CTSA Coordination, Communication, & Operations Support

CTSA Program Webinar

March 25, 2026

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Agenda

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Lauren Fitzharris, MPH, PMP CCOS
2:01 – 2:10 PM	NCATS/CTSA Updates	Michael Kurilla, MD, PhD DCI/NCATS
2:10 – 2:15 PM	CCOS Updates	Lauren Fitzharris
2:15 – 2:45 PM	ClinicalTrials.gov Registration and Reporting: Keys to Success at Duke	Jessica Houlihan, Duke University Denise Snyder, MS, RD Duke University
2:45 – 3:00 PM	Translational Impact Working Group	Amelia Bucek, MPH, Northwestern University Manny Tetteh, MD, MPH Washington University at St. Louis Kristi Holmes, PhD, Northwestern
3:00 PM	Adjourn	

NCATS
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NCATS/CTSA Program Updates

Michael G. Kurilla, MD, PhD

Director, Division of Clinical Innovation
NCATS

March 25, 2026

National Center for Advancing Translational Sciences

CTSA Program NOFO Updates

- **Notice of Change to PAR-24-272 Clinical and Translational Science Award (UM1 Clinical Trial Optional) in Award Information (NOT-TR-26-003) (Released March 4, 2026)**
- This notice reflects the update of the "Hub Tiers" with respect to the *5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, PLUS 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s) based on FY2020-FY2024 NIH Funding Data.*
- **REMINDER: Verification of Funding Tier Calculation:**
  - Applicants are strongly encouraged to verify their funding tier calculation with NCATS in advance of application submission by sending an email to **CTSA NOFO Questions**. Applicants should list the primary applicant organization and any partner institution(s) that contribute to the funding tier calculation. Requests to verify the funding tier calculation should be submitted by the institution's authorized organization representative.
- We have released the CTSA partner list for FY25 on our website: https://ncats.nih.gov/research/research-activities/ctsa/applicant-information/CPUBRT
- Please reach out to CTSANOFOQuestions@mail.nih.gov if you have questions.

Award Budget Requests for CTSA Applications

Receipt Dates of May 28, 2026, September 28, 2026 (NOT-TR-26-003) for FY27 Funding

Hub Tier Size	5-year avg of NIH DC of applicant institution PLUS NIH DC of any partners*	UM1 Budget (Direct Cost)	K12 Budget (Direct Cost)	T32 predoc slots	T32 postdoc slots	R25 Budget (Direct Cost)
A	>$400M	$6.5M	$1.5M	10	5	$100K
C	$265M - $399,999,999M	$5.0M	$1.0M	8	4	$100K
T	$190M - $264,999,999	$3.6M	$900,000	6	3	$100K
G	<$189M	$2.6M	$700,000	4	2	$100K

Calculated from the 5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, PLUS 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s) (based on FY2018-FY2022 NIH Funding data)

https://ncats.nih.gov/ctsa/funding/CPUBRT

NIH National Center for Advancing Translational Sciences

CTSA NOFO Forecasts

- **Limited Competition: Small Grant Program for the NCATS Clinical and Translational Science Award (CTSA) Program (Clinical Trial Optional)**
  - Link to Grants.gov: https://www.grants.gov/search-results-detail/361317
  - Forecast Date: February 18, 2026
  - Opportunity Number: PAR-26-123
  - Estimated Post Date: August 17, 2026
  - Earliest Application Due Date: October 17, 2026
  - Questions: CTSA_R03_NOFO_Questions@nih.gov

- **Limited Competition: High Impact Specialized Innovation Programs in Clinical and Translational Science (Clinical Trials Optional)**
  - Link to Grants.gov: https://www.grants.gov/search-results-detail/361427
  - Forecast Date: March 9, 2026
  - Opportunity Number: PAR-26-128
  - Estimated Post Date: June 1, 2026
  - Earliest Application Due Date: September 28, 2026
  - Questions: RC2NOFO@nih.gov

Reminder: How should I include clinical trials in my UM1 application?

This is important because:

1. **Misclassified clinical trial applications may be withdrawn**
   - For help with NIH's definition of a clinical trial, please see **Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical Trial?**
2. **It should be anticipated that research projects involving clinical trials might be initiated during the seven-year grant period**
   - **Delayed Onset Study**: A research project that is anticipated within the period of award, but definite plans are not yet known and cannot be described in the application. For delayed onset studies, all applicants should check the Anticipated Clinical Trial box and complete all related sections. Please see the instructions in **G.500 PHS Human Subjects and Clinical Trials Information**.
     - This will occur with pilots under the Element D: Clinical and Translational Resources & Pilots.
     - This will occur with the project(s) under Element E: Clinical and Translational Science Research Program if the project(s) cannot be described at the time of application.
     - This will occur with described project(s) under the Element E: Clinical and Translational Science Research Program if the described project(s) are not delayed start.

- **Questions? CTSANOFOQuestions@mail.nih.gov**

From page: https://ncats.nih.gov/research/research-activities/ctsa/applicant-information/par-24-272-faq

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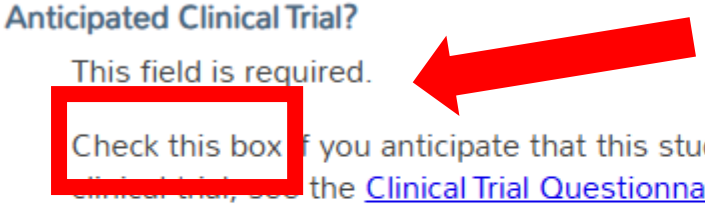
Anticipated Clinical Trial? Check the Dang Box!

Check the Dang Box (CTDB)!



Anticipated Clinical Trial?

This field is required.

Check this box if you anticipate that this study will be a clinical trial. For help determining whether your study meets the definition of clinical trial, see the Clinical Trial Questionnaire below.

Read your NOFO carefully to determine whether clinical trials are allowed in your application.

Note on multiple delayed onset studies: If you are including multiple delayed onset studies in one delayed onset study entry, and you anticipate that any of these studies will be a clinical trial, check the "Anticipated Clinical Trial?" checkbox.

Justification Attachment

This attachment is required.

Attach the justification as a PDF file. See NIH's Format Attachments page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

- All delayed onset studies must provide a justification explaining why human subjects study information is not available at the time of application.
- If NIH's Policy on the Dissemination of NIH-Funded Clinical Trial Information will apply to your study, this justification must also include the dissemination plan.

Note on multiple delayed onset studies: If you are including more than one delayed onset study in any given delayed onset study entry, address all the included studies in a single justification attachment.

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#Delayed

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NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

- **Plan for Disseminating Clinical Trial Results:**
  - NOT-OD-16-149 (Released Sept 16, 2016)
  - As part of their applications or proposals, applicants and offerors seeking NIH funding will be required to submit a plan for the dissemination of NIH-funded clinical trial information that will address how the expectations of this policy will be met.
  - Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant.
  - Results information from those trials generally must be submitted not later than one year after the trial's primary completion date.

- **Informed Consent Forms:**
  - Clinical trials are required to post one IRB-approved version of a consent form that has been used to enroll participants on a public federal website designated for posting such consent forms.
  - Two sites: ClinicalTrials.gov or Regulations.gov
  - The form must be posted after recruitment closes, and no later than 60 days after the last study visit.

Sources:
- https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials
- https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/informedconsent

(NIH) Inviting Input on a Proposed Clinical Trial Specific Application Form

- NOT-OD-26-058 (Released March 18, 2016)
- Response Date: April 17, 2026
- NIH seeks public input on a **Proposed Clinical Trial Specific Application Form** designed to streamline investigator-initiated clinical trial applications.
  - Specifically, NIH proposes to combine components of the current *Research Plan* in clinical trial applications and the *PHS Human Subjects and Clinical Trials Information Form* into a single, consolidated form.
  - By requiring a semi-structured application specifically designed for clinical trials, NIH aims to:
    - (1) simplify the application process for investigators and
    - (2) improve the availability of critical information needed for the review of clinical trials.
- Please direct all inquiries to: CTFormsRFI@mail.nih.gov

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NIH Notices and NOFOs

- NIH Requires Use of the eRA Prior Approval Module for the Submission of ALL Prior Approval Requests (NOT-OD-26-026) (Released Jan 21, 2026)
  - All Prior Approvals must be submitted through eRA starting **2/23/26** (inclusive of JIT materials). **WARNING:** VERY LITTLE can now be received by email – plan accordingly.
  - NCATS is in the process of updating guidance related to pilot project prior approval submissions to align with this new policy requirement.
  - **WARNING:** deviations and exceptions to prior approval requests will only be considered in extremely rare circumstances and require NIH prior approval.

