

CTSA Program Webinar

September 25, 2024



Agenda

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Lauren Fitzharris, M.P.H., P.M.P.
2:01 – 2:10 PM	NCATS/CTSA Updates	Erica Rosemond, Ph.D. NCATS
2:10 – 2:15 PM	CCOS Updates	Kerry James, M.P.H., P.M.P. CCOS
2:15 – 2:30 PM	NIH Care Update	Antonella (Tony) Punturieri, Ph.D, M.D. NIH
2:30 – 3:00 PM	CTSA Dental Schools Program	Erica Rosemond, Ph.D. Raj Prasad (Ruth O'Hara, Ph.D.) Stanford David Lam, M.D., Ph.D., D.D.S. University of the Pacific
3:00 PM	Adjourn	





NCATS/CTSA Program Updates

Erica Rosemond, PhD

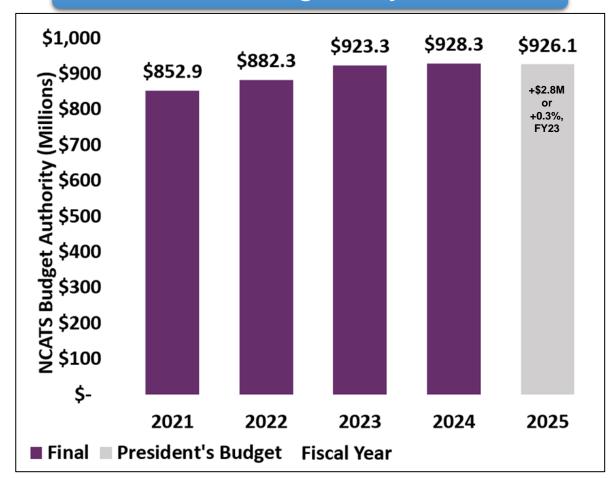
Deputy Director (Acting), Division of Clinical Innovation NCATS

September 25, 2024

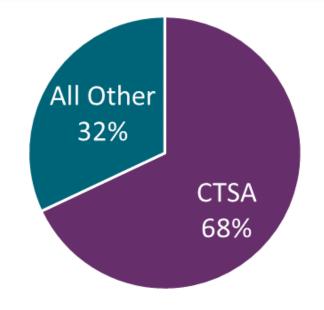


FY 2025 NCATS President's Budget

Funding History



FY24 Budget by Activities



NCATS Appropriations



https://ncats.nih.gov/about/budget



NCATS Strategic Plan for 2025 - 2030

2025 — 2030 NCATS Strategic Plan



ncats.nih.gov/about/ncats-overview/strategic-plan

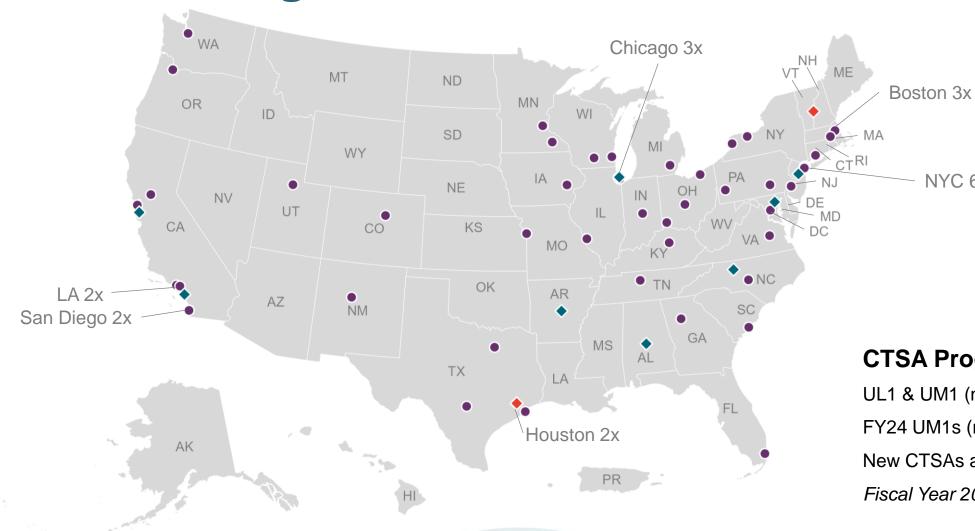


- Read the plan
- Share it with your networks
- Use it in your own work

NCATS Director Roundtable Series

- Public Roundtable: September 30, 3-4 pm
- Community Advisors: October 2, 3-4 pm
- Pls and Deans: October 4, 1-2 pm

FY24 CTSA Program Hubs



CTSA Program Hubs

UL1 & UM1 (n = 52)

NYC 6x

FY24 UM1s (n = 11) ◆/◆

New CTSAs are shown in red

Fiscal Year 2024





NCATS Advisory Council September 19, 2024

- Program Update Presentation: Division of Clinical Innovation
 - Michael G. Kurilla
- Advisory Council Letter to the NCATS Director
 - Formally requesting the initiation of a process to transition NCATS to an Institute
- Agenda
- Videocast



Seeking New CTSA Program Steering Committee Members!

