CTSA Coordination, Communication, & Operations Support

CTSA Steering Committee Meeting
January 13, 2025

2:30pm-3:30pm ET

digital Infuzion®

Deloitte. ICF UNIVERSITY of ROCHESTER

Agenda: January 13, 2025

Time	Topic	Speaker(s)
2:30-2:35pm ET	Welcome & Element E Announcement	Michael Kurilla and Ted Wun
2:35-2:40pm ET	Survey: 2024 Standard Agreements Proposed Revisions	Daniel Ford
2:40-2:55pm ET	Introduction of New Steering Committee Members	
2:55-3:00pm ET	Introduction of New Pods	Cindy Mark
3:00-3:20pm ET	WG Report Out: CTSA Pharmacies and Compounding for Translational Research (Final)	Robert MacArthur
3:20-3:30pm ET	Instruction for Pod Feedback Site	Lauren Fitzharris
3:30pm ET	Adjourn	Michael Kurilla

Welcome and Announcements

Michael Kurilla

Ted Wun

Request: CTSAs to share information about the Element E projects

- Element E Research Projects are to address a truly significant roadblock in CTS
- Research project(s) should:
  - address a translational research question in a particular disease or intervention development/dissemination context, but also
  - provide generalizable CTS innovations or insights that can be applied to other translational research projects and thereby increase the overall efficiency or effectiveness of translation
- Applicants have flexibility to tailor its Program's research activities to address local priorities
- Budget: $125,000 DC / year for a suggested period of 2-3 years / project; not to exceed $500,000 per year in DC
- PAR-21-293: One project per hub is required; **multiple projects** can be undertaken concurrently
- PAR-24-272: Although multiple projects ideas may be introduced, each application must include **only one fully described CTS research project** with a corresponding detailed budget for the project described.

Snapshot of UM1 Element E Projects – FY23

Institution	Described Projects	Duration of Project(s)	Translational Roadblock (as described in the application)
1*	1	3 years	clinical research recruitment (focus on people with disabilities)
2	1	7 years (aims split over the years)	health equity / healthcare disparities; use of technology to engage patients in research
3	1	7 years (aims split over the years)	integrated and comprehensive predictive health models
4	2	3 years (2 studies sequentially)	participation in research in routine clinical care
5	1	7 years (support multiple CTs)	pragmatic EHR-embedded clinical trials (conduct of clinical trials)
6	1	3 years	equitable participation in clinical research
7	1	7 years (aims split over the years)	protocol writing (support for rigorous, comprehensive, and well-designed protocols)
8	1	1 project over 7 years	structural racism
9	1	7 years (aims split over the years)	clinical research recruitment
10	2	2 and 3 years (in parallel)	research participation and conduct
11	2	sequentially	lack of trust of the scientific community (for community engagement)
12	2	2 in parallel for 2 yrs each until year 7	data equity [participant diversity, SDoH, access, outcome (research impact from data)]
13*	2	sequentially	research barriers related to healthcare access and transitions of care [improve diagnostic opportunities and therapeutic effectiveness in rural populations]
14	2	2 in parallel	data interoperability and how to shorten the time to intervention adoption
15	3	3 in parallel	integrating clinical and translational science into usual clinical care
16	6	2 in parallel	conduct of clinical and translational research

*presented at the 2023 Fall CTSA Program Meeting

Request: CTSAs to share information about the Element E projects

- Idea communicated at the 2024 Fall CTSA Program Meeting and elsewhere
- Why?
  - Collaboration
  - Identify new niches of Clinical and Translational Science research
- How to share project information?
  - CCOS Website: with other CTSAs via the CCOS website (access limited to members of the CTSA Program as approved by CTSA Administrators)
- What information would be useful?
  - Title/purpose
  - Aims & Abstract
  - POC
- Other?
  - How many years is the project is designed to be?
  - What is the budget?
  - What are the deliverables or expected outcomes of the project?

Survey: 2024 Standard Agreements Proposed Revisions

Daniel Ford

National Center for Advancing Translational Sciences

Survey: 2024 Standard Agreements Proposed Revisions

- Why is it needed?
  - Standard agreements require updates to keep pace with the current state of clinical and translational research
  - Most agreements were last updated pre-COVID (see table)
- Goals
  - To identify and prioritize (1) standard agreements for revision, (2) terms within agreements for revision, and (3) identify any new terms not covered by current agreements for which language will need to be drafted
- Who will complete survey?
  - TIN Standard Agreements Workgroup members (i.e., SA points of contact)
- CTSA Hub Role
  - SA POC to complete survey and participate in Working Group to update standard agreement terms
- Survey Link
  - https://redcap.vumc.org/surveys/?s=NAECRY4FP9XX3Y8L
- Communication of results
  - Results will be collected, synthesized, and redistributed to workgroup members
  - Used to prioritize agreements for revision and subject areas within agreements

Standard Agreements Revisions

Agreement	Date of Last Revision
Accelerated Clinical Trials Agreement (ACTA)	Dec 2019
ACTA-CRO	Oct 2016
ACTA-Prime CRO	November 2016
International ACTA	December 2019
Investigator-Initiated ACTA	August 2017
Accelerated Confidential Disclosure Agreement (ACDA)	February 2016
ACDA-CRO	February 2016
Federal Demonstration Project-Clinical Trial Subaward Agreement (FDP-CTSA)	July 2016
Clinical and Translational Science Award – Data Transfer and Use Agreement (CTSA-DTUA)	August 2017

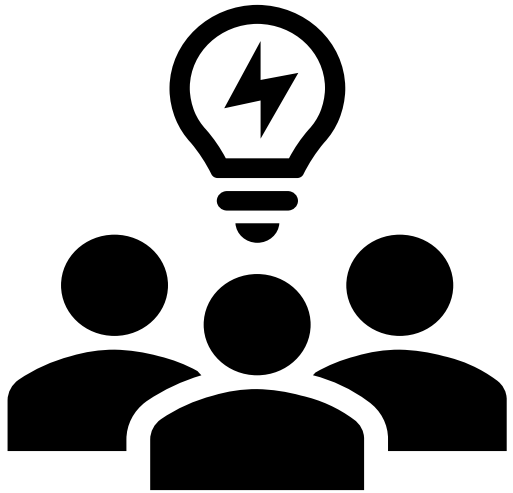
The Institutional Experiences of sIRB Survey

SIRB WORKING GROUP

The Institutional Experiences of sIRB Survey

Survey Aims

- Use data collected to ***foster*** understanding of the diverse working cultures within the sIRB community.
- Use data collected to ***aid*** the development of new tools and resources to support sIRB review.
- Use data collected to ***direct*** plans for changes/optimizations of the sIRB process as needed.
- Use data collected to ***enhance*** site and national capacity for sIRB review



The Institutional Experiences of sIRB Survey

Who will complete the Survey?

