CTSA Coordination, Communication, & Operations Support

CTSA Program Webinar

May 28, 2025

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Deloitte. ICF UNIVERSITY of ROCHESTER

Agenda

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Lauren Fitzharris, M.P.H., P.M.P. CCOS
2:01 – 2:05 PM	NCATS/CTSA Updates	Michael Kurilla, M.D., Ph.D. NCATS
2:05 – 2:07 PM	CCOS Updates	Lauren Fitzharris
2:07 – 2:17 PM	National Clinical Cohort Collaborative (N3C)	Hythem Sidky, Ph.D. NCATS
2:17 – 2:31 PM	TL1 Visiting Scientists WG	Kathryn Sandberg, Ph.D., Georgetown Dexter Lee, Ph.D., Howard University
2:31 – 2:45 pm	CTSA Pharmacies and Compounding for Translational Research WG	Robert MacArthur, PharmD. M.S. Rockefeller
2:30 – 3:00 PM	Biostatistics, Biomedical Informatics and Data Science (BIDS) EC	Thomas Campion, Ph.D., Weill Cornell Meredith Zozus, Ph.D., UT Health San Antonio
3:00 PM	Adjourn	

NCATS

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NCATS/CTSA Program Updates

Michael G. Kurilla, MD, PhD

Director, Division of Clinical Innovation

NCATS

May 28, 2025

National Center for Advancing Translational Sciences

Update on CTSA Applications Assigned to October Council Review Panels

CTSA applications have been sorted into the following review panels:

- CTSA specific panel: UM1
- CTSA K12s with CTSA T32s [and some other similar grants]
- CTSA specific panel: RC2 / CCIA / R03
- CTSA R25s in an NIH-wide R25 panel

*data accurate as of 5.16.2025

*these review panels are Special Emphasis Panels and meeting dates are not scheduled yet

* Thirty days before the meeting, the meetings should be posted publicly here: https://public.csr.nih.gov/StudySections/SpecialEmphasis

*management of the organization of these review assignments is now under the purview of the NIH Center for Scientific Review and subject to change

National Center for Advancing Translational Sciences

NIH Notices

- **Updated Procedures for Childcare Costs for Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Awards (NOT-OD-25-100) (Released April 25, 2025)**
  - Effective with the date of this notice, NIH will provide the annual childcare costs (currently $3,000) for 25% of the full-time predoctoral or postdoctoral NRSA training appointment slots at the time each new, renewal or continuation awards is made. In line with current policy, when the costs are awarded, they are restricted and must be use for childcare expenses. Unused funds cannot be rebudgeted and must be reported as an unobligated balance on the FFR.
  - If more than 25% of the full-time predoctoral or postdoctoral trainees appointed on an NRSA institutional training award have eligible childcare costs, the recipient may request an administrative supplement to provide childcare costs for the additional trainee slots, as appropriate.
  - All of other aspects of the policy remain the same (see NOT-OD-24-116).

NIH Notices

- **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 NIH[1], 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.

NIH Notices

- **Updated NIH Processes for No-Cost Extensions (NOT-OD-25-110) (Released May 7, 2025)**
  - This notice alerts the extramural community that NIH has temporarily disabled the No-Cost Extension functionality in eRA Commons. The Director of NIH has directed NIH staff to review all existing grants and cooperative agreements to ensure that NIH awards do not fund off-mission activities or projects. Therefore, temporarily disabling the NCE functionality in eRA Commons will allow NIH staff to review and assess all NCE requests to confirm that the activities proposed during the extension align with the NIH mission and agency priorities.
  - At this time, all requests for NCEs must be submitted as a prior approval request in eRA Commons, for NIH review and approval. Requests for activities that do not align with the NIH mission and agency priorities will not be approved.

NIH Notices

- **Notice of Civil Rights Term and Condition of Award (NOT-OD-25-090) (Released April 21, 2025)**
  - New Civil Rights term and condition that modifies the current terms and conditions for all NIH grants, cooperative agreements, and other transaction (OT) awards.
  - Policy "…..

(2) Grant award certification.

(a) By accepting the grant award, recipients are certifying that:

(i) They do not, and will not during the term of this financial assistance award, operate any programs that advance or promote DEI, DEIA, or discriminatory equity ideology in violation of Federal anti-discrimination laws; and

(ii) They do not engage in and will not during the term of this award engage in, a discriminatory prohibited boycott.

- *(3) NIH reserves the right to terminate financial assistance awards and recover all funds if recipients, during the term of this award, operate any program in violation of Federal anti-discriminatory laws or engage in a prohibited boycott.*

….."

NIH Notices

- **Reminder: Application Requirements for Projects Involving Activities Outside of the United States or Partnerships with International Collaborators (NOT-OD-25-098) (Released April 23, 2025)**
  - If the applicant checks “Yes” to this question, they must include a “Foreign Justification” attachment in Field 12, Other Attachments.
  - As a reminder, this attachment is required for all applications that involve activities outside of the United States or partnership with international collaborators, regardless of whether the foreign component will receive funds from the NIH award. Applications that do not include this attachment, as required, will be withdrawn and will not be reviewed.
- **Updated NIH Policy on Foreign Subawards (NOT-OD-25-104) (Released May 1, 2025)**
  - NIH recognizes that some recipients do not accurately report on subawards consistent with Federal Funding Accountability and Transparency Act (FFATA) subaward reporting requirements (NIH GPS 8.4.1.5.5)
  - NIH is establishing a new award structure that will prohibit foreign subawards from being nested under the parent grant.
  - NIH anticipates implementing the new award structure by no later than September 30, 2025, prior to Fiscal Year 2026. Notices of Funding Opportunities (NOFOs) that state that foreign components are allowed are superseded by this notice. NIH will revise NOFOs to reflect the new award structure.

Upcoming Dates to Remember

Next CTSA Program Webinar

June 25, 2025; 2-3 PM ET.

Register here for the 2025 series

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National Center for Advancing Translational Sciences

CCOS Updates

Lauren Fitzharris
CCOS

NEW!

Community of Practice to Facilitate Effective LHS-CTSA Partnerships

1st Wed. every other month, 12-1pm ET / 9-10am PT

June 4th topic: Engaging key stakeholders

Share knowledge and experiences

Learn best & promising practices

Acquire strategies for overcoming challenges

All are invited !

Register here: https://zoom.us/meeting/register/d2X0FiCzSAKpHesqaRabew

Questions? Email LHS-CTSA.Partnerships@ccos.ctsa.io

Scan for more information:

CCOS Policy Update

- Starting **September 1**, a CCOS account will be required for CTSA members to join a CTSA Group
  - Enterprise Committees
  - Consortium Groups
  - Working Groups

- Applies to new members
  - Current members without active CCOS accounts will be contacted to complete registration in the coming months

Account Access Includes:

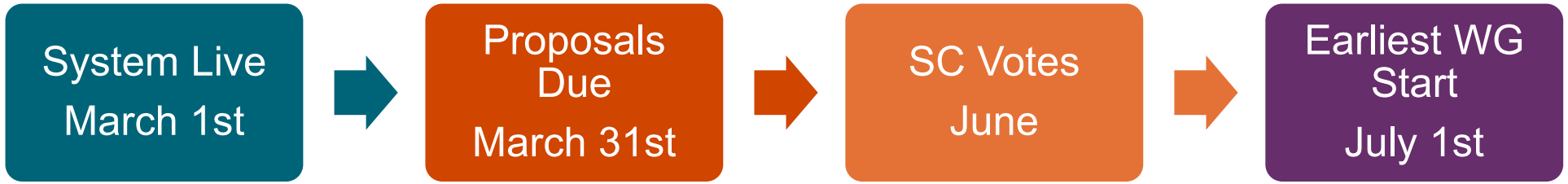
- Meeting Materials/Archives
- CTSA Member Directory
- Collaborative Workspaces
- Discussion Forums

To sign up, visit
ccos-cc.ctsa.io/user-account-request

Questions? Please email support@ccos.ctsa.io

Working Group Proposal Cycle XIV Closed

- CCOS received 4 proposals in Cycle XIV
- Next step: Steering Committee will review and vote on the proposals



CCOS General Reminders

Register on the CCOS Website: https://ccos-cc.ctsa.io/user-account-request

- Get step-by-step guidance on getting started including how to create a CCOS account and how to log in can be found here: Getting Started Page
- 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

Scan to Receive CTSA-wide Communications

Thank you!