- NCATS is seeking 4UL1/UM1 PIs to serve on the committee for the next 2-3 years (2025 2028).
- If you would like to self-nominate or suggest a fellow PI, please submit the PI name, institution, and brief explanation by Wednesday, October 16th (here)

The eligibility criteria for SC appointments:

- A PI must be officially named in the Notice of Grant Award of an active CTSA Program hub
- The Pl's hub award must have at least 3 years remaining during the project period
- The PI has not served on the SC since December 2018
- Please Review expectations and responsibilities (linked here)





Clinical and Translational Science Award (UM1 Clinical Trial Optional)

- PAR-24-272: Released September 4, 2024
- First receipt date: March 13, 2025 (6 months to prepare)
- Highlights:
 - No significant changes this is a <u>renewal</u> of <u>PAR-21-293</u>
 - Element D: Clinical and Translational Science Resources and Pilots
 - Module D3 Name change from Health Informatics to Data Science (to be more inclusive, representing the goal of supporting and performing the most cutting-edge research across the field of translational science, and to be aligned with NIH priorities)
 - Included language and examples encouraging <u>research</u> as well as <u>service</u>
 - Element E: Clinical and Translational Science Research Program
 - Increased the page length from 6 to 12 pages, only 1 single initial discrete project
- Technical Assistance Webinar Date Coming Soon!
- Questions: Email: <u>CTSANOFOQuestions@mail.nih.gov</u> FAQs: <u>here</u>





Other Updates on the CTSA Suite of Funding Opportunities

- Notices of Intent to Publish the UM1, K12, T32s and R25s were published <u>very early</u> (February 22, 2024) with the intention to alert the community that all the opportunities were to be renewed (<u>renewed = no significant changes</u>) and indicated that the CTSA suite was intended to be published in the summer of 2024 with an expected application due date in January 2025 (best laid plans!!)
- NCATS remains committed to ensuring CTSA hub PIs have 6 months lead time to prepare the UM1 application and will accommodate the compressed timeline which will have no impact on when awards will be made
- Other opportunities (K12, T32s, R25) are delayed due to NIH funding opportunity templates being revised <u>NOT-OD-24-149</u>, however, the intent is to have these mechanisms released with the same first receipt date as the UM1 (due to CTSA Suite eligibility requirements).



NCATS Small Business Innovation Grants

Topics of High Interest:

- Preclinical Drug Discovery & Development
- Biomedical, Clinical & Health Research Informatics
- Clinical, Dissemination & Implementation Research



Other SBIR/STTR:

- Small Business Transition Grant for New Entrepreneurs
 - SBIR: PAR-24-131 / STTR: PAR-24-133
- Addressing Health Inequities in Clinical Diagnostics
 - SBIR: PAR-24-158 / STTR: PAR-24-157
- Miniaturization and Automation of Tissue Chip Systems (MATChS)
 - SBIR: <u>RFA-TR-23-017</u> / STTR: <u>RFA-TR-23-018</u>







Online Application Period: Sep 1, 2024 - Nov 21, 2024

- Extramural Loan Repayment Program for Clinical Researchers (LRP-CR) (NOT-OD-24-134)
- Extramural Loan Repayment Program for Pediatric Research (LRP-PR) (NOT-OD-24-135)
- Extramural Loan Repayment Program for Health Disparities Research (LRP-HDR) (NOT-OD-24-136)
- Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (LRP-IDB) (NOT-OD-24-138)
- Extramural Loan Repayment Program for Contraception and Infertility Research (LRP-CIR) (NOT-OD-24-139)
- Extramural Loan Repayment Program for Research in Emerging Areas Critical to Human Health (LRP-REACH) (NOT-OD-24-137)
 - REACH Priority Statements for NCATS:
 - Data science and health informatics to provide clinical decision support of health care providers
 - Telehealth and mobile health research approaches to improve the health of under-served and under-represented populations





NCATS POC: Dr. David Wilde: wilded@mail.nih.gov

https://www.lrp.nih.gov/

Agency for Healthcare Research & Quality (AHRQ) Funding Opportunity

- State-based Healthcare Extension Cooperatives to Accelerate Implementation of Actionable Knowledge into Practice (U19) (<u>RFA-HS-24-004</u>)
 - See: <u>press release</u>
 - Technical Assistance Webinar on September 27th NOT-HS-24-025
 - Contact: Matthew Simpson, MD, MPH Email: <u>AHRQ_HES@ahrq.hhs.gov</u>
- Coming soon! Two additional funding opportunity notices for:
 - National Coordinating Center
 - National Evaluation Center to support the Healthcare Extension Cooperatives
- Updates about these as well as other information can be found on <u>AHRQ's</u>
 <u>Healthcare Extension Service website</u>



Upcoming Dates to Remember

Next CTSA Program Webinar

Last webinar of 2024!

October 23, 2024; 2-3 PM ET. Register here.



NGATS

COLLABORATE. INNOVATE. ACCELERATE.