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NCATS CTSA Program Guidance for HS/VA Prior Approval Requests

Prior Approval Module Information	Information for Prior Approval of the use of Vertebrate Animals Research	Information for Prior Approval of the use of Human Subjects Research
Description	The VAR study title; VAR study PI	The HSS study title; HSS study PI; HSS#
Effective Date	The date the study is requested to start (effective date to be at least 30 days from the submission of the request)	The date the study is requested to start.
Justification Document	Please use the instructions provided on the OLAW landing page for Vertebrate Animals Section (VAS) requirements and provide the 4 requirements (**Description of Procedures, Justifications, Minimization of Pain and Distress, Method of Euthanasia).**	Justification for delayed onset studies.
Budget Document	Upload budget	Leave empty - available in the HSS study record.
Other Supporting Documents	Please provide the verification of IACUC approval	Leave empty - available in the HSS study record.

The main change for HSS and VAR prior-approvals is that the AOR will need to submit a prior-approval request to the eRA prior-approval module and NOT to the NCATS PRIOR APPROVAL REQUEST email box (NCATSPRIORAPPROVALREQUEST@mail.nih.gov.)

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Update on National Clinical Cohort Collaborative (N3C)

Happening NOW!

National **COVID** Cohort Collaborative → National **Clinical** Cohort Collaborative

Key Points:

- The N3C platform officially reopened to members that had been previously registered on Monday, March 2, 2026

Data Submissions:

- The N3C platform is no longer accepting new COVID-19 data submissions
- COVID-19 data contributions are frozen as of October 2025 and preserved in archive form to support research continuity
- All data have remained untouched, secure, and have not been moved outside of N3C platform during the offline period or since
- New Data Transfer Agreements will be sent to all CTSAs this week
- New Data Transfer Agreements must be executed

Research Project Data Use Requests (DURs):

- Investigators will need to submit their DURs for reapproval (expedited review) and rebuild their projects using their code and concept sets.

QUESTIONS?: ncats_n3c@mail.nih.gov

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Feedback Requested

- How could we spur innovation to establish nationally recognized benchmarks for transportable, reproducible analytic performance across heterogeneous clinical data environments, thereby strengthening the reliability of real-world evidence generated through N3C?

- BIDS EC was asked this question on March 6
- Email: Michael G. Kurilla: Michael.Kurilla@NIH.gov

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NIH Public Access Policy

- The NIH Public Access Policy requires Author Accepted Manuscripts accepted for publication in a journal, on or after July 1, 2025, to be submitted to PubMed Central upon acceptance for publication, for public availability without embargo upon the Official Date of Publication
- Any issues with embargo of a publication need to be addressed between the academic institution and the publisher; NIH has no role in lifting embargos
- A publication will not be in compliance until the embargo is lifted
- NIH cannot issue a Notice of Award until all publications are compliant. This is creating delays in award issuances.
- Awards that report publications not in compliance with the NIH Public Access Policy may be released fully restricted at the end of the FY (August/September) upon direction of the NIH Office of Policy for Extramural Administration (OPERA)

https://grants.nih.gov/policy-and-compliance/policy-topics/public-access/nih-public-access-policy-overview

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RFI: Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for Fiscal Years 2027-2031

- **Request for Information (RFI): Inviting Comments and Suggestions on a Framework for the NIH-Wide Strategic Plan for Fiscal Years 2027-2031 (NOT-OD-26-047) Released March 16, 2026**

- **NIH-Wide Strategic Plan Framework:**
  - **Priority 1: Research Areas**
    - Goal 1: Advance Foundational Knowledge of Human Health and Disease
    - Goal 2: Prevent Disease and Promote Health Across the Lifespan
    - Goal 3: Advance and Optimize Interventions, Treatments, and Cures
  - **Priority 2: Research Capacity**
    - Goal 1: Develop and Sustain an Interdisciplinary Research Workforce
    - Goal 2: Build, Improve, and Sustain Research Resources and Infrastructure
  - **Priority 3: Research Operations**
    - Goal 1: Enhance Scientific Stewardship and Decision-Making
    - Goal 2: Foster Transparency and Accountability to Improve Public Trust in Science

- **How to Submit a Response:**
  - All comments must be submitted electronically on the submission website.
  - **Responses must be received by 11:59:59 pm (ET) on May 16, 2026.**

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Upcoming Dates to Remember

Next CTSA Program Webinar

May 27, 2026

****April webinar cancelled due to ACTS Conference**

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CCOS Updates

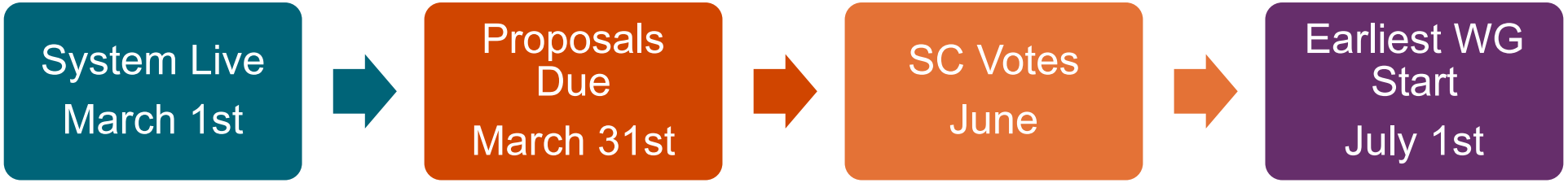
Cycle XVI Working Group Proposals is Open!

Key topic areas of interest

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

Details available on the Working Group Proposal page

Timeline



Rigor and Reproducibility of Real-World Data (RWD) Platforms Collaborative Workshop

Tuesday, May 12, 2026

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

Click here to register or scan the QR code below

Stay updated on Collaborative Workshops!
Visit: https://ccos-cc.ctsa.io/groups/collaborative-workshops
Email: collaborative_workshop@ccos.ctsa.io

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Stanford MEDICINE | Spectrum Stanford CTSA Hub

TEAM SCIENCE

Save the Date!

Community of Practice to Facilitate Effective LHS-CTSA Partnerships

Wednesday, April 1, 12-1pm ET / 9-10am PT

Discussion with Sarah M. Greene, MPH

Senior Advisor, Research Advocate, and Consultant

Editorial > Learn Health Syst. 2025 Oct 24;9(4):e70044. doi: 10.1002/lrh2.70044. eCollection 2025 Oct.

Ten Reasons Why Learning Health Systems Will Have a Transformational Effect on Health and Health Care

Charles P Friedman [1], Sarah M Greene [2], Joshua C Rubin [3 4]

All are welcome! *Clinicians, community members, health system representatives, CTSA hubs, researchers, funders*

To receive the link, email: LHS-CTSA.Partnerships@ccos.ctsa.io

CCOS Feedback Form

We want to hear from you!

Share your feedback and suggestions about:

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

Use this Link or Scan the QR Code to Provide Feedback on this Group

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

CCOS is now on Bluesky!

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

@ccos-ctsa.bsky.social

ClinicalTrials.gov Registration and Reporting: Keys to Success at Duke

Denise Snyder, MS, RD

Associate Dean for Clinical Research

Jessica Houlihan

Associate Director, Research Operations

Duke University School of Medicine

Let’s remember why…

- Ensures transparency in how public funds are used
- Provides faster and broader access to information than traditional publications
- Prevents suppression of research results, which undermines scientific progress
- Helps the public make informed medical decisions
- Flags unacknowledged protocol changes that could affect interpretation of findings
- Addresses gaps in publications that omit prespecified outcome measures
- Creates a resource for researchers to identify ongoing work and avoid duplication

Clinical Trial Disclosure Requirements – BEFORE DOCR

1997: FDAMA establishes ClinicalTrials.gov

2000: ClinicalTrials.gov launched

2005: ICMJE endorses ClinicalTrials.gov registration

2007: FDAAA expands ClinicalTrials.gov to include more studies and results and adds penalties for noncompliance

2010: ClinicalTrials.gov adds AE, results & patient flow modules

Prior to 2012…we told researchers what to do

eIRB DukeMedicine Institutional Review Board for Clinical Investigations

View: Application - Pro00000466

Required registration of studies in ClinicalTrials.gov

On September 27, 2007 Congress enacted U.S. Public Law 110-85 (also known as H.R. 3580, or Food and Drug Administration Amendments Act of 2007). This act mandates the expansion of ClinicalTrials.gov, expands the required submission elements and establishes penalties for not listing a trial. Investigators and sponsors must ensure that applicable drug, biologic and device trials are registered within 21 days of enrollment of the first subject and preferable before first subject enrollment.

Which studies must be registered?

