CTSA Coordination, Communication, & Operations Support

CTSA Steering Committee Meeting
April 28, 2025

2:30pm-3:30pm ET

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Deloitte. ICF University of Rochester

Agenda: April 28, 2025

Time	Topic	Speaker(s)
2:30-2:35pm ET	Welcome & Announcements	Michael Kurilla, Ted Wun
2:35pm-2:50pm ET	BIDS Transition Update	Meredith Zozus, Thomas Campion
2:50-2:55pm ET	Vote: TS-CBA WG Extension Vote: Engaging Individuals with Disability in the Research Process	Cindy Mark
2:55pm-3:10pm ET	Pod Feedback	Chris Hartshorn
3:10pm-3:30pm ET	Brainstorm for Fall CTSA Meeting	Michael Kurilla, Grace McComsey
3:30pm ET	Adjourn	Michael Kurilla, Ted Wun

Welcome and Announcements

Michael Kurilla

Ted Wun

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

Monday, April 28, 2025

CTSA Steering Committee Meeting

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

Overview

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

Objectives

- Develop a shared vision for 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

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  - 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 mult

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

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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.

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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,

- 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
- Platforms for research collaboration and algorithm performance evaluation

Courtesy of Justin Starren

Background: History

- September 2024
  - NIH changed CTSA NOFO
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  - iEC compared and contrasted disciplines
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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

- September 2024
  - NIH changed CTSA NOFO
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  - 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
    - BIDS Meet & Greet

Approach

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  - **In-person**
    - **BIDS EC Transition**
    - **BIDS Meet & Greet**

Approach: In-Person Meetings

- BIDS EC Transition Meeting
  - A transition for the AMIA Biomedical Informatics community
  - March 14th 8a-2p
  - Pittsburgh PA
  - In conjunction with AMIA Informatics Summit
  - https://amia.org/education-events/amia-2025-informatics-summit/ncats-bids
- BIDS Meet & Greet
  - An introduction for BERD and Biomedical Informatics communities
  - April 14th 2:15-4:15p
  - Washington DC
  - In conjunction with ACTS Translational Science
  - Separate from but coordinated with ACTS Informatics SIG meeting April 14th 12-2p
  - https://events.rdmobile.com/Sessions/Details/2792766