- IRB/HRPP points of contact
  - IRB/HRPP Director or Manager
  - SMART IRB Point of Contact
  - IRB Reliance Specialist/Coordinator
  - Ect.

CTSA Hub Responsibilities

- Provide input on tool/resource development using survey data

The Institutional Experiences of sIRB Survey

For a link to the Survey click here!

2025-2026 Steering Committee Co-Chairs

Theodore Wun, MD
UC Davis
UPI Member
Co-Chair

Michael Kurilla, MD, PhD
Director, Division of Clinical Innovation
NCATS Co-Chair

Past Co-Chair Role

- 2024 SC Co-Chair
- Will remain on SC for 2025 as *Past Co-Chair (*non-voting member)

Ruth O'Hara, PhD
Stanford University
UP1 Member
Past Co-Chair

Incoming Steering Committee Members

Julie Lumeng, MD, is the Contact PI of the University of Michigan CTSA and Executive Director of the Michigan Institute for Clinical and Health Research. She also serves as the Associate Dean for Clinical Research at the Medical School, the Associate Vice President for Clinical and Human Subjects Research at the University. She is a Professor of Pediatrics at the Medical School and Professor of Nutritional Sciences at the School of Public Health. She holds the Thomas P. Borders Family Research Professorship of Child Behavior and Development. She is trained as a developmental and behavioral pediatrician, and her NIH-funded research examines the development of children's eating behavior. **Julie is a U PI representative to the Steering Committee.**

Steven Bernstein, MD is the inaugural Chief Research Officer at Dartmouth Hitchcock Medical Center and the Senior Associate Dean for Clinical and Translational Research at the Geisel School of Medicine at Dartmouth, Director of SYNERGY, Dartmouth's Clinical and Translational Science Institute, Director of the C. Everett Koop Institute, and Professor of Emergency Medicine and Health Policy and Clinical Practice and at Geisel. His interests are in the use of implementation science methods to expand access to treatment of substance use, development of novel clinical trial designs, and training the next generation of investigators. His work has been supported by the National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute on Drug Abuse, Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Robert Wood Johnson Foundation, and the American Legacy Foundation, among others. Dr. Bernstein has served in advisory capacities developing tobacco policies and measures for the National Cancer Institute, Centers for Medicare and Medicaid Services, the Joint Commission, and the National Committee for Quality Assurance. **Steve is a U PI representative to the Steering Committee.**

Incoming Steering Committee Members

Reynold A. Panettiere, Jr, MD, is Professor of Medicine, Vice Chancellor for Translational Medicine and Science, and the Director of the Rutgers Institute for Translational Medicine and Science. He is the recipient of numerous honors and awards, including the Robert E. Cooke Memorial Lectureship at the American Academy of Allergy, Asthma and Immunology, the Joseph R. Rodarte Award for Scientific Distinction and the Recognition Award for Scientific Accomplishments from the American Thoracic Society. Dr. Panettiere is principal investigator on several NIH-sponsored grants and industry-sponsored clinical studies, director of a program project grant examining novel approaches in modulating G protein-coupled receptor function and is Principal Investigator of New Jersey's CTSA Hub 'New Jersey Alliance for Clinical and Translational Science' or NJ ACTS, which was recently awarded renewal for 7 years. He has authored over 525 peer-reviewed publications. Dr. Panettiere manages the clinical care of patients with asthma and is engaged in clinical investigations focused on the management of asthma and COPD. **Rey is a U PI representative to the Steering Committee..**

Eric Vilain, MD, PhD, is the Director of the Institute for Clinical and Translational Science and the Associate Vice Chancellor of Scientific Affairs at the University of California, Irvine. Dr. Vilain has a long-standing interest in the translational genetics (from diagnostic to clinical management) of rare diseases, as well as differences of sex development. He has identified many novel genetic variants in sex-determining genes and developed animal models with atypical sexual development. He works with representatives of the Community of individuals with Variations of Sex Characteristics to improve clinical research in ways relevant to the Community. He has published extensively in the fields of genetics and endocrinology. After earning his medical degree and PhD, Dr. Vilain completed a post-doctoral fellowship in medical genetics at the University of California, Los Angeles, where he became professor of Human Genetics, Pediatrics and Urology in the David Geffen School of Medicine and the Chief of Medical Genetics. He then became the director of the Center for Genetic Medicine Research and Chair of Genomics and Precision Medicine at Children's National Hospital and George Washington University, returning to California to lead the CTSA at the University of California, Irvine. He has received numerous awards, notably from the National Institute of Health, the March of Dimes, the Doris Duke Charitable Foundation and the Society for Pediatric Research. He is a fellow of the American College of Medical Genetics and a longstanding advisor to the International Olympic Committee on Hyperandrogenism in Athletes. **Eric is a U PI representative to the Steering Committee.**

