

Transitional Phase

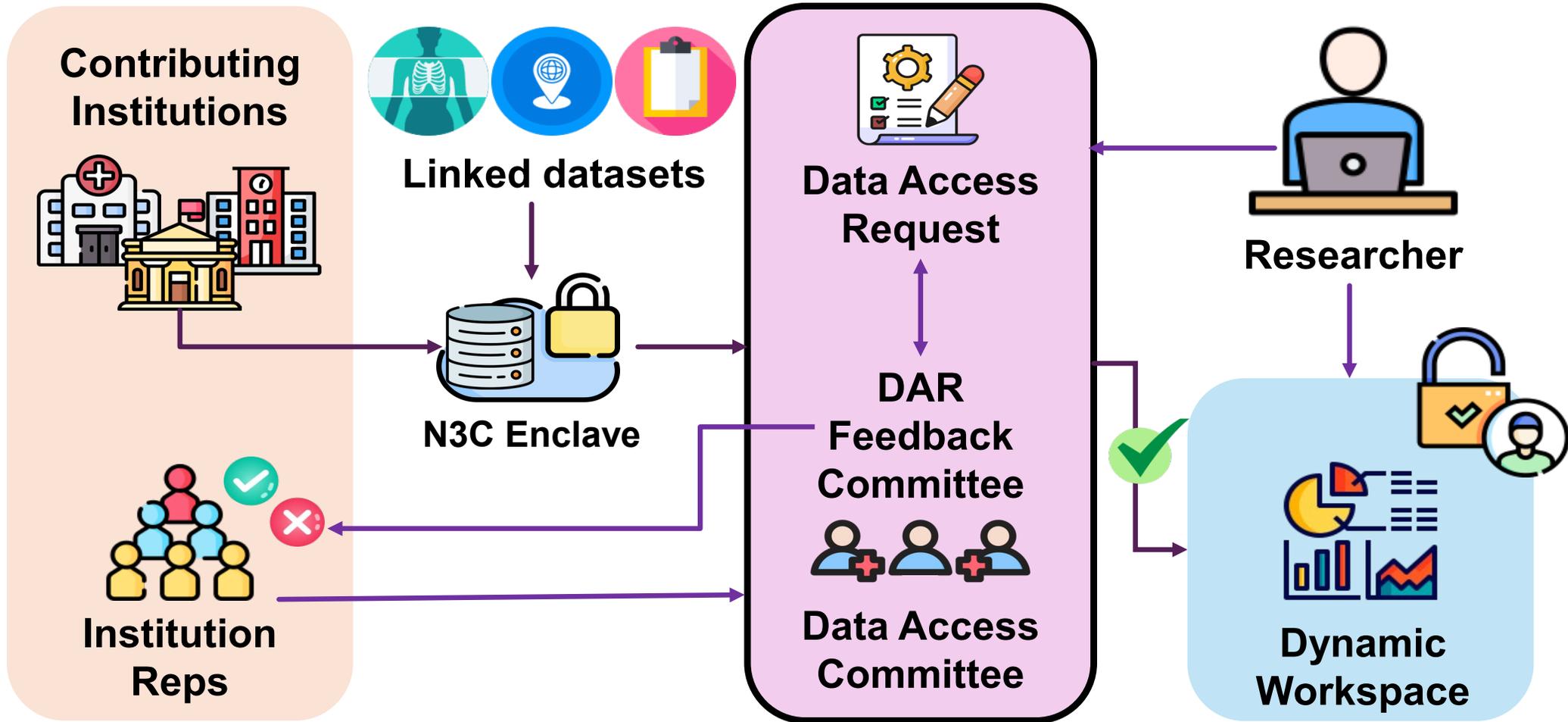
- **Bridging to the Next Phase**
- **Governance and review processes evolve**
- **Architectural decoupling**

Looking Ahead

- **Dynamic Workspaces**
- **Modernized data access model**
- **Flexible, project-based workspaces**
- **Scalable infrastructure to support broader research**