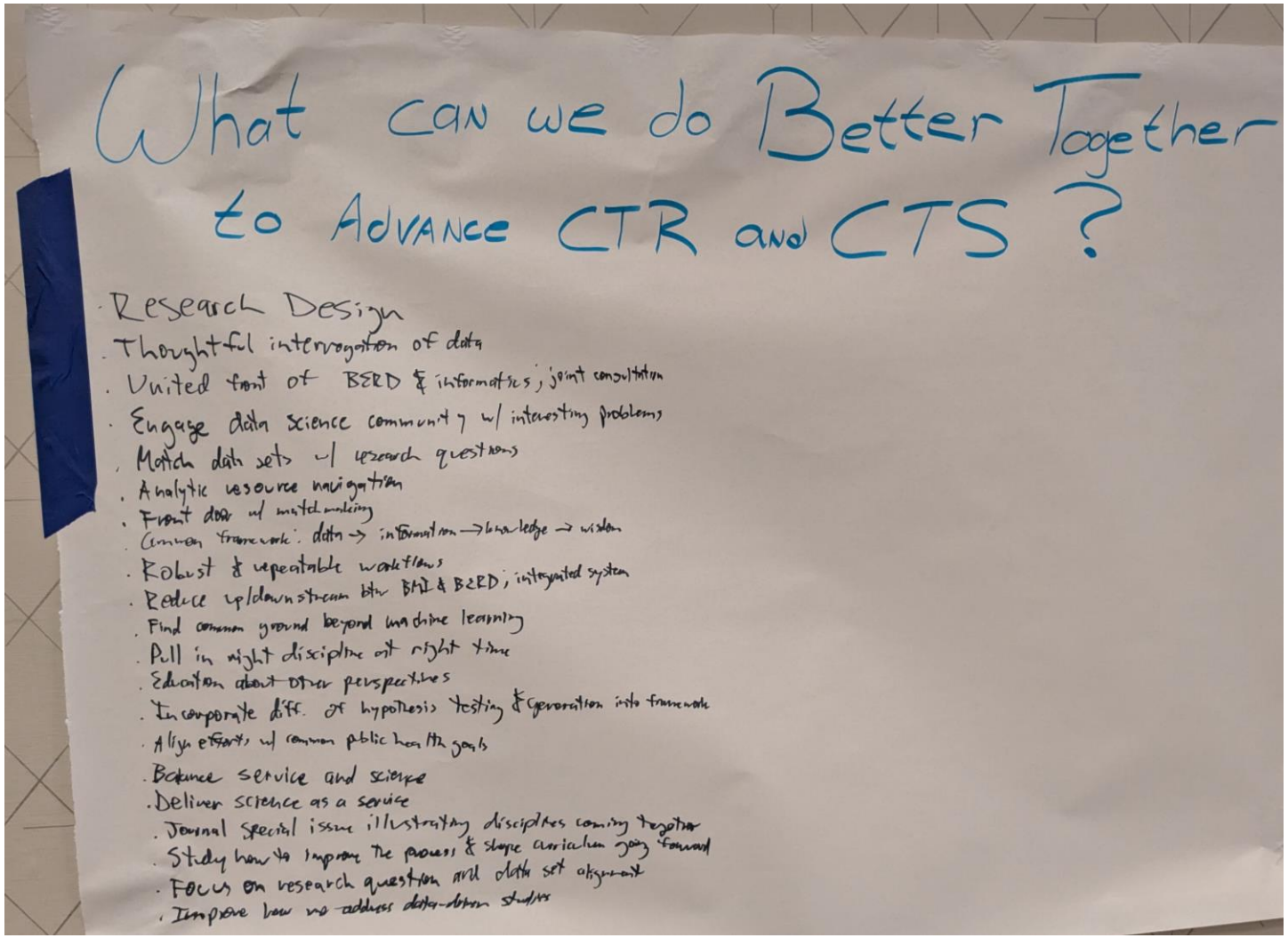
Approach: In-Person Meetings - BIDS EC Transition

Time	Topic
8:00	Welcome
8:15	BIDS EC transition history
8:25	BIDS language
8:45	NOFO transition
9:45	Break
10:00	Data compliance and role of CTSA hub
11:00	Open source software support
12:00	Lunch w/ opportunities for NCBI resource integration
1:00	Informatics for pilot projects
2:00	Adjourn

Approach: In-Person Meetings - BIDS Meet & Greet

Time	Topic
2:15	Welcome
2:30	Develop shared vision
3:30	Break
3:45	Define charter
4:45	Adjourn

