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Technical Assistance Webinar for CTSA Program Collaborative and Innovative Acceleration (CCIA) Award (PAR-22-167)

Soju Chang & Kristopher Bough, CTSA Program Branch, Division of Clinical Innovation

Lourdes Ponce, Scientific Review Branch, Division of Extramural Activities

Steve Elsberg, Grants Management Branch, Division of Extramural Activities

December 4, 2023

NIH National Center for Advancing Translational Sciences

Outline of CCIA Technical Assistance (TA) Webinar

- Overview of the Clinical and Translational Science Awards (CTSA) Program
- Introduction of the CCIA Initiative
- Overview of Programs from the Participating Agency and NIH Institutes, Centers and Offices
- Overview of the CCIA Notice of Funding Opportunity (PAR-22-167)
- Overview of the Notice of Change (NOT-TR-24-004)
- Overview of the Notice of Participation of Food and Drug Administration (NOT-TR-24-005)
- Overview of the Notice of Special Interest (NOT-TR-24-006 and NOT-TR-23-026)
- Additional Resources and NCATS, FDA and NIH Staff Contact
- Questions and Answers

Questions during the webinar?

Please send them to:

CCIAFOAQuestions@mail.nih.gov

There will be Q&A at the end of the presentations

National Center for Advancing Translational Sciences

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Overview of Clinical and Translational Science Awards (CTSA) Program

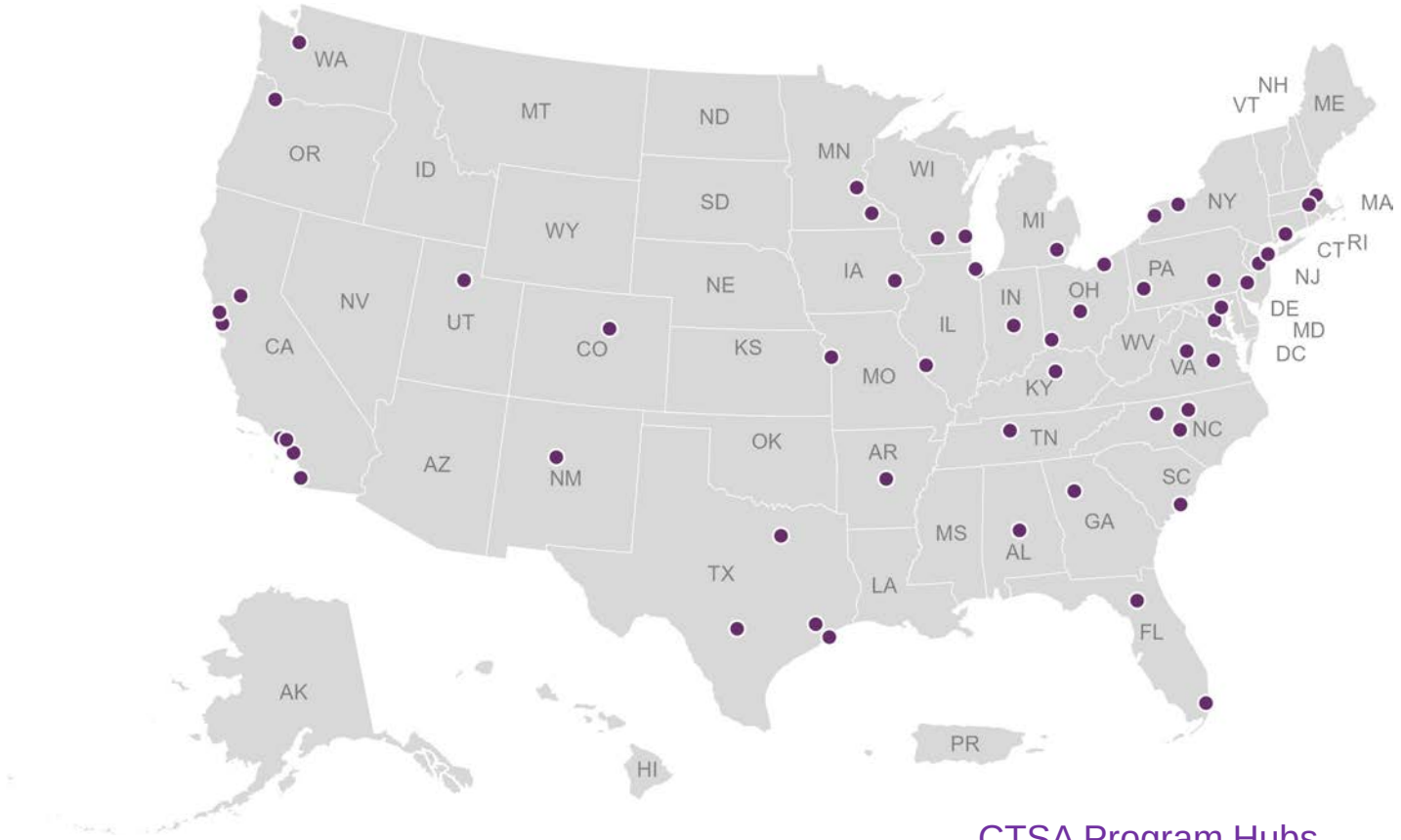
Michael Kurilla, MD, PhD

Director, Division of Clinical Innovation

December 4, 2023

National Center for Advancing Translational Sciences

NCATS Clinical and Translational Science Awards (CTSA) Program



CTSA Program Hubs
September 2023

- National network of medical 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

National Center for Advancing Translational Sciences

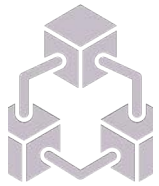
NCATS Division of Clinical Innovation

Innovating Clinical and Translational Science

Plans, conducts, and supports research to develop new methods that enhance clinical processes

Plans, conducts, and supports research to evaluate existing approaches and technologies in the clinical spectrum

Allocates resources to clinical and translational infrastructure and investigators



Supports training programs relevant to clinical phases of translational science

National Center for Advancing Translational Sciences

CTSA Program Focus

- Develop, demonstrate, and disseminate innovations that turn science into health faster
- Provide a national resource for the rapid response to urgent public health needs
- Promote impactful partnerships and collaborations
- Promote training and career support
- Address health disparities
- Nurture emerging field of translational science

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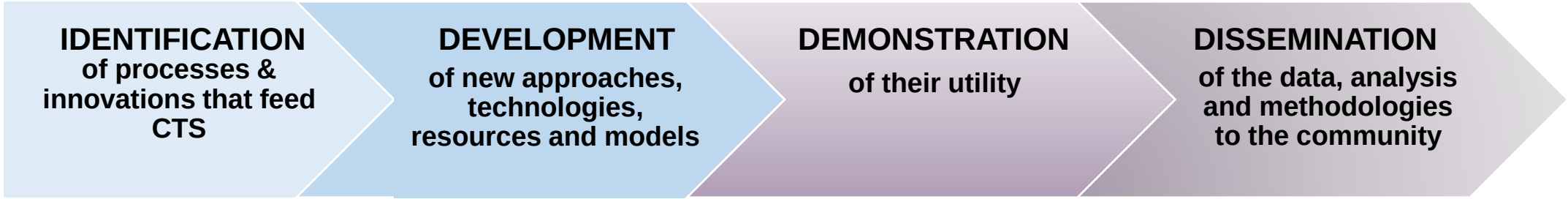
CTSA Mechanisms
Mapped to Stages of Clinical and Translational Science (CTS)

Single Site	**CTSA Hubs**
Multi-Site	**CTSA Collaborative Innovation Awards**
Consortium	***Consortium-Wide Centers: Resources for Rapid Demonstration & Dissemination***



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Introduction of CTSA Program Collaborative Innovation Award (CCIA) Initiative