CCOS Updates

Kerry James CCOS



Fall 2024 CTSA Program Meeting

Theme: Building CTSA Program Impact through Innovation, Collaboration and Equity

Date: November 13-15

Location: Bethesda North Marriott

- Registration closes on Nov 1st
- Hotel Room block closes on Oct 22nd
- Poster Submission portal closes on Oct 25

See more details on the CCOS Website

Questions? Contact FallMtg@ccos.ctsa.io

CTSA Program Meeting Agenda – Nov 13th

November 13				
8:30am – 11:30am	TIN Meeting			
10:00am – 6:00pm	Hub Administrators Meeting			
1:30pm – 6:00pm Steering Committee Meeting				

UPDATE: The U-PI meeting has been moved to Nov 14th at 6pm-7pm

CTSA Program Meeting Agenda – Nov 14th

November 14				
8:30am – 9:00am	Session1: Welcome	Mike Kurilla, NCATS Ruth O'Hara, Stanford		
9:00am – 10:30am	Session 2: CTSA Collaborations with Primary Care Practice-Based Research Networks (PBRNs)	Invitations pending Moderator: Cynthia Morris, Oregon Health & Science U		
10:30am- 11:15am	Session 3: Keynote	Monica Bertagnolli, NIH (Invited)		
11:30am - 12:15pm	Poster Session A			
12:15pm -1:45pm	Break			
1:45pm - 3:15pm	Session 4: PCORnet / TIN / ENACT / N3C Engagement	Dan Hanley, Johns Hopkins Emily Pfaff, UNC School of Medicine Steven Reis, U of Pittsburgh Elizabeth Shenkman, U of Florida		
3:30pm- 4:15pm	Poster Session B			
4:15pm- 5:45pm	Session 5 : Equity in Focus: Advancing Women's Health Research through Diversity Action Plans	Janine Clayton, NIH (Invited) Jenica Patterson, ARPA-H Tiffany Whitlow, Acclinate Moderator: Gelise Thomas, Case Western Reserve		
6:00pm-7:00pm	UPI Meeting	Networking Session Facilitators TBD		

CTSA Program Meeting Agenda – Nov 15th

November 15			
8:00am- 9:15am	Session 6 : CTSA Experiences with Transition from Translational Research to Translational Science	Patricia Wimokur, U Iowa Julie Johnson, Ohio State Julie Lumberg, U Michigan Moderator: Ted Wun, UC Davis	
9:30am- 10:45am	Session 7: Application of Generative AI and Large Language Models in Translational Science	Matthew DeCamp, U of Colorado Menisha Desai, Stanford Eneida Mendonca, U Cincinnati (Invited)	
11:00am – 12:30pm	Session 8: Element E/RC2/303 Approaches	Ange-Therese Akono, NC State Geoff Curran, U of Arkansas Thomas Houston, Wake Forest Ruth O'Hara, Stanford Olena Taratula, Oregon State Moderator: Mike Kurilla	
12:30pm – 1:00pm	Closing: Poster Awards, Top Ten Takeaways	Mike Kurilla, NCATS Ruth O'Hara, Stanford	

2024 Fall Poster Submissions

Poster Submission portal is open on CCOS website

- One poster per hub related to meeting theme
- Poster presenter not limited to scholars and trainees
- Hub Pls (U, K and Ts) and Hub Administrator work together to select the poster author to represent hub
- Hub Administrator to submit the poster for their hub

Poster Submission portal to close on **October 25th**

Poster Gallery to open on **November 6th**



Poster Session Jury and Awards

- Poster Sessions will take place on Nov 14th
 - All posters will remain up throughout the day
 - Presentations will be spread across two sessions (one in am and one in pm)
- Poster session will be juried (~20-26 jury members)
- Posters will be evaluated for:
 - Scientific Value, Presentation Delivery, Poster Design
 - How best they exemplify Innovation, Collaboration and / or Equity
- Awards (8 total)
 - Best overall scores (5 awards)
 - Also awards for top equity, collaboration, innovation posters (3 awards)

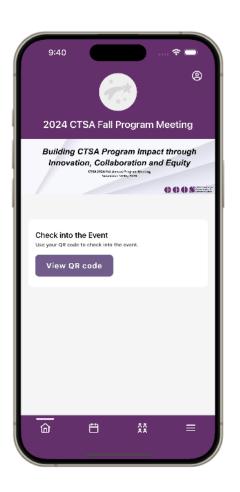


Cvent Conference Website & Mobile App

Fall 2024 Website Live!



Fall 2024 Mobile App



- For Registrants only (both virtual and in person)
- Access to the mobile app will be included in the "Before You Arrive" email the week before the Meeting.
- You may download the CVENT App in the app store.



Cvent Conference Website & Mobile App

Registration

Poster Gallery

Poster Submission

- The detailed CTSA
 Program Agenda is
 now on <u>Cvent Fall</u>
 <u>Meeting website</u>
- You may access the link to the full agenda on the CCOS Fall Meeting webpage

Meeting Details 2024 Fall CTSA Program
Annual Meeting

November 13, 2024 - November 15, 2024

Building CTSA Program Impact through Innovation, Collaboration, and Equity

The Fall 2024 CTSA Program Annual Meeting brings together personnel from CTSA Program Hubs with active grants for networking, sharing best practices and knowledge sharing. Topics to be addressed include:

- Primary Care Practice-Based Research Networks (PBRNs)
- PCORnet
- · The Women's Health Initiative and DEI
- Translational Research to Translational Science
- Generative AI and Large Language Models in Translational Science

Agenda

The agenda for the Fall CTSA Program Meeting can be accessed below.





