

# Steering Committee Meeting

**June 23, 2025**  
**2:30-3:30pm ET**

# Agenda

Time	Topic	Speaker(s)
2:30-2:35pm ET	Welcome & Announcements - TIN Survey	Michael Kurilla, Ted Wun Dan Ford
2:35-2:55pm ET	Review & Vote on New WG Submissions	Amanda Scott
2:55pm-3:15pm ET	EHR/RWD Task Force	Jareen Meinzen-Derr
3:15pm-3:30pm ET	Report Out: Workforce Development EC	Maija Williams and Vicki Ellingrod
3:30pm ET	Adjourn	Michael Kurilla, Ted Wun

# RIC CTSA POC Needs Assessment Survey

## Purpose:

- Assess usage and dissemination of current resources and tools at the CTSA level
- Inform and guide the RIC as they develop new resources and guidance
- Help identify potential gaps and guide the development of future tools in terms of format and relevance

## Areas of assessment:

- Recruitment and engagement of rural populations, decentralized trials, and the use of AI
- Utilization and distribution of RIC-developed resources at the CTSA site level
- Potential areas to develop new innovative tools and recruitment strategies.
- Opportunity for CTSA POCs to inform the RIC about additional ways we can support the CTSA sites in regards to recruitment and retention efforts.



**Focus:** Survey to gather information on the utilization of RIC resources during the current and previous grant periods and assess potential new areas of innovative resource development



**Audience:** HUB Liaison POCs, who can then forward it to the appropriate personnel at their institution for them to complete all or part of the assessments



**Distribution:** To be disseminated by email to Liaison POC's by the end of June 2025

# Cycle XIV Working Group Proposals

- Proposals Received: 4
- Working Group slots: 2
- Start Date: July 1, 2025
  
- Each proposal has 3 slides
  - Goals & Deliverables
  - Overall Score, Feedback and Recommendations
  - Reviewer comments
- Discussion time for each proposal is limited to 5 minutes, as needed

# Current Working Groups

- 21 CFR Part 11 Compliance for RedCAP
- Advancing Dissemination and Implementation Sciences
- Engaging Individuals with Disability in the Research Process
- TL1 Visiting Scientist
- Translational Science Competency-Based Assessment
- Translational Science Case Studies
- CTSA Translational Impacts
- Real World Data Workforce Development Across the Translational Spectrum
- Translational Case Studies in Commercialization
- Learning Health Systems-CTSA Partnerships
- Overcoming Barriers to Women's Health Research