Soju Chang, MD, MPH

Chief, Initiatives and Consortium-Wide Activities Section

CTSA Program Branch, Division of Clinical Innovation

December 4, 2023

NIH National Center for Advancing Translational Sciences

CTSA Program Collaborative and Innovation Award (CCIA) Initiative

- Purpose: The CCIA Initiative aims to provide support to investigators to tackle a translational science problem no single organization can solve alone.
- History: U01 (2015 - 2021) and R21 (2016 - 2021) → UG3/UH3 (2022 - present)
- PAR-22-167 (UG3/UH3):
  - Food and Drug Administration (FDA)
  - National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
  - Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
  - National Institute of Dental and Craniofacial Research (NIDCR)
  - National Institute of General Medical Sciences (NIGMS)
  - National Institute on Minority Health and Health Disparities (NIMHD)
  - Office of Behavioral and Social Sciences Research (OBSSR)
  - Office of Research on Women's Health (ORWH)

Related Notices to PAR-22-167 Published in FY23 and FY24

- NOT-TR-23-026 Notice of Special Interest (NOSI): Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3) (Clinical Trial Optional) for **Advancing Recruitment through Trial Innovation Network (AR-TIN)**

- NOT-TR-24-006 Notice of Special Interest (NOSI): Collaborative and Innovative Research to Advance Regulatory Science: **Partnership of FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) and NIH Clinical and Translational Science Awards (CTSA) Programs**

- NOT-TR-24-005 Notice of **Participation of the Food and Drug Administration** in PAR-22-167, Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional)

- NOT-TR-24-004 Notice of **Change to Update Part 2, Section III**, PAR-22-167, Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional)

Outline of CCIA Technical Assistance (TA) Webinar

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Overview of Programs from the Participating Agency and NIH Institutes, Centers, and Offices

Monica Donerson, MBA

CCIA Initiative Coordinator

Division of Clinical Innovation

FDA, NIGMS, NIDCR, NIMHD, ORWH

December 4, 2023

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Food and Drug Administration (FDA)

Tracy Chen, PhD, DABT

Senior Advisor, Office of Regulatory Science and Innovation

Office of the Chief Scientist, Office of the Commissioner

December 4, 2023

FDA Mission and Regulatory Science Framework

The goal of the framework is to harness regulatory science research to accomplish the following three charges that directly align with FDA's mission:

Regulatory Science is the science of developing tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products

modernize development and ***evaluation*** of FDA-regulated products

strengthen post-market surveillance and ***labeling*** of FDA-regulated products

invigorate public health preparedness and ***response*** of FDA, Patients & Consumers

Product Areas

devices, drugs, biologics, combination products, veterinary medicine, food, cosmetics, dietary supplements, & tobacco products

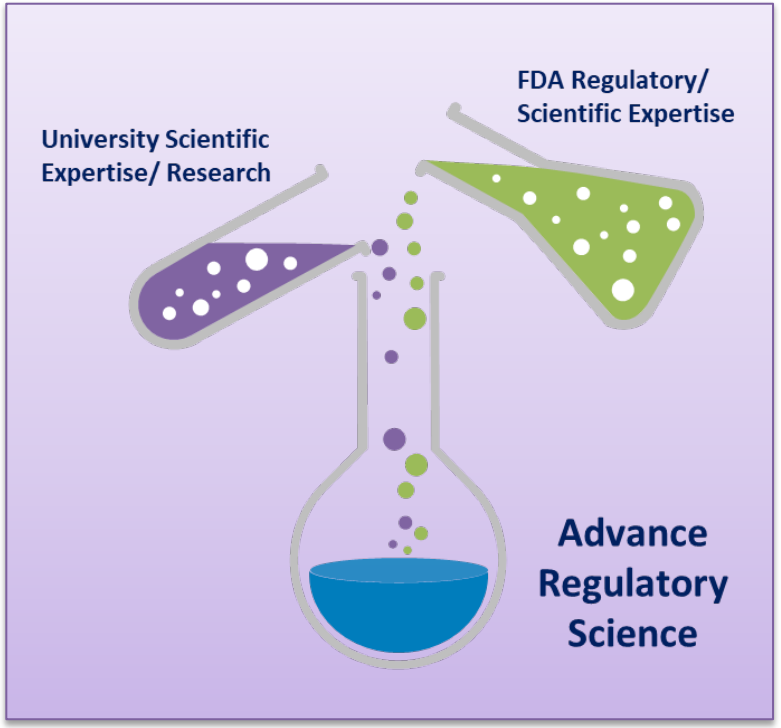
Populations

racial & ethnic minorities, sex & gender minorities, women, children & adolescents, older adults, persons from rural geographies, immunocompromised persons, pregnant and lactating persons, persons with HIV infection, persons receiving gender-affirming medical interventions, persons with disabilities, persons with cancer, persons with rare diseases, & populations that include patients from multiple groups

https://www.fda.gov/science-research/advancing-regulatory-science/**regulatory-science-framework**

Centers of Excellence in Regulatory Science and Innovation (CERSIs)

- FDA's CERSIs are collaborations between ***FDA*** and ***academic institutions*** to advance regulatory science through innovative research, training, and scientific exchanges
- We renewed the four existing CERSIs and funded a new CERSI at University of North Carolina, Chapel Hill in a partnership with Duke University (Research Triangle CERSI) under cooperative agreement (RFA-FD-23-004, 5 years (9/1/23-8/31/28)).
- More about CERSIs https://www.fda.gov/science-research/advancing-regulatory-science/centers-excellence-regulatory-science-and-innovation-cersis



CERSI Johns Hopkins University
CERSI UCSF - Stanford
Triangle CERSI
CERSI University of Maryland
CERSI Yale-Mayo Clinic

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National Institute of General Medical Sciences (NIGMS)

Michele McGuirl, PhD

Acting Director, Division for Research Capacity Building

December 4, 2023

NIH National Center for Advancing Translational Sciences

IDeA program: Impact through Creativity, Synergy, & Efficiency

- Basic, clinical, behavioral, and translational research in all NIH mission areas
- Research workforce development
- Infrastructure enhancement