Incoming Steering Committee Members

Michael Holinstat, PhD is a professor in the department of pharmacology and a fellow of the American Heart Association. Dr. Holinstat's research interests focus on understanding lipid, lipoxygenase and oxygenase regulation of platelet signaling and function and how it relates to regulation of hemostasis and thrombosis. He serves as the inaugural Director of the Platelet Physiology and Pharmacology Platelet Core at the University of Michigan and serves on several national boards including the sub-committee on Hemostasis and Thrombosis at the American Society for Hematology and the Director for the NIH CTSI-funded T32 training grant in clinical research. Dr. Holinstat has received numerous patents from the US, EU, and Japan patent offices for various therapeutic discoveries to treat cardiovascular disease. In addition to his NIH-funded research, Dr. Holinstat continues to translate his discoveries into potential clinical application through collaborations with Veralox Therapeutics, Cereno Scientific and Lexicon Pharmaceuticals. Dr. Holinstat has spent the last 20 years training the next generation of clinical and translational scientists in the area of blood clotting, platelet biochemistry, and discovery of novel therapeutic approaches for treating thrombosis including undergraduates, graduate students, postdoctoral fellows, clinical fellows, and basic and clinical faculty. **Mike is the T PI representative to the Steering Committee.**

Incoming Steering Committee Members

Mark R. Schleiss, MD, is a Professor of Pediatrics in the University of Minnesota Medical School. Dr. Schleiss received his MD degree from the Oregon Health and Sciences University, Portland, Oregon. He completed his residency at Doernbecher Children's Hospital, Oregon Health and Sciences University, Portland, Oregon, and his Pediatric Infectious Diseases fellowship at Seattle Children's Hospital/Medical Center, University of Washington, Seattle, Washington. He also completed a fellowship in Molecular Medicine studying cytomegalovirus (CMV) molecular genetics at the Fred Hutchinson Cancer Research Center, Seattle, Washington. **Mark is the Integration Across the Lifespan EC Representative to the Steering Committee.**

David Ingbar, MD is a Professor of Medicine (Pulmonary & Critical Care), Assistant Dean for Faculty Development & Mentoring and Co-Director of the CTSI Education, Research Training & Career Development Core at the University of Minnesota. David is a physician-scientist with research focused on speeding repair of the injured lung, spanning basic alveolar epithelial cell biology to clinical trials based on his lab discoveries. He is P.I. of the UMN CTSI K12 and previously was President of the American Thoracic Society, and for more than 20 years was both Division Director and pre-& post-doc T32 P.I. **David is the Workforce Development EC representative to the Steering Committee.**

Incoming Steering Committee Members

Sarah Wiehe, MD, MPH is the Jean & Jerry Bepko Professor of Pediatrics; Associate Dean of Community and Translational Research at Indiana University School of Medicine; a Research Scientist at the Regenstrief Institute and Adjunct Professor of Epidemiology at Fairbanks School of Public Health. She has expertise in community engagement, patient-centered research methods, creative use of existing data, data-sharing partnerships and health services research. Her research focuses on identifying and addressing inequitable outcomes among vulnerable populations, including individuals involved with the justice system, living in poverty, diagnosed with mental health and substance use disorder diagnoses, experiencing trauma, and living with HIV, partnering with a diverse array of community and academic partners on this research to identify opportunities for interventions to promote health equity. She co-directs the Indiana Clinical and Translational Sciences Institute (CTSI), and has led the community engagement aspects of the program, including as the founding director of Research Jam, its patient engagement core. The Indiana CTSI partners with patients and community members, community-based organizations, healthcare systems, and governmental agencies to engage with vulnerable populations throughout the state and translate scientific evidence into practice and policy. She also serves on the US Preventive Services Task Force. **Sarah is the Collaboration & Engagement EC representative to the Steering Committee.**

Elmer Bernstam, MD, MSE, holds the joint appointment of professor at McWilliams School of Biomedical Informatics at UTHealth Houston, formerly UTHealth Houston School of Biomedical Informatics (SBMI), where he also serves as associate dean for research, and at McGovern Medical School. Bernstam is also the director of the Biomedical Informatics Group at UTHealth's Center for Clinical and Translational Sciences (CCTS). His lab at CCTS created and maintains the UTHealth clinical data warehouse, which contains health data for over 400,000 patients. Bernstam is board-certified in internal medicine and continues to practice. His research focuses on clinical and translational informatics, specifically on information retrieval, consumer informatics and clinical decision support. He is a fellow of the American College of Physicians and the American College of Medical Informatics. In 2004, Bernstam received the John P. McGovern Outstanding Teacher Award, as voted by McWilliams School of Biomedical Informatics student body. Bernstam completed a National Library of Medicine fellowship at Stanford Medical Informatics. **Elmer is the BIDS EC Representative to the Steering Committee.**

Current Steering Committee Members

Arleen Brown, MD, PhD
UCLA
U PI Member

Andrea Carnegie, PhD
North Carolina Translational and Clinical Sciences Institute (NC TraCS)
Administrator Representative

Stephanie Ezequiel, MPS
NCATS
Executive Secretary to the Steering Committee

Daniel Ford, MD, MPH
Johns Hopkins University
TIN Representative

Current Steering Committee Members

Vesna Garovic, MD, PhD
Mayo Clinic
U PI Member

Grace McComsey, MD
Case Western Reserve University
School of Medicine
U PI Member
Chair for Fall Meeting Planning and Steering Committee Co-Chair for 2026-2027

Mimi Kim, ScD
Albert Einstein College
of Medicine
U PI Member

Frederick "Gerry" Moeller, MD
Virginia Commonwealth University
U PI Member

Current Steering Committee Members

Elizabeth Ofili, MD, MPH
Morehouse School of Medicine
U PI Member

Steven Reis, MD
University of Pittsburgh
ENACT Representative

Doris Rubio, PhD
University of Pittsburgh
KL2 Member

Rosalind Wright, MD, MPH
Icahn School of Medicine at Mount Sinai
U PI Member

2025 CTSA Pods

Michigan Institute for Clinical and Health Research SC Pod Leader: Julie Lumeng email: jlumeng@umich.edu
University of Texas Medical Branch Galveston
University of Texas Health Science Center at Houston and University of Texas MD Anderson Cancer Center for Clinical and Translational Sciences
Institute for Integration of Medicine & Science: A Partnership to Improve Health
Frontiers Clinical and Translational Science Institute at the University of Kansas
University of Arkansas for Medical Sciences Translational Research Institute
Consortium for Translational and Precision Health (Baylor and University of Houston)