NCATS

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National Clinical Cohort Collaborative

Past, present, and future

Hythem Sidky, PhD

National Center for Advancing Translational Sciences

N3C Past and Present

N3C has grown from a COVID-19 response into a national translational research infrastructure, combining harmonized EHR data, scalable governance, and team science to accelerate discovery across diseases and institutions.

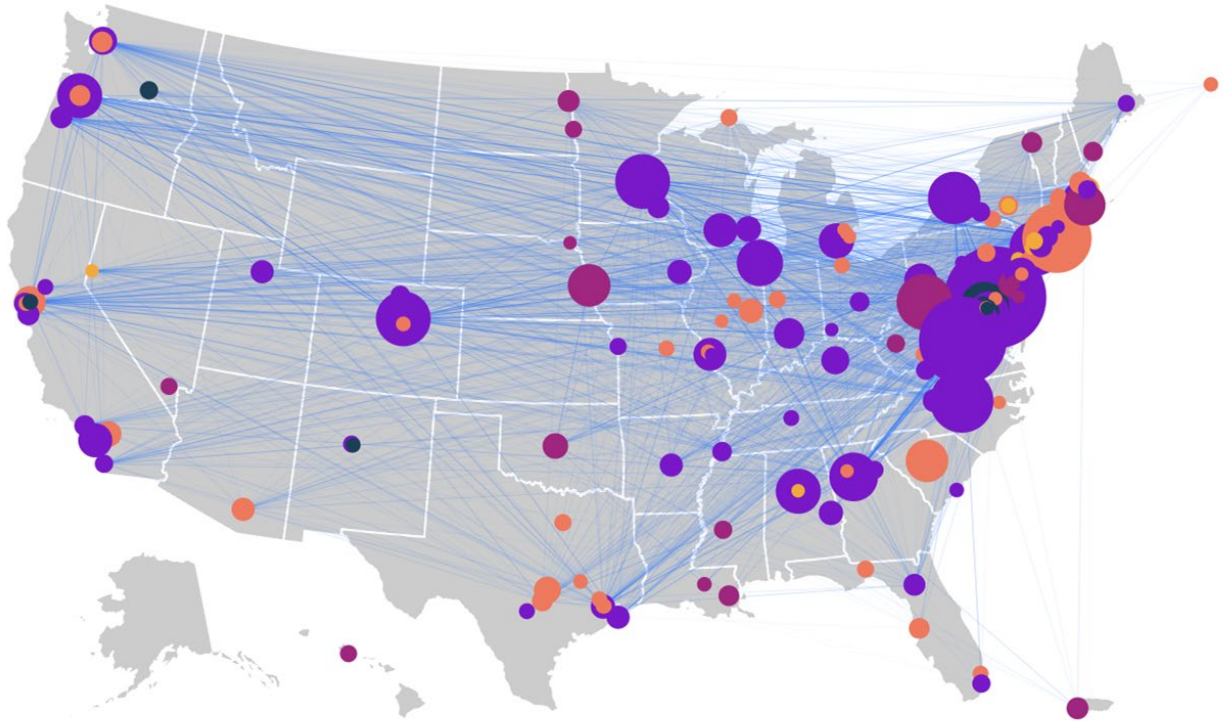
2020	Today	2022-2023	2024-2027
N3C is Launched!	**N3C's impact**	**Phase 1 Clinical Pilot**	**Phase 2 Clinical Pilot**
In response to the COVID-19 pandemic, the National COVID Cohort Collaborative was formed to create the largest publicly available, harmonized EHR dataset in U.S. history.	5000+ citations, H-index 33, 1589 authors. N3C enabled transformative research and care guidelines, disease definitions, and predictive models for outcomes across comorbidities.	N3C successfully expanded beyond COVID-19, piloting clinical tenants for Alzheimer's, COPD, and Renal disease across 12 institutions.	Building on Phase 1, Phase 2 scales with enhanced PPRL, data integration (e.g., CMS, SEER), and supports new tenants like cancer and renal.

96 Data Contributors signed the original COVID Data Transfer Agreement

76 Data Contributors signed the COVID Data Transfer Agreement Extensions

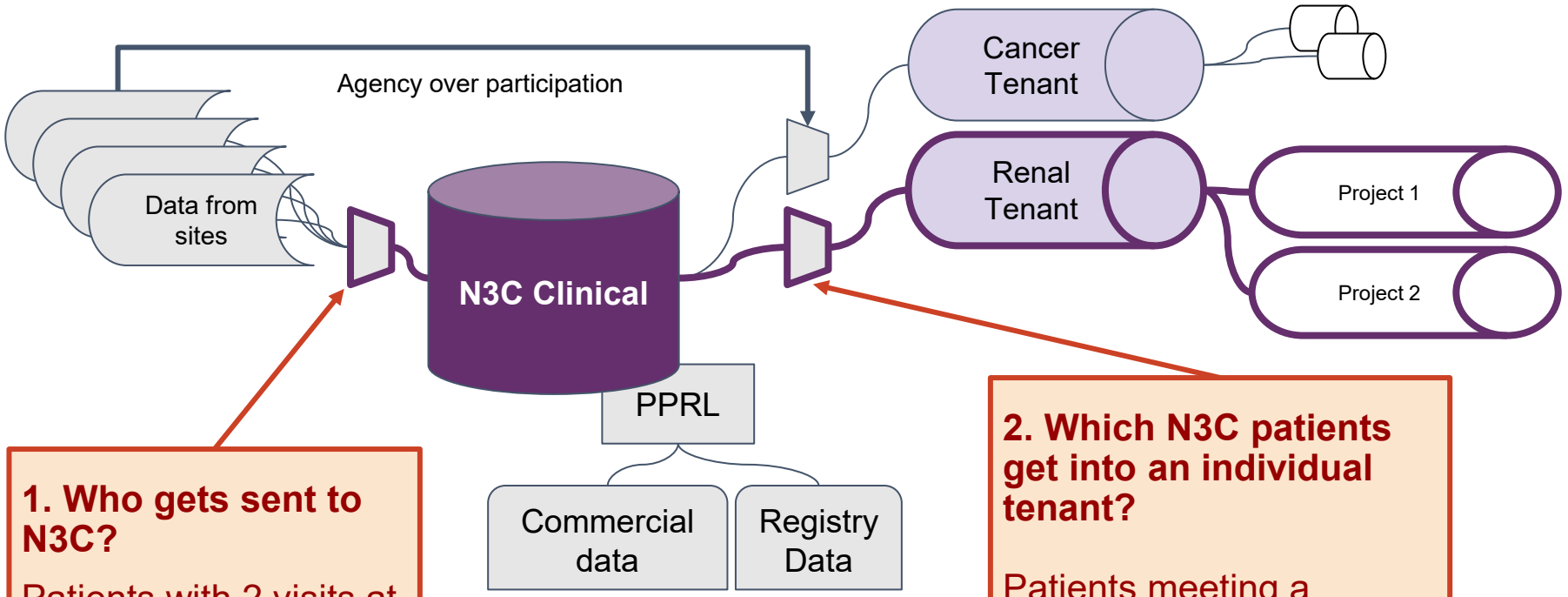
12 institutions participated in the Phase I Clinical Pilot

18 institutions are participating in the Phase II Clinical Pilot



National Center for Advancing Translational Sciences

Phase 2 N3C Clinical Pilot Model



Objectives of the N3C Clinical Pilots

- N3C Clinical pilots were meant to help NCATS more accurately understand the financial, infrastructure, and community resources needed to develop and maintain future tenants.
- Pilots will facilitate refining operations, governance, and technical architecture.
- Establish partnerships with CMS, HRSA, NCI, NIDDK.
- Next-generation healthcare interoperability is being developed (HL7 FHIR US Core).
- New capabilities will expand the space of scientific questions that can be asked and answered.