# Principles for AI Translation in Healthcare (PATH)

- **EC Support:** BIDS

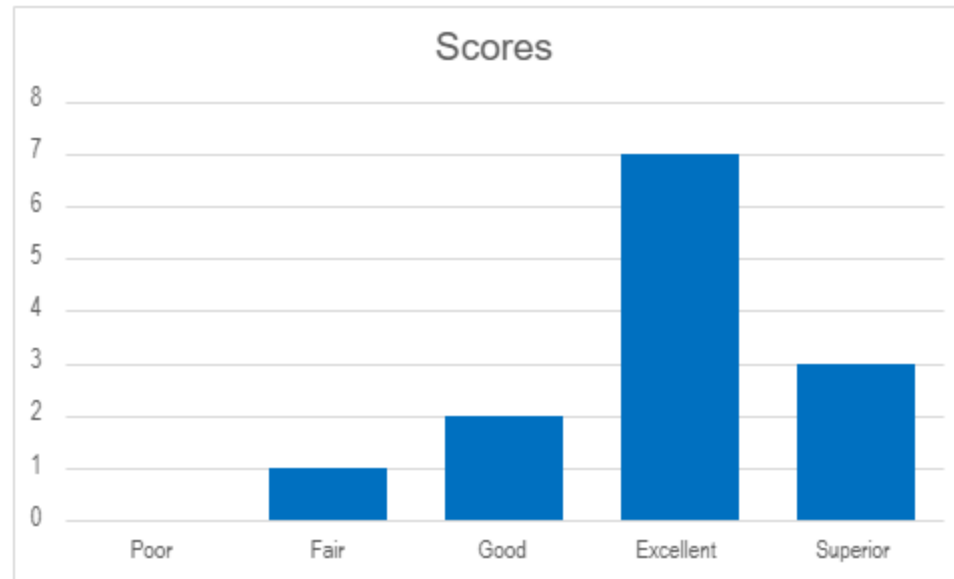
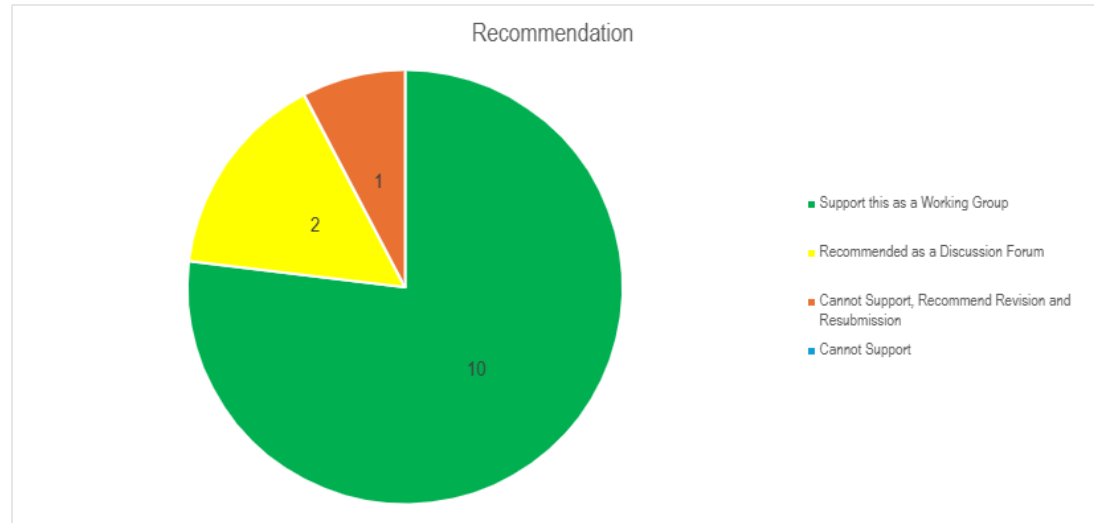
- **Goals:**

- Establish a translational AI evaluation
- Adopt and refine a core set of standardized criteria
- Develop best practices and actionable guidance for deploying validated AI models in healthcare settings
- Foster multi-institutional collaboration
- Design a sustainability and scalability strategy

- **Deliverables:**

- AI Evaluation framework for CTSA AMCs
- Multi-Institutional AI Validation Strategy
- Sustainability & scalability strategy
- Dissemination strategy
- CTSA position paper on AI Governance

# Reviewer Feedback



# Reviewer Comments

## Strengths:

- Timely, well-conceived proposal that will engage talent across several hubs.
- Highlights the need to generate real-world evidence to support AI for healthcare innovations as this is a barrier to adoption.
- Wide range of CTSAs involved in the WG.

## Areas for Consideration:

- Include more community and patient input in training.
- Consider merging with the other AI proposal so there's one working group on AI.
- Engage with researchers who have developed AI solutions for clinical care.
- The proposal may be overly ambitious, especially considering the rapid evolution of AI and the need for alignment across CTSA hubs.
- It appears to prioritize clinical care over research facilitation.
- Provide specific examples of clinical & translational research challenges; align with other initiative to avoid overlap.