New Jersey Alliance for Clinical Translational Science: NJ ACTS SC Pod Leader: Reynold Panettieri email: rp856@rbhs.rutgers.edu
Indiana Clinical and Translational Sciences Institute
University of Minnesota Clinical and Translational Science Institute
University of Wisconsin Institute for Clinical and Translational Research
University of Florida Clinical and Translational Science Institute
University of Iowa Institute for Clinical and Translational Science

Orange Shadowing Notes New Pod Leader

COORDINATION

2025 CTSA Pods

Conduits: Mount Sinai Health System Translational Science Hub SC Pod Leader: Rosalind Wright email: rosalind.wright@mssm.edu
University of Illinois at Chicago Center for Clinical and Translational Science
Vanderbilt Institute for Clinical and Translational Research
Rockefeller University Center for Clinical and Translational Science
Northwestern University Clinical and Translational Science Institute
Penn State Clinical and Translational Science Institute

Wright Regional Center for Clinical and Translational Science SC Pod Leader: Frederick “Gerry” Moeller email: frederick.moeller@vcuhealth.org
NYU Langone Health's Clinical and Translational Science Institute
University of Massachusetts Center for Clinical and Translational Science
integrated Translational Health Research Institute of Virginia
Georgetown-Howard Universities Center for Clinical and Translational Science
Yale Center for Clinical Investigation

2025 CTSA Pods

Einstein-Montefiore Clinical and Translational Science Award Hub **SC Pod Leader: Mimi Kim** **email: mimi.kim@einsteinmed.org**
Harvard Clinical and Translational Science Center
Columbia University's Clinical and Translational Science Award
Washington University in St. Louis Institute of Clinical and Translational Sciences
University of Rochester Clinical and Translational Science Institute
University of Chicago Rush University Institute for Translational Medicine

Clinical and Translational Science Collaborative at Case Western Reserve University **SC Pod Leader: Grace McComsey** **email: gam9@case.edu**
Kentucky Center for Clinical and Translational Science
University of Alabama at Birmingham Center for Clinical and Translational Science
UT Southwestern Medical Center Clinical and Translational Science Award
Cincinnati Center for Clinical and Translational Science and Training
Boston University Clinical and Translational Science Institute

2025 CTSA Pods

Institute for Clinical and Translational Science at the University of California-Irvine SC Pod Leader: Eric Villain email: evilain@ucla.edu
University of New Mexico Health Sciences Clinical and Translational Science Center
University of California, San Francisco Clinical and Translational Science Institute
Colorado Clinical and Translational Sciences Institute
Utah Clinical & Translational Science Institute
University of Washington Institute of Translational Health Sciences

Mayo Clinic Center for Clinical and Translational Science SC Pod Leader: Vesna Garovic email: garovic.vesna@mayo.edu
Tufts Clinical and Translational Science Institute
Ohio State University Clinical and Translational Science Institute
Southern California Clinical and Translational Science Institute
Clinical and Translational Science Institute of Southeastern Wisconsin
UC Davis Clinical and Translational Science Center

Orange Shadowing Notes New Pod Leader

2025 CTSA Pods

Dartmouth Clinical and Translational Science Institute SC Pod Leader: Steven Bernstein email: Steven.L.Bernstein@hitchcock.org
Weill Cornell Medicine Clinical and Translational Science Center
Johns Hopkins Institute for Clinical and Translational Research
University of Pittsburgh Clinical and Translational Science Institute
University at Buffalo Clinical and Translational Science Institute
University of Pennsylvania Institutional Clinical and Translational Science Award

Georgia Clinical and Translational Science Alliance SC Pod Leader: Elizabeth Ofili email: eofili@msm.edu
Miami Clinical and Translational Science Institute
North Carolina Translational and Clinical Sciences Institute
Duke Clinical and Translational Science Awards
South Carolina Clinical & Translational Research Institute
Wake Forest Clinical and Translational Science Institute

Orange Shadowing Notes New Pod Leader

2025 CTSA Pods

University of California Los Angeles Clinical and Translational Science Institute **SC Pod Leader: Arleen Brown** **email: abrown@mednet.ucla.edu**
Stanford Center for Clinical & Translational Education and Research (Spectrum)
Scripps Clinical and Translational Science Hub
UC San Diego Clinical and Translational Research Institute
Oregon Clinical and Translational Research Institute

CTSA Research Pharmacy Working Group

SCIENCE FOR THE BENEFIT OF HUMANITY

Robert B. MacArthur, PharmD, MS, BCSCP
Pharmacy Director
Rockefeller University Hospital

Molly Camis, PharmD, MSHA, BCPS
Assistant Pharmacy Director – CMK Inpatient & IDS Pharmacies
UMKC School of Pharmacy

Donna L. Capozzi, PharmD, BCOP
Director, Oncology Pharmacy and Investigational Drug Services
Hospital of the University of Pennsylvania

David C. M. Chan, PharmD, PhD
Coordinator, Investigational Drug Service, Clinical Assistant Professor
University of Illinois Hospital,

Chris Chapleau, PharmD, PhD, MBA
Manager, Investigational Drug Services
Department of Pharmacy, University of Alabama Birmingham

Jason A. Christensen PharmD, MS, MBA
Senior Director, Department of Pharmacy
Mayo Clinic

Sarah E. Dunsmore, PhD
NCATS, Rockville, MD

Amanda Ewald, Pharm.D.
Senior Manager – Pharmacy Research
Mayo Clinic

Elizabeth M George RPh BCOP
Clinical Research Pharmacist
Rutgers: Robert Wood Johnson Medical School

David. H. Kim PharmD, BCOP
Assistant Director, IDS
University Hospital of Pennsylvania