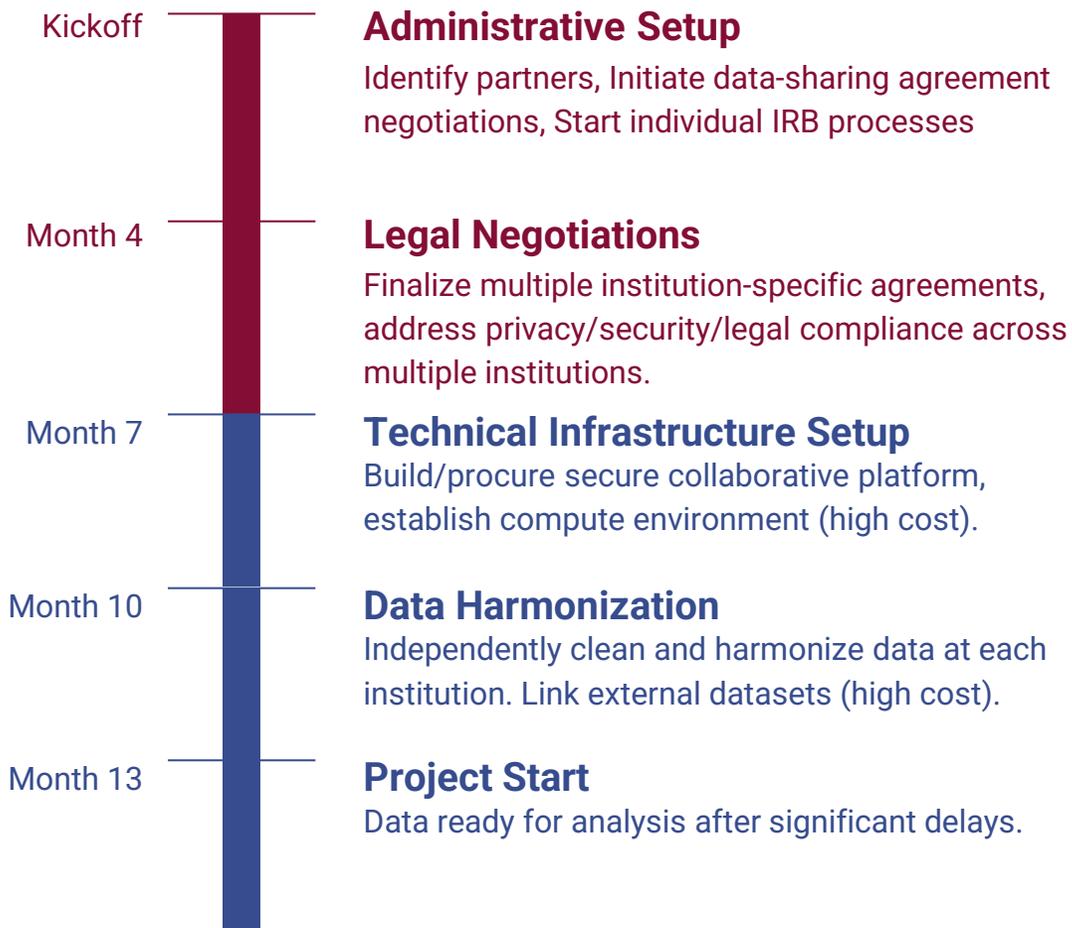
N3C: Dynamic Workspaces



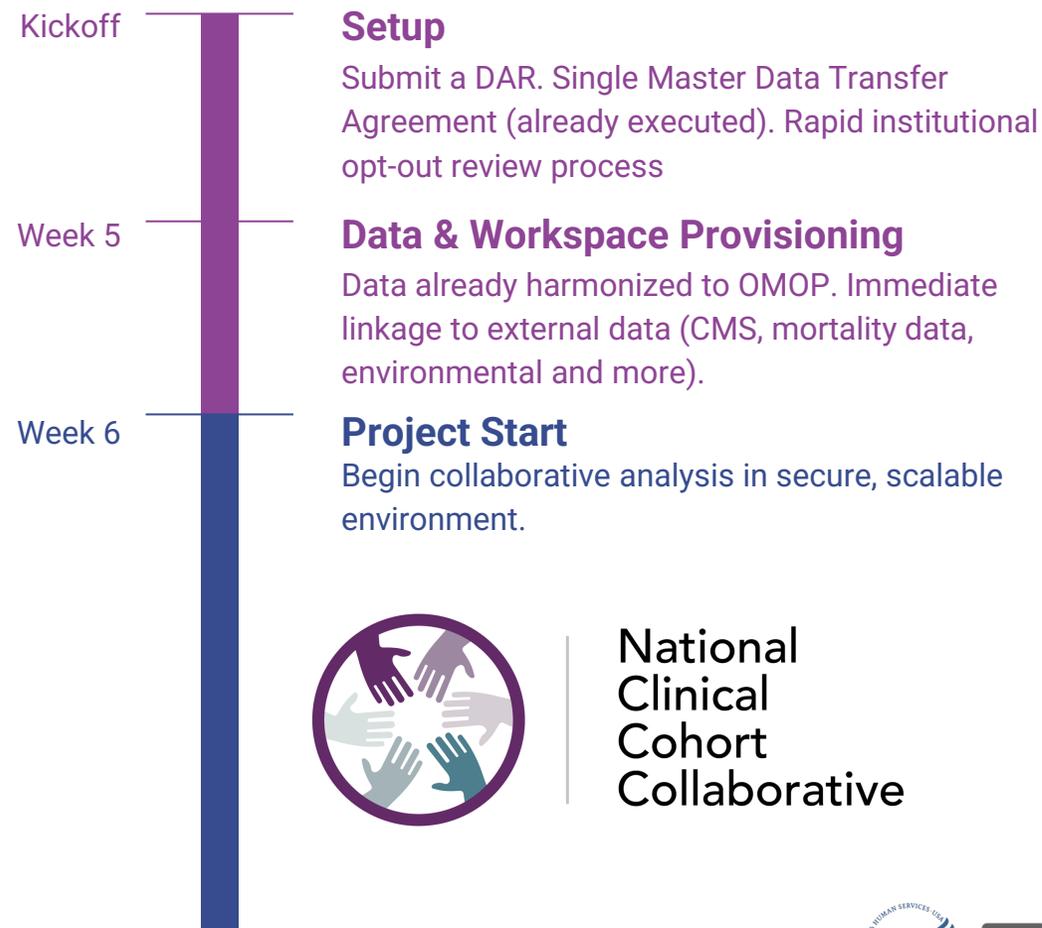


Imagine if... you want a research-ready database with EHR and additional linkages

Without N3C



With N3C

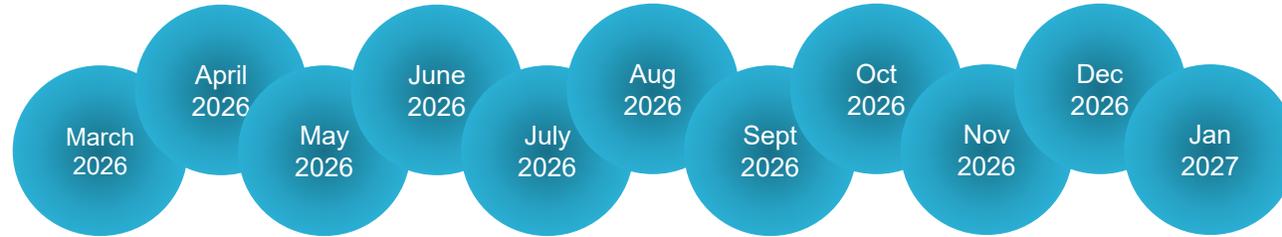


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Augmenting Value of Institutional Data



Immediate Impact – Free Delivery

- Data cleaned, harmonized, standardized to OMOP
- Research-ready dataset returned to your institution
- Data Quality Report on Institutional Data
- Secure compute and analytic tools
- Grant-ready environment for multi-site collaboration

Free Data Linkage and Enrichment Services

(Compounding value over time)

- CMS data seamlessly integrated with EHR
- USCDI FHIR harmonized data returned to sites
- SRTR and SEER registries linkage and integration
- Geospatial and environmental exposures data linked
- Gold-standard mortality data linked



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Chris Dillon
Team Lead, Office of Strategic Alliances, NCATS



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New Agreements with Transparency

- Revised but contain core Terms and Conditions from original agreements
- Auto renew: no extensions needed
- D.A.M.E. (Data Access Management Environment) system to assist in the workflow and transparency
- Flexibility implemented to allow for the graduation out of Pilot phase



Governance Pilot – How will your data be used?