# Vote: Principles for AI Translation in Healthcare (PATH)



# AI Value in Translational Research

- **EC Support:** N/A

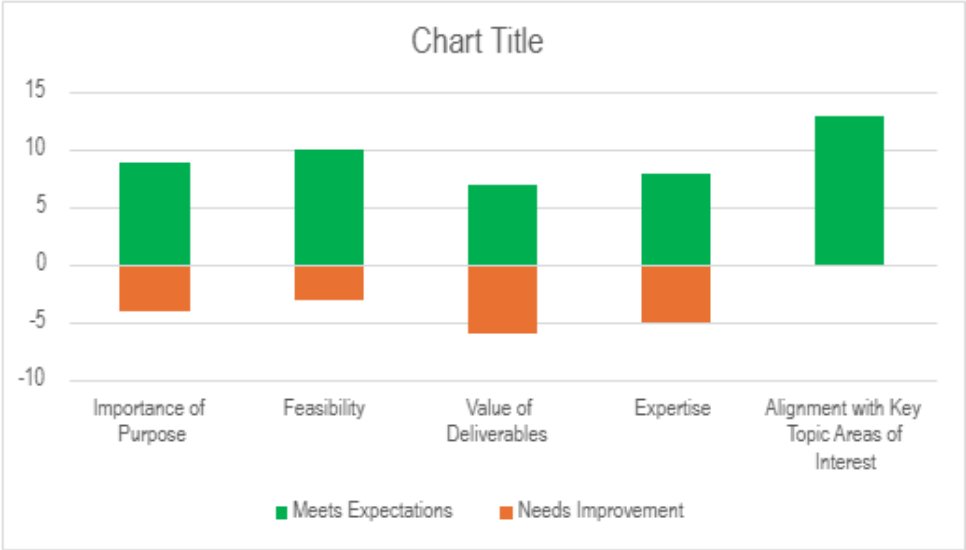
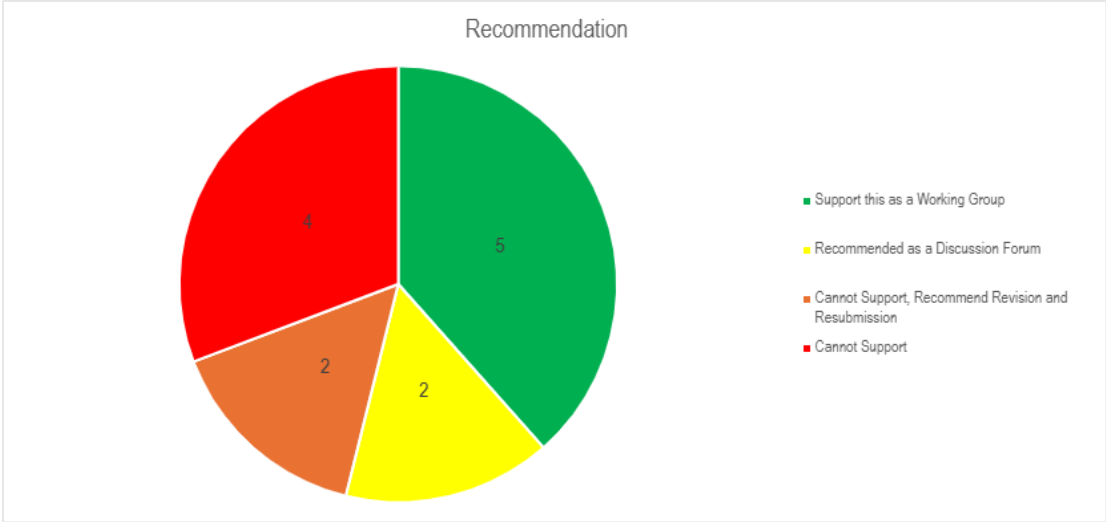
- **Goals:**

- Develop a Framework for AI Value:  
Establish clear, evidence-based criteria to assess the effectiveness, reliability, and translational value of AI tools to advance translational research.
- Conduct a Scoping Review of AI Value in Translational Research
- Engage Key Stakeholders in AI Adoption and Policy
- Build consensus on AI Standards for Translational Science

- **Deliverables:**

- AI Evaluation Framework
- Scoping Review on AI Value in Translational Research
- Stakeholder Engagement and Consensus Building

# Reviewer Feedback



# Reviewer Comments

## Strengths:

- Emphasizes the growing importance and value of AI.
- Highlights the need to generate practical evidence to support AI adoption in healthcare.
- Addresses the current lack of real-world evidence as a key challenge.
- Includes compelling ideas, particularly around evaluating the value of AI.

## Areas for Consideration:

- Expand participation to include more CTSA hubs to increase relevance, visibility, and collaborative potential.
- Strengthen the proposal with a sharper value proposition, focusing specifically on AI in research rather than clinical care.
- Provide concrete examples of how AI could transform clinical research to better illustrate impact and innovation.
- Address concerns about limited participation and lack of EC endorsement by recruiting additional collaborators and aligning with other AI-focused proposal.