Approach: In-Person Meetings - BIDS Meet & Greet



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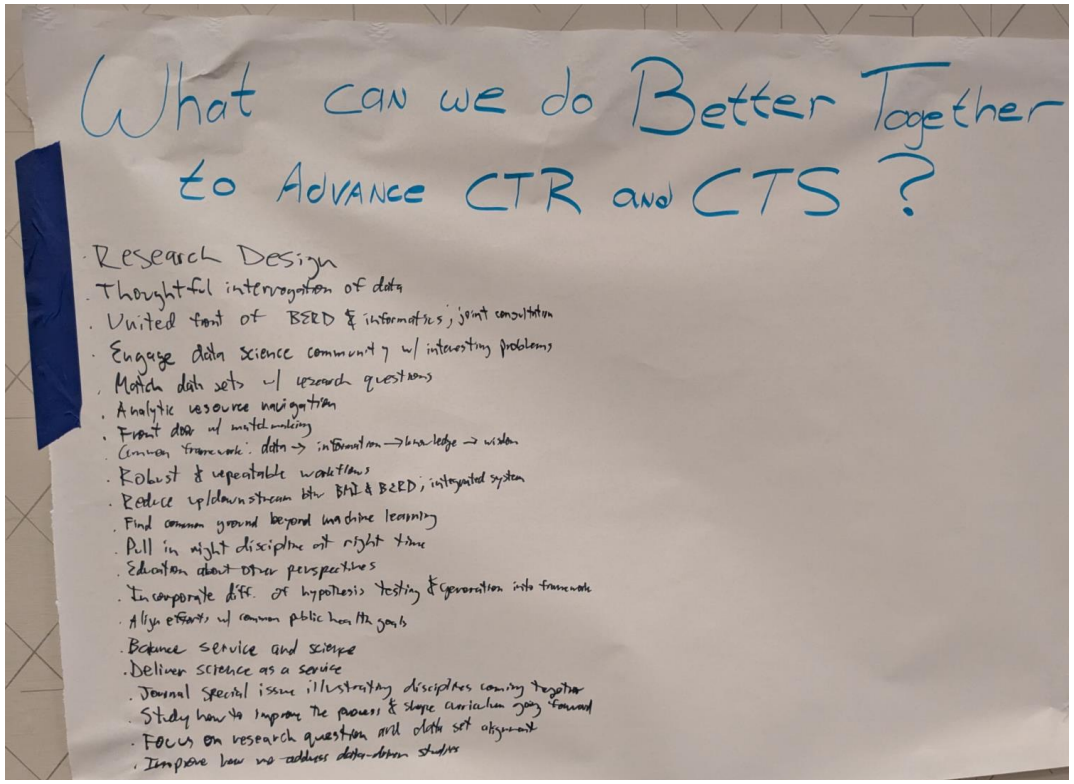
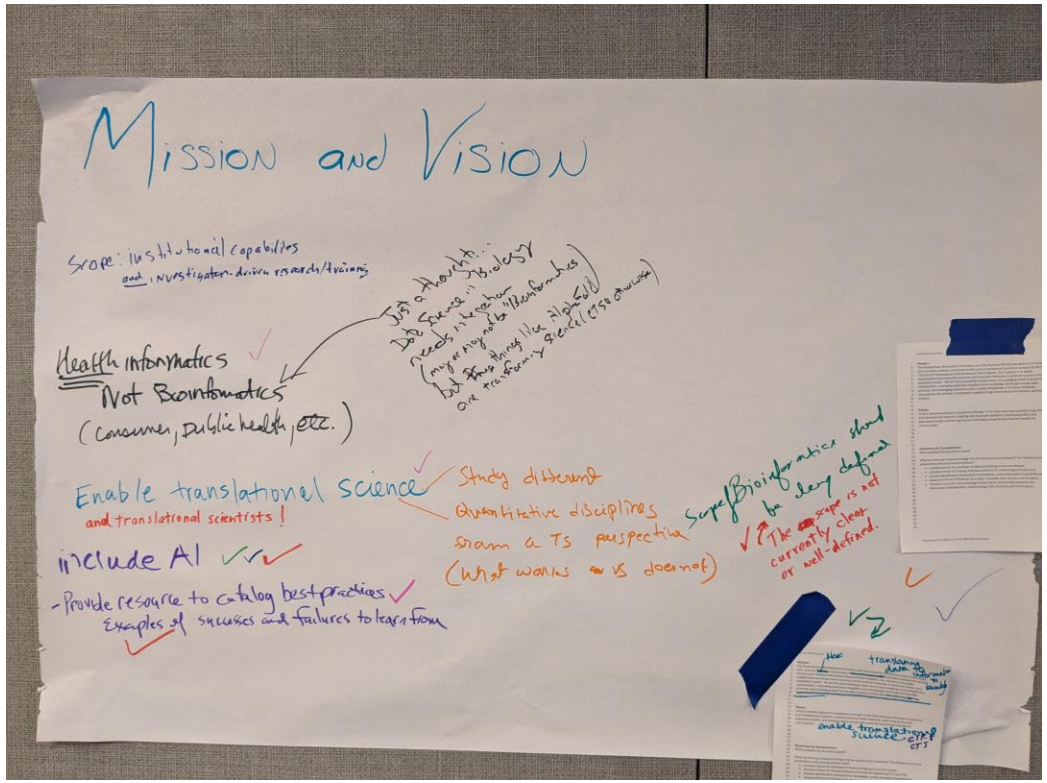
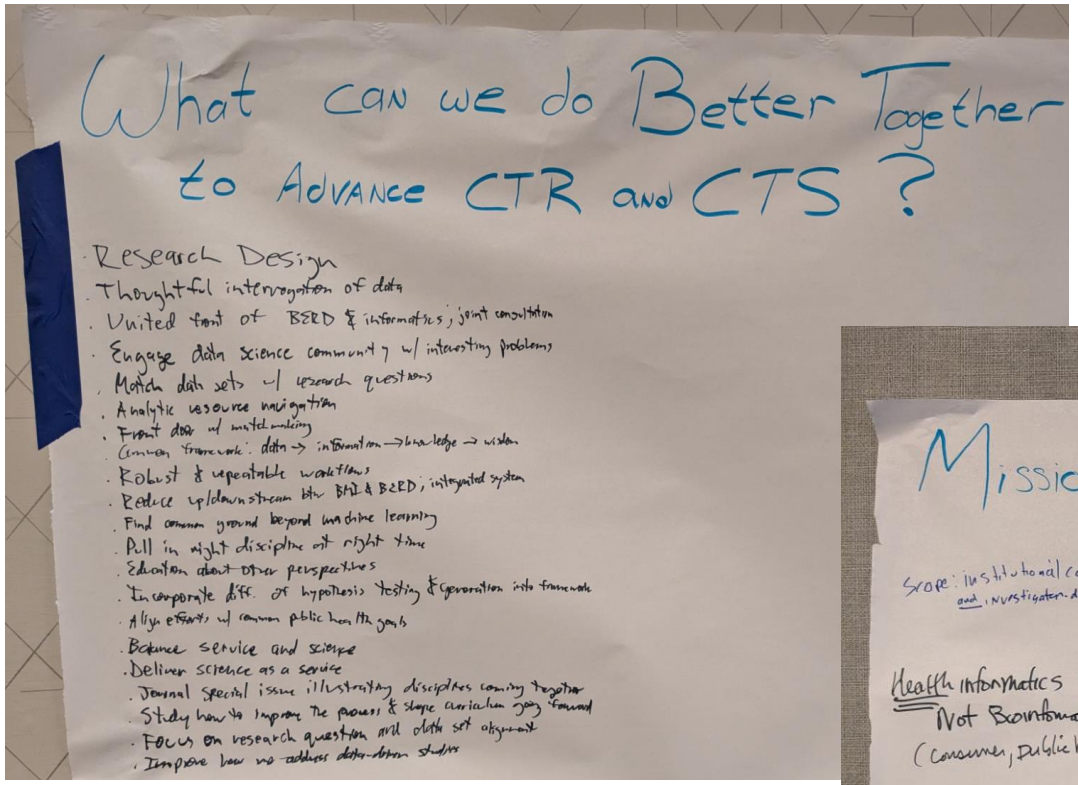