Feedback We have Received

- More granular institutional control of data
- Time-limited investigator access to institutional data
- Interest in disease areas beyond the pilots
- Maximize use of linked datasets
- A lot more!

Next Phase of N3C: Dynamic Tenants

Dynamic Workspaces
Per-project tenants grant access only to data needed for a specific study.

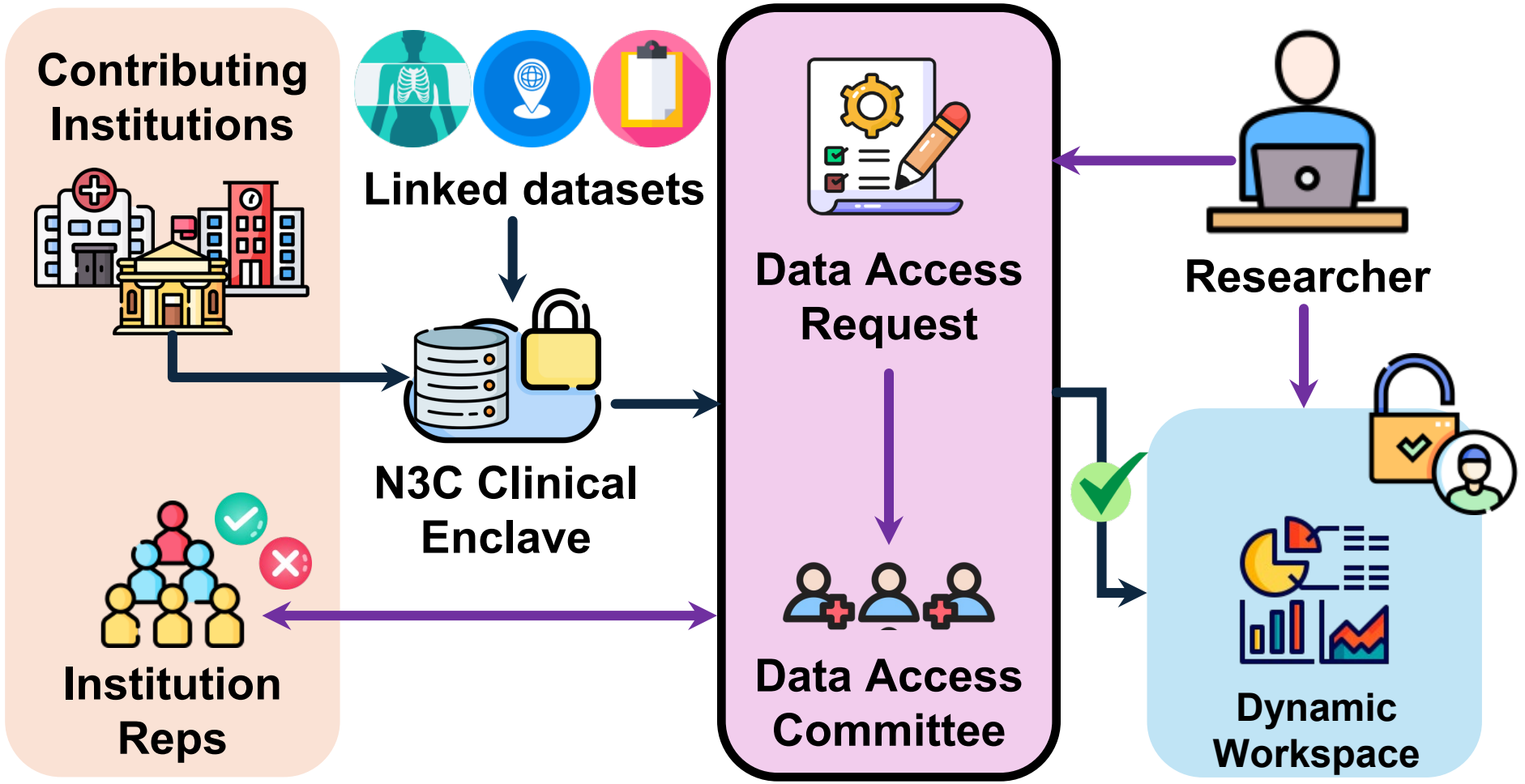
Phenotype Playground
A synthetic data environment allows researchers to build, test, and refine computable cohort definitions.

Single DTA + Opt-Out Control
A streamlined agreement model gives institutions granular and efficient oversight opt-out review process.

N3C Platform
- Security-compliant, no row-level export, full audit trails, and disclosure controls.
- Supports flexible, cross-cutting, and time-sensitive studies across diseases.
- Link EHRs to mortality, claims, and environmental data via PPRL.

Data access aligned precisely with scientific intent. Dynamic tenants reshape how collaborative research scales, shares, and safeguards clinical data.

Next Phase of N3C: Dynamic Tenants



N3C Community Forum - June 2nd

National Clinical Cohort Collaborative

NCATS' N3C Team will be reconvening the National Clinical Cohort Collaborative (N3C) Community Forum virtually on Monday, June 2, from 4:00 p.m. to 5:00 p.m. EDT. This meeting marks the beginning of what we anticipate will be a continuing series of Forum conversations as N3C moves into its next phase.

Since the last gathering of the N3C Community, N3C has been evolving in exciting new directions. NCATS' N3C Team has been working on the N3C Clinical Pilot and incorporating the extensive feedback received from many of the community members. The results point to an exciting evolution of N3C and changes that will shape how institutions engage with N3C in the future.

During the Forum, NCATS' N3C Team will share its progress, offer a first look at the pilot, outline the path ahead and invite questions.

We look forward to community participation and to building the next chapter of N3C together.

https://ncats.nih.gov/research/research-activities/n3c/n3c-community-forum

National Center for Advancing Translational Sciences

CTSA TL1 Visiting Scientist Working Group (William Schnaper Visiting Scientist Program)

Chair: Dexter Lee, PhD

Co-Chair: Kathryn Sandberg, PhD

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Georgetown-Howard Universities
Center for Clinical and Translational Science

William Schnaper Visiting Scientist (WSVS) Working Group

- The WSVS Working Group was established in 2021 to devise a program that provides TL1/T32 trainees across the Clinical Translational Science Award (CTSA) consortium opportunities to network and foster collaborations.
- These venues include the WSVS virtual grand rounds, the debate forum and the minisymposium.
- The Committee meets twice a month with administrative support for the meeting alternating between CCOS (Ms. Talia Hernandez and Ms. Melissa Brady) and Georgetown University (Ms. Danika Campbell).

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WSVS Debate Forum

- **The Spring WSVS Debate Forum was organized by Dr. Adisa Kalkan (Washington University).**
- **On April 29, 2025, the WSVS Debate Forum debated the topic: *The Pros and Cons of the Trillion Dollar Shot*.**
- **Four TL1/T32 trainees and K12 Scholars from the University of Michigan argued the Pros while four TL1/T32 trainees from Washington University argued the Cons.**
- **Dr. Linda Shapiro Manning, a nationally recognized expert in obesity served as the moderator.**
- **A subgroup of the WSVS Program Committee is meeting on a manuscript that focuses on the history and evolution of the WSVS Debate venue with an anticipated completion date the summer of 2025. This subgroup committee is led by Dr. Adisa Kalkan.**

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WSVS Minisymposium

The Fall WSVS Minisymposium was held on December 11, 2024. This is the second time the Minisymposium was organized by a TL1 trainee. In the summer of 2024, Mr. Mark Hatcher, (Predoctoral candidate at Howard University and a TL1 trainee in the Translational Biomedical Science Training Program at Georgetown Howard Universities Center for Clinical and Translational Science) sent out a Request for Abstracts on the topic: *Focusing on Unmet Needs in Clinical and Translational Science*.