# Vote: AI Value in Translational Research



# Building a National Criminal Justice Translation and Clinical Science Network (CJ TRACS)

- **EC Support:** N/A

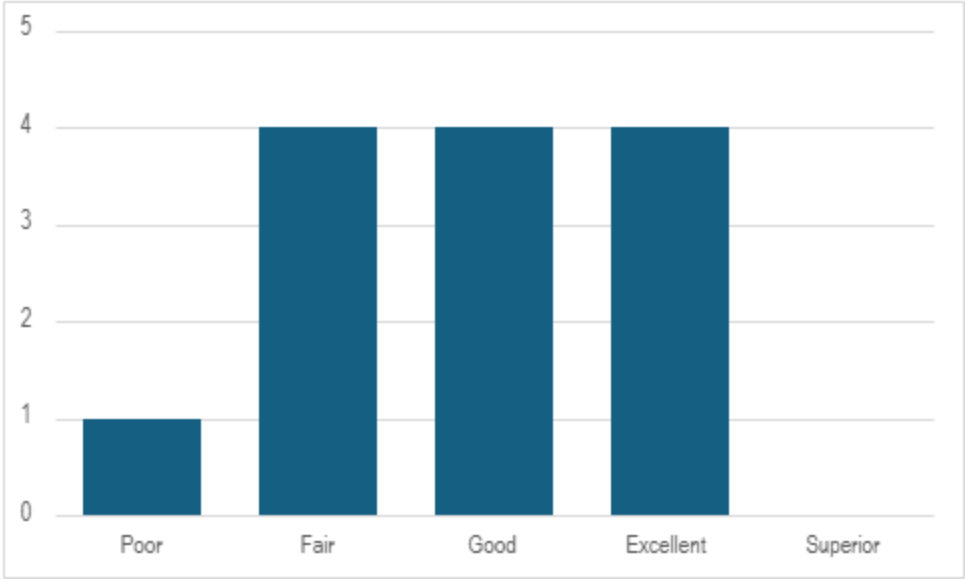
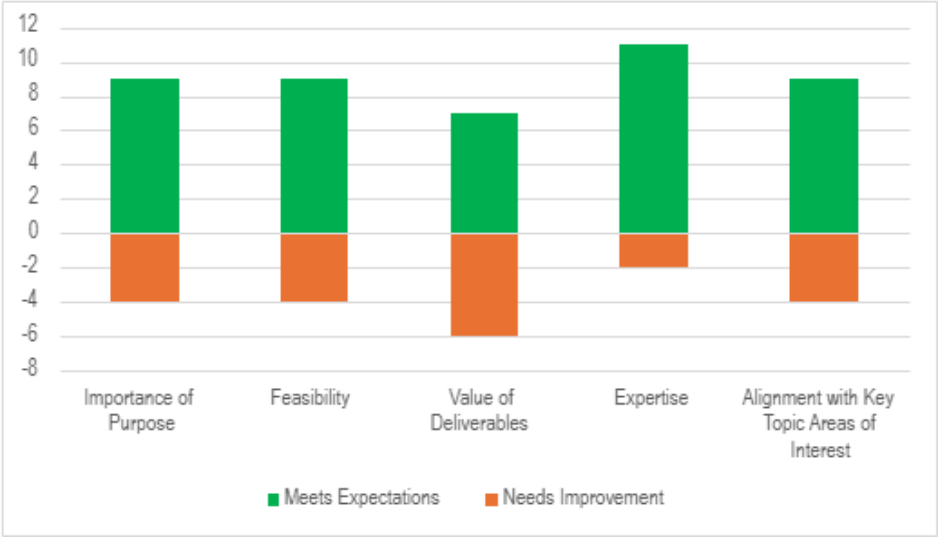
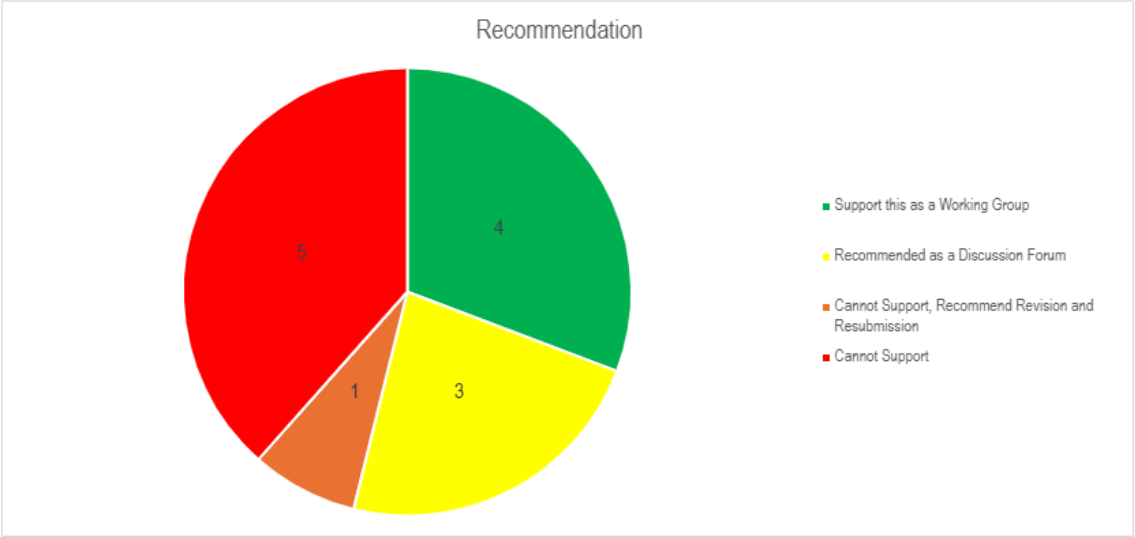
- **Goals:**