Collaborations & Participation in NIH-Wide Initiatives

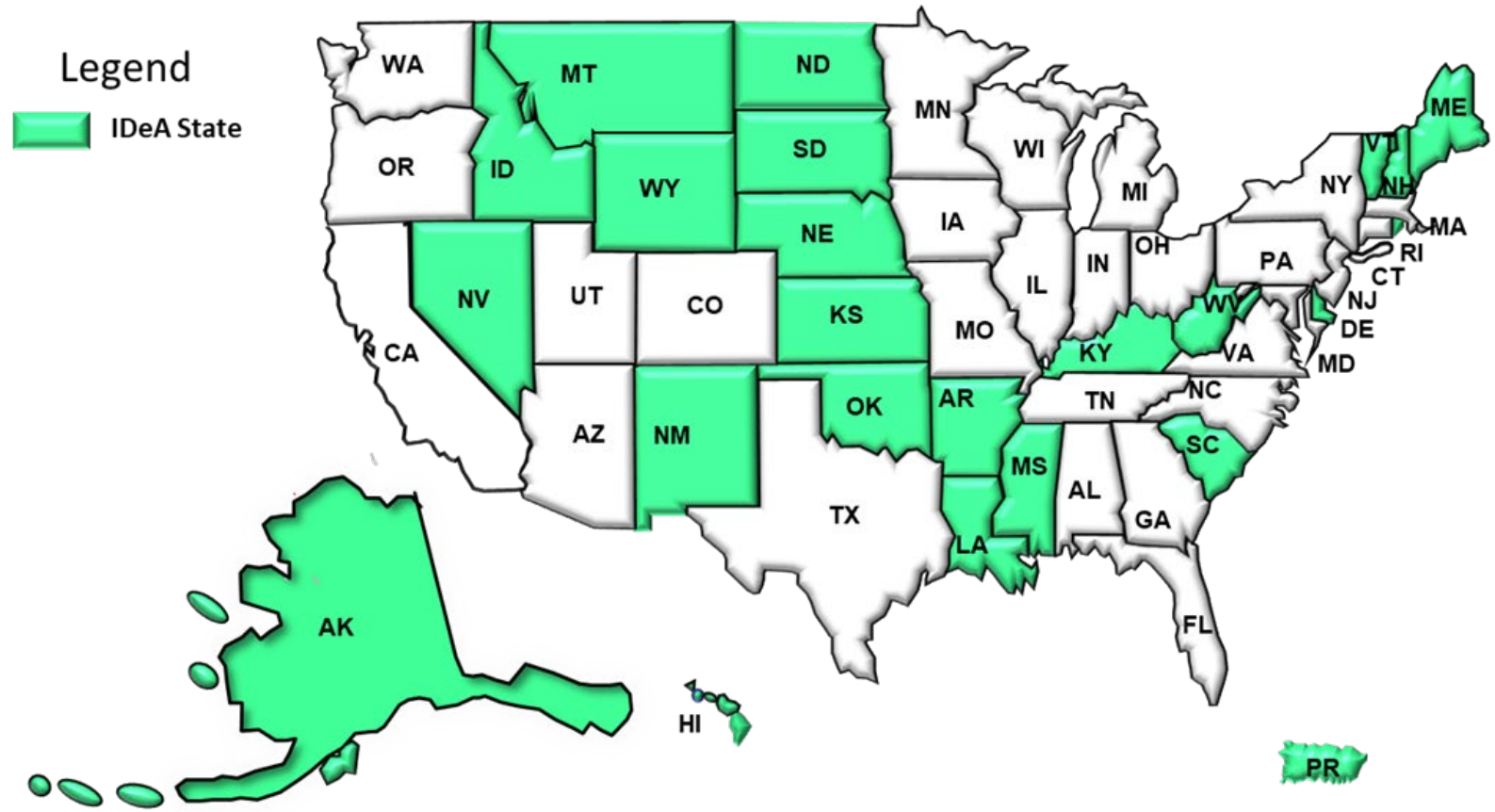
COBREs

INBREs

IDeA-CTRs

Co-Funding

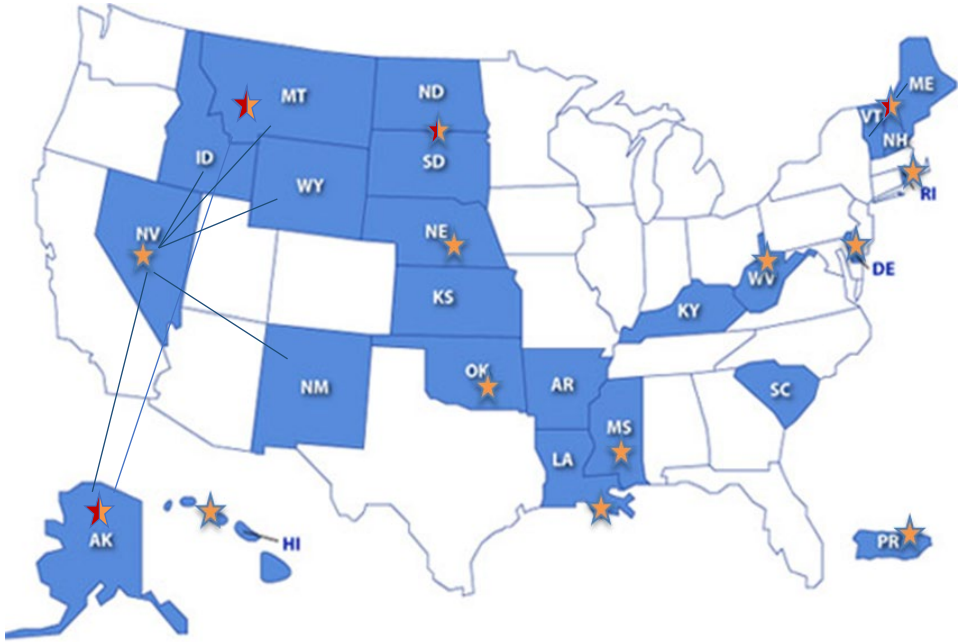
I-RED



NIGMS Eligible Grants are the IDeA-CTRs

IDeA-Clinical and Translational Research Networks

CTR Programs: State-wide/Multi-State Networks that support clinical and translational research



- **Develop research workforce and infrastructure**
- **Enhance** the ability of investigators and institutions to develop **competitive clinical research programs**
- **Strengthen collaborative research** that targets health conditions prevalent in IDeA states

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National Institute of Dental and Craniofacial Research (NIDCR)

Lu Wang, PhD

Chief, Translational Genomics Research Branch

Division of Extramural Research

December 4, 2023

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COLLABORATE. INNOVATE. ACCELERATE.

National Institute of Dental and Craniofacial Research (NIDCR)

Lu Wang, PhD

Chief, Translational Genomics Research Branch

Division of Extramural Research

December 4, 2023

NIDCR Mission

Advance fundamental knowledge about dental, oral, and craniofacial (DOC) health and disease and translate the findings into prevention, early detection, and treatment strategies that improve overall health for all individuals and communities across the lifespan

NIDCR Interests

- Development, validation, and implementation of methods and tools to improve translational DOC research, training, and clinical practices.
- Development and use of community engagement approaches and tools to improve the effectiveness of oral health prevention, early diagnoses, and interventions for all individuals.
- Development and deployment of team science capacity to accelerate the development, validation, and implementation of oral health interventions.
- Establishment and/or integration of cohorts of diverse populations to strengthen DOC translational research.
- Establishment and implementation of best practices to ensure the efficiency of clinical research and clinical trials that are aimed at improving DOC health for all individuals.

NIDCR Requirement

An application must have PD(s)/PI(s) affiliated with one or more US dental schools.

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National Institute on Minority Health and Health Disparities (NIMHD)

Lynne Padgett, PhD, FAPOS

Dolly Penn White MD, MSCR

Division of Clinical and Health Services Research

December 4, 2023

National Center for Advancing Translational Sciences

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COLLABORATE. INNOVATE. ACCELERATE.

National Institute on Minority Health and Health Disparities (NIMHD)

Lynne Padgett, PhD, FAPOS

Dolly Penn White MD, MSCR

Division of Clinical and Health Services Research

December 4, 2023

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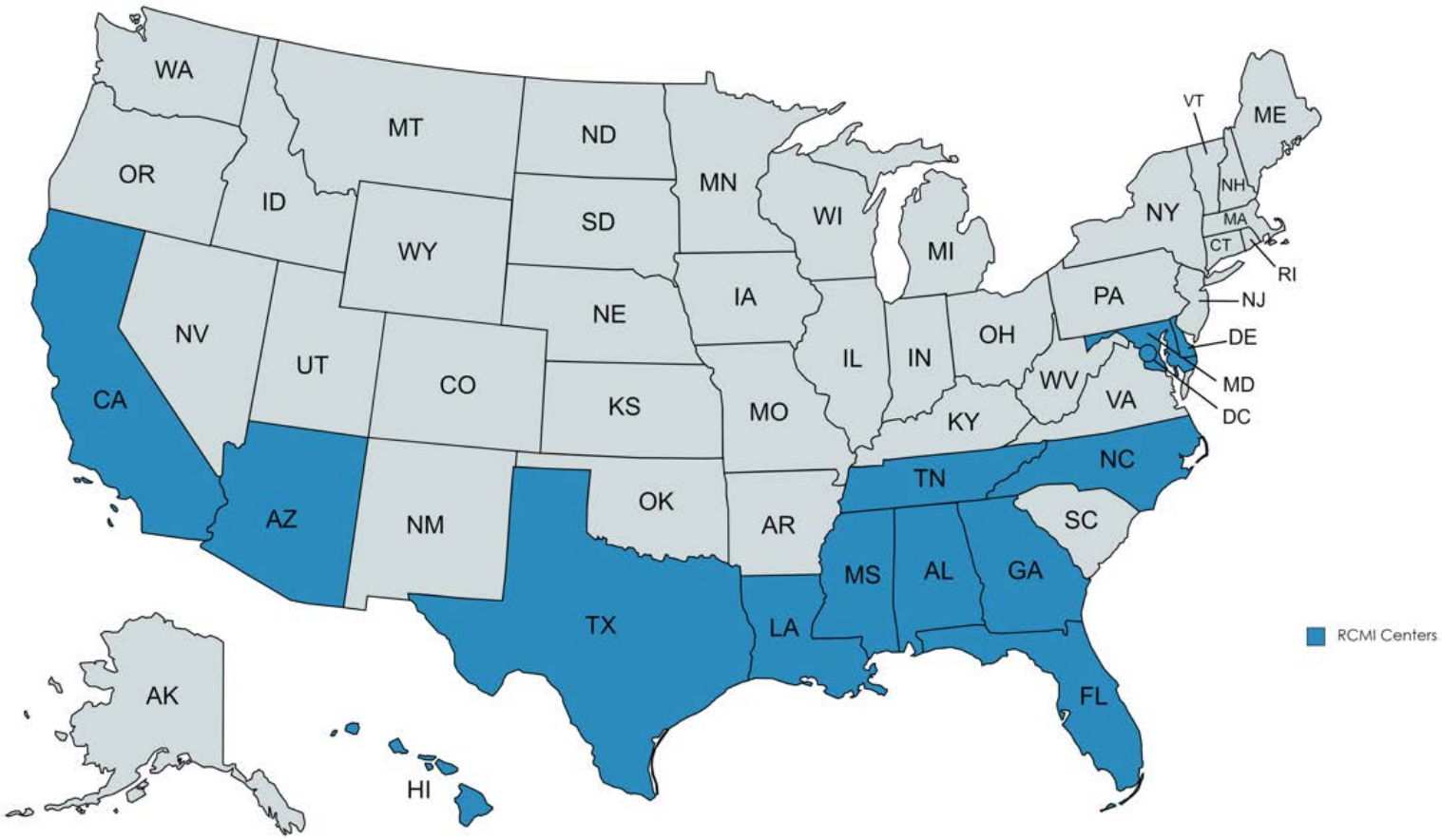
National Institute on Minority Health and Health Disparities (NIMHD)