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WSVS Minisymposium

- **TL1/T32 peers throughout the national TL1/T32 consortium were selected to grade and to select 8 speakers for the program. Mr. Hatcher also organized a group of his peers throughout the TL1/T32 national consortium to judge the platform presentations.**
- **A subgroup of the WSVS Program Committee is meeting twice a month on a manuscript that focuses on the History and Evolution of the WSVS Minisymposium venue with an anticipated completion date of June 2025. The subgroup committee members include: Drs. Kathryn Sandberg (Georgetown University), Alexander Brunfeldt (Postdoctoral Fellow Representative, TL1/T32 National Organization) and Desiree Sigala (University of California, Davis).**

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WSVS Minisymposium

- **10 TL1/T32 trainees have signed up for the WSVS Virtual Grand Rounds. They have been matched with 7 institutions and all are being contacted to schedule for a presentation and half day virtual meetings with faculty and their peers in 2025.**

- **A subgroup of the WSVS Program Committee is meeting (~ once a month) on a manuscript that focuses on the History and Evolution of the WSVS Grand Rounds venue with an anticipated completion date the summer of 2025. The subgroup committee members include: Drs. Dan Moglen (University of California, Davis University), Chris Frei (University of Texas, Austin) and Alexander Brunfeldt (Postdoctoral Fellow Representative, TL1/T32 National Organization).**

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Additional Contributors

Drs. Belen Hurle (NCATS/NIH) and My Linh Nguyen-Novotny (Weill Cornell University) are also participating in the manuscript writing by focusing on over-arching themes of the WSVS Minisymposium, Debate and Grand Rounds. Dr. Scott McIntosh (University of Rochester) and Ms. Abby Spike (CCOS) are contributing to all three manuscripts through construction and analyses of surveys distributed after WSVS events. Dr. Brittany Martinez (Postdoctoral Fellow, University of Kansas) and Mr. Jonathan Hatfield (PhD Candidate, University of Minnesota) are also contributing to the WSVS Program Committee in their role as the newly elected representatives of the national TL1/T32 organization.

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CTSA Research Pharmacy Working Group (N=10)

SCIENCE FOR THE BENEFIT OF HUMANITY

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Rockefeller University Hospital

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Assistant Pharmacy Director – CMK Inpatient & IDS Pharmacies
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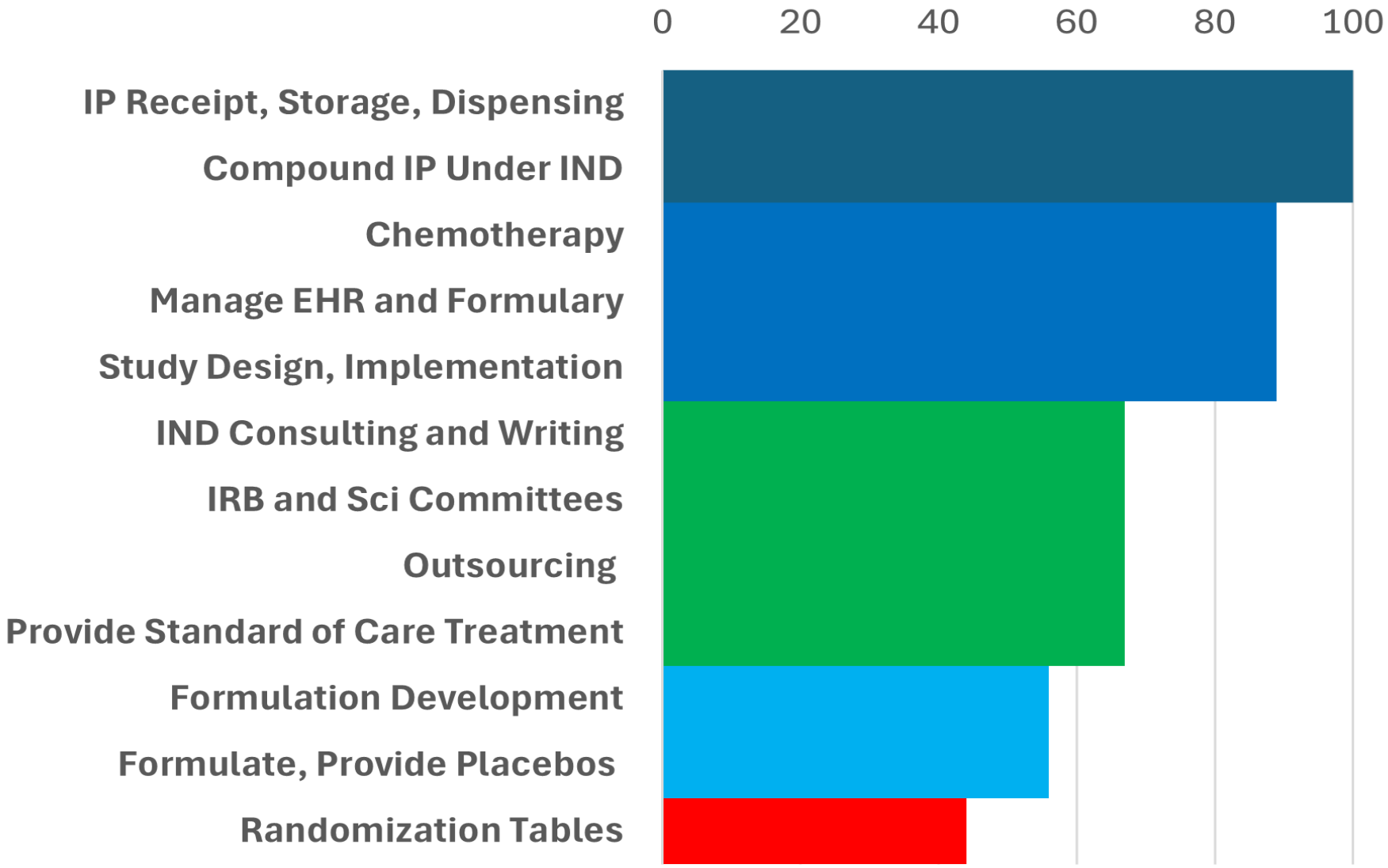
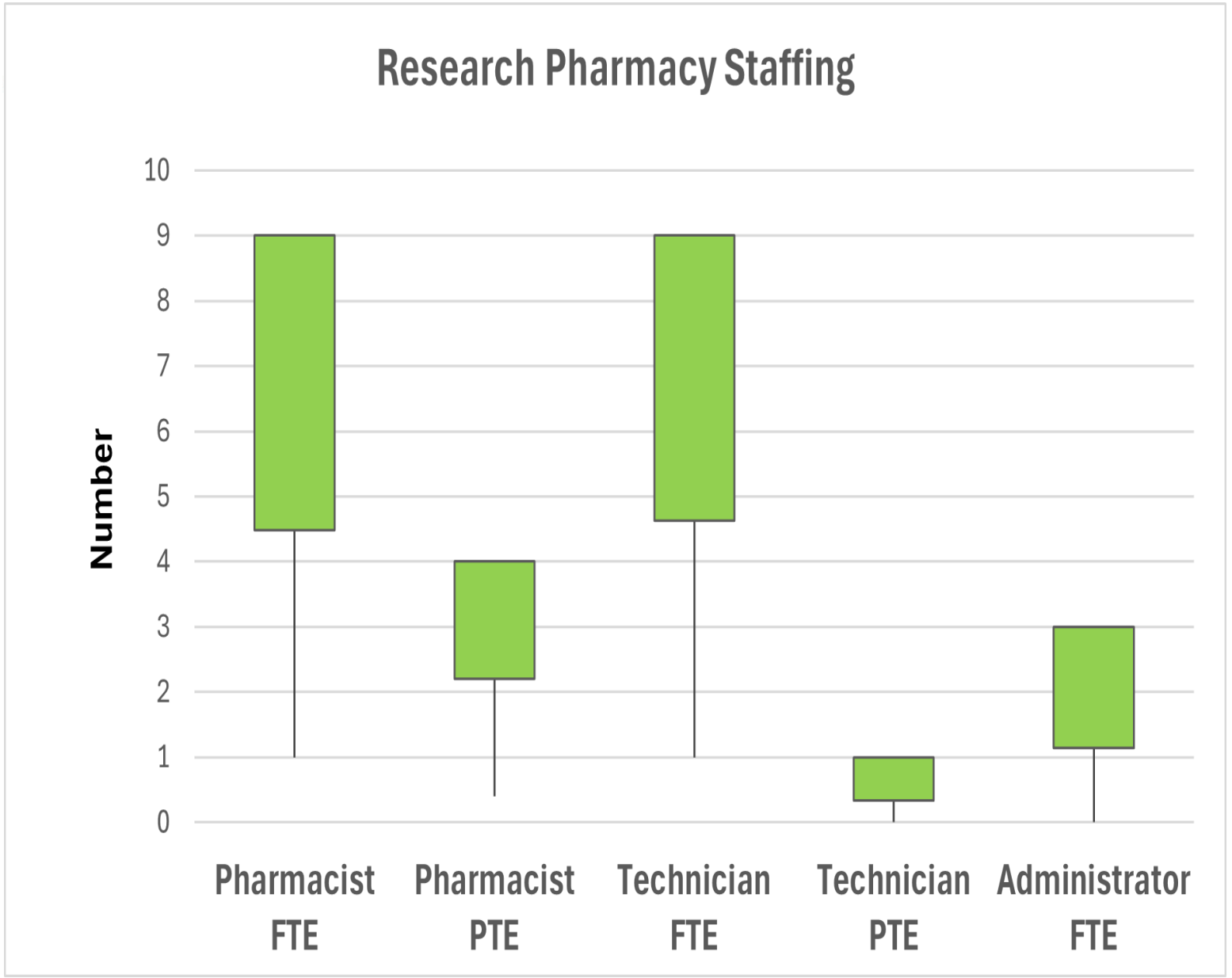
Sarah Shami, PharmD
IDS Manager
Howard University College of Medicine