- Leverage CTSA infrastructure to develop CJ-related training and networking opportunities
- Facilitate multidisciplinary research collaborations and skill development
- Build robust mentor-mentee and collaborative networks
- Identify opportunities for research, policy action, and health care systems improvement that align with the mission of CTSA

- **Deliverables:**

- The development of the CJTRACS network
- A consensus-based index of translational research competencies for established and new CJ CTSA researchers
- A suite of training and networking opportunities aimed at increasing related workforce capacity

# Reviewer Feedback



# Reviewer Comments

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- This is an important topic that has been understudied and would benefit from this coordinated approach.
- Fills an important role in expanding competencies in training of translational scientists focused on this population that is underrepresented in TR.

## Areas for Consideration:

- Current strategies for involving investigators and trainees across the CTSA network are limited, with concerns about the ability to attract individuals at various career stages and with the necessary expertise.
- There is a lack of clarity and detail around the proposed deliverables, with skepticism about whether they are achievable given the small team size and limited Working Group (WG) participation.
- While the initiative addresses an important and noble issue—research involving incarcerated individuals—its background rationale and implementation plans need strengthening before advancing to a WG.
- Questions remain about the long-term viability of the initiative, including where it should be housed and how it aligns with broader CTSA programmatic priorities.
- Despite the initiative's value, there are concerns that launching it now could attract negative scrutiny to the CTSA program, especially given the sensitive nature of the target population and the current political climate.