Decentralized Clinical Trials Collaborative Workshop

Co- Sponsored by:

CTSA Coordination, Communication & Operations (CCOS) Support University of Southern California Clinical and Translational Science Institute





Wednesday

February 12, 2025 8:00 am – 4:30 pm PT

In-Person Event

The California Endowment 1000 North Alameda Street Los Angeles, CA 90012

Event Page

Registration is Open!



Scan Here to Register



Why Attend?

Who's Invited

Panel Sessions

Opportunities

- CTSA Program Representatives
- Researchers
- Clinicians
- Policymakers
- Healthcare innovators
- Opinion leaders
- Other healthcare professionals
- Industry

- Demystifying Decentralized Clinical Trials (DCT)
- Building Successful DCT: Key Components
- Navigating the Evolving Landscape

- Form teams around DCT research
- Learn about the ways the CTSA have and can support DCT
- Networking



Stay Updated on Collaborative Workshops!

Visit ccos.ctsa.io/groups/collaborative-workshops

Email collaborative workshop@ccos.ctsa.io

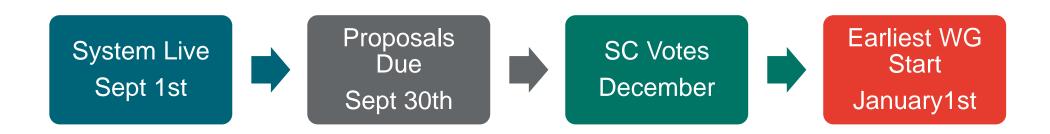
Thank you!



Next Cycle for Working Group Proposals – Closing Soon!

Working Groups Proposal Submission portal for Cycle XIII open on CCOS website during the month of **September 2024**

- The proposal submission period opened on September 1st
- All proposals should be submitted no later than September 30 at 3pm ET



CCOS Website Account

Getting Started

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

Getting Started Page

Account Access Includes:

- Meeting Materials/Archives
- CTSA Hub Directory

Questions? Please email support@ccos.ctsa.io

Want to stay up to date on the CTSA Program?

Follow this link or scan the QR code to join the CCOS All Communications Email List to receive CTSA Program communications and updates:

http://eepurl.com/iw9nZA



Remember to add <u>communications@ccos.ctsa.io</u> to your contacts list to prevent important CCOS emails from ending up in your spam folder!



Communities Advancing Research Equity for Health™ (CARE for Health™)

Advancing Clinical Research with and for Primary Care

CTSA Presentation

September 25, 2024

Antonello (Tony) Punturieri MD PhD

Senior Clinical Research Officer, CARE for Health™



The health of the U.S. population is declining.

Decline is steepest among the underserved and underrepresented.

Communities Advancing Research Equity (CARE) for Health™

"Clinical trials should reflect the diversity of Americans –

because we know that delivers the best results. We are taking a big step towards ensuring communities that are historically underrepresented in clinical research are fully included and have the same access to the best available results and analysis.

There has never been more potential for progress than we have today."

- HHS Secretary, Xavier Becerra



EDITORIAL

Connecting lab, clinic, and community

will offer a

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-Monica M. Bertag

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NEWS RELEASES

Thursday, June 6, 2024

NIH launches \$30 million pilot to test feasibility of a national primary care research network

Initiative aims to improve health outcomes by integrating research in everyday primary care settings.

The National Institutes of Health (NIH) is investing approximately \$30 million in total over fiscal years 2024 and 2025 to pilot a national primary care research network that integrates clinical research with community-based primary care. The new initiative called Communities Advancing Research Equity for Health – or CARE for Health – seeks to improve access to clinical research to inform medical care, particularly for those in communities historically underrepresented in clinical research or underserved in health care. Informed by the health needs of these





Read the announcement

NIH National Institutes of Health

Communities Advancing Research Equity for Health™

CARE for Health™

Integrate research into the clinical care environment

Engender trust in science by addressing community needs

Achieve longitudinal collection of clinical data to address health across the lifespan

Conduct research addressing issues important to diverse communities, particularly those underrepresented in biomedical research



Reduce burden on providers using innovative data collection methods

Increase adherence to evidencebased care Improve
efficiency of
care
delivery



Establishing an NIH Network for Research in Primary Care Settings

Coordinated infrastructure that embeds innovative research into routine clinical care in primary care settings to:

- Support primary care-based clinical research in mission areas spanning prevention and treatment and with a focus on health equity and whole person health
- Establish a foundation for sustained engagement with communities underrepresented in clinical research
- Implement innovative study designs suitable for primary care settings that address common health issues, inform clinical practice, and enhance dissemination and implementation

...thereby facilitating and accelerating research advances for adoption and implementation into everyday clinical care, improving health outcomes, and advancing health equity for all



Approach to Network Building



Expand enrollment efforts of existing NIH studies and develop new studies as the infrastructure is established



Partner with existing clinical research networks and resources, expanding with new collaborations as the network grows



Engage primary care sites and their community network partners on prioritizing and planning research



Implement study designs across the landscape of clinical trial innovations to minimize burden on patients and providers