Claire Warner, Ph.D.
Data Services Specialist
The Rockefeller University

Scope of Research Pharmacy Services (%)





Pharmacists:

Avg	4
Min	1
Max	9

Technicians:

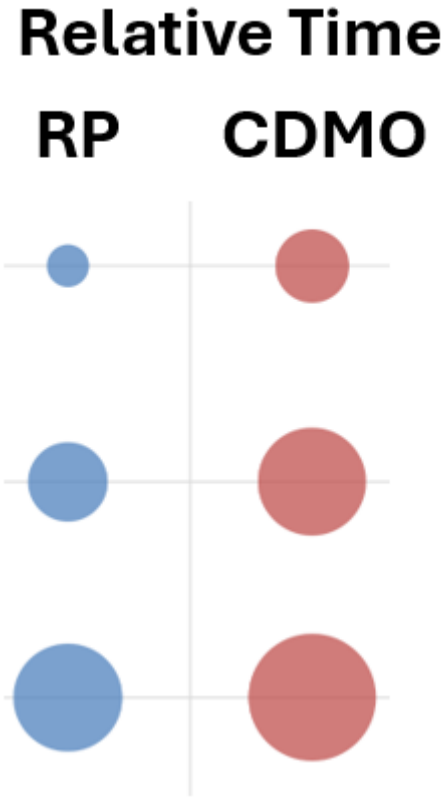
Avg	4
Min	1
Max	9

Cost - RP vs CDMO

Scenarios	RP cost ($)	CDMO cost ($)
Over-encapsulate 1000 capsules (500 active 500 placebo) 100 kits for 100 patients Randomize, blind, label, package, ship	**$8,000**	**$326800**
100 small volume drug infusions 50 x 100 mL IV bags 2 doses, high and low Randomize, blind, label, package, ship	**$5500**	**$488000**
120 prefilled syringe Vaccine @ 3 different doses. Randomize, add blinded labeling, package Randomize, blind, label, package, ship	**$15000**	**$458000**

Time - RP vs CDMO

Scenarios	RP time (months)	CDMO time (months)
Over-encapsulate 1000 capsules (500 active 500 placebo) 100 kits for 100 patients Randomize, blind, label, package, ship	2	6
100 small volume drug infusions 50 x 100 mL IV bags 2 doses, high and low Randomize, blind, label, package, ship	7	13
120 prefilled syringe Vaccine @ 3 different doses. Randomize, add blinded labeling, package Randomize, blind, label, package, ship	13	18



FDA Approved Study Products with Supported by CTSA RPs

Drug name	Study start date(s)	FDA approval date	FDA indication on approval date	Study NCT No(s).
Triheptanoin	09/01/2011 01/01/2012	6/30/2020	To treat molecularly long-chain fatty acid oxidation disorders	NCT01379625 NCT02018315
Larotrectinib	08/01/2015	11/26/2018	To treat patients whose cancers have a specific genetic feature (biomarker)	NCT02465060
Ropeginterferon Alfa-2b-Njft	08/01/2015	11/12/2021	To treat polycythemia vera, a blood disease that causes the overproduction of red blood cells	NCT02370329
Tremelimumab	07/01/2008 02/01/2010	10/21/2022	To treat unresectable hepatocellular carcinoma	NCT00702923 NCT01103635
Parathyroid Hormone	06/01/1999 01/01/2000 01/07/2005 01/07/2005 09/01/2006	01/23/2015	To control hypocalcemia (low blood calcium levels) in patients with hypoparathyroidism	NCT00021827 NCT00007306 NCT00177411 NCT00222872 NCT00377312

RP Advantages:

- Lower cost & faster
  - Just-in-time compounding and dispensing
  - Inventory control
  - Distribution control
  - Investigator and institution control
  - Immediately responsive to protocol amendments

- Wide range of services, simple to complex
  - Novel formulations
  - Active:Placebo matching
  - IND support

Next Steps:

- Publication of findings
  - Survey of Research Pharmacy Services
    - First time publication
  - CTSA Contribution to FDA drug approvals
    - Data driven
- Research pharmacist and technicians training modules
  - Rockefeller and U Penn collaboration

Biostatistics, Biomedical Informatics, and Data Science Enterprise Committee (BIDS EC) Update

CTSA Program Webinar

Wednesday, May 28, 2025

Meredith N. Zozus, PhD and Thomas R. Campion, Jr., PhD

Overview

- Objectives
- Background
- Approach
- Current state
- Next steps

Objectives

- Develop a shared vision for Biostatistics, Biomedical Informatics, and Data Science (BIDS)
  - Illustrate a whole greater than the sum of its parts
  - Clarify a path forward
- Define a charter for CTSA BIDS Enterprise Committee (EC)
  - Share with CTSA Program Steering Committee for approval
  - Enable November 2025 election cycle for 2026 BIDS EC Lead Team

Background: History

- September 2024
  - NIH changed CTSA NOFO

Background: History - CTSA NOFO Change

Before September 4, 2024

CTSA Program UM1 Hub Application Structure

Each CTSA Program hub application must include the five Elements, and where appropriate, the associated Modules:

- Element A: Overview (no Leader)
- Element B: Strategic Management (SM Module Leader & Application PI)
- Element C: Training & Outreach
  - Module C1: Workforce Development for Clinical Research Staff Professionals (WD Module Leader)
  - Module C2: Community and Stakeholder Engagement Research (C&SE Module Leader)
- Element D: Clinical and Translational Science Resources and Pilots
  - Module D1: Resources and Services (R&S Module Leader)
  - Module D2: Clinical and Translational Science (CTS) Pilot (Pilot Module Leader)
  - Module D3: Health Informatics (HI Module Leader)
- Element E: Clinical and Translational Science Research Program (Research Program Leader)

An individual may have more than one Leader role, and co-Leaders are allowed. Element B will also include a Hub Liaison Team diagram of the application elements can be found here.