# **Vote: Building a National Criminal Justice Translation and Clinical Science Network (CJ TRACS)**



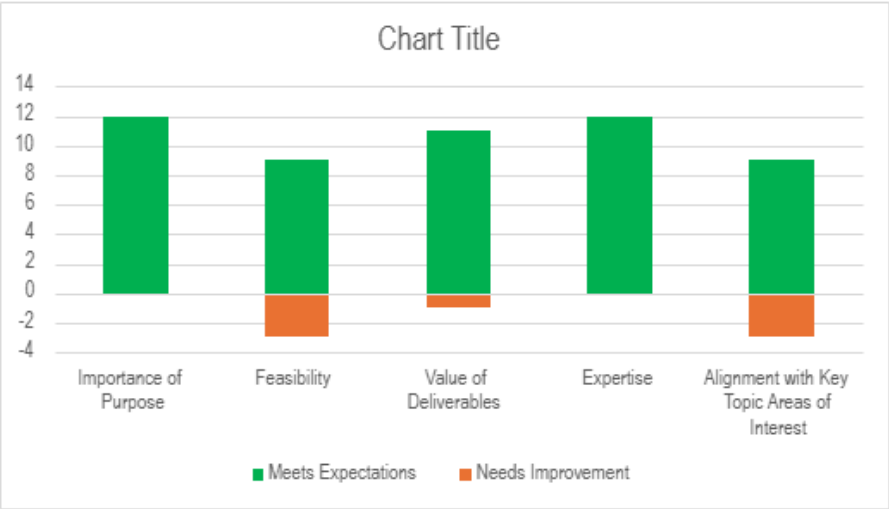
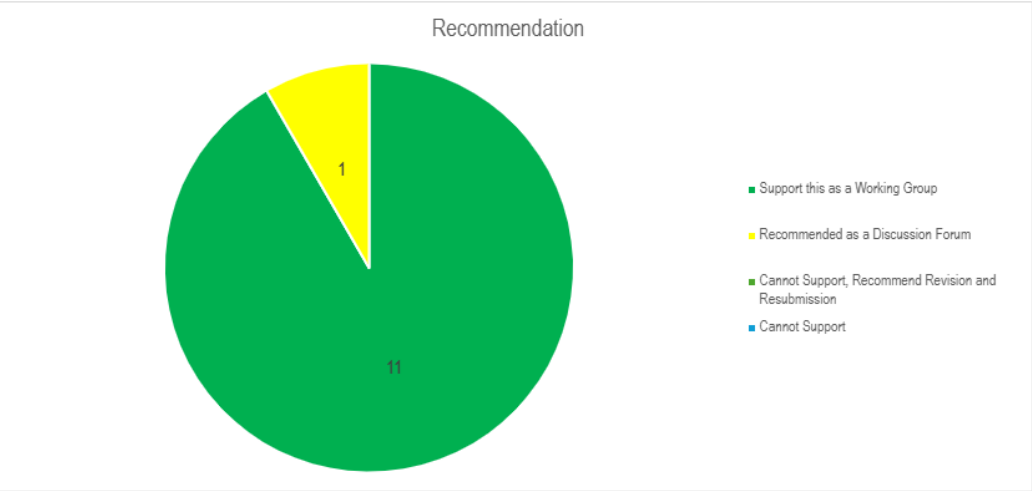
# Pediatric Clinical Trials

- **EC Support:** Integration Across the Lifespan.
- **Goals:**
  - Identify existing research networks nationally engaged in supporting pediatric clinical trials
  - Determine best practices from existing pediatric clinical trials networks that can be applied in emerging/underserved areas of pediatric health
  - Identify barriers and facilitators to conducting pediatric clinical trials
  - Understand knowledge gaps in pediatric clinical trials
  - Explore innovative opportunities to facilitate pediatric clinical trials

- **Deliverables:**
  - A completed survey of CTSA Hubs
  - A manuscript
  - A virtual meeting on Innovations in Pediatric Clinical Trials
  - A toolkit for pediatric clinical research network leaders
  - At least one multi-center team convened to write a grant that would test one of the novel designs from deliverable 2 (manuscript)

***This proposal is a resubmission***

# Reviewer Feedback



# Reviewer Comments

## Strengths:

- Presents a clear and well-structured plan to address a critical and high-impact topic in pediatric clinical trials.
- Offers significant potential to enhance the CTSA program by identifying and addressing barriers to efficient pediatric trial execution.
- Targets a partially unmet need with high potential value, even if not fully aligned with existing categories.
- Led by recognized experts in the field, demonstrating credibility and capability.
- The resubmission reflects a more specific and compelling approach, strengthening its overall value.
- The survey and scoping work, along with the virtual meeting, are seen as valuable contributions to the field.

## Areas for Consideration:

- Developing, administering, and analyzing the pediatric clinical trials survey alone is expected to take about one year.
- The goals are broad and ambitious, raising concerns about the feasibility of completing all activities within a 2-year timeframe.
- While the revised proposal shows progress, key concerns about feasibility and deliverables remain unaddressed.
- There is skepticism about the practicality and necessity of producing another toolkit.

# Vote: Pediatric Clinical Trials



# CTSA Program Steering Committee Update: Real World Data Task Force

Jareen Meinzen-Derr, PhD, MPH

Co-Director, Center for Clinical and Translational Science & Training

# Outline for the meeting

- Reminder Origins of the RWD Task Force
- Priorities
- Deliverables
- Transitions with BIDS EC
- Where we could be going - recommendations



# Real World Data Task Force

Arleen Brown

Manisha Desai (co-chair)

Melissa Haendel

Tesheia Johnson

Karen Johnston (co-chair)

Jareen Meinzen-Derr (co-chair)

Ruth O'Hara

Muredach Reilly

Steve Reis

Ken Gersing

Jim Dickens

Josh Fessel

CCOS Team

- Serve to help focus the CTSAs' data science goals and needs
- Communicate those goals and needs to the Steering Committee and to NCATS leadership
  - “We’re not looking for the roadmap. We’re looking for the destinations.” – Mike Kurilla
- Meet monthly on Mondays at 4pm ET
- “Wait, wasn’t this the EHR/RWD Task Force?”
  - Yes, and still is. But we’ve learned a lot about how we all think and use words in this space....