Ruiyang Li, PhD
Department of Biostatistics
Columbia University

Kuldip R. Patel, PharmD, FASHP
Senior Associate Chief Pharmacy Officer
Duke University Health System

Matthew Serna, PharmD, BCPS
Senior Pharmacist, Investigational Drug Service
UC Davis Medical Center

Sarah Shami, PharmD
IDS Manager
Howard University College of Medicine

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

THE ROCKEFELLER UNIVERSITY HOSPITAL

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Table : Research Pharmacy Products and Services Described in Clinical Trials Publications (n=110)		
Services	N	%
Randomization	93	83.8%
Supplying placebos	88	79.3%
Compounding	83	74.8%
Distribution	28	25.2%
Supplying actives	6	5.4%
Compounding non-sterile		
Capsules	42	37.8%
Solutions/suspensions	17	15.3%
Tablets	11	9.9%
Compounding sterile		
Syringe	28	25.2%
Small volume infusions	19	17.1%
Large volume infusions	7	6.3%
Inhalation products	5	4.5
Isotopes	5	4.5
Vaccines	4	3.6%

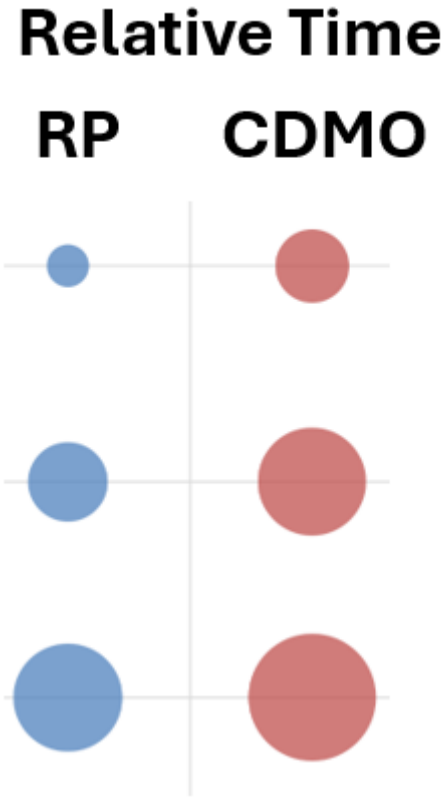
Out of ~485 journal articles, only 110 mention RP services although most must have use RP services

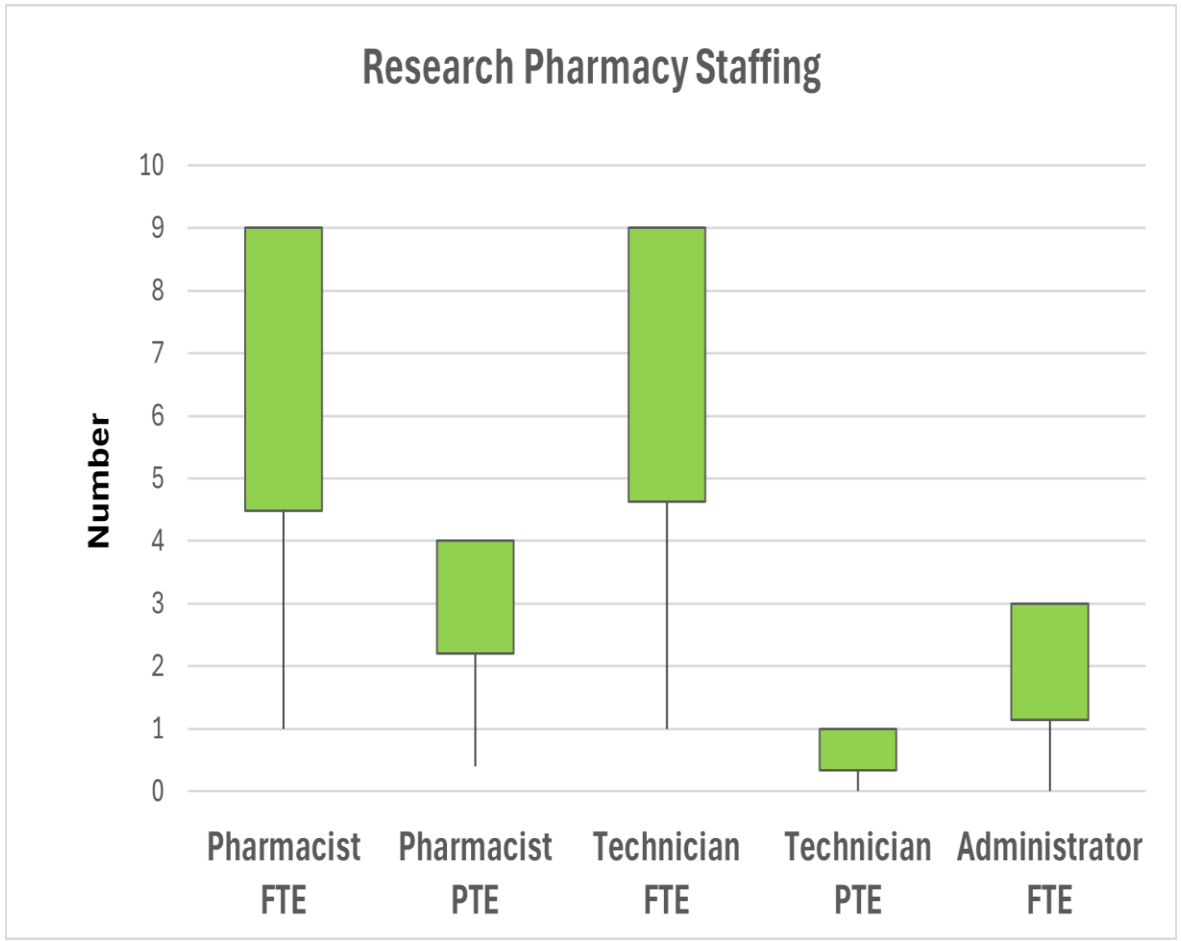
Comparison of RP vs CDMO Cost for Common Projects