Key Components

Practice-Based and Patient-Centered | Research Prioritization and Planning | Clinical Study Innovations | Sustained Community Engagement



Potential Synergistic Partnerships



IDeA | Clinical and Translational Research



Professional Societies

Industry



Rethinking Clinical Trials®

CTSA Clinical & Translational Science Awards Program





Patients. **Communities**



CARE for Health™ **Partners**

> **Practice** Based Research **Networks**















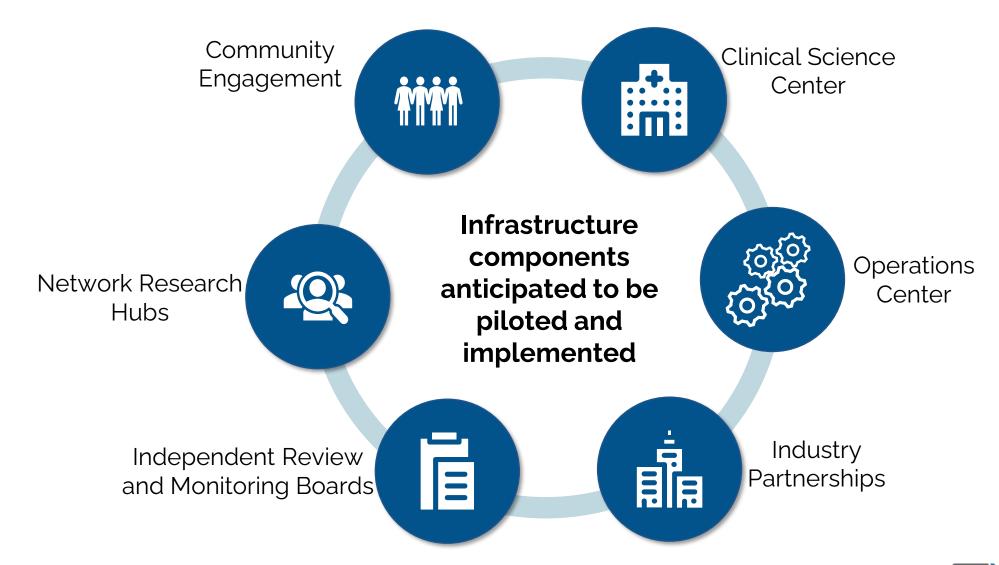




Agency for Healthcare Research and Quality



Infrastructure to Embed Research into Primary Care



Network Research Hubs

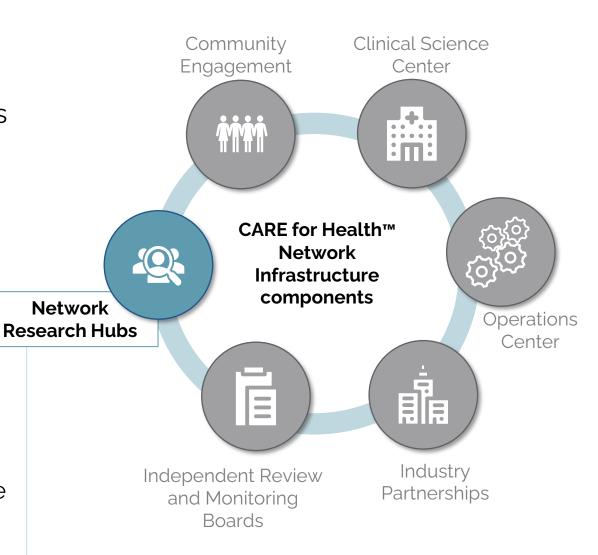
Key Elements of Pilot Launch

- Leveraging existing clinical research Networks for rapid launch
- Focusing on populations that are medically under-served and historically underrepresented in biomedical research, with emphasis on rural populations in pilot phase

Research Opportunity Announcement (ROA): Integrating Clinical Pessarch into Primary Ca

Integrating Clinical Research into Primary Care Settings through Network Research Hubs - A Pilot (OT2)

Purpose: Invite applications for organizations to serve as "Network Research Hubs" and establish infrastructure to conduct clinical research in rural primary care settings as a two-year pilot



CARE for Health™ Research Opportunity Announcement (OTA-24-016) for Network Research Hubs: Initial Awards

Awarded Organization	Research Network Affiliation	FQHC	PBRN
Oregon Health and Science University	NIH CTSA	✓	*
University of Wisconsin - Madison	NIH CTSA	√	√
West Virginia University	IDeA-CTR	√	✓

^{*} Indicates >1 PBRN

Building a Foundation for CARE for Health™ Network of Networks: Clinical Community Reach

The network research hubs will

- 1. Participate in clinical trials with existing NIH funded studies.
- 2. Engage additional clinics as part of efforts to understand communities' research priorities and preferences.

In total, the hubs will be working with over 50 clinics in Year 1.