Background: History - CTSA NOFO Change

Before September 4, 2024

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  - Module C1: Workforce Developme
  - Module C2: Community and Stake
- Element D: Clinical and Translational Sci
  - Module D1: Resources and Servic
  - Module D2: Clinical and Translatio
  - Module D3: Health Informatics (HI
- Element E: Clinical and Translational Sci

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As of September 4, 2024

CTSA Program UM1 Hub Application Structure

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- Element A: Overview (no Leader)
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- Element D: Clinical and Translational Science Resources and Pilots
  - Module D1: Resources and Services (R&S Module Leader)
  - Module D2: Clinical and Translational Science (CTS) Pilot (Pilot Module Leader)
  - Module D3: Data Science (DS Module Leader)
- Element E: Clinical and Translational Science Research Program (Research Program Leader)

In the structure above, a single individual may have more than one Leader role and any Module or Element may have mul

Background: History - CTSA NOFO Change

Before September 4, 2024

Health Informatics Module

The CTSA Program is uniquely positioned to harness the power of digital assets by making them interoperable for research, ensuring data security, and implementing innovative informatics solutions, all with the goal of improving human health. Health Informatics programs are required to specifically support the CTSA Program goals of advancing clinical and translational science and increasing the quality of clinical research. Informatics capabilities and a commitment to open science principles across all aspects of the CTSA hub are critical to a successful clinical and translational science environment that can translate knowledge into practice and improve health. The capability to share and implement resources across CTSA hubs, when appropriate, offers opportunities to accelerate scientific discovery as well as improve the efficiency, quality, and impact of translational research.

To meet these goals, CTSA hubs and their partners are required to utilize a range of expertise and capabilities in the areas of Health Informatics (applied research and practice of informatics across the clinical and public health domains); Clinical Research Informatics (the use of informatics in the discovery and management of new knowledge relating to health and disease, including management of information related to clinical trials, and informatics related to the secondary research use of clinical data.); and Translational Bioinformatics (the development of storage, analytic, and interpretive methods to optimize the transformation of increasingly voluminous genomic and other biomedical data, into proactive, predictive, preventive, and participatory health, including research on the development of novel techniques for the integration of biological and clinical data and the evolution of clinical informatics methodology to encompass biological observations). Newly found knowledge that can be disseminated to a variety of stakeholders, including biomedical scientists, clinicians, and patients, is the end product of these integrated efforts.

CTSA hubs and their partners are expected to embrace a culture of Open Science and Data Sharing that promote the F.A.I.R. principles (see: NIH Strategic Plan for Data Science). Open Science is the practice of science in such a way that others can collaborate and contribute, where research data, lab notes and other research processes are freely available, under terms that enable reuse, redistribution and reproduction of the research and its underlying data and methods. The sharing of data, tools, algorithms, methodologies (e.g., machine learning, predictive analytics), governance principles and policies, and software; making research tools compatible with common data elements (CDEs), including social determinants of health CDEs in its domain areas (see https://cde.nlm.nih.gov/home); and developing and deploying research systems with broadly accepted content and technical standards including those adopted by the Department of Health and Human Services (DHHS) for use in U.S. health care and public health operations will promote the translation of scientific discoveries into health improvements. Embracing this culture, Health Informatics Modules are encouraged to use the Fast Healthcare Interoperability Resources (FHIR) standard to capture, integrate, and exchange clinical data for research purposes and to enhance capabilities to share research data (NOT-OD-19-122).

Examples of activities that may be supported:

- Education and technology support for users of research informatics and open science (e.g., data management and sharing, tools, analytics, software, computing resources and other

Background: History - CTSA NOFO Change

Before September 4, 2024

Health Informatics Module

The CTSA Program is uniquely positioned to harness the power of digital assets by making them interoperable for research, ensuring data security, and implementing innovative informatics solutions, all with the goal of improving human health. Health Informatics programs are required to specifically support the CTSA Program goals of advancing clinical and translational science and increasing the quality of clinical research. Informatics capabilities and a commitment to open science principles across all aspects of the CTSA hub are critical to a successful clinical and translational science environment that can translate knowledge into practice and improve health. The capability to share and implement resources across CTSA hubs, when appropriate, offers opportunities to accelerate scientific discovery as we

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Examples of activities that may be supported:

- Education and technology support for users of research informati

As of September 4, 2024

Data Science Module

The CTSA Program is uniquely positioned to harness the power of digital assets by making them interoperable for research, ensuring data security, and implementing innovative informatics solutions, all with the goal of improving human health. Data Science programs are required to specifically support the CTSA Program goals of advancing clinical and translational science and increasing the quality of clinical research. Further, informatics capabilities and a commitment to open science principles across all aspects of the CTSA hub are critical to a successful clinical and translational science environment that can translate knowledge into practice and improve health. The capability to share and implement resources across CTSA hubs, when appropriate, offers opportunities to accelerate scientific discovery as well as improve the efficiency, quality, and impact of translational research.

To meet these goals, CTSA hubs and their partners are required to utilize a range of expertise and capabilities in the areas of data science including: 1) Health Informatics (applied research and practice of informatics across the clinical and public health domains); 2) Clinical Research Informatics (the use of informatics in the discovery and management of new knowledge relating to health and disease, including management of information related to clinical trials, and informatics related to the secondary research use of clinical data.); and 3) Translational Bioinformatics (the development of storage, analytic, and interpretive methods to optimize the transformation of increasingly voluminous genomic, digital health, and other biomedical data, into proactive, predictive, preventive, and participatory health, including research on the development of novel techniques for the integration, and subsequent multimodal analysis, of biological and clinical data and the evolution of clinical informatics methodology to encompass biological and Real-world observations). Novel research and resources that can be disseminated to a variety of stakeholders, including biomedical scientists, clinicians, and patients, should be the end product of these integrated efforts within this module.

CTSA hubs and their partners are expected to embrace a culture of Open Science and Data Sharing that promote the F.A.I.R. principles (see: NIH Strategic Plan for Data Science). Open Science is the practice of science in such a way that others can collaborate and contribute, where research data, lab notes and other research processes are freely available, under terms that enable reuse, redistribution and reproduction of the research and its underlying data and methods. The sharing of data, tools, algorithms, methodologies (e.g., machine learning, predictive analytics), governance principles and policies, and software; making research tools compatible with common data elements (CDEs), including social determinants of health CDEs in its domain areas (see https://cde.nlm.nih.gov/home); and deploying research systems with broadly accepted content and technical standards including those adopted by the Department of Health and Human Services (DHHS) for use in U.S. health care and public health operations will promote the translation of scientific discoveries into health improvements. Embracing this culture, Data Science Modules are encouraged to use the Fast Healthcare Interoperability Resources (FHIR®) standard to capture, integrate, and exchange clinical data for research purposes and to enhance capabilities to share research data (NOT-OD-19-122).