Registration is required for any research study that:

- Uses a drug, biologic, or device as the intervention or control/comparison AND
- Prospectively assigns human subjects to intervention and at least one concurrent control or comparison groups AND
- Studies the safety, efficacy or cause-and-effect relationship between an intervention and a health outcome

The registration requirement does not apply to:

- **The use of FDA approved, marketed products used in the course of medical practice**
- **Phase I clinical investigations of drugs or biologics**
- **Small clinical trials to determine the feasibility of a device or clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes**
- **FDA required pediatric postmarketing surveillance of devices**

Investigators and sponsors are encouraged to register all studies to ensure they meet the publication requirements of the International Committee of Medical Journal Editors (ICMJE) and to promote transparency in clinical research.

Who is responsible for registering the study?

- **For investigator-initiated trials, the lead principal investigator responsible for conducting and coordinating the overall clinical trail should take responsibility for registration**
- **For Sponsor-initiated trials the sponsor should take responsibility for registration**
- **Trials sponsored by the federal government (e.g. NIH) should be registered by the grantee**
- **Trials associated with Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications with the U.S. FDA should be register by the IND/IDE holder**
- **If the individual or sponsor who should register the trial is unwilling or unable to register the trial it should be registered by a participating investigator**

How do I register a study at Duke?

ORIGINAL CONTRIBUTION

Califf RM, Zarin DA, Kramer JM, Sherman RE, Aberle LH, Tasneem A. JAMA. 2012 May 2;307(17):1838-47..2012

Characteristics of Clinical Trials Registered in ClinicalTrials.gov, 2007-2010

Robert M. Califf, MD
Deborah A. Zarin, MD
Judith M. Kramer, MD, MS
Rachel E. Sherman, MD, MPH
Laura H. Aberle, BSPH
Asba Tasneem, PhD

Context Recent reports highlight gaps between guidelines-based treatment recommendations and evidence from clinical trials that supports those recommendations. Strengthened reporting requirements for studies registered with ClinicalTrials.gov enable a comprehensive evaluation of the national trials portfolio.

Objective To examine fundamental characteristics of interventional clinical trials registered in the ClinicalTrials.gov database.

Methods A data set comprising 96 346 clinical studies from ClinicalTrials.gov was downloaded on September 27, 2010, and entered into a relational database to analyze aggregate data. Interventional trials were identified and analyses were focused on 3 clinical specialties—cardiovascular, mental health, and oncology—that together encompass the largest number of disability-adjusted life-years lost in the United States.

Main Outcome Measures Characteristics of registered clinical trials as reported data elements in the trial registry; how those characteristics have changed over time; differences in characteristics as a function of clinical specialty; and factors associated with use of randomization, blinding, and data monitoring committees (DMCs).

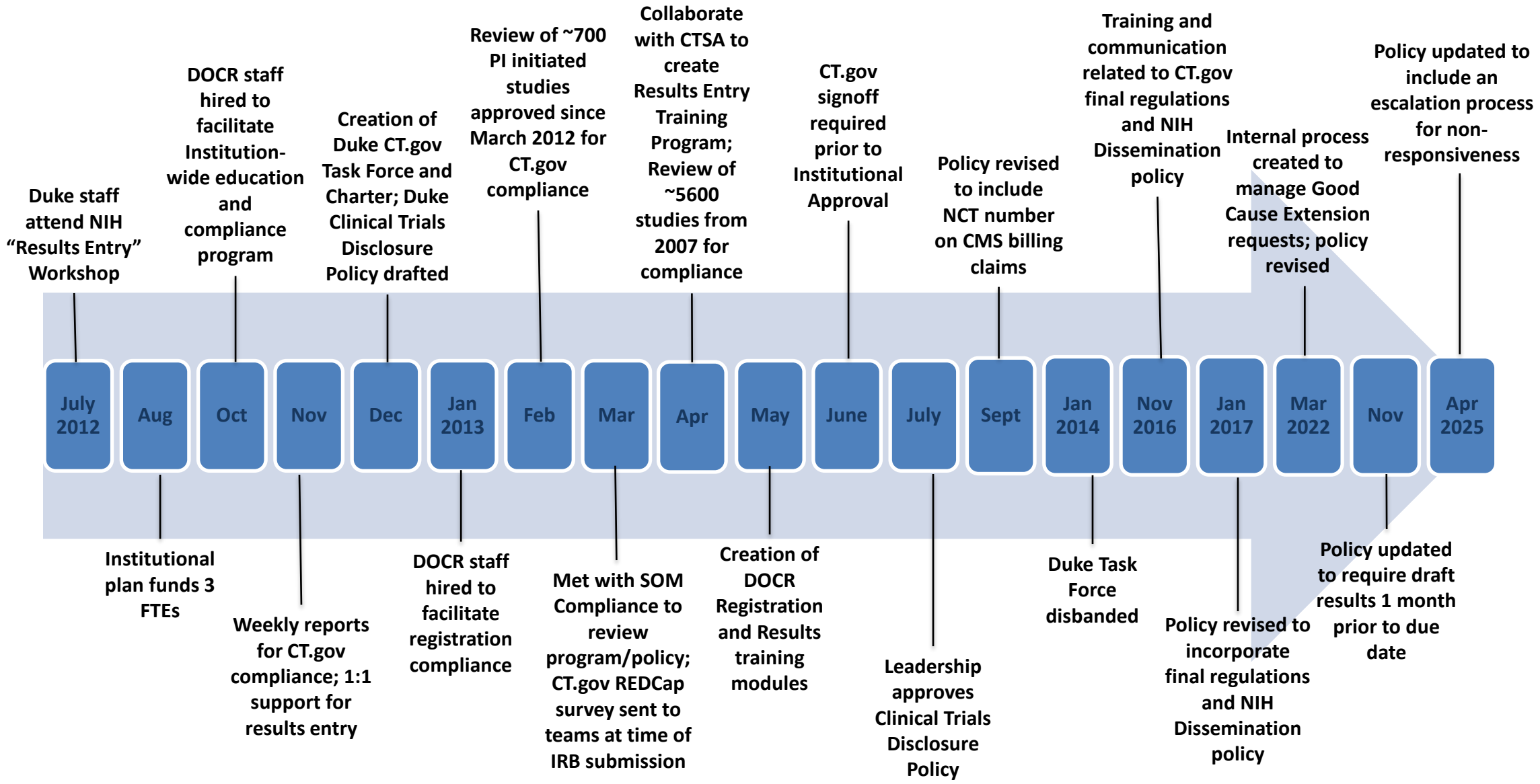
Results The number of registered interventional clinical trials increased from 28 881 (October 2004–September 2007) to 40 970 (October 2007–September 2010), and the number of missing data elements has generally declined. Most interventional trials registered between 2007 and 2010 were small, with 62% enrolling 100 or fewer participants. Many clinical trials were single-center (66%; 24 788/37 520) and funded by organizations other than industry or the National Institutes of Health (NIH) (47%; 17 592/37 520). Heterogeneity in the reported methods by clinical specialty; sponsor type; and the reported use of DMCs, randomization, and blinding was evident. For example, reported use of DMCs was less common in industry-sponsored vs NIH-sponsored trials (adjusted odds ratio [OR], 0.11; 95% CI, 0.09-0.14), earlier-phase vs phase 3 trials (adjusted OR, 0.83; 95% CI, 0.76-0.91), and mental health trials vs those in the other 2 specialties. In similar comparisons, randomization and blinding were less frequently reported in earlier-phase, oncology, and device trials.

Conclusion Clinical trials registered in ClinicalTrials.gov are dominated by small trials

CLINICAL TRIALS ARE THE CENtral means by which preventive, diagnostic, and therapeutic strategies are evaluated,[1] but the US clinical trials enterprise has been marked by debate regarding funding priorities for clinical research, the design and interpretation of studies, and protections for research participants.[2-4] Until recently, however, we have lacked tools for comprehensively assessing trials across the broader US clinical trial enterprise.