Scenarios	RP cost ($)	CDMO cost ($)
Over-encapsulate 1000 capsules total, as 500 active and 500 matching placebo capsules. Create 100 kits with 10 individual doses in vials (1 capsule per vial) per kit. Randomize, add blinded labeling, package. Ship out all in one shipment, to one location.	$8,000	$326800
Manufacture 2 different strengths (high, low) of a sterile drug for infusion. Package in 50 small 100 mL IV bags (25 IV bags high-dose and 25 low-dose). Randomize, add blinded labeling, package. Ship out all in one shipment, to one location.	$5500	$488000
Manufacture 120 prefilled syringe containing vaccine, at 3 different doses. 40 high-dose, 40 low-dose, 40 placebo. Each active dose vaccine syringe contains 3 ingredients (antigen, adjunvant, vehicle). Placebo syringes contain only vehicle. Randomize, add blinded labeling, package. Ship out every 2 weeks for 6 months (12 shipments total).	$15000	$458000

Comparison of RP vs CDMO Time for Common Projects

Scenarios	RP time (months)	CDMO time (months)
Over-encapsulate 1000 capsules total, as 500 active and 500 matching placebo capsules. Create 100 kits with 10 individual doses in vials (1 capsule per vial) per kit. Randomize, add blinded labeling, package. Ship out all in one shipment, to one location.	2	6
Manufacture 2 different strengths (high, low) of a sterile drug for infusion. Package in 50 small 100 mL IV bags (25 IV bags high-dose and 25 low-dose). Randomize, add blinded labeling, package. Ship out all in one shipment, to one location.	7	13
Manufacture 120 prefilled syringe containing vaccine, at 3 different doses. 40 high-dose, 40 low-dose, 40 placebo. Each active dose vaccine syringe contains 3 ingredients (antigen, adjunvant, vehicle). Placebo syringes contain only vehicle. Randomize, add blinded labeling, package. Ship out every 2 weeks for 6 months (12 shipments total).	13	18




Research Pharmacy Staffing
Number
10
9
8
7
6
5
4
3
2
1
0
Pharmacist FTE
Pharmacist PTE
Technician FTE
Technician PTE
Administrator FTE

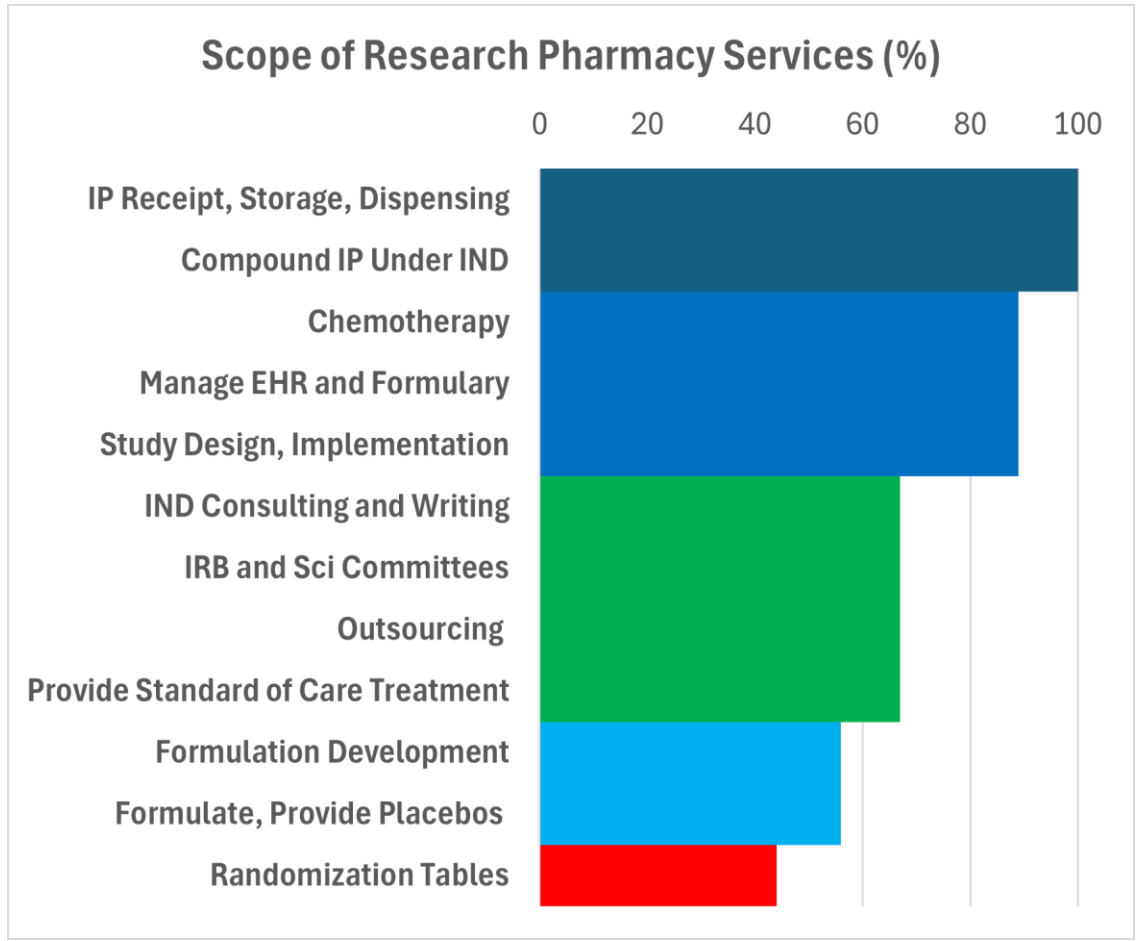

Scope of Research Pharmacy Services (%)
0
20
40
60
80
100
IP Receipt, Storage, Dispensing
Compound IP Under IND
Chemotherapy
Manage EHR and Formulary
Study Design, Implementation
IND Consulting and Writing
IRB and Sci Committees
Outsourcing
Provide Standard of Care Treatment
Formulation Development
Formulate, Provide Placebos
Randomization Tables