- **Mission:** to lead scientific research to improve minority health and reduce health disparities
- **Vision:** an America in which all populations will have an equal opportunity to live long, healthy, and productive lives
- **Priorities:**
    1. Promote research to understand and to improve the health of racial/ethnic minority populations
    2. Advance scientific understanding of the causes of health disparities
    3. Develop and test interventions to reduce health disparities
    4. Create and improve scientific methods, metrics, measures, and tools that support health disparities research

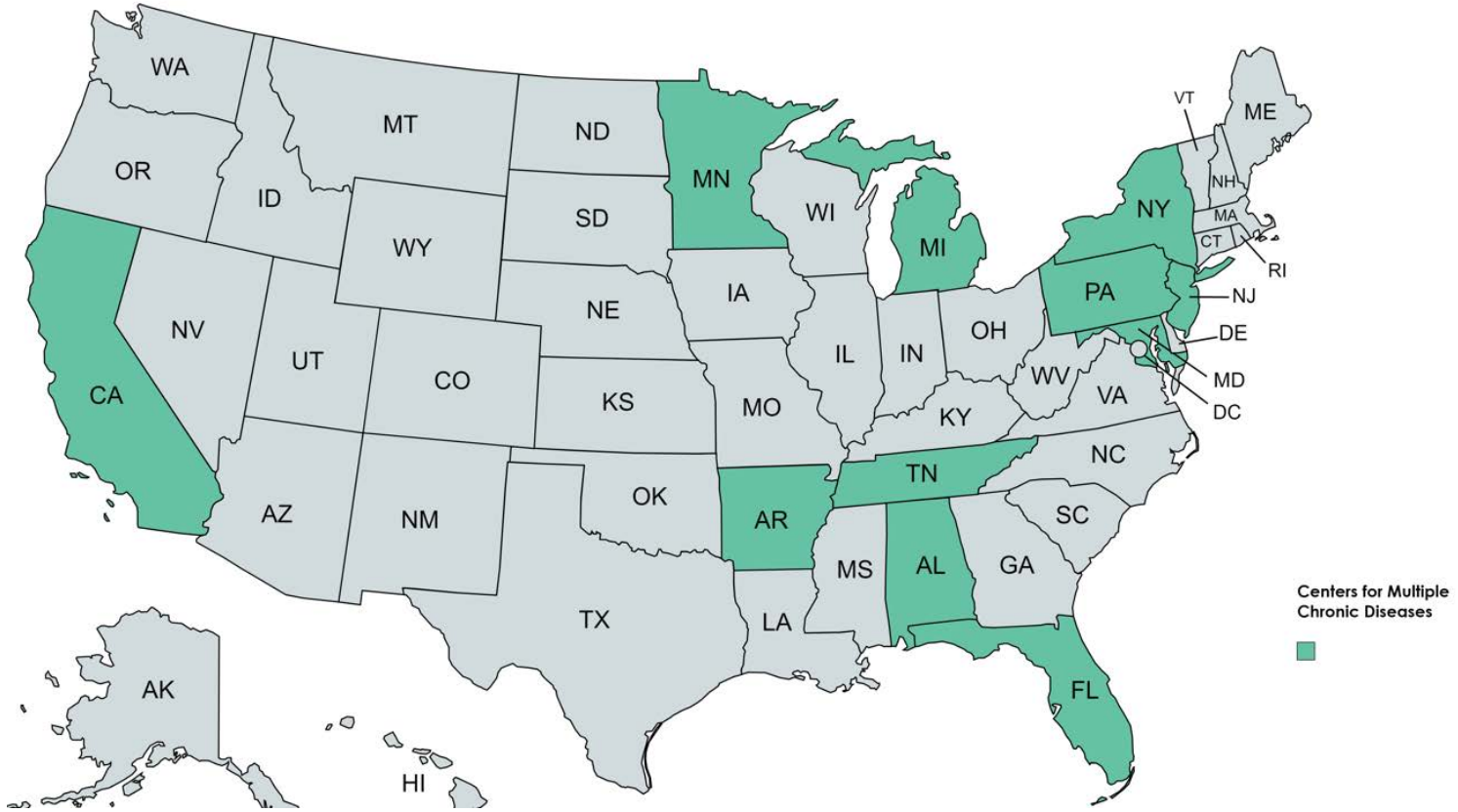
Research Centers in Minority Institutions (RCMI) (U54)

1. Enhance institutional research capacity
2. Enable investigators to become more successful in obtaining competitive extramural support
3. Foster development of new and early career investigators
4. Promote research on minority health and health disparities
5. Establish relationships with community-based organizations



Centers for Multiple Chronic Diseases (P50)

- Perform comprehensive research on the prevention, treatment, and management of comorbid chronic diseases.
- Address determinants of health at two or more levels of influence
- Pilot Project Program
- Community engagement



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Office of Research on Women's Health (ORWH)