In 1997, Congress mandated the creation of the ClinicalTrials.gov registry to assist people with serious illnesses in gaining access to trials.[5] In September 2004, the International Committee of Medical Journal Editors (ICMJE) announced a policy, which took effect in 2005, of requiring registration of clinical trials as a

Timeline for Improving Trial Disclosure Compliance



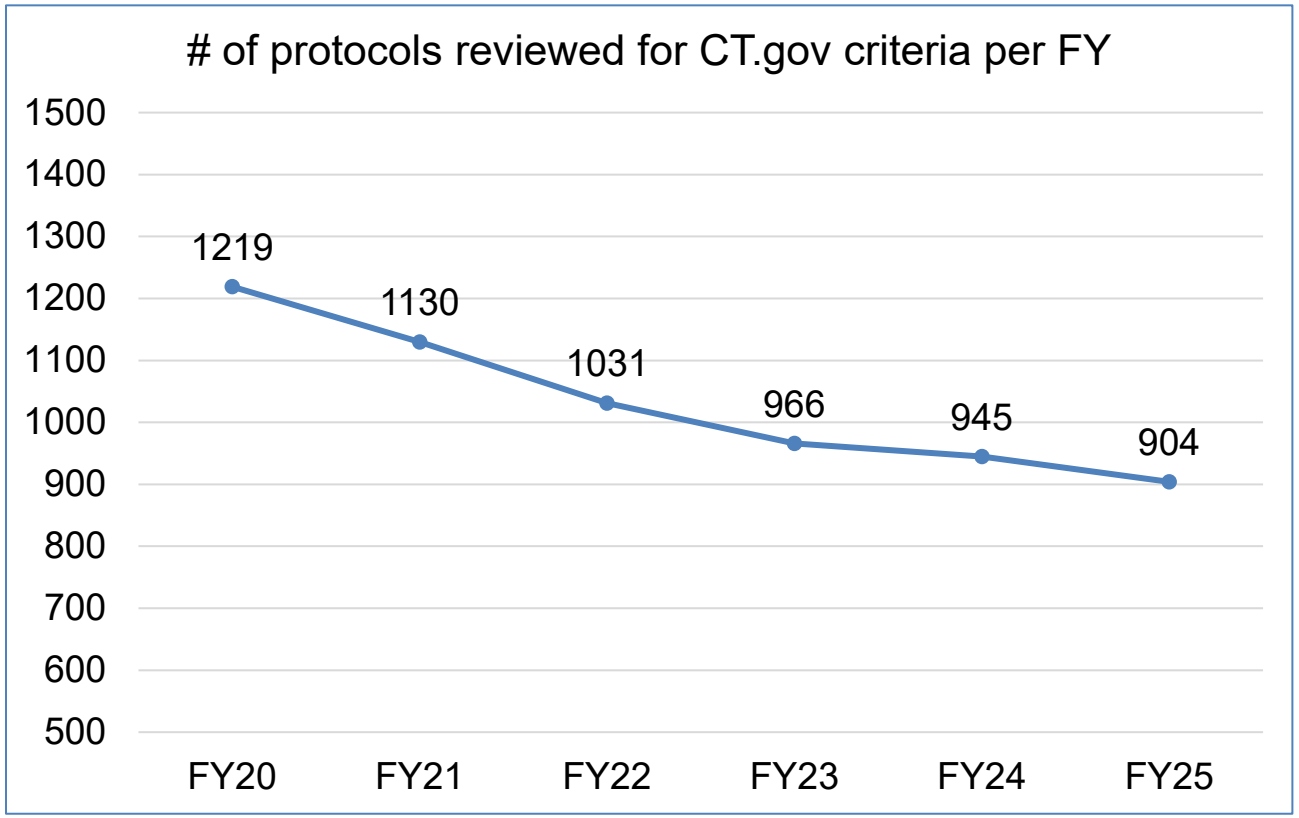
Duke ClinicalTrials.gov Team

- Centralized approach
  - Duke is the Responsible Party (unless there is an IND/IDE)
  - ClinicalTrials.gov team is part of the Duke Office of Clinical Research (separate from Compliance and IRB)
  - Allows for proactive compliance monitoring and streamlined support

- 2 FTEs
  - 1 FTE: primary contact registration and results, new study review
  - .5 FTE: registration back-up, new study review, problem record follow-up
  - .5 FTE: registration/results back-up, new study review, compliance questions, misc. tasks (e.g. presentations, metrics, internal policy)

Process Overview: New Study Review

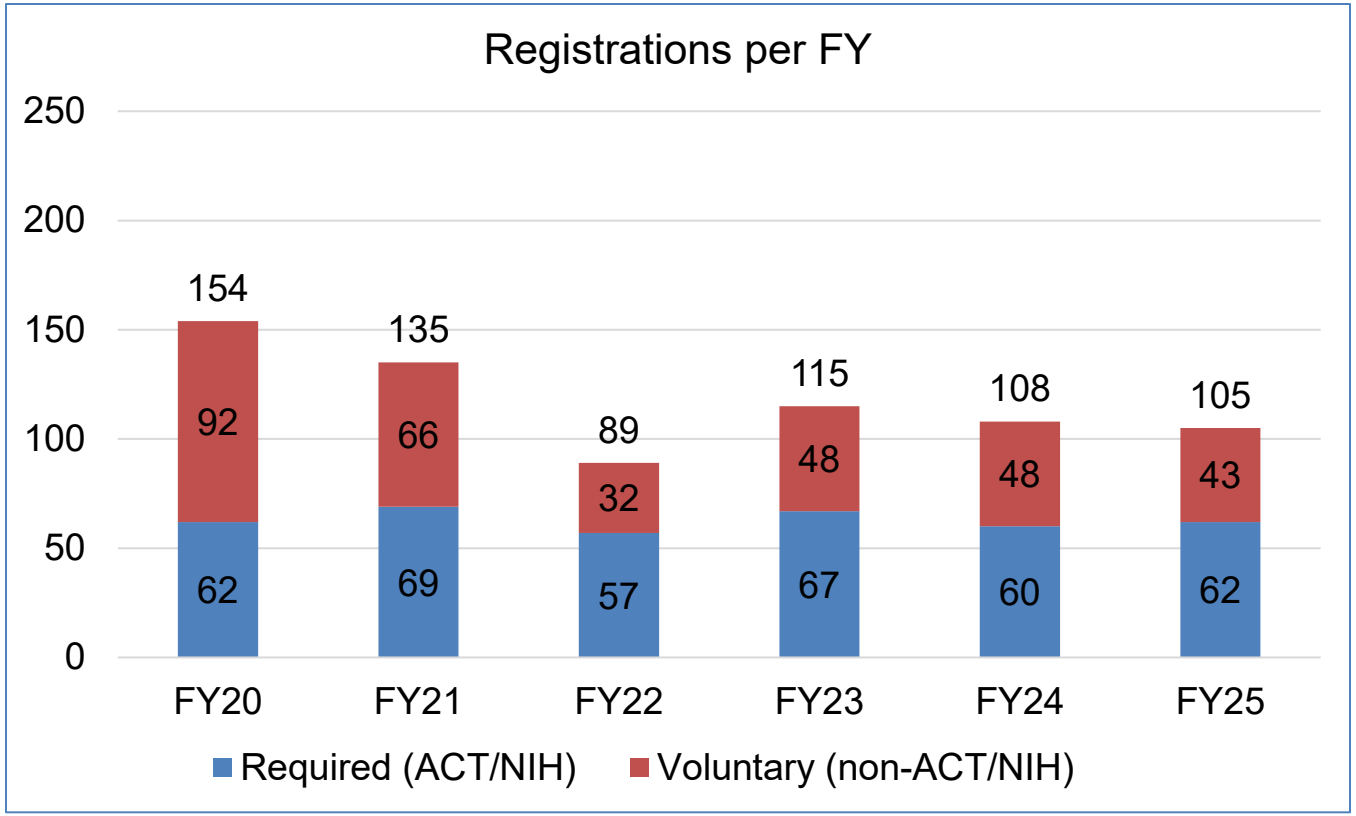
- Review all studies submitted to the DUHS IRB
- Determine Responsible Party (internal vs. external)
- Determine ClinicalTrials.gov requirements (e.g. ACT, NIH trial)
- Track in REDCap and OnCore CRMS (Institutional Approval)



Average 1032 new study reviews per year

Process Overview: Study Registration

- Email study team w/ expectations and resources
- New AI-assisted registration process
- Perform QC review prior to releasing to CT.gov