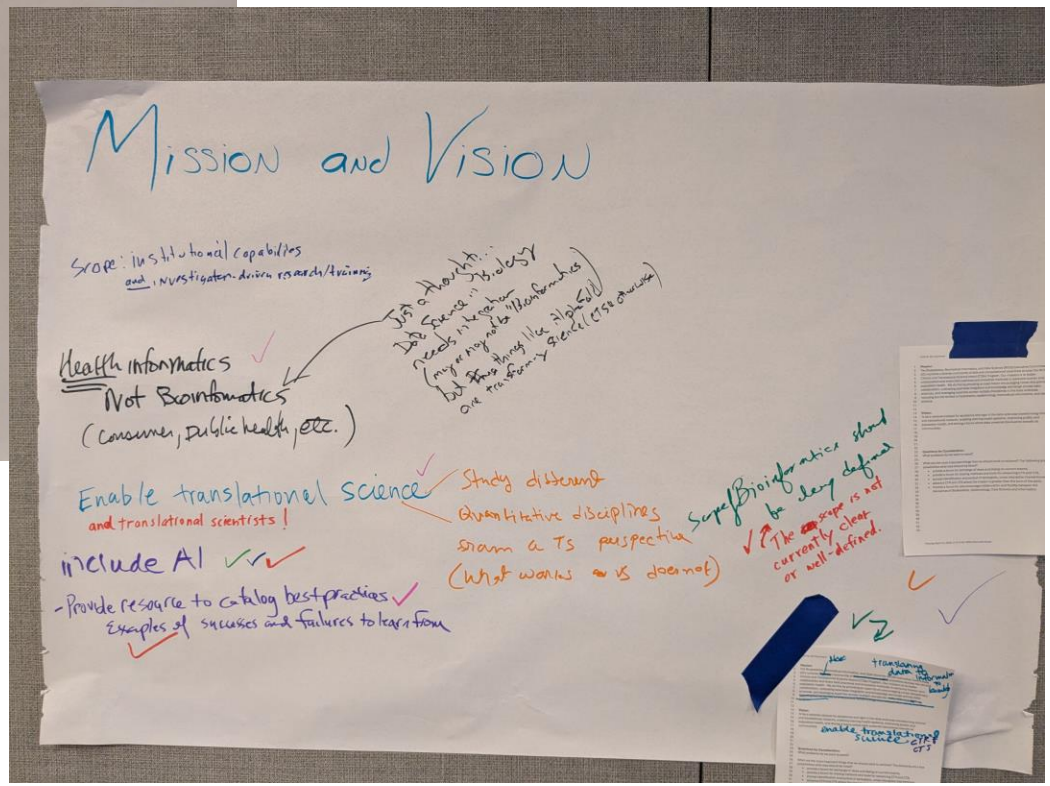
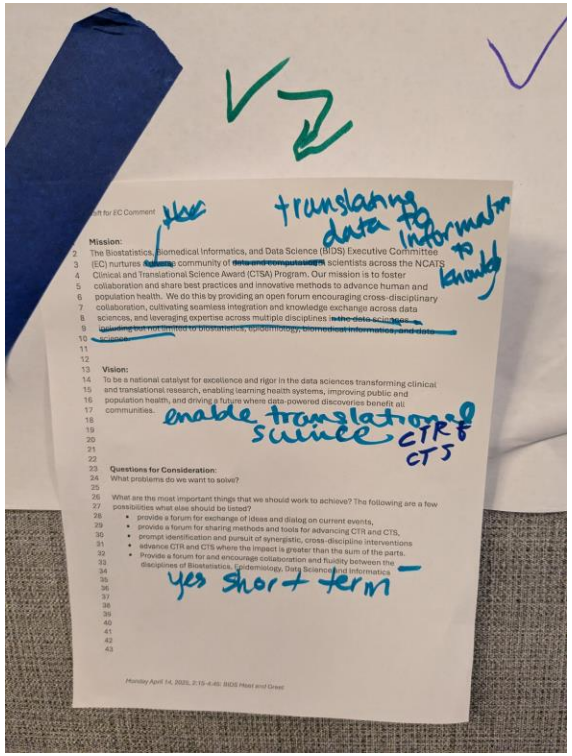