Examples of activities that may be supported:

- Education and technology support for users of research informatics and open science (e.g., data management and sharing, tools, analytics, software, computing resources and other

Background: History - CTSA NOFO Change

As of September 4, 2024

Examples of activities that may be supported:

- Education and technology support for users of research informatics and open science (e.g., data management and sharing, tools, analytics, software, computing resources and other capabilities)
- ~~Data management, storage, organization~~Natural language processing, generative AI, and ~~data sharing resources~~
- ~~Data~~text mining~~, visualization, and analytics tools and platforms~~ approaches
- Clinical decision support and treatment planning tools
- Technology to support next generation clinical trials and clinical trial matching
- Behavioral intervention tools
- ~~Data processing methods such as data compression, data provenance, and data wrangling~~
- ~~Data annotation tools, including common data elements, and ontologies~~
- ~~Data integration and workflow tools and platforms~~
- Tools, platforms and/or applications to collect and validate DHT-derived data for its use as Real-World Data and subsequent linking to other sources (e.g., other reliable clinical and/or public health data sources) to support Real-World Evidence
- AI/ML algorithm validation and quality control tools
- Statistical, graph and network theory, and machine learning methods research to advance analytical AI and CTS
- Development of data standards, data exchange formats, data quality assurance methods, and data security and privacy management tools
- Performance evaluation of software tools, algorithms, and data collection methods
- ~~Statistical methods, graph and network theory approaches, and machine learning methods~~
- ~~Natural language processing and text mining approaches~~
- Platforms for research collaboration and algorithm performance evaluation

- Data management, storage, organization, and data sharing resources; data processing methods such as data compression, data provenance, and data wrangling; data mining, visualization, and analytics tools and platforms; data annotation tools, including common data elements, and ontologies; and data integration and workflow tools and platforms
- Environments for interactive modeling and simulation

Courtesy of Justin Starren

Background: History

- September 2024
  - NIH changed CTSA NOFO
  - CTSA SC and Informatics Enterprise Committee (iEC) discussed high-level changes

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  - CTSA SC and iEC discussed in-depth changes

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  - CTSA SC approved change from iEC to BIDS EC with specific deliverables
  - iEC held elections for 2025 iEC Lead Team

Background: History

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- October 2024
  - iEC compared and contrasted disciplines
  - CTSA SC and iEC discussed in-depth changes
- November 2024
  - CTSA SC approved change from iEC to BIDS EC with specific deliverables
  - iEC held elections for 2025 iEC Lead Team
- December 2024
  - BIDS EC gathered together with ACTS BERD SIG leaders for BIDS expansion
  - NCATS requested charter draft by April 2025

Background: CTSA BIDS EC Lead Team

- Nick Anderson (UC Davis)
- Jiang Bian (Indiana)
- Elmer Bernstam* (UTHSCH)
- Tom Campion** (Weill Cornell)
- Heath Davis (Iowa)
- Tim Huerta (Ohio State)
- Meredith Zozus** (UTHSCSA)
- Manisha Desai (Stanford)
- Chris Lindsell (Duke)
- Jareen Meinzen-Derr (Cincinnati)
- Shari Messinger (Miami)

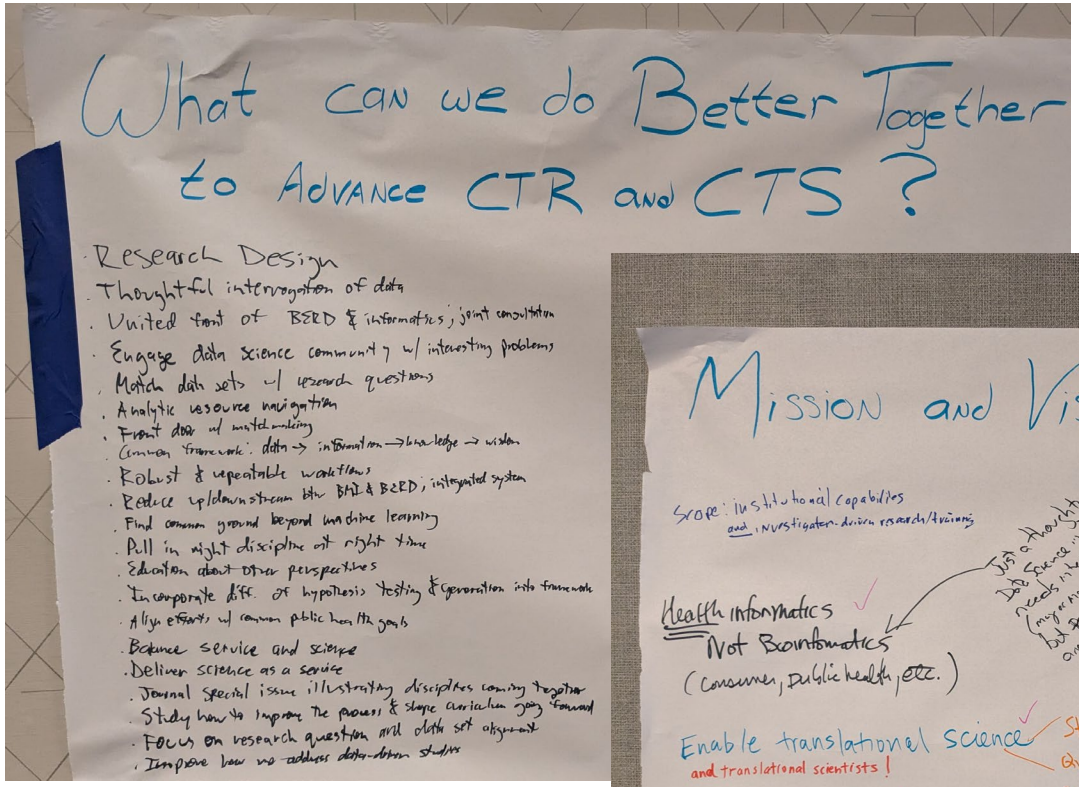
*CTSA Steering Committee representative for BIDS EC
**Co-chairs for BIDS EC