Average 117 new registrations per year

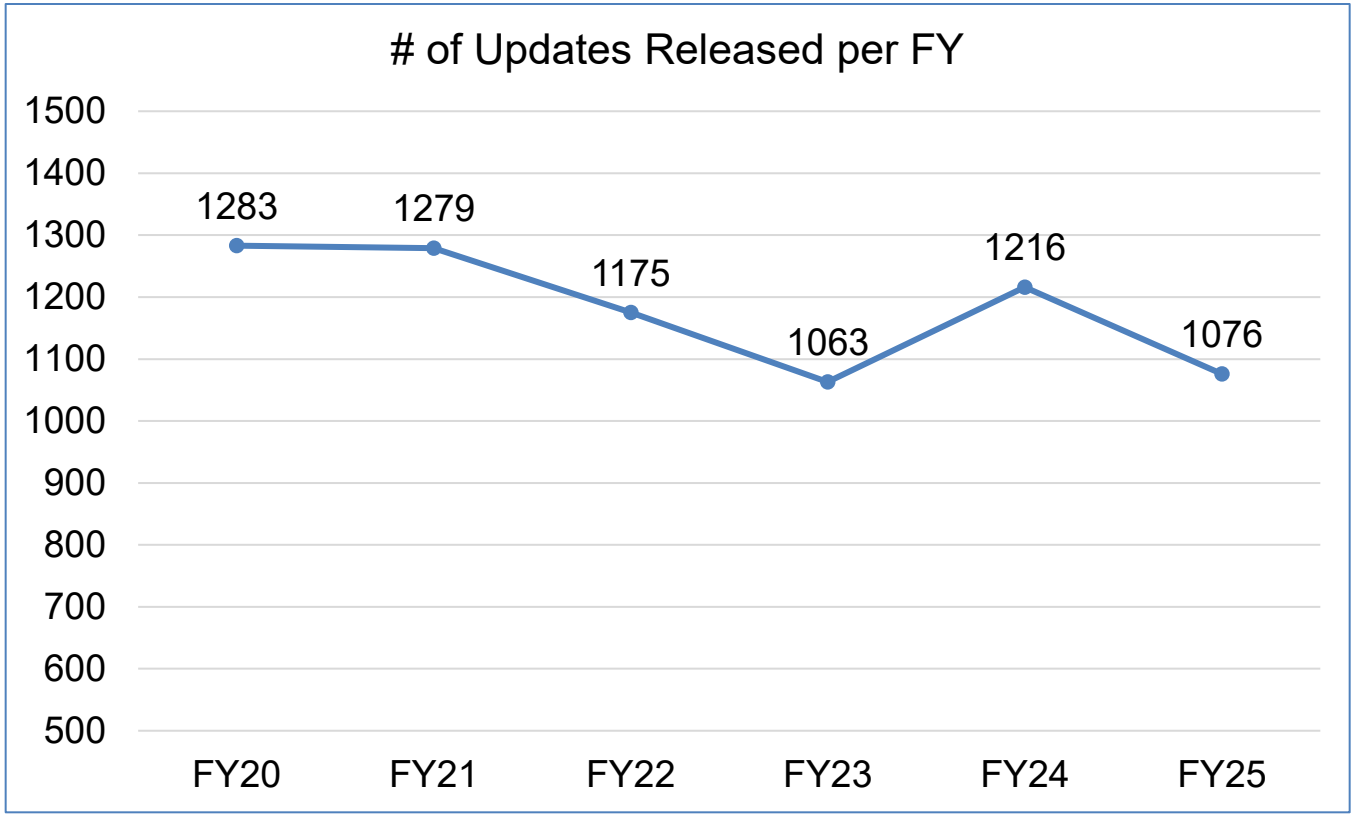
Process Overview: AI-assisted Registration

- Started pilot in November 2025
  - Identify eligible protocols during new study review; track in REDCap
  - Enter prompts and source documents into Microsoft Copilot
  - Generate XML file
  - Upload XML file to ClinicalTrials.gov
  - Perform Basic QC and send to study team for review/edits

- Pilot Metrics
  - 11/12 study teams agreed to participate
    - 1 did not reply
  - 10/11 records have been created successfully
    - 1 wants to wait until funding is awarded
  - 3/3 submissions were accepted by ClinicalTrials.gov during their first review cycle

Process Overview: Record Maintenance

- Monthly outreach for “problem” records
- Pay special attention to **study status** and **Primary Completion Date** using OnCore and IRB
- Misc. tracking (Good Cause Extension requests, record transfers)