Three Applicant Network Research Hubs Funded in FY24 to Participate in NIH-funded Clinical Trials

Hub	# Anticipated Clinical Partners for Enrollment	% of Catchment Area Zip Codes that are Rural (RUCA 4-10)	Clinical Trial	Clinical Indication	Intervention(s)	Population
Oregon Health and Science	2 FQHCs (8 Clinic Locations)	58%	Non-pharmacologic pain management in FQHC Primary Care Clinics (BeatPain Utah)	Chronic high-impact back pain	Behavioral RCT parallel assignment, double masked	Adult 18 - 80 y/o with chronic high-impact pain for > 3 months
University	1 FQHC (4 Clinic Locations)	81%	Collaborative Care for Polysubstance Use in	Poly- substance	Treatment: Behavioral Intervention at 2	Adults > 18 y/o
University of Wisconsin	2 FQHCs (4 Clinic Locations)	70%	Primary Care Settings (Co-Care)	Use Disorder	levels: PCP and Patient	Addits <u> 2</u> 10 y/ 0
West Virginia University	6 Clinics	36%	Treat-to-target serum urate vs. treat-to-avoid symptoms in gout: A RCT (TRUST)	Gout	Prevention: Allopurinol (Rx); and Treatment: Anti-inflammatory (Rx)	Adults 18 - 90 y/o

CARE for Health™ - Future Plans

FY24 and Early FY25

- FY24-funded Hubs initiate enrollment into existing NIH-funded studies
- Engage with funded Hubs to identify and develop clinical research priorities relevant to their practitioners and communities
- Anticipate funding additional Hubs



FY26 and Beyond

- Continue expanding and developing infrastructure components of the program
- Launch new studies developed by and for the network



- Develop the Clinical Science Center and Operations Center
- Design innovative studies tailored to practitioner- and communityidentified priorities







Visit the program website to stay in touch!



go.nih.gov/CARE-for-Health





CTSA Dental Schools Network Discussion Forum

Erica Rosemond, PhD, NCATS



CTSA Dental Schools Network Discussion Forum

- CTSA Dental Schools Network (DSN) Discussion Forum is supported by NCATS and CCOS established in June 2024
- Why join?
 - This DF offers a dynamic platform and opportunities to share CTSA-related resources, connect, and engage in discussions to collaborate and disseminate knowledge within the dental schools and the CTSA community.
- All dental professionals affiliated or collaborating with CTSA hubs are welcome.
- Please join from the CCOS Discussion Forum landing page at: https://ccos-cc.ctsa.io/groups/discussion-forums (Log in is required.)

For questions reach out to Gallya Gannot (<u>Gallya.gannot@nih.gov</u>) or Raj Prasad (<u>rprasad2@Stanford.edu</u>)

For technical support to the CCOS support team (support@ccos.ctsa.io)



Image obtained, with permission from <u>Schools</u> and <u>Colleges | University of the Pacific</u>



Dental Schools Network Discussion Forum FY 2025 Webinar Series

Every second Friday at 1PM (ET) every two months

<u>Date</u>	Title	Presenters
9/13/2024	Decentralized Clinical Trials	Pablo Cure, NCATS Tom Radman, NCATS
11/8/2024	Successful Collaborations Between Dental Schools and CTSA Hubs. A case study	David Lam, University of the Pacific Ruth O'Hara, Stanford University
1/10/2025	CTSA Program Collaborative Innovation Awards Funding Opportunity	Kris Bough, NCATS
3/14/2025	Diversity Administrative Supplements to the Hub Awards and the training resources	Patrick Brown, NCATS Irina Krasnova, NCATS
5/9/2025	Trial Innovation Network and the Recruitment Innovation Center	Ken Wiley, NCATS
7/11/2025	RC2 presentation and opportunities for the dental school community	Pablo Cure, NCATS

- Link to registration: https://nih.zoomgov.com/meeting/register/vJlsdu-srz8uHX7mJtOltnGylEwc88gNMzU
- Questions: Gallya Gannot, NCATS gannotg@mail.nih.gov or Raj Prasad, Stanford CTSA rprasad2@Stanford.edu



Pacific-Stanford PRIMED Program

David K. Lam, MD, DDS, PhD, FACS

Professor and Chair, Dept. of Oral & Maxillofacial Surgery Associate Dean for Medical Integration University of the Pacific, Arthur A. Dugoni School of Dentistry

RUTH O'HARA, PhD

PI and Director: Spectrum, Stanford's Center for Clinical and Translational Research and Education Senior Associate Dean of Research, Stanford School of Medicine Lowell W. and Josephine Q. Berry Professor, Department of Psychiatry and Behavioral Sciences







Spectrum

Spectrum—the Stanford Center for Clinical and Translational Research and Education— is part of the Stanford University School Of Medicine Office of the Senior Associate Dean of Research. The Center is home to the Stanford Clinical & Translational Science Award (CTSA), funded by the NIH National Center for Advancing Translational Sciences (NCATS) since 2008.