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Translational Sciences



# Genesis of the Task Force

- Initial goal came from two separate places that seemed to be closely related
  - From the SC side, help the CTSAs get a handle on the various NCATS-supported data assets
  - From the NCATS side, help understand what the CTSAs most want to do in the realm of data sciences related to RWD
- Fairly quickly discovered that the TF mission needed modification
  - It's not the “what” but rather the “who” and the “how”
  - There are basic language barriers to this kind of transdisciplinary team science
  - Some silos existed
- Focus shifted
  - Needs assessment
  - 3 impactful areas – education, democratization of data sciences, community engagement



# Established Priorities for Democratization and Community Engagement

- Recognized that data sciences are a broad and inclusive umbrella
- Recognized that the CTSAs collectively are leaders in data sciences
  - Experts and areas of expertise are unevenly distributed
  - What type of structures do we need in place to leverage the multi-disciplinary strengths across the CTSAs hubs?
- Desire for democratization
  - Requires many factors, including accessibility, usability, data literacy, governance & security
  - Need to really begin with education
- The imperative of engaging communities
  - Many communities to consider and to engage
  - Barely scratched the surface and many opportunities remain



# Major Deliverable - Education

- First major goal identified and the one most consistently topping the list
- Shared vocabulary needed
  - Development of an open access living glossary for data sciences terms and concepts
  - [Informatics Glossary - Google Docs](#)
  - FAQs (with same link as above) with a practical set of questions for investigators thinking about any given big data asset
- Training materials needed
  - Course materials developed for a host of data sciences topics - machine learning, good algorithmic practices, artificial intelligence, and many others
  - Designed to be a living resource
  - All available to the entirety of the CTSA via the CCOS website
- Training space needed to actually practice
  - National Clinical Cohort Collaborative Education Tenant
  - Synthetic datasets with complete functionality of N3C
  - Designed to be as frictionless as possible to access



# Major Deliverable - Education

## Real World Data Workforce Development Across the Translational Spectrum Working Group

- **RWD Training and Education Needs Assessment** – what are the educational needs for people in using RWD in TS?
- **RWD Education Inventory** - what is currently available in terms of educational resources and events to aid investigators learning how to use RWD in translational science? Do in collaboration with T, K, R25, AMIA, and other programs to increase educational collaboration opportunities and promote higher-quality, accessible RWD training.
- **RWD Maturity Model** - What educational materials, environments, data, and opportunities does an institution need to provide to realize the professional development needed to effectively utilize RWD in translational science?



# Major Deliverable - Education

## AIM-AHEAD and NCATS Training Curriculum

- Partnered to develop a traineeship in AI/ML using NCATS Data, the N3C Data Enclave, and AIM-AHEAD's Data Science Training Core
- Designed to reduce barriers for AIM-AHEAD researchers to access and analyze real-world clinical data

<https://www.aim-ahead.net/programs/aim-ahead-ncats-training-program/>



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# Major Deliverable – BIDS Enterprise Committee

- Biostatistics, Biomedical Informatics and Data Science (BIDS)
  - Includes highly complementary data science and related fields
  - “Leveraging the science of BIDS disciplines to advance the CTSA program is the central BIDS goal”
  - Charter recently approved by SC
- BIDS EC’s multi-disciplinary nature makes it ideal for addressing priority areas identified by the current TF



# Possible priority areas identified by TF

- Guidelines for rigorous science using automated tools with real-world data platforms
- Gaps in methods for optimally leveraging real-world data in target trial emulation
- Guidelines for causal inference studies using publicly available real-world data sources
- Types of studies to be promoted by real-world data sources



# Future of the Task Force - Recommendations

- Suggest **shifting from the TF to existing ECs** to support priorities
  - **BIDS EC** – take on agreed upon priority areas
  - **Collaboration & Engagement** – Engaging communities [broad term] regarding the use of EHR/RWD – how do we do this effectively? -
- Create targeted WG topic focused on identified priorities
  - RWD WG focused on workforce development education
- Leverage the ACTS Special Interest Groups to help lead some of these efforts (many have overlap with EC membership)