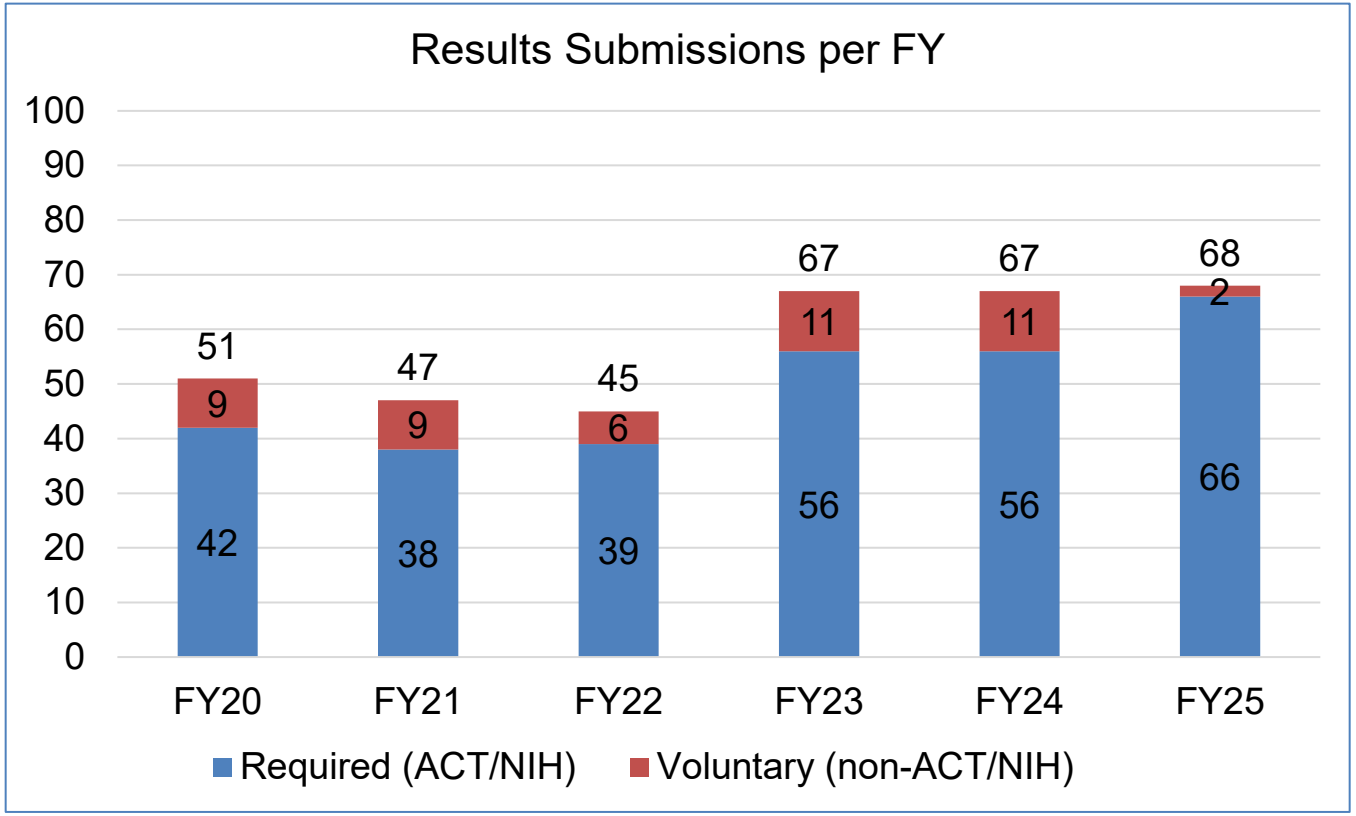


Average 1182 record updates per year

*Does not include initial registration or initial results submissions

Process Overview: Results Submissions

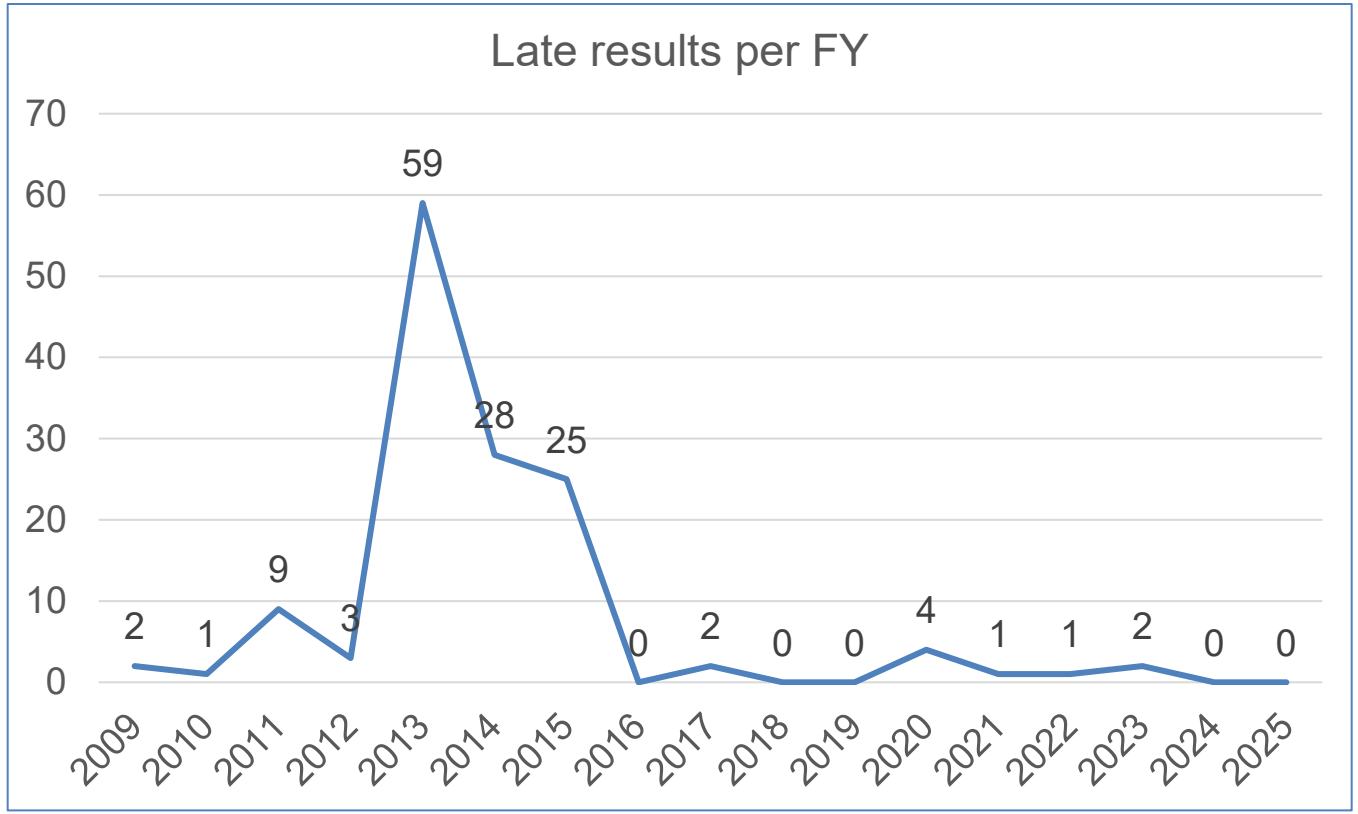
- Email reminders at 12, 6, 3, 2, 1 month
- Excel template to gather data
- DOCR will enter data if study team sends completed template or paper
- Perform QC review prior to releasing to CT.gov



Average 57 results submissions per year

Process Overview: Results Submissions

- Escalation policy, including Unit Director and Associate/Vice Dean
  - Results must be submitted to DOCR for internal review 1 month prior to due date
  - Process for non-responsive study teams

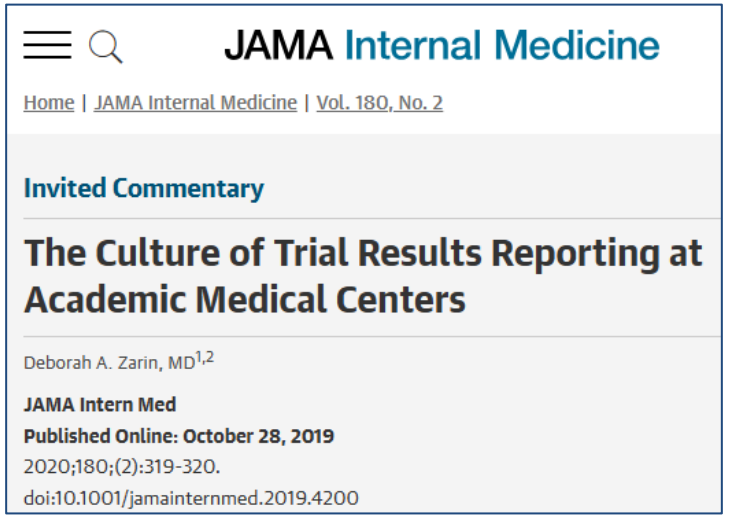


Related publications

https://ctti-clinicaltrials.org/wp-content/uploads/2024/01/CTTI_SuggestedPractices_ClinicalTrials-gov_FINAL.pdf

https://www.ncbi.nlm.nih.gov/pubmed/25387802

https://www.cambridge.org/core/journals/journal-of-clinical-and-translational-science/article/evaluating-the-current-landscape-of-clinical-trials-registration-and-results-reporting-policies-procedures-and-staffing-at-usbased-academic-centers-survey-revisited/94110799D1D37177FC6A4828D8CA0E34



https://doi.org/10.1001/jamainternmed.2019.4200

Keys to success

- Leadership support
  - Consistent messaging to faculty, staff, department leadership
  - Escalation policy
- Proactive mindset
  - Internal tracking – ACT/NIH CT, PCD
  - Access to internal systems and collaboration across offices (IRB, grant managers, regulatory office)
- Balance of compliance and support
  - Centralized approach and proactive mindset support compliance efforts
  - Don’t reinvent the wheel – resources are available for PRS Admins and study teams (ClinicalTrials.gov, CTRR Taskforce)

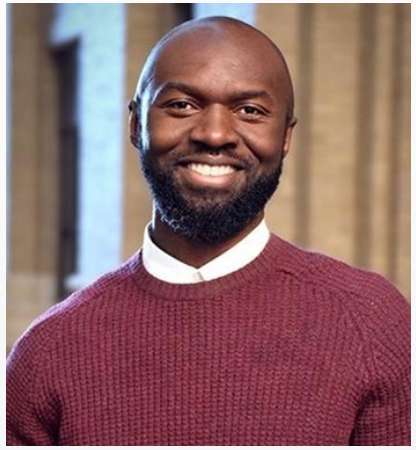
Questions?

denise.snyder@duke.edu
Jessica.Houlihan@duke.edu

Duke Office of Clinical Research
Clinical Translational Science Institute
CTSA Grant Number 1UL1TR005436

Translational Impacts Working Group

Kristi Holmes, PhD
Northwestern University
Clinical & Translational
Sciences Institute



Emmanuel Tetteh, MD, MPH
Washington University
in St. Louis Institute for
Clinical and Translational
Science

Translational Impacts Working Group:
https://ccos-cc.ctsa.io/groups/working-groups/ctsa-translational-impacts

Impact Summit Steering Committee

Pamela Davidson, PhD
UCLA Clinical Translational Science Institute

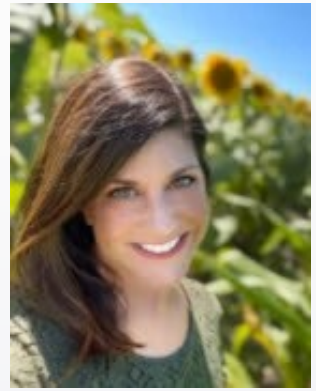
John Farrar, MD, PhD
University of Pennsylvania CTSA

Michelle Maclay
NC TraCS Institute
UNC at Chapel Hill

Liz Middleton, PhD
Harvard Catalyst
Harvard Medical School

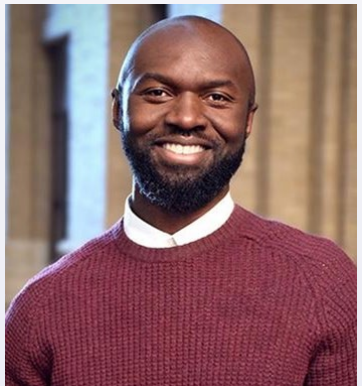
Andrea Molzhon, PhD
Wright Center, Virginia Commonwealth University

Rechelle R. Paranal, MSW, MA
South Carolina Clinical & Translational Research Institute



Lauren Rieger, MNM
Center for Clinical and Translational Science
University of Illinois Chicago

Amelia Bucek, MPH
Northwestern University Clinical and Translational Sciences Institute



Emmanuel Tetteh, MD, MPH
Washington University in St. Louis Institute for Clinical and Translational Science

Impact Summit

Hosted virtually March 2-3, 2026

Meeting Objectives

1. Highlight the Broader Landscape of Translational Impact

Showcase key collaborations and successful examples of translating science into policy and population health, with insights from other sectors.