Table : Examples of FDA Approved Study Products with Early Phase Studies at CTSA sites

Population	Drug name	Study start date(s)	FDA approval date	FDA indication on approval date	Study NCT No(s).
adult and pediatric patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).	Triheptanoin	09/01/2011 01/01/2012	6/30/2020	To treat molecularly long-chain fatty acid oxidation disorders	NCT01379625 NCT02018315
Adult and Pediatric Patients with the presence of a NTRK gene fusion	Larotrectinib	08/01/2015	11/26/2018	To treat patients whose cancers have a specific genetic feature (biomarker)	NCT02465060
adults with polycythemia vera	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
treatment of adult patients with unresectable hepatocellular carcinoma	Tremelimumab	07/01/2008 02/01/2010	10/21/2022	To treat unresectable hepatocellular carcinoma	NCT00702923 NCT01103635
an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism	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

Research Pharmacies:

very actively support clinical trials at CTSA sites

lower research costs and speed drug development

provide a wide array of highly specialized services

CTSA sites:

very actively contribute to the development of drugs approved by FDA

Pod Overview

- A Pod represents 5-6 CTSA program hubs which is led by a Pod Lead

- Pod Composition:
  - One Pod Lead: CTSA Program SC Principal Investigator- Current SC member
  - Five to six Pod Members: CTSA Program U PI; Administrator (optional)

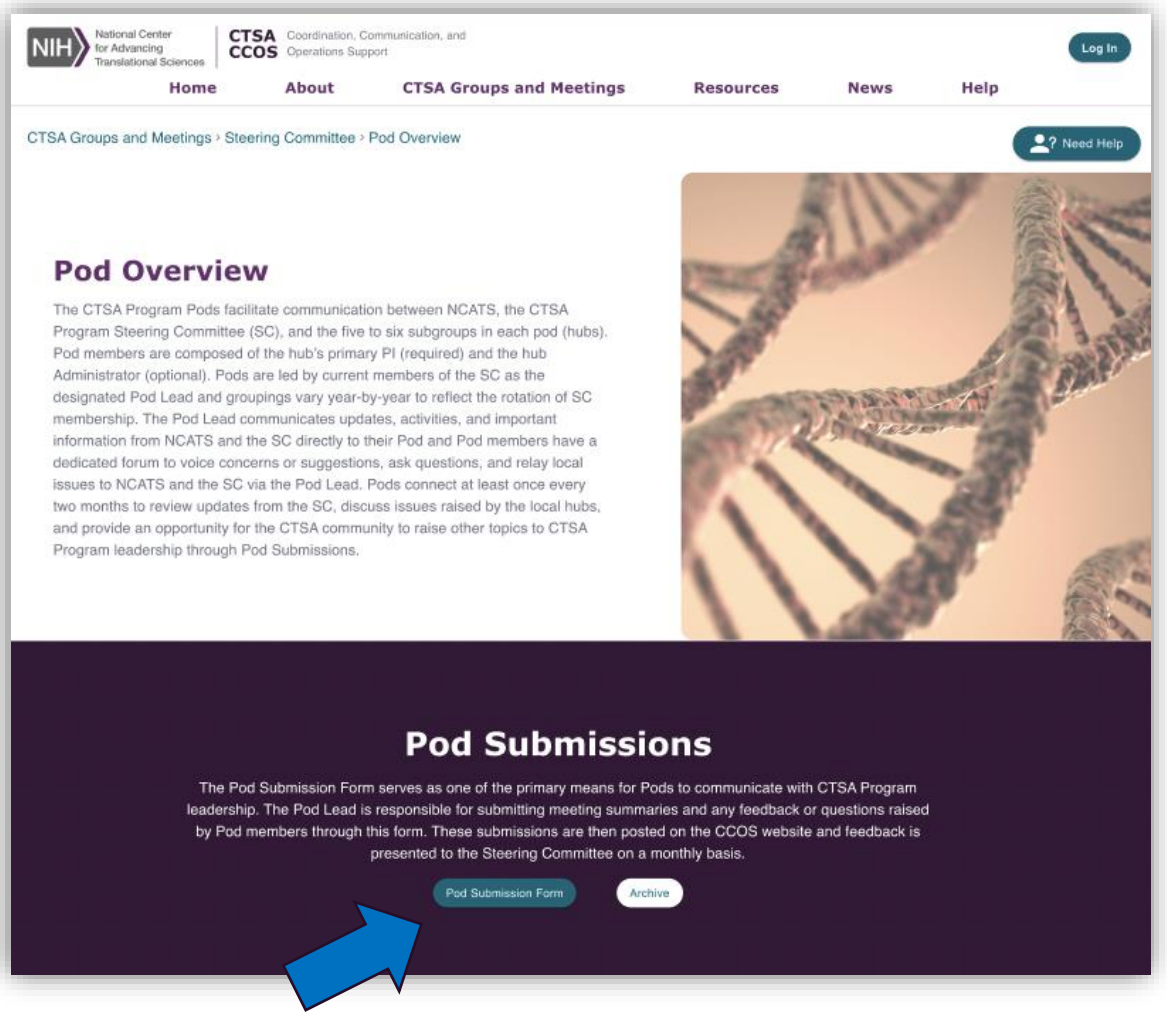
- Pod Leader Role:
  - Share information and updates from previous SC members
  - Gather ideas, questions, concerns and feedback from Pod members
  - Act on behalf of the Pod members by reporting ideas, questions, feedback to the SC and NCATS on a regular basis.
  - Summarize discussion points from Pod members on a variety of topics, projects, and NCATS activities, as requested by NCATS

Pod Submissions

- Pod leads will submit a Pod meeting summary report
- CCOS will provide a standard meeting summary template for Pods
- Pod feedback to the SC (e.g., questions, crowd-sourced topics, other feedback) is included in the summary template
- Meeting summaries will be publicly viewable
- Use online submission form on CCOS website