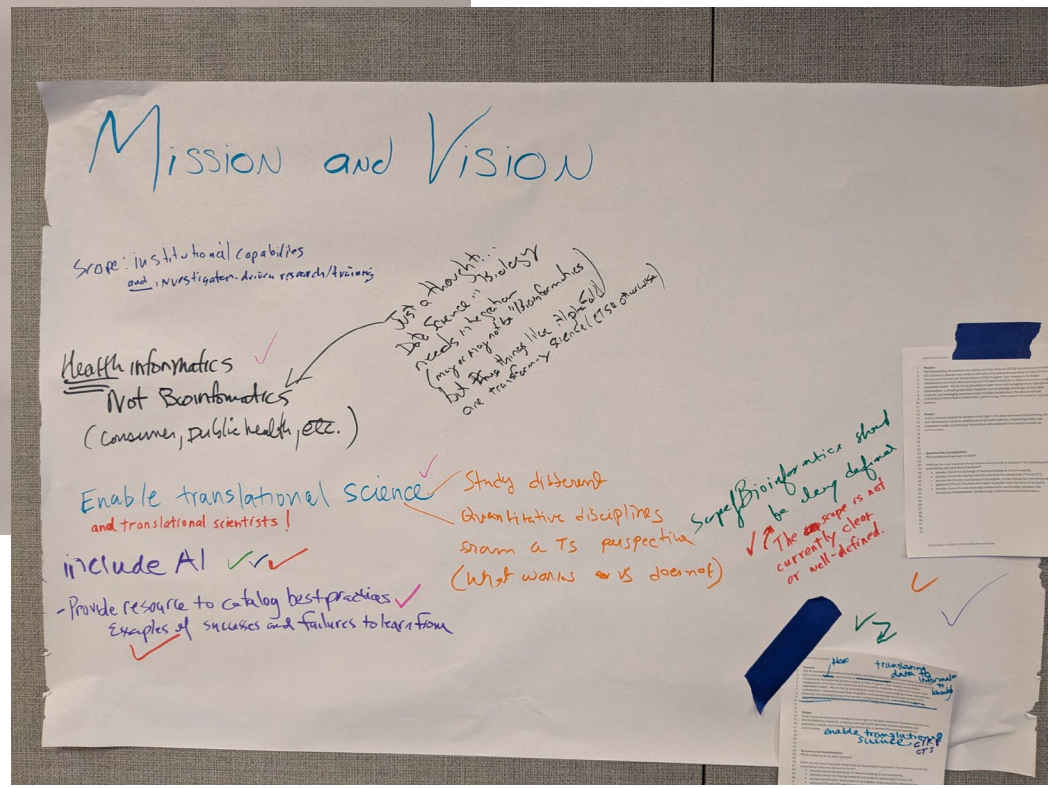
Approach

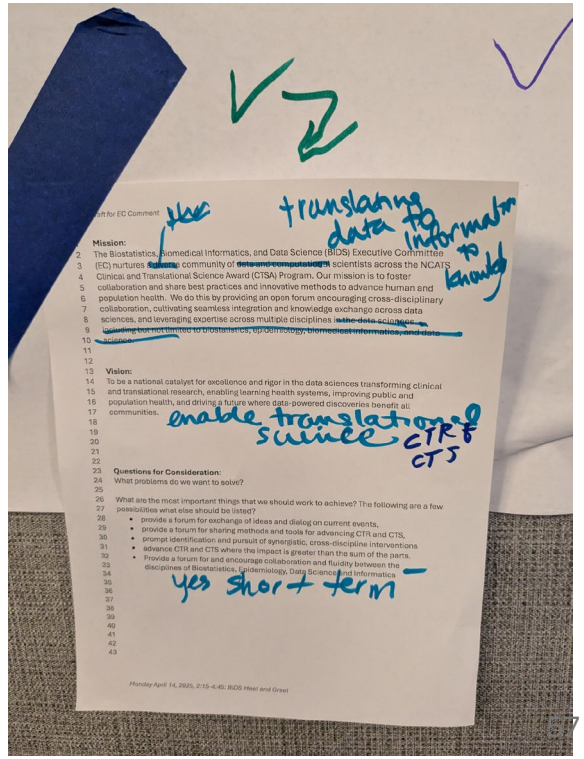
- Membership expansion
  - Soft launch
  - Formal messaging to CTSA PIs
  - Coordination with CCOS and NCATS
- Meetings
  - Virtual
    - Full Membership
    - Lead Team
  - In-person
    - BIDS EC Transition: March 14 w/ AMIA Informatics Summit
    - BIDS Meet & Greet: April 14 w/ ACTS Translational Science

Approach: In-Person Meetings - BIDS Meet & Greet

Charter Gallery Walk



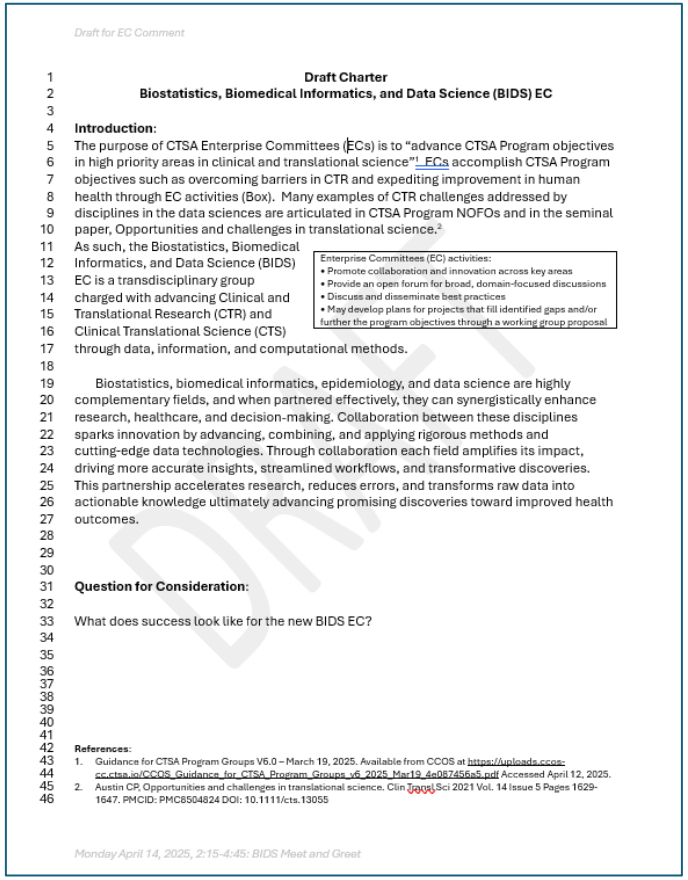




[Available via NCATS BIDS Google Drive]

Current State

- Full Members: 380+
  - Registration via NCATS BIDS Google Forms
- In-Person Meeting registrants
  - BIDS EC Transition (March 14th w/ AMIA): 32
  - BIDS Meet & Greet (April 14 w/ ACTS): 59 (20 hybrid)
- Finalization of charter
  - Available via NCATS BIDS Google Drive



Draft for EC Comment

Draft Charter
Biostatistics, Biomedical Informatics, and Data Science (BIDS) EC

Introduction:
The purpose of CTSA Enterprise Committees (ECs) is to "advance CTSA Program objectives in high priority areas in clinical and translational science"[1]. ECs accomplish CTSA Program objectives such as overcoming barriers in CTR and expediting improvement in human health through EC activities (Box). Many examples of CTR challenges addressed by disciplines in the data sciences are articulated in CTSA Program NOFOs and in the seminal paper, Opportunities and challenges in translational science.[2]
As such, the Biostatistics, Biomedical Informatics, and Data Science (BIDS) EC is a transdisciplinary group charged with advancing Clinical and Translational Research (CTR) and Clinical Translational Science (CTS) through data, information, and computational methods.

Enterprise Committees (EC) 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

Biostatistics, biomedical informatics, epidemiology, and data science are highly complementary fields, and when partnered effectively, they can synergistically enhance research, healthcare, and decision-making. Collaboration between these disciplines sparks innovation by advancing, combining, and applying rigorous methods and cutting-edge data technologies. Through collaboration each field amplifies its impact, driving more accurate insights, streamlined workflows, and transformative discoveries. This partnership accelerates research, reduces errors, and transforms raw data into actionable knowledge ultimately advancing promising discoveries toward improved health outcomes.

Question for Consideration:

What does success look like for the new BIDS EC?

References:
1. Guidance for CTSA Program Groups V6.0 – March 19, 2025. Available from CCOS at https://uploads.ccos-cc.ctsa.io/CCOS_Guidance_for_CTSA_Program_Groups_v6_2025_Mar19_4e087456a5.pdf Accessed April 12, 2025.
2. Austin CP. Opportunities and challenges in translational science. Clin Transl Sci 2021 Vol. 14 Issue 5 Pages 1629-1647. PMCID: PMC8504824 DOI: 10.1111/cts.13055

Monday April 14, 2025, 2:15-4:45: BIDS Meet and Greet

Next Steps

- Obtain approval from Steering Committee for BIDS EC
  - Charter
  - Voting member increase (2)
  - Election approach: new lead team members (7)
- Implement shared vision
- Foster community
- Prepare elections

Acknowledgments

- CTSA BIDS colleagues
- ACTS
- AMIA
- CCOS
- iEC Lead Team 2024
  - Jim Cimino (UAB)
  - Peter Elkin (Buffalo)
  - Jomol Mathew (Wisconsin)
- NCATS

Questions

- BIDS EC Co-Chairs
  - Meredith Zozus: zozus@uthscsa.edu
  - Tom Campion: thc2015@med.cornell.edu
- References
  - BIDS EC Charter DRAFT: https://docs.google.com/document/d/1D1Xyhx3ZU4NNROCd-fHzKXYWc2JrYokN/edit
  - BIDS EC Meet & Greet Charter Gallery Walk Materials: https://docs.google.com/spreadsheets/d/1s4Lyo54Q-EfJqIaVDaXdqItic0D3hGEb/edit?gid=1664061997#gid=1664061997
  - BIDS EC Membership Registration: https://docs.google.com/forms/d/e/1FAIpQLSdzcPYtXluH7lN3XKzgaE9V1XpAGDCu8q78HUFt58a2P9153w/viewform

Reminder: June 2025 CTSA Webinar

The next webinar is **June 25**, **2025;** 2-3 PM ET