Jamie White, MS

Health Science Strategy and Relation Lead

December 4, 2023

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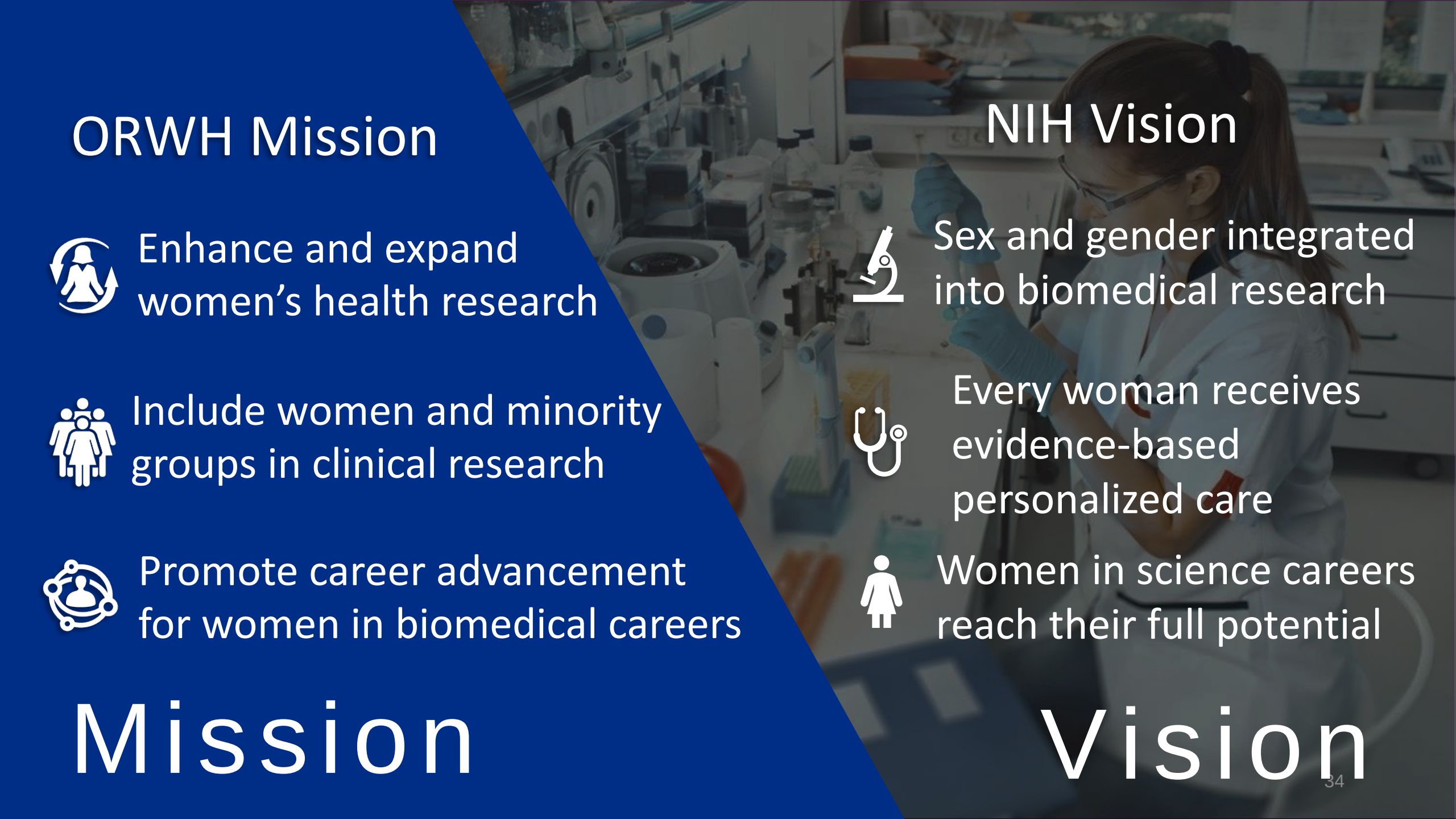
Office of Research on Women's Health (ORWH)

Jamie White, MS

Health Science Strategy and Relation Lead

December 4, 2023

National Center for Advancing Translational Sciences



ORWH Mission

- Enhance and expand women's health research
- Include women and minority groups in clinical research
- Promote career advancement for women in biomedical careers

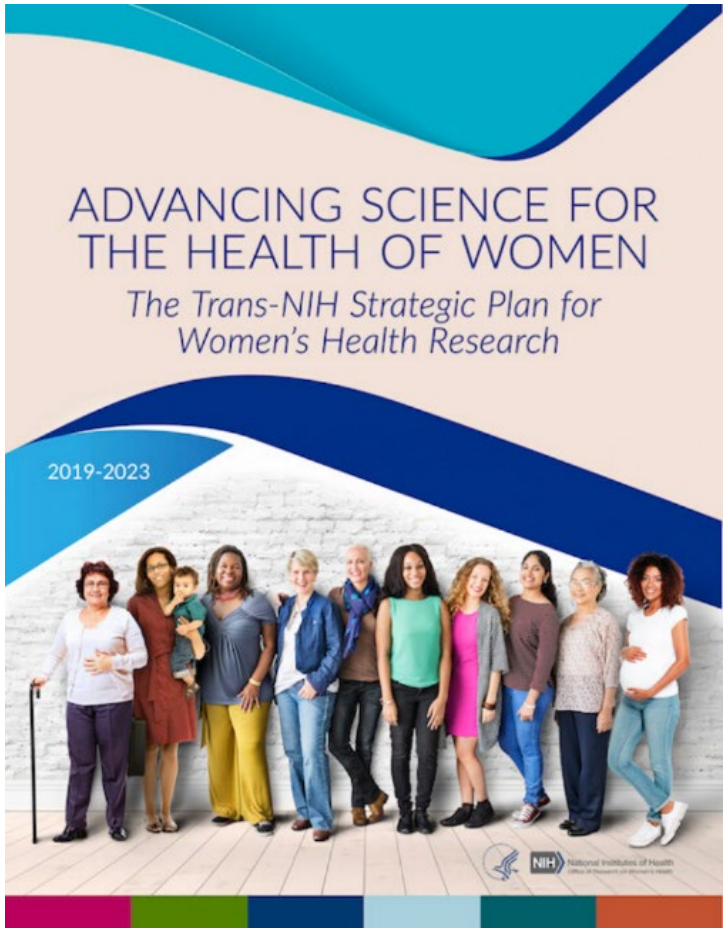
Mission

NIH Vision

- Sex and gender integrated into biomedical research
- Every woman receives evidence-based personalized care
- Women in science careers reach their full potential

Vision

2019-2023 Trans-NIH Strategic Plan for Women's Health Research



Strategic Goals

Advance rigorous research that is relevant to the health of women

Develop methods and leverage data sources that consider sex and gender

Enhance dissemination and implementation of evidence to improve the health of women

Promote training and careers to advance science for the health of women

Improve evaluation of research that is relevant to the health of women

https://report.nih.gov/strategicplans | https://orwh.od.nih.gov

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Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional) (PAR-22-167)

Kristopher Bough, PhD

Program Director, CTSA Program Branch

Division of Clinical Innovation

December 4, 2023

National Center for Advancing Translational Sciences

Overview of PAR-22-167 (UG3/UH3 Clinical Trial Optional)

- Purpose and Scientific Scope
- Examples of NCATS Areas of Interest
- Funding Mechanism
- Project Period and Award Budget
- Funds Available and Number of Awards
- Eligibility Information
- Specific Aims & Research Strategy
- Attachments
- Responsiveness and Completeness
- Application Review Information
- Review and Selection Process
- Important Dates
- Application Types Allowed and Instructions
- Notice of Change
- Reminders to Applicants

Purpose and Scientific Scope

- The Collaborative and Innovative Acceleration (CCIA) Award supports synergistic activities that accelerate the translational research process through collaboration and innovation.

- NCATS intends to support translational science projects that collaboratively develop, adapt, demonstrate, disseminate and implement as well as evaluate innovative solutions that overcome scientific and/or operational roadblocks and accelerate translational research process.

https://ncats.nih.gov/ctsa/projects/ccia

Examples of NCATS Areas of Interest

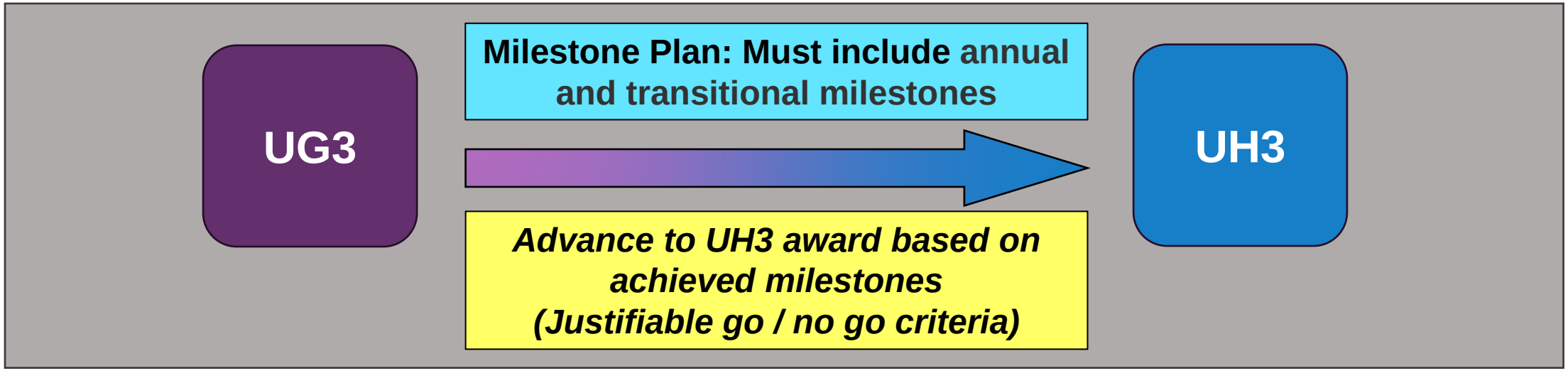
- Community engagement methods and technologies that increase the efficiency and effectiveness of intervention development and deployment, and measurement of their effects on improving health outcomes.
- Assessment of and approaches to improve clinical research and clinical trial efficiency.
- Transformative technologies to increase efficiency during implementation of clinical research studies or clinical trials
- Clinical, genetic or machine-learning approaches that speed the identification or accurate diagnosis of rare disease patients