Approach: In-Person Meetings - BIDS Meet & Greet

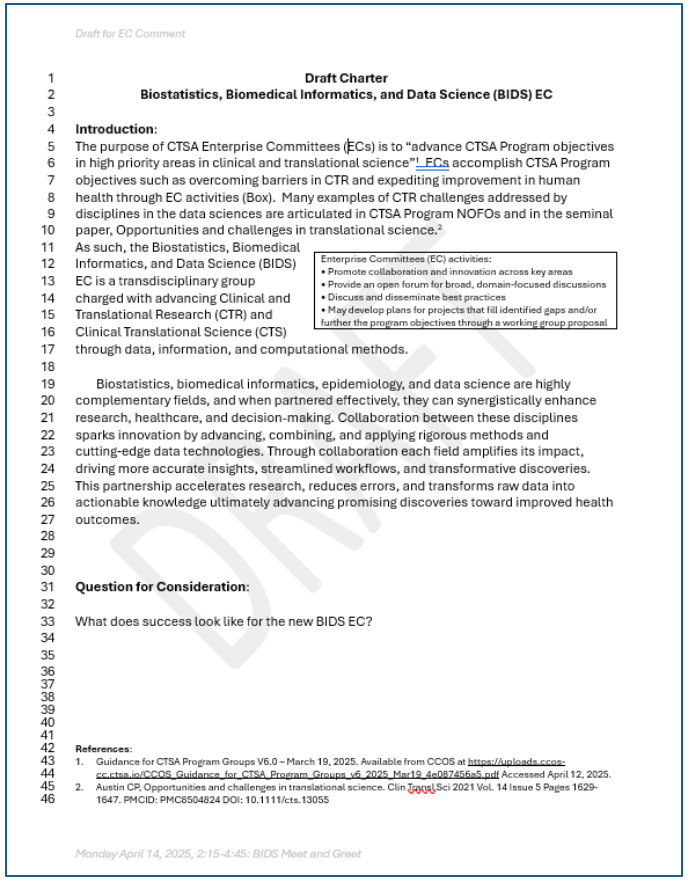






Current State

- Full Members: 365
- In-Person Meeting registrants
  - BIDS EC Transition (March 14th w/ AMIA): 32
  - BIDS Meet & Greet (April 14 w/ ACTS): 59 (20 hybrid)
- Finalization of DRAFT charter
  - Available for edit/comment
  - Shared via email



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

- Finalize charter with Steering Committee approval
- Implement shared vision
- Foster community
- Prepare elections

Acknowledgments

- ACTS
- AMIA
- CCOS
- iEC Lead Team 2024
  - Jim Cimino (UAB)
  - Peter Elkin (Buffalo)
  - Jomol Mathew (Wisconsin)
- NIH

Questions

- BIDS EC Co-Chairs
  - Tom Campion: thc2015@med.cornell.edu
  - Meredith Zozus: zozus@uthscsa.edu
- References
  - Guidance for CTSA Program Groups: https://uploads.ccos-cc.ctsa.io/CCOS_Guidance_for_CTSA_Program_Groups_v6_2025_Mar19_4e087456a5.pdf
  - BIDS EC Charter DRAFT: https://medcornell-my.sharepoint.com/:w:/r/personal/thc2015_med_cornell_edu/Documents/2025-0413-CTSA%20BIDS%20EC%20Charter.docx?d=wed97041a933649839021dba5d05251eb&csf=1&web=1&e=QHweux

Vote: TS-CBA Working Group
Vote: Engaging Individuals with Disability in the Research Process

Two working groups have asked for 6-month extensions. Their formal requests were disseminated to Steering Committee members on April 21.

The “pause” caused them to fall behind on their deliverables; they are requesting the extensions to complete their work by the end of 2025.

If approved, there will be 3 open working group slots for this cycle.

Poll Everywhere Voting Instructions

Please click on the link or the QR code below. Voting is anonymous and you will not be able to change your response after submitting your vote.

PollEv.com/cindymark459

Do you approve a 6-month extension for the TS-CBA Working Group?

Do you approve a 6-month extension for the Engaging Individuals in the Research Process Working Group?

0

POD FEEDBACK

Christopher Hartshorn, PhD
Section Chief
Clinical and Translational Science Awards Program Branch
Division of Clinical Innovation
Digital & Mobile Technologies Section

COORDINATION

Pod Meeting Summary: February 18, 2025

Date Received: February 18, 2025
Pod Lead: Arleen Brown, UCLA Clinical and Translational Science Institute
Pod Membership: Stanford, Scripps, University of California- San Diego, OHSU

Discussion:

- Site updates on submissions, responses to reviews, RPPR submissions
- NIH updates
- ACTS meeting will on April 14-17, 2025 – the UL1/UM1 meeting is scheduled for Thursday, April 17th 1-2, pending NIH approval – registration for the NCATS meeting is not yet open.
- Fall meeting – reviewed topics and solicited volunteers for planning committee
- Topic for future POD meetings (next meeting March 17, 2025, 3-4 pm PT)
- Translational research around wildfire response at UCLA – will invite leads to March meeting

Pod Meeting Summary: February 20, 2025 and April 10, 2025

Date Received: February 20 and April 10
Pod Lead: Julie Lumeng, Michigan- Ann Arbor
Pod Membership: Case Western, University of Kansas, University of Arkansas, University of Texas – San Antonio, University of Texas- Galveston, University of Texas- Houston

February 20, 2025

Topics Discussed:

- Member organization: Introductions were made, structure of the meeting discussed, and bi-monthly meetings confirmed.
- Update from Steering Committee
- Roundtable: Hubs hared their impressions of current expectations and next steps.