# NCATS

**COLLABORATE. INNOVATE. ACCELERATE.**



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Translational Sciences

# WORKFORCE DEVELOPMENT ENTERPRISE COMMITTEE (WFD EC)

## WFD CO-CHAIRS

**VICKI L. ELLINGROD, PHARM.D**

Dean, College Of Pharmacy

Associate Director, Michigan Institute For Clinical And  
Health Research (MICHHR)

**MAIJA NEVILLE WILLIAMS, MPH**

Chief Operating Officer; Administrative Director,  
Rockefeller Center For Translational Science

# Workforce Development EC Lead Team



Vicki Ellingrod, PHARM D  
Co-Chair  
University of Michigan



Maija Neville-Williams, MPH  
Co-Chair  
Rockefeller University



Lisa Cicutto, PhD, RN,  
University of Colorado  
Denver



Terri Edwards, RN  
Vanderbilt University



Janice Gabrilove, MD  
Icahn School of  
Medicine at Mount  
Sinai



David Ingbar, MD,  
University of Minnesota



Dixie Thompson, BSN  
University of Utah



Jennie Conroy, PhD  
NCATS



Cindy Mark  
CCOS (Retiring  
Coordinator)



Alex Paquet  
CCOS (Incoming  
Coordinator)

LOGISTICS



# Purpose and Priorities

- Purpose and Focus Areas

- Promote training and career development
- Foster impactful partnerships and collaboration
- Nurture development of all workforce involved in translational science and research
- Effective communication channel across all CTSA Hubs, NCATS, NIH

- Goals

- Provide a venue for sharing lessons learned (what does and does not work)
- Share new ideas, programs and peer-group problem-solving
- Span the entire workforce- trainees to clinical research professionals to translational scientists/researchers

# Updates

- Since June 2024 we have:
  - Met a total of 6 times over zoom for full EC meetings.
    - These meeting's have had an average attendance of 60
  - Planned the Spring Meeting and facilitated the WFD unofficial conversation at TS25
- Conducted an educational assessment to identify topics of interest to the community. Topics covered include:
  - Clinical Research Professional Apprenticeship Programs
  - Community Health Worker Research Training
  - Updates from the CTSA+ Mentorship Community of Practice (CoP) and Resources for Assessing Mentorship

# Spring WFD Conversation

- Theme: Adapting and Thriving: Navigating Change with Resilience
- Conversation Topics:
  - Supporting scholars/trainees during challenging times
  - Supporting scholars/trainees with topics that are no longer NIH priorities
  - Creative ways to find funding / carry out activities on limited budgets
  - Research Resilience
  - Pivoting to maximize resilience- individual, programs, workforce, university
  - How do we prioritize rest? How do we beat burnout and boost resilience



# Spring WFD Conversation Notes

<https://michmed.org/JDQrr>



# Highlights of the Year

Focus on Clinical Research Professionals: Needs and Activities

Active engagement with other groups

- N3C: “Strategies for Successful Real World Data Research and Workforce Development”
- Clinical Research Professional Taskforce - Special Interest Group
  - Michelle Jenkerson, Washington University



# Sponsorship of Working Groups

## Translational Scientist Competency-Based Assessment Working Group

Wayne McCormick PhD, University of Florida

## Integrating CTS into the CTSA Virtual Visiting Scholar Working Group

Miriam Bredella, MD, MBA, New York University

Susan Pusek, DRSc, University of North Carolina

Joel Tsevat, MD, MPH, University of Texas San Antonio

Steven Asch, MD, MPH, Stanford University

## Supported two proposals during Working Group Proposal: Cycle XII

- Digital Badges
- Real World Data

# Focus for Upcoming Year

An emphasis for the Workforce Development EC is Clinical Research Professionals' learning needs and best models for education

- Interprofessional education or CRP focused
  - TIN will be evaluating CRP and PI dyad learning
- Badging and/or microcredentials

Continued involvement of members to inform topics highlighted and sharing of new developments and insights

Collaboration with EC and Workgroups



○

# THANK YOU

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CCOS Staff

Cindy Mark

Alex Paquet

NCATS

Jennie Conroy



# Adjourn

- Next Meeting: July 14, 2025

# Questions?