Funding Mechanism: UG3/UH3 Cooperative Agreement

- The UG3/UH3 is a bi-phasic award and is milestone driven
- Both UG3 and UH3 phases are required in a single application

UG3 ***Development, Adaptation, Demonstration and Feasibility Assessment***

UH3 ***Dissemination, Implementation and Evaluation***



National Center for Advancing Translational Sciences

Milestones

What is a milestone?

- A milestone is defined as a scheduled event in the project timeline that signifies the completion of a major project stage or activity.
- Milestones must be performance-based to enhance the likelihood that the project will be completed on-time and on-budget.

Milestone Plan

Your application must include a Milestone Plan that includes:

1. A list of **specific milestones** (i.e., justifiable go/no-go criteria) for the transition from UG3 Phase to UH3 Phase must be included.

2. A set of **annual milestones** for each UG3 and UH3 Phase should also be included.

3. **Contingency plans must also be provided** in the event the UG3 and/or UH3 milestones are not achieved.

National Center for Advancing Translational Sciences

Project Period

- The maximum project period for both UG3/UH3 phases is 5 years

- Examples of allowed UG3/UH3 Phases include:
  - UG3/UH3 (5 years): UG3 (1 year) + UH3 (4 years)
  - UG3/UH3 (5 years): UG3 (2 years) + UH3 (3 years)
  - UG3/UH3 (5 years): UG3 (3 years) + UH3 (2 years)

- The scope of the proposed project should determine the length of each project period

Award Budget

- Application budgets need to reflect the actual needs of the proposed project.
- Direct cost funding support may not exceed $650,000 per year for both the UG3 and UH3 Phases of awards.
- A separate budget and budget justification is required for both the UG3 and UH3 Phases in the application.
- Funds may not directly support any clinical trial beyond Phase IIB, with the exception of Phase III clinical trials for the treatment of rare diseases. (see NOT-TR-18-025)

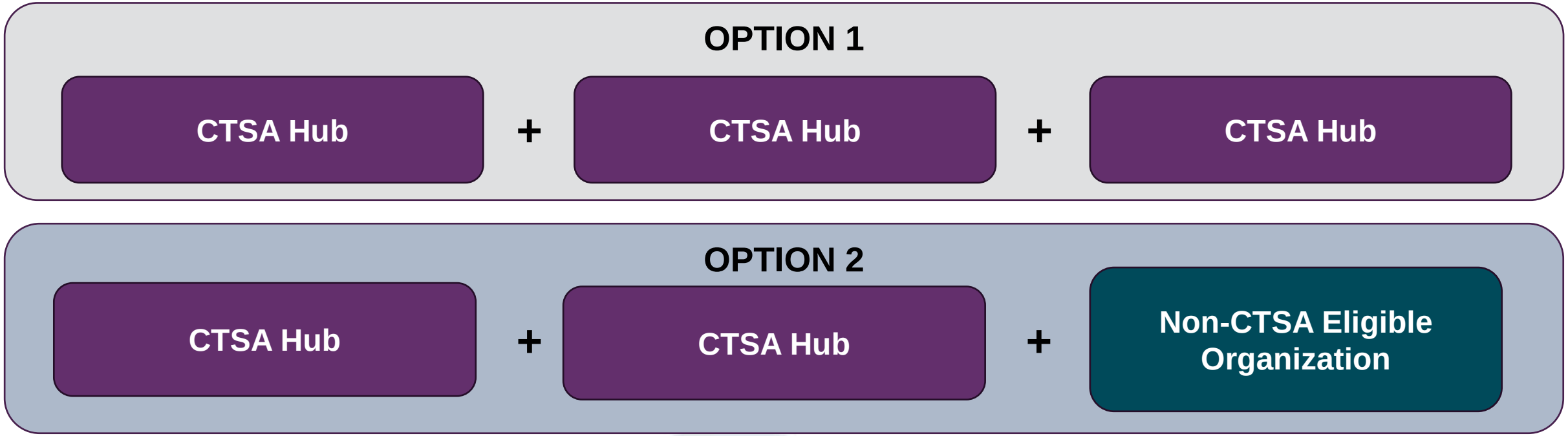
Funds Available and Anticipated Number of Awards

- NCATS intends to commit up to $6 million per Fiscal Year for CCIA Awards

- The number of awards is contingent upon NIH appropriations and the number of meritorious applications

Eligible Organizations: Two Options

- Only active CTSA Hub prime and partnering organizations are eligible to apply *as the CCIA prime recipient organization.*
- Applicants must be from at least 3 currently active eligible organizations as of the due date of the application and may choose one of the following options:



Non-CTSA Eligible Organizations (Option 2)

FDA and NIH program organizations of participating ICOs described below include only the prime recipient organization of the FDA program and NIH Program eligible grants and subsequent reissues

- **FDA:** Centers of Excellence in Regulatory Science and Innovation (RFA-FD-23-004)
- **NCATS:** Rare Diseases Clinical Research Network (RFA-TR-18-020; RFA-TR-18-021)
- **NIAMS:** Core Centers for Clinical Research (RFA-AR-22-002; RFA-AR-17-002) and Centers of Research Translation (RFA-AR-22-001; RFA-AR-17-001; RFA-AR-16-001)
- **NIGMS:** Institutional Development Award (IDeA) Clinical and Translational Research Networks (PAR-20-175, PAR-18-265, PAR-17-304, PAR-14-303)
- **NIMHD**: Research Centers in Minority Institutions (RFA-MD-22-002, RFA-MD-20-006, RFA-MD-18-012, RFA-MD-17-006, RFA-MD-17-003) and Centers for Multiple Chronic Disease Associated with Health Disparities (RFA-MD-21-007)

Eligible Organizations: Additional Information (Option 2)

- The FDA program and NIH program sub-award recipient organizations are eligible to participate as additional collaborating organizations, but only the prime recipient organization meets the requirement for at least 3 active eligible organizations

- If the collaboration involves the recipient organization and partnering organization of the same CTSA Program or participating FDA program and NIH Program award, these organizations are considered as a single eligible organization for the purpose of meeting the minimum number of eligible organizations

Example: (University A CTSA Hub) + (University A eligible organization from collaborating agencies or ICs) = considered as a ***single*** eligible organization

Eligible Individuals (PDs / PIs)

- The contact PD/PI must be an investigator from a prime or partnering organization where there is currently an active CTSA Program hub as of the due date of the application.

- Investigators who are not from CTSA hubs, can co-direct a project using the multiple PD/PI option in collaboration with a contact PD/PI.

Eligible Individuals – Eligibility Statement (required)

- An **Eligibility Statement** signed by the CTSA affiliated program contact PD/PI that provides a description of the translational science expertise and period of affiliation on the applicable CTSA program.

- Translational science expertise is defined as having at least one year of affiliation in a CTSA hub program role or an alumnus of a CTSA training programs.

- The application must include at least one PD/PI with expertise in translational science for both Phases.