2025 Fall CTSA Program Meeting

- The group suggested themes for the Fall CTSA Program meeting including community engagement, dissemination and implementation, translational science, health disparities and equity, and research ethics.
- The group suggested more networking opportunities for PIs and speakers from outside the CTSA community, ensuring low noise levels for conversation

April 10, 2025

Topics Discussed

- Updates from 2/24, 3/10, and 3/24 SC meetings.
- Roundtable: Each hub shared how they address salary caps and shared best practices for budgeting over the course of the entire grant, as well as for each individual grant year.

Hub Report Out:

- Each hub shared an update on current states, initiatives, and events.
- Several hubs are working on their RPPR submissions.
- Discussion on how hub work continues to evolve given current events.

Pod Meeting Summary: February 13, 2025 & March 19, 2025

Date Received: February 13, 2025 and March 19, 2025
Pod Lead: Mimi Kim, Albert Einstein College of Medicine
Pod Membership: Columbia University, Harvard University, University of Chicago, University of Rochester, Washington University

February 13, 2025

General discussion

- The impact of the recent EOs and NIH policy changes on hubs are of concern. Suggested to create forum where stories of impact to better demonstration value of CTSAs in improving individual and public health.

Hub Sharing

- Suzi Birz (University of Chicago) presented on the Sociome Data Commons, an innovative informatics resource.

March 19, 2025

Discussion on how federal priorities are impacting CTSA hubs (funding, staffing, research areas, etc.)

- Hubs provide more support to investigators with grant resources, cross-field collaborations, and increased meetings.
- Working with other hubs to jointly develop guidance for aligning research and training with federal priorities would be beneficial and efficient.
- Advocate for CTSA work and improve communication about its impact to government and public.

Hub Sharing

- Christina Gurnett, Associate Director of CTSA and Pediatric Neurologist at Washington University, gave an interesting presentation on “Genetic Data Precision Health Functions.

National Center for Advancing Translational Sciences

Pod Meeting Summary: March 18, 2025

Date Received: March 18, 2025
Pod Lead: Grace McComsey, Case Western Reserve University
Pod Membership: Case Western, University of Kentucky, University of Alabama at Birmingham, Boston University, UT Southwestern Medical Center

Discussion Topics

- If members have ideas for the Fall CTSA Program meeting, or would like to volunteer, email Dr. McComsey.
- How do Pod members link a program, resource, product etc. to your CTSA hubs?
- CWRU: Educating investigators about the NIH-funded program and the importance of acknowledging CTSA support. It's not mandatory but beneficial.
- Kentucky: Using vignettes to highlight how their program enabled research and leveraging Overton and Large Language Models to find affiliations and associations.
- UAB: Developing relationships with key centers for mutual recognition of CTSA support, and manually tracking CTSA-cited papers by staying in touch with investigators
- CTSAs ability to address Dr. Bhattacharya's five goals and introduction of those goals and need to look at revisions to these goals
- How long do you follow trainees and scholars to capture their outputs and impacts?
- UAB: Use Flight Tracker

Pod Meeting Summary: March 25, 2025 and April 22, 2025

Date Received: March 25, 2025 and April 25, 2025
Pod Lead: Gerry Moeller, Wright Regional Center for Clinical & Translational Science
Pod Membership: VCU, NYU Langone, Translational Science Institute, U Massachusetts, Georgetown/Howard University, Yale University, University of Virginia

March 25, 2025

Topics Discussed

- Steering Committee updates were provided.
- The group discussed how CTSA hubs could potentially engage/work with state governments. Such engagement could potentially promote the value of the CTSA program.
- The State University Partnership Learning Network was presented: Link
- Rutgers discussed the effectiveness of K12 vs. K08 or K23 in getting R01s funded. Dr Kurilla will look into NIH data on this topic.

Additional Discussion

- Uncertainty in Washington
- ACTS has space reserved for CTSA PIs to meet. Details to be announced soon.

April 22, 2025

Topics Discussed

- Michael Kurilla attended the Pod meeting.
- CR status: On March 14, 2025, Congress enacted the "Full-Year Continuing Appropriations and Extensions Act, 2025" (H.R. 1968), which funds NIH at the FY 2024 enacted level.
- RPPR Review Delays & Priority Alignment: RPPRs are experiencing delays, particularly for March 1 start dates.
- N3C Transition: The N3C is transitioning to the National Clinical Collaborative, with Axle Informatics continuing as the lead contractor.
- Potential Freezing of Awards: There is a hypothetical risk that NIH may freeze awards if funds are not used by the end of the fiscal year.