Funding Period July 2024 – June 2031: **NIH NCATS 1UM1TR004921** Funding Period July 2019 – June 2024: **NIH NCATS 1UL1TR003142**





Stanford CTSA 2024: Overarching Aims

- <u>Aim 1</u>: Educate and Train: Educate and train the next generation of investigators who make up the clinical and translational "workforce" with the knowledge and skills in both Translational Research and the Science of Translation to conduct innovative CTSRE to achieve the vision of translational medicine in the 21st century and meet the opportunities and challenges of providing optimal, equitable treatments with delivery and access for all.
- <u>Aim 2</u>: Enhance and Innovate: Develop and implement innovative, data driven, and clinical operational approaches to accelerate, scale and diversify our clinical, translational and science of translation efforts.
- Aim 3: Engage, Collaborate and Scale:
 - a) Maximize community engagement, team science, and the engagement of diverse and inclusive approaches throughout the CTSA enterprise so our CTSRE products benefit all segments of the population
 - (b) Ensure our CTSRE efforts are scaled and implemented equitably, across diverse populations, including people with rare diseases, minorities, women, and across the lifespan from children to elderly
 - (c) Ensure CTSRE products are implemented across Stanford, regionally through our Stanford healthcare system, at our collaborating institutions (University of Hawaii and Kaiser Permanente CHR), and across the CTSA consortium and relevant networks, including N3C and the Trial Innovation Network.
- <u>Aim 4</u>: Impact: Develop and employ innovative state-of-the-field evaluative approaches to determine the effectiveness of all our approaches and to develop effective redeployment approaches to respond to challenges and opportunities in real time, measuring the impact of our Stanford CTSA CTSRE efforts.

NCATS Clinical and Translational Science Awards (CTSA) Program

Fiscal Year 2023



- National network of biomedical research institutions and their partners/collaborators
- In fiscal year 2023, NCATS invested \$629M in the CTSA Program to speed translation of research discoveries into improved patient care
- 39 of the hubs include dental schools



Nationally renowned institution, highly regarded for its:

- Humanistic model of education
- Accelerated 3-year predoctoral program
- Innovation in dental curriculum, including comprehensive patient care and competency-base education





118K 28K **ANNUAL PATIENT VISITS**

ACTIVE PATIENTS

2.8K 4.1K

ALUMNI DENTISTS GREATER BAY AREA

ALUMNI DENTISTS NORTHERN CALIFORNIA





UNMET NEEDS:

- Resources to support researchers and research teams
- Training and research support tools
- Infrastructure to support clinical and translational science
- Overcoming barriers in clinical and translational research to deliver health solutions faster
- Encouraging research collaboration from different scientific and health fields







TRAINING THE NEXT GENERATION OF CLINICAL ORAL HEALTH RESEARCHERS

NIH NIDCR 1U01DE033276-01

Pacific-Stanford PRIMED Program

Practice-Based
Research
Integrating
Multidisciplinary
Experiences in
Dental Schools
(PRIMED)

- In 2023, a grant was awarded by the NIH National Institute of Dental and Craniofacial Research (NIDCR) to fund the Pacific-Stanford PRIMED Program.
- This collaboration between The University of the Pacific, Arthur A. Dugoni School of Dentistry, Stanford University, and the Stanford CTSA is an innovative program that integrates research and clinical practice in dentistry.
- This program draws upon the unique strengths of both institutions and marks the beginning of mandatory clinical research training at the Dugoni School for all first-year students.





Our Vision

Draw upon the unique strengths of both institutions and marks the beginning of mandatory clinical research training at University of the Pacific for all first-year dental students by:

- 1. Integrating research learning into dental students' clinical practicums.
- Collecting data and samples at dental school to help drive future research projects and collaborations with CTSA hubs.
- Pique student interest in conducting their own research during dental school and beyond.
- 4. Motivate the current dental students to integrate clinical research into their practices once they graduate.





The Team





















This year we developed and implemented our first course through this program:

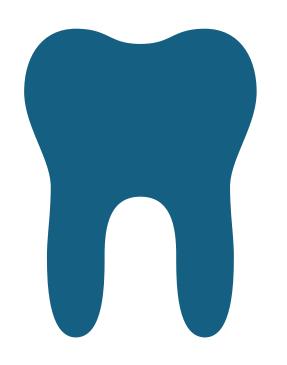
Fundamentals of Clinical Research

This course is modeled after the *Fundamentals* course offered by the Stanford CTSA.





Year 1



Goal: Integrate Clinical Research into the 1st Year Curriculum

- Train 140+ first year dental students with no prior clinical research exposure on the essentials of clinical research and research compliance.
- Emphasize the importance of evidence-based practice and how clinical research helps to achieve this in dentistry.
- Understand that high quality clinical research requires a thorough understanding of good clinical practice (GCP).





Course Outline

Course Background



We used a traditional virtual and in-person lecture format, as well as hands on sessions.



Our aim was to train students using interactive real-world scenarios for HIPAA compliance and Good Clinical Practice (GCP).



Hands on sessions included a workshop on consenting patients using clinical consent forms and developing your own research protocol.





Course Outline



Course Topics included:

- Overview of good clinical practice
- Data integrity and documentation
- Ethics in clinical research
- Informed consent
- Reporting requirements
- Phases of clinical research
- Registration and ClinicalTrials.gov
- Finding and using scholarly literature
- Developing clinical research protocols





Year 1 Cohort in action







Year 1 Cohort in action



Pacific students collaborating to develop research protocols | March 18th, 2024 | Taken with their permission





Dugoni School Students Take First-Ever "Dentist-Scientist Oath" to Ethics and Professionalism in Research





DENTIST-SCIENTIST OATH

"I, **[NAME]**, have entered the serious pursuit of new knowledge as a member of the community of dentist-scientists at the University of the Pacific.