Specific Aims (Key Points)

- Applicants must address the translational science (e.g., operational barrier) and translational research (e.g., scientific barrier) questions to be answered in separate specific aims.
- Specific aims must be scientifically appropriate for the distinct phases of the project.
- Briefly state how the specific aims of the project will contribute to advancing translational science.
- Include separate aims for both the UG3 and UH3 Phases.

Research Strategy (Key Points)

- **Overall Impact Statement** – For example, it should include a statement of the significance and powerful influence of the project on the advancement of the translational science.
- **Collaboration** – For example, describe how the project will stimulate complementary and/or synergistic collaborations to build on the strength and resources of each collaborating organization.
- **Innovation** – For example, discuss how the project applies big, bold, paradigm-shifting ideas to advance translational science.
- **Acceleration** – For example, describe how the project will catalyze a transformation so that observations and discoveries in the laboratory, clinic, and community turn into biomedical and behavioral interventions to improve health for all people and communities more quickly.
- **Dissemination and Implementation** – For example, discuss how the project will engage the collaborating organizations for dissemination and implementation of innovative interventions.
- **Evaluation** – For example, define the success for the proposed project and describe how success can be evaluated and quantified.

Research Plan – Other Plans (Key Points)

Data Management and Sharing Plan: NIH has issued the Data Management and Sharing (DMS) policy to promote the sharing of scientific data (see NOT-OD-23-161 and NIH's Scientific Data Sharing website)

Resource Sharing Plan: If Model Organism Sharing Policy or Research Tools Policy are applicable; see Data Management and Sharing Plan vs. Resource Sharing Plan (Extramural Nexus posted March 20, 2023)

Other Attachments (Key Points)

Milestone Plan: Single attachment – Limited to 3 pages. The plan must include: (1) justifiable go/no go criteria for continuation from UG3 Phase into UH3 Phase, (2) provide clearly defined and appropriate measurable annual milestones for both the UG3 phase and the UH3 phase, and (3) contingency plans.

Sustainability Plan: Single attachment – Limited to 2 pages. Include a plan to describe how the award recipient would sustain and/or expand the dissemination and implementation of the innovative interventions, deliverables and/or products of the project besides the collaborating organizations within and/or beyond the CTSA Program Consortium after the end of award period.

Examples of non-responsive applications

Applications that are non-responsive and/or proposing projects not supported by this NOFO will not be reviewed.

- Translational research projects focused on basic research.
- Translational research projects that lack innovative and collaborative approach and prospect of accelerating translational research process.
- Translational research projects focused on a specific disease that does not have broader implications for translational science.
- Applications that do not involve at least 3 active eligible organization as of the due date of the application.
- Applications that do not include both UG3/UH3 Phases.
- Projects that include administration of pilot programs or pilot modules.
- Applications submitted without a well-defined set of milestones for the UG3 Phase and the UH3 Phase as well as a list of specific milestones (i.e., justifiable go/no go criteria) for the transition from UG3 Phase to UH3 Phase.
- Applications that directly support any clinical trial beyond Phase IIB with the exception of Phase III clinical trials for treatment of rare diseases.
- Applications in response to NIDCR research priority statement that do not include PD(s)/PI(s) affiliated with one or more US dental schools.

Application Completeness (Key Points)

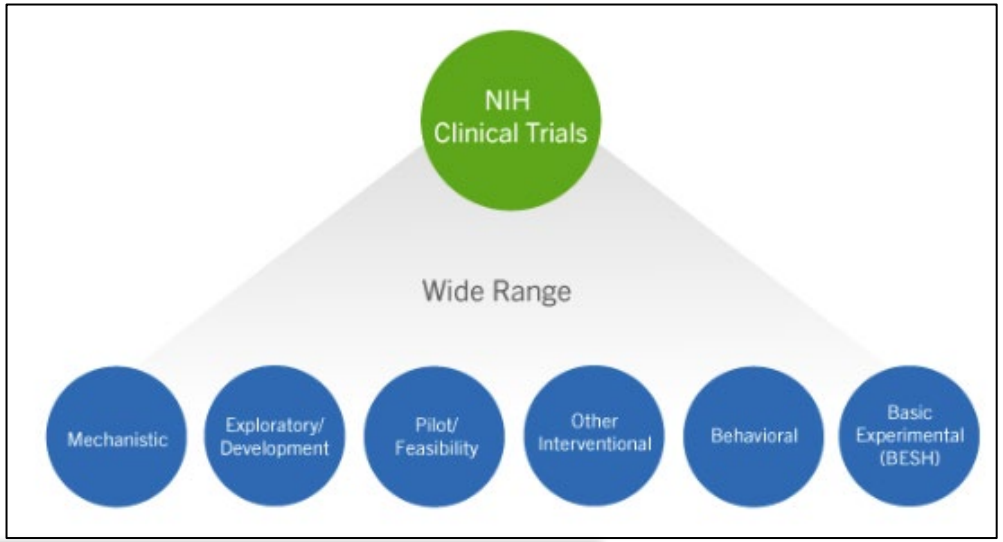
Upon receipt, applications will be evaluated for completeness and compliance with application instructions by NIH's Center for Scientific Review. Applications that are incomplete or non-compliant will not be reviewed.

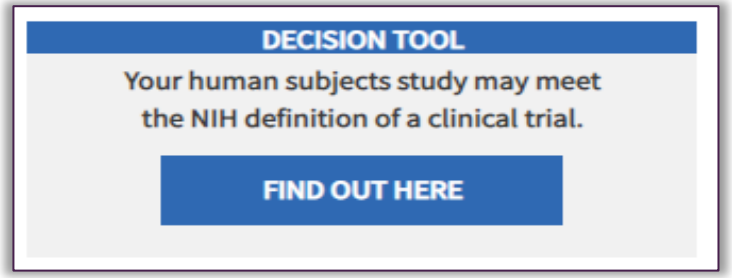
Applications must have:

- A budget / budget justification for both UG3 and UH3 phases
- A Milestone Plan
- A Sustainability Plan
- An Eligibility Statement from the contact PD/PI of the CTSA Program hub
- A Data Management and Sharing (DMS) Plan
- A Resource Sharing Plan
- Letters of Support from all collaborating organizations including:
  - Contact PD/PIs of the CTSA Program Hub
  - Contact PD/PIs of the non-CTSA eligible organizations (*option 2 only*)

UG3/UH3 – Clinical Trial Optional

- A wide-range of clinical research can fit NIH's definition of a clinical trial.
- See **NIH's definition of a clinical trial.**
- Leverage NIH's **decision tool.**
- Misclassified clinical trial in either UG3 phase or UH3 phase of the application may be withdrawn.





Use the following four questions to determine the difference between a clinical study and a clinical trial:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Sources: https://grants.nih.gov/policy/clinical-trials/definition.htm; https://grants.nih.gov/policy/clinical-trials/review-criteria.htm

Application Review Information (Key Points)

Overall Impact: Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria: Significance, Investigator(s), Innovation, Approach, Environment

Please pay close attention to the "Specific to this FOA" in the Scored Review Criteria. This can be found in the 'Application Review Information' - Section V of the NOFO.

Additional Review Criteria: As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- Milestone Plan
- Sustainability Plan
- Study Timeline: Specific to applications involving clinical trials
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards
- Resubmission

Review and Selection Process (Key Points)

- Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NCATS, in accordance with NIH peer review policy and procedures.
- All applications will receive a written critique.

Key elements of funding decisions:

- The scientific and technical merit of the proposed project as determined by scientific peer review.
- The relevance of the proposed project to CTSA program priorities.
- The availability of funds.