 <p>National Clinical Cohort Collaborative</p>	<p>Option A: N3C Data Access Committee (DAC) Administered Review</p>	<p>Option B: Categorical Data Use Limitations (DUL)</p>	<p>Option C: Real- Time Opt-Out</p>
<p>Control Level</p>	<p>Institutional Trust</p>	<p>Categorical Restrictions</p>	<p>Project-Specific granularity</p>
<p>Institutional Effort</p>	<p>Minimal (set once)</p>	<p>Low (Periodic Updates)</p>	<p>Active (preset review cycles)</p>
<p>Governance</p>	<p>N3C DAC</p>	<p>N3C DAC + Preset Limitations</p>	<p>N3C DAC + Contributor Review</p>



NIH Controlled Access Data Repository (CADR) Transition

Binding Official – This individual has the legal authority to bind the institution to the terms and conditions of the agreement.

Institutional Signing Official – This role is for approving Data Access Requests (DAR) and is typically someone who oversees grant actions e.g. Sponsored Research Officer

Data Access Requestor – Is a permanent employee equivalent to but not limited to a tenure/tenure track or senior level researcher. This role will have oversight and accountability for the Users and how they use the data

Approved User - Anyone approved by the NIH DAC to access data within a DAR and perform research consistent with the approved DAR





Questions?

Mike Kurilla, M.D., Ph.D.
Director, Division of Clinical Innovation, NCATS

Next CTSA Program Webinar

The next webinar is **March 25, 2026**; 2-3 PM ET

A New **Zoom** Registration Link will be Emailed in Early March

Please Check the [Webinar Page](#) on the CCOS Website for Updates