"I solemnly declare the following:

Pride: I declare my pride in belonging to the international community of research scholars.

Inclusion: I will incorporate diversity into preclinical and clinical studies, and foster a culture of prioritizing and sustaining diversity at all levels of research and be inclusive of racial and ethnic minority groups, as well as other populations experiencing health disparities.

Integrity: I promise never to allow financial gain, competitiveness, or ambition cloud my judgement in the conduct of ethical research and scholarship.

Pursuit: I will pursue knowledge and create knowledge for the greater good, but never to the detriment of colleagues, supervisors, research subjects or the international community of scholars of which I am now a member.

By pronouncing this **Dentist-Scientist Oath**, I affirm my commitment to professional conduct and to abide by the principles of ethical conduct and research policies as set out by the University of the Pacific, Arthur A. Dugoni School of Dentistry."

Inspired and modified from
 Karen D. Davis et al. SCIENCE 2008

Year 2 and beyond



Next Steps

- Develop our next course, which will be more indepth and intensive.
- Will be built upon a model similar to the Intensive Course in Clinical Research (ICCR) offered by the Stanford CTSA.
- Will be offered to students, faculty, and alumni of the Dugoni School starting in Fall 2024.





Year 2 Comprehensive Clinical Research Kick-off





Pacific students, faculty, and alumni collaborating to develop research protocols | September 14th, 2024 | Taken with their permission





IMPACT.

- Enhance the infrastructure and climate for research at both *Pacific* and *Stanford* through the development of the program itself, through the creation of a *Pacific-Stanford Biobank*, and by increasing opportunities for integrated medical and dental research.
- End result will bridge the research to practice gap, accelerate knowledge translation
 to disseminate evidence-based treatments to prevent and manage oral diseases, and
 increase the pipeline for future clinical oral health researchers.
- Set a **new standard for dental education** in America with **mandatory training** of all students and residents in fundamental clinical research methods equipping graduates to successfully carry out practice-based research in their future careers.





IMPACT.

- Comprehensive clinical research training available to motivated, clinically faculty, dental alumni, students and residents will serve to **stimulate increased oral health scientific contributions as well as the pipeline of future oral health leaders**.
- Given our strong Pacific alumni community, the comprehensive clinical research training
 for dental alumni will enable the expansion of an alumni practice-based research
 network, further serving as affiliated clinical sites for large scale funded clinical research
 or trials.





Launch of CTSA Dental Schools Network (DSN) discussion forum

CTSA Dental Schools Network Discussion Forum

The CTSA Dental Schools Network (DSN) aims to facilitate seamless communication, foster collaboration, and encourage information-sharing among CTSA Program dental schools or partners and collaborators to any of the CTSA hubs.

The DSN Discussion Forum (DF) seeks to create a cohesive environment where DSN members can engage in meaningful discourse. The DF is a dynamic platform offering the opportunity to connect, share CTSA-related resources, and engage in discussions pertaining to collaborative efforts and knowledge dissemination within the dental schools and the CTSA community. This forum will convene bi-monthly, providing a structured space for members to come together, discuss pertinent topics, and learn from one another.

Members are strongly encouraged to utilize the forum to share resources, pose questions, and provide recommendations.

The DF will include personnel from the National Center for Advancing Translational Sciences (NCATS) and the National Institute of Dental and Craniofacial Research (NIDCR) that will offer insights, answers, and guidance as needed.

Discussion Group Posts

To post a new topic or to read the current discussions, open the Google Groups in a new window; please click here. Note that you must first join the Discussion Forum to access this feature.



CTSA Links

About Discussion Forums/Getting
Started

<u>List of Discussion Forums</u>

Google Meet Web Conferencing

Contact Support

CTSA DF Links



Dental Network Discussion Forum FY2025 webinar series:

- Every second Friday at 1PM (ET) every two months.
- Link to registration:
- https://nih.zoomgov.com/meeting/regis ter/vJlsdusrz8uHX7mJtOltnGylEwc88gNMzU
- Series moderators and coordinators Gallya Gannot, NCATS and Raj Prasad, Stanford CTSA.

<u>Date</u>	Title	Presenters
9/13/2024	Decentralized Clinical Trials	Pablo Cure, NCATS Tom Radman, NCATS
11/8/2024	Successful Collaborations Between Dental Schools and CTSA Hubs. A case study	David Lam, University of the Pacific Ruth O'Hara, Stanford University
1/10/2025	CTSA Program Collaborative Innovation Awards Funding Opportunity	Kris Bough, NCATS
3/14/2025	Diversity Administrative Supplements to the Hub Awards and the training resources	Patrick Brown, NCATS Irina Krasnova, NCATS
5/9/2025	Trial Innovation Network and the Recruitment Innovation Center	Ken Wiley, NCATS
7/11/2025	RC2 presentation and opportunities for the dental school community	Pablo Cure, NCATS

Reminder: October 23 CTSA Webinar

The next webinar is October 23, 2024; 2-3 PM ET

TL1 Visiting Scientist CTSA Working Group Update Housing-Based Socioeconomic Status (HOUSES)

Please register and add the new invite to your calendar: https://zoom.us/webinar/register/WN_qy2vYoxnSdGzbhABVjQFzQ