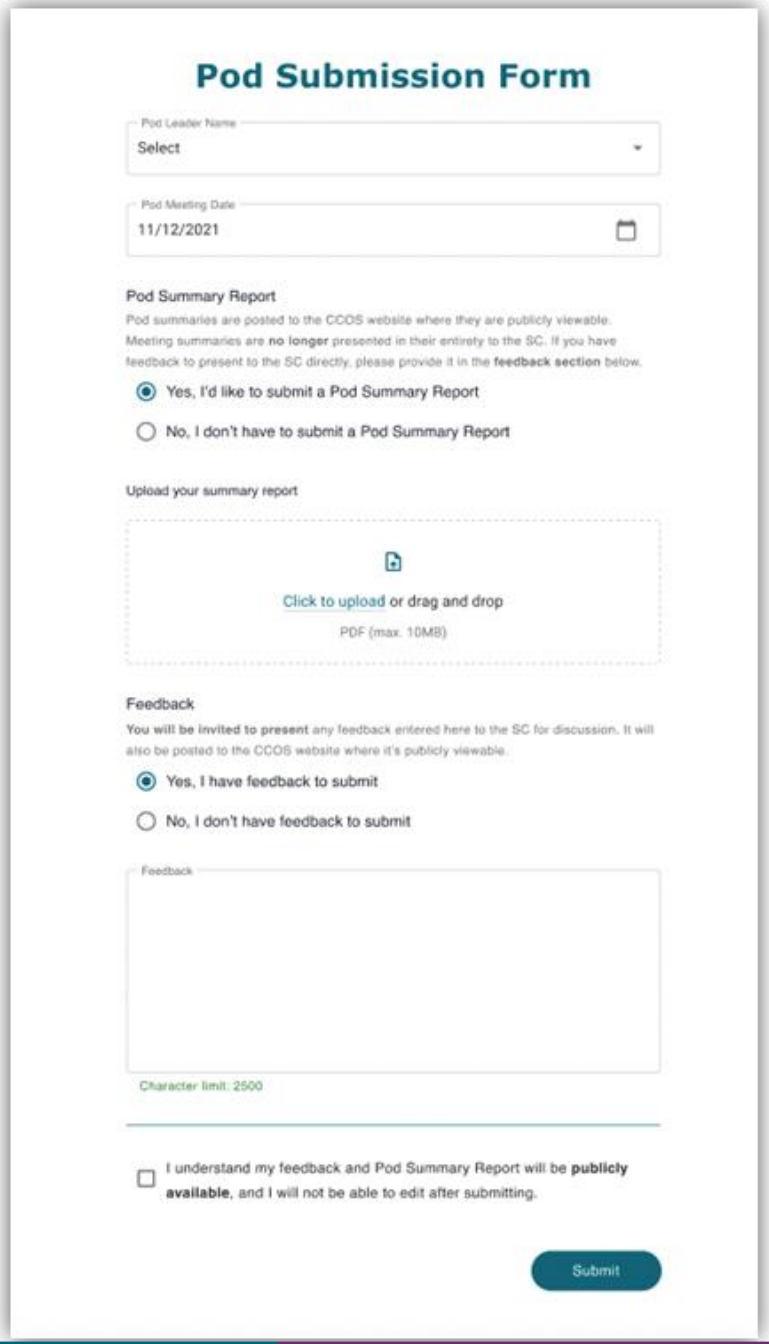
Pod Submission Steps

1. Login to your CCOS account
2. Once logged in, navigate to the CTSA Program Steering Committee page.
3. Click ‘Learn More’ under the Pods section to navigate to the Pods Overview page.
4. On the Pods Overview page, click the teal ‘Pod Submission Form’ button to complete a Pod submission.



Pod Submission

- Select your name under “Pod Lead Name”
- Identify the Pod meeting date
- Upload or drag/drop a PDF of Pod meeting summary report
- Click the check box and Submit
- The meeting summary template will capture general notes and feedback for the SC



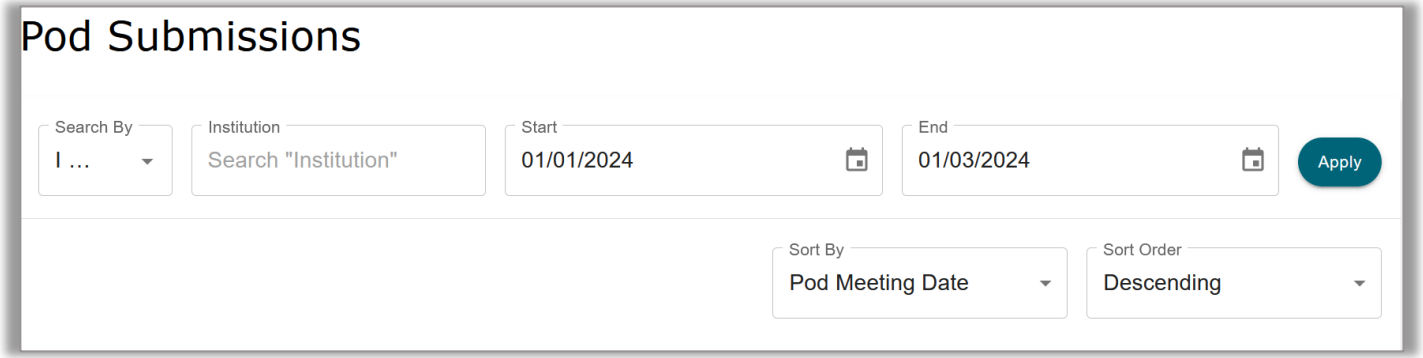
Who can submit in the Pod submission portal?

- Only Pod leads can submit content on the Pod submission form

- Send CCOS names and emails of designated individuals who will submit on your behalf

Pod Submission Archive

- To view or search for previous Pod Submissions go to the Pod Overview page
- Click “Archive” button



January 27, 2025
2:30-3:30pm ET

National Center
for Advancing
Translational Sciences