Pod Meeting Summary: April 1, 2025

Date Received: April 1, 2025
Pod Lead: Eric Vilain, University of California - Irvine
Pod Membership: University of New Mexico, University of California- San Francisco, University of Colorado, University of Utah, University of Washington

Pod Membership and Meeting Management

- Introduction of new Pod leadership and member introductions
- The Pod agreed for all Pods to submit agenda topics before the next meeting.

Discussion Topics

- Rachel Hess provided an update on Utah CTSA funding status and experiences of funding reinstatement and importance of showing scientific value
- Group Discussion on Scientific Arguments for CTSAs
- CTSAs ability to address Dr. Bhattacharya's five goals and introduction of those goals and need to look at revisions to these goals
- Invite Dr. Kurilla to join a Pod meeting.

Pod Meeting Summary: March 25, 2025

Date Received: April 28, 2025
Pod Lead: Reynold Panettieri, Rutgers University
Pod Membership: Indiana University, University of Minnesota, University of Wisconsin, University of Florida, University of Iowa

Presentation on strategies and examples on engaging state governments to support TS

- Key engagement areas
  - Recognition and marketing
  - Resource acquisition and partnerships
  - Crisis response capacity
  - WFD and training opportunities

- Best practices shared
  - Rutgers engaging former state health commissioners for consulting roles.
  - Indiana's VOICE program addressing mental health costs leading to legislative action.
  - Other examples from Iowa, Minnesota, and Colorado on entrepreneurship and innovation.

Advocacy and communication strategy

- Sharon Moe introduced a draft one-pager designed to uniformly present CTSA hubs to state legislatures and other government bodies.
- Discussion about branding consistency across hubs—different names (CTSA, CTSI, NJX, etc.) create confusion.
- Proposed using standardized CTSA branding followed by institution-specific naming in brackets.
- Emphasis on capturing metrics that demonstrate job creation and economic impact for political support.

Brainstorming for the Fall CTSA Meeting

Please raise your hand, unmute and share your ideas OR put your idea(s) in Chat OR send an email to: Grace and Mike, cc Cindy, Lauren, Amanda and Stephanie:

gam9@case.edu

Michael.Kurilla@nih.gov

Cindy.mark@icf.com

Lauren.fitzharris@icf.com

Amanda.scott@icf.com

stephanie.ezequiel@nih.gov

Fall Annual Meeting Topic Recommendations from UPIs

Translational Science & Research

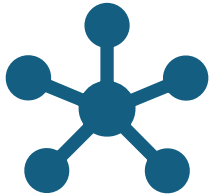
Transformation of Translational Science and Research by Ambient Artificial Intelligence

Artificial Intelligence and Clinical and Translational Science

Ensuring that translational science benefits all Americans

How to address gaps in TS

Role of CTSA Program in Chronic Disease Research



Collaboration & Communication

How to create cross-hub collaborations

Communicating the value of the CTSA to multiple audiences

How can the CTSA promote the public view of academic research centers as responsible and reliable research partners

Support & Mentoring

Effective approaches to supporting faculty, trainees and staff

Strategies to build a resilient hub

Mentoring of new PIs

Survey closes May 7

Ideas for Fall Meeting (April 2025)

- NIH Director (=/- Dr Ritter) on his vision and how CTSAs may help
- Effective communication strategies and marketing across hubs
- More PI only time
- Real World Data panel (TriNetX, cosmos, n3C and Enact) and panel discussion of pros/cons
- Integrative Medicine/Nutrition studies/preventive studies within the CTSA network; how can we help RFK Jr agenda?
- Leadership training (young and mid/upper investigators separately) across CTSAs
- Element E: lessons learned so far. How do we translate this knowledge to wider practice across hubs
- Trust in Research; added value of NIH research
- Government Relations: how do we better communicate our success with policy makers

Adjourn

May 12, 2025
2:30-3:30pm ET

National Center
for Advancing
Translational Sciences