2. Equip Attendees with Tools and Strategies to Enhance Impact

Share practical methods to evaluate, communicate, and embed impact using health and economic indicators

3. Strengthen Shared Capacity Across the CTSA Network

Foster collaboration by sharing effective strategies for planning, implementing, and disseminating impact-driven research

Impact Summit

Topics & speakers sourced by the TI WG and Summit Steering Committee

13 sessions

34 speakers & moderators

- 19 CTSA hubs + NCATS
- Community organization & Public health department

Presentations spanned the translational spectrum

Impact Summit Day 1

Policy Impact in Action

Robin Mermelstein, PhD
University of Illinois Chicago

Shari Bolen, MD, MPH
Case Western Reserve University at The Metro Health System

Justin Blackburn, PhD
Indiana University Indianapolis

Communities Driving Impact

Lori Carter Edwards, PhD, MPH
Kaiser Permanente Bernard J. Tyson School of Medicine

James D. Gailliard
Word Tabernacle Church

Economic & Commercial Impact

Maryann Feldman, PhD
Arizona State University

Umut Gurkan, PhD
Case Western Reserve University

Elan Ness-Cohn, PhD
Northwestern University Querrey InQbation Lab

Kristopher Bough, PhD
NIH | NCATS

Global & Cross Sector Impact

Mark Huffman, MD, MPH
Washington University in St. Louis

Bradley Kramer, PhD
Public Health, Seattle & King County

Impact Summit Day 2

Rinad Beidas, PhD
Northwestern University
Feinberg School of Medicine

Multi-CTSA Research

Clara M. Pelfrey, PhD
Case Western Reserve University

Nikki Llewellyn, PhD
Georgia Clinical & Translational Science Alliance, Emory University

Margaret Schneider, PhD University of California, Irvine

TSBM State of the Science

Anna La Manna, MPH, MSW Washington University in St. Louis

Douglas Luke, PhD
Washington University in St. Louis

Joe Hunt
Indiana Clinical & Translational Sciences Institute

Pamela Davidson, PhD
UCLA Clinical & Translational Science Institute

Impact Summit Day 2

Oral Poster Presentations

Farra Kahalnik, MPH, MSSW
University of Texas Southwestern Medical Center

Larissa Myaskovsky, PhD FAST
University of New Mexico School of Medicine

Carl I. Schulman, MD, PhD, MSPH
University of Miami Miller School of Medicine

Supporting Impact in ESI Development

Naomi S. Bardach, MD
University of California San Francisco

Cath Kane, MPA
New York University

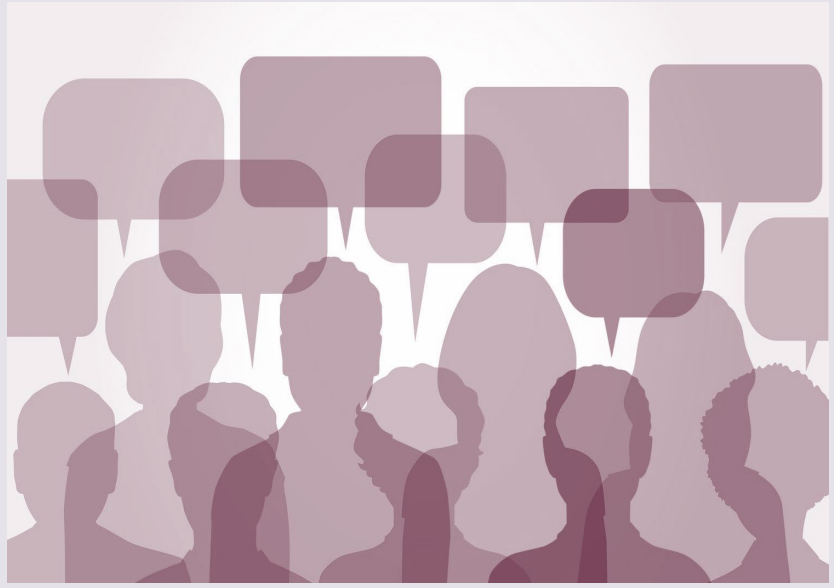
Andrea Molzhon, PhD
Virginia Commonwealth University

Closing Plenary with Dr. Rutter

Joni L. Rutter, PhD
Director, National Center for Advancing Translational Sciences

Kristi Holmes, PhD
Northwestern University Clinical & Translational Sciences Institute

Working Sessions



3-Part Modified Delphi

Gathered input on strategic priorities for translational impact measurement, support, and dissemination

Translational Science Impact Instruments Task Group

Opportunities for alignment in impact measurement

Alyson Eggleston, PhD
Penn State Clinical & Translational Science Institute

Joe Hunt
Indiana Clinical & Translational Sciences Institute

Lixin Zhang, PhD
Clinical and Translational Science Collaborative, Case Western Reserve University

Modified Delphi Survey

Purpose:

To build toward a shared, consensus-driven set of strategic priorities. These priorities can guide Consortium-level action, investment, and coordination in the area of translational impact measurement, support, and dissemination.

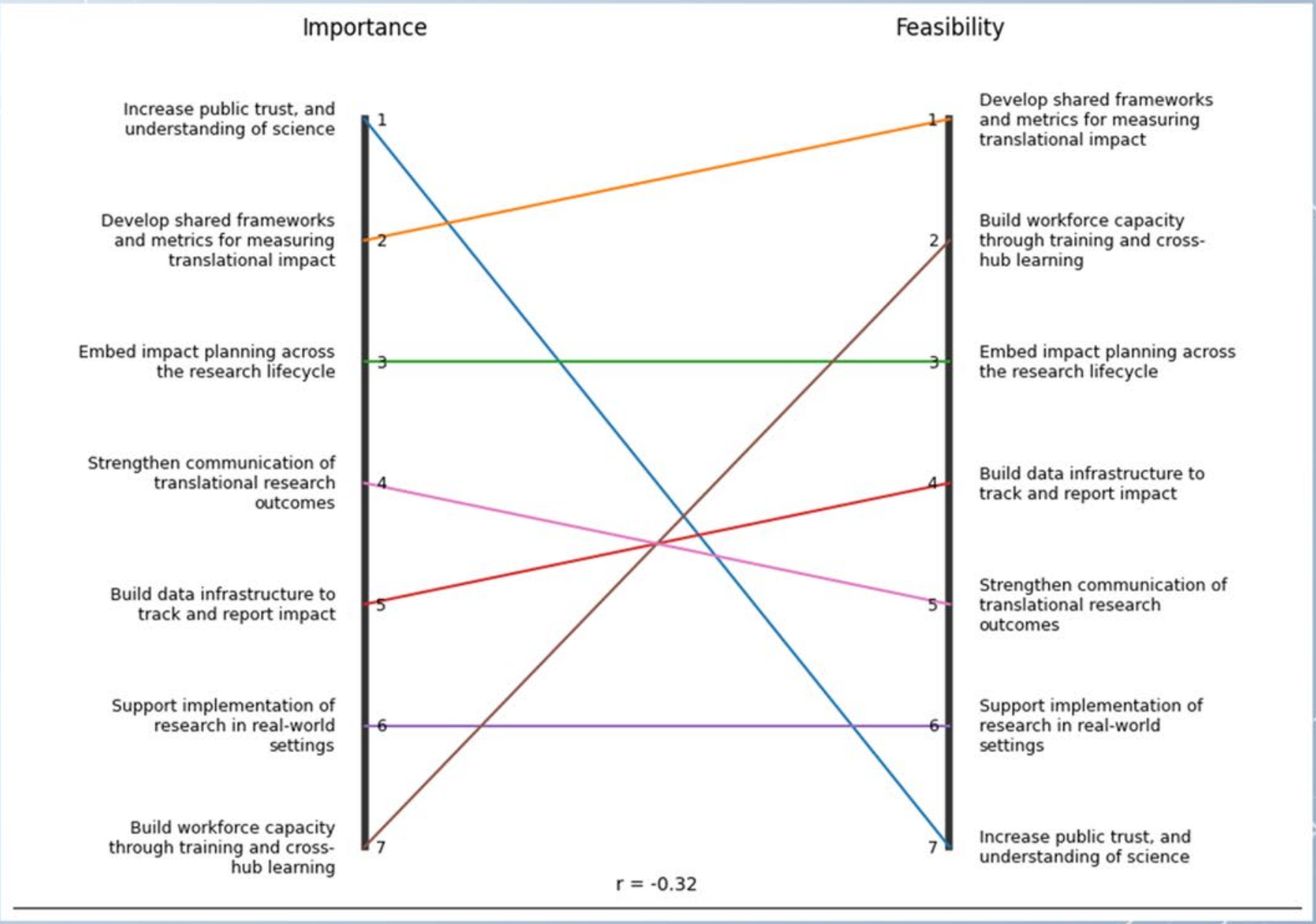
Steps:

- Round 1 – Exploration (Ask questions and collect Priorities)
- Round 2 – Structured Ranking (Participants rank Priorities)
- Round 3 – Re-ranking & Rating (Participants review Rank results and Rate)

Results *(Respondent Characteristics)*

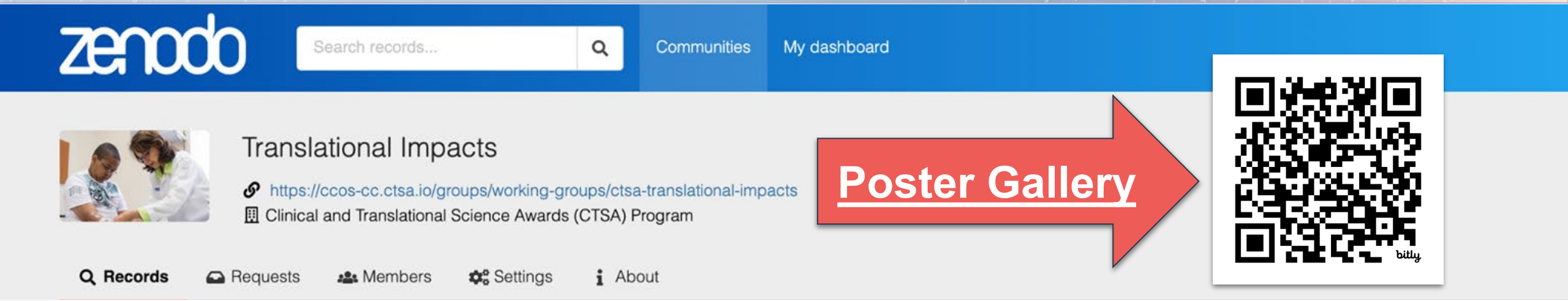
Respondent Characteristic	Category	Round 1; N=89	Round 2; N=96
Years involved with CTSA	0–2 years	23 (25.8%)	23 (24.0%)
	3–5 years	26 (29.2%)	26 (27.1%)
	6–10 years	16 (18.0%)	19 (19.8%)
	>10 years	24 (27.0%)	28 (29.2%)
Role within CTSA hub	Evaluator	33 (37.1%)	37 (38.9%)
	Administrative / Operational Staff	16 (18.0%)	25 (26.3%)
	Hub Leadership (PI/MPI/Director)	9 (10.1%)	8 (8.4%)
	Research Staff	9 (10.1%)	8 (8.4%)
	Investigator / Faculty	7 (7.9%)	6 (6.3%)
	Trainee	2 (2.2%)	2 (2.1%)
	Community Partner	2 (2.2%)	—
	Other roles	11 (12.4%)	9 (9.5%)
CTSA hub affiliation	**Unique CTSA hubs represented**	**26 (41.2%) hubs**	**43 (68.0%) hubs**
	Participants reporting hub affiliation	77 (86.5%)	83 (86.5%)
	Hub affiliation not reported	12 (13.5%)	13 (13.5%)

Pattern Match Map of Importance and Feasibility of Strategic Priorities



Provide your input

Virtual Posters

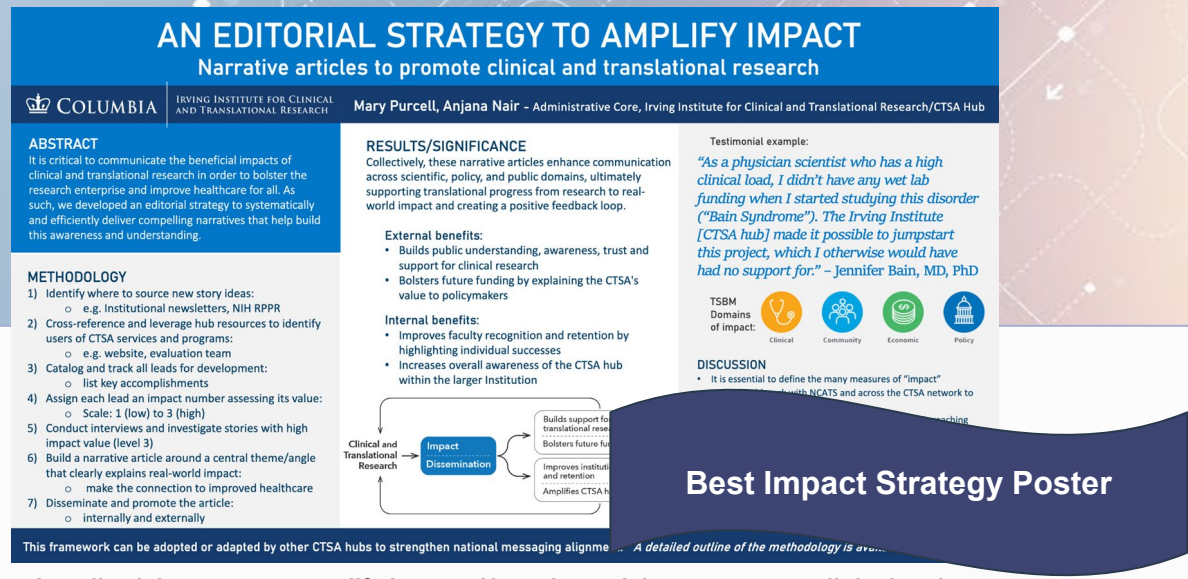


Shannon Casey, PhD
University of Wisconsin-Madison
Institute for Clinical and
Translational Science

Bart Ragon, MLIS, EdD
University of Virginia
Claude Moore Health Sciences
Library

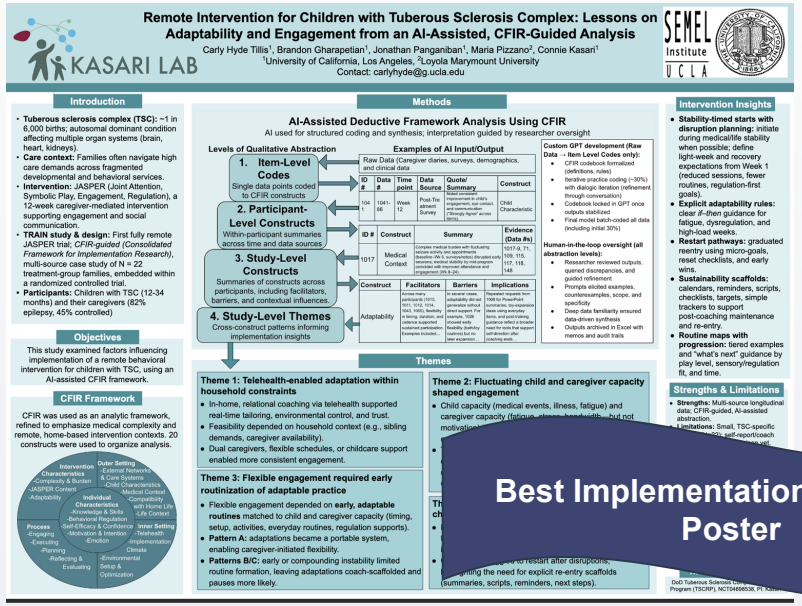
Best Team-Based Impact/CQI Approach Poster

Speeding the Translation of Research: An Integrated Model of Wisdom-Driven Evaluation and Continuous Quality Improvement and Dissemination. https://doi.org/10.5281/zenodo.18644094



Best Impact Strategy Poster

An editorial strategy to amplify impact. Narrative articles to promote clinical and translational research. https://doi.org/10.5281/zenodo.18645089



Best Implementational Science Poster

Remote Intervention for Children with Tuberous Sclerosis Complex: Lessons on Adaptability and Engagement from an AI-Assisted, CFIR-Guided Analysis. https://doi.org/10.5281/zenodo.18635670

Best Community Partnership Poster

Building Community Capacity for Translational Impact: A Human-Centered Research Fellowship Model. https://doi.org/10.5281/zenodo.18645181

Impact Summit

Next Steps

1) Share summit materials via CCOS and Zenodo
2) Distribute Summit article
3) Conduct summit evaluation
    a) Registration and attendance data (>400 attendees)
    b) Post-event survey
    c) Zenodo engagement
4) Analyze working sessions data
5) Draft manuscript

If you attended the Summit, and have not yet completed a survey, please do so by Friday, March 27

Advancing Translational Science Impacts: Lessons from a Cross-Consortium Working Group

Tuesday, April 21 3:15 PM – 4:15 PM CDT

Track: Evaluation | Track: Research Management, Operations, and Administration | Track: Team Science

BAIRD CENTER | MILWAUKEE, WI

Join us in Milwaukee!

Advancing Translational Science Impacts: Lessons from a Cross-Consortium Working Group

Tuesday, April 21 3:15 PM – 4:15 PM CDT

Amelia Bucek, MPH
Shannon Casey, PhD
Joe Hunt, MPH
Emmanuel Tetteh, MD, MPH

Northwestern University NUCATS Clinical and Translational Sciences Institute

Institute for Clinical and Translational Research, University of Wisconsin–Madison

INDIANA CTSI Clinical and Translational Sciences Institute

WashU Institute of Clinical and Translational Sciences

Impact Summit

Thank You

Speakers, Moderators, and Poster Authors

Translational Impact WG, Impact Summit Steering Committee,
Impact Repository Group, Impact Measurement Group, and CCOS

Next CTSA Program Webinar

No Program Webinar in April

The next webinar is **May 27**, **2026;** 2-3 PM ET

Please Check the Webinar Page on the CCOS Website for Updates