Important Dates

Due Dates	Review & Award Cycles		
New *or* Resubmission	**Scientific Merit Review**	**Advisory Council Review**	**Earliest Start Date**
February 15, 2024	June 2024	Oct 2024	Dec 2024
June 18, 2024	Oct 2024	Jan 2025	Apr 2025
October 17, 2024	Feb 2025	May 2025	July 2025

AIDS Receipt Dates Not Applicable

Additional due dates as well as review and award cycles will be published upon reissue of PAR-22-167

National Center for Advancing Translational Sciences

Types Allowed & Instructions

- **Application Type Allowed**
  - New
  - Resubmission applications

- **Application Instructions**
  - It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise in this NOFO or in a Notice from NIH Guide for Grants and Contracts

Notice of Change to Update Part 2, Section III (Key Points)

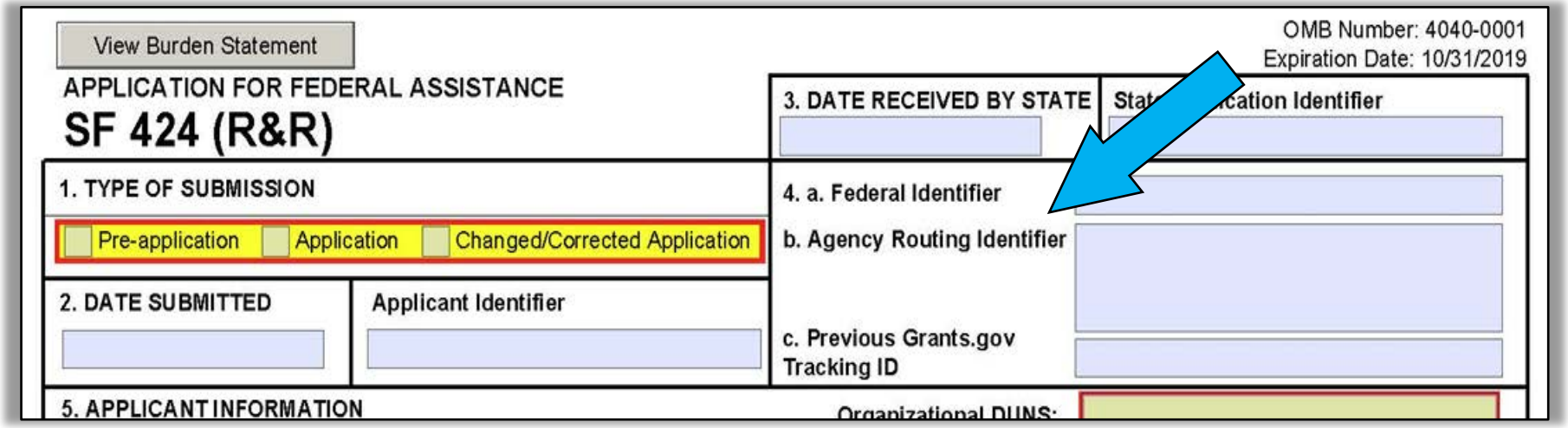
Notice Number: NOT-TR-24-004

- **Eligible Organizations**
  - Added "***Only active CTSA Hub prime and partnering organizations are eligible to apply***"
  - Modified to include the "***FDA program***"

- **Eligible Individuals (PD/PI)**
  - Added "***investigators who are from a participating organization supported by FDA***" who wish to bring an innovative project to the CTSA Program, can co-direct a project using the multiple PD/PI option in collaboration with a contact PD/PI

Applying to the Notice of Special Interest?

If you are applying to this Notice of Special Interest (NOSI) be sure to include the notice number "NOT-TR-23-026" or "NOT-TR-24-006" in the Agency Routing Identifier – Box 4b on the cover page of your application.


View Burden Statement

OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE

1. TYPE OF SUBMISSION
Pre-application Application Changed/Corrected Application

4. a. Federal Identifier

b. Agency Routing Identifier

2. DATE SUBMITTED

Applicant Identifier

c. Previous Grants.gov Tracking ID

5. APPLICANT INFORMATION

NOT-TR-23-026 Notice of Special Interest (NOSI): Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3) (Clinical Trial Optional) for **Advancing Recruitment through Trial Innovation Network (AR-TIN)**

NOT-TR-24-006 Notice of Special Interest (NOSI): Collaborative and Innovative Research to Advance Regulatory Science: **Partnership of FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) and NIH Clinical and Translational Science Award (CTSA) Programs**

Applications to NOSI must comply with the instructions and requirements for PAR-22-167.

Additional Reminders

PLEASE READ THE NOTICE OF FUNDING OPPORTUNITY CAREFULLY!

Funding Opportunity Title	Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional)
Activity Code	UG3/UH3 Exploratory/Developmental Phased Award Cooperative Agreement
Announcement Type	New
Related Notices	See Notices of Special Interest associated with this funding opportunity **November 2, 2023** - Notice of Participation of the Food and Drug Administration in PAR-22-167, Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional). See Notice NOT-TR-24-005 **November 2, 2023** - Notice of Change to Update Part 2, Section III, PAR-22-167, Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional). See Notice NOT-TR-24-004 **November 2, 2023** - Notice of Information: Technical Assistance Webinar for PAR-22-167: Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional). See Notice NOT-TR-24-003 NOT-OD-23-012 Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available NOT-OD-22-190 - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022 NOT-TR-18-025 - National Center for Advancing Translational Sciences (NCATS) Policy for Support of Phase III Clinical Trial Activities for a Rare Disease or Condition
Funding Opportunity Announcement (FOA) Number	PAR-22-167

A pre-application consultation is strongly encouraged!

Please contact us at: CTSA_COLLABORATIVEINNOVATION@mail.nih.gov

Outline of CCIA Technical Assistance (TA) Webinar

- Overview of the Clinical and Translational Science Awards (CTSA) Program
- Introduction of the CCIA Initiative
- Overview of Programs from the Participating Agency and NIH Institutes, Centers and Offices
- Overview of the CCIA Notice of Funding Opportunity (PAR-22-167)
- Overview of the Notice of Change (NOT-TR-24-004)
- **Overview of the Notice of Participation of Food and Drug Administration (NOT-TR-24-005)**
- **Overview of the Notice of Special Interest (NOT-TR-24-006 and NOT-TR-23-026)**
- Additional Resources and NCATS, FDA and NIH Staff Contact
- Questions and Answers

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Overview of NOT-TR-24-005 and NOT-TR-24-006

Tracy Chen, Ph.D., DABT
Senior Advisor
Office of Regulatory Science and Innovation (ORSI)
U.S. Food and Drug Administration

Carol Merchant, M.D.,MPH
Program Director
Division of Clinical Innovation
National Center for Advancing Translational Sciences, NIH

December 4, 2023

- NOT-TR-24-005 Notice of Participation of the Food and Drug Administration in PAR-22-167, Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3 Clinical Trial Optional);
- NOT-TR-24-006 Notice of Special Interest (NOSI): Collaborative and Innovative Research to Advance Regulatory Science: Partnership of FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) and NIH Clinical and Translational Science Award (CTSA) Program

NIH National Center for Advancing Translational Sciences

FDA-NCATS Collaboration

- **NOT-TR-24-006** The NIH's National Center for Advancing Translational Sciences (NCATS) and FDA's Office of the Chief Scientist (OCS) intend to collaborate and foster partnership between the Clinical and Translational Science Award (CTSA) Program and the CERSI Program to advance regulatory science.

- The CERSI Program is funded and managed by the FDA's Office of Regulatory Science and Innovation. The CTSA Program Collaborative and Innovative Acceleration (CCIA) Award will serve as the funding mechanism.

- Eligibility: Option 2 – the UG3/UH3 application must include investigators from at least two different currently active CTSA Program hubs and one **prime recipient** organization of the FDA-CERSI program. The contact PD/PI named on the application must be from a prime organization with an active CTSA Program hub.
  EXAMPLE: Johns Hopkins U, U California – San Francisco, U North Carolina – Chapel Hill, U Maryland, and Yale U may count toward the minimum number of organizations. However, the CERSI partners may still be a collaborating site.

- Collaborative research teams will focus on developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products and applications. Workforce training designed to accelerate the translation of knowledge addressing regulatory science is strongly encouraged.

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THE AREAS OF RESEARCH INTEREST AND PRIORITY

- Area 1 - Modernize Product Development, Evaluation and Surveillance Methodologies
- Area 2 - Community Engagement to Promote Public Health Preparedness for FDA, Patients and Consumers
- Area 3 - Data Science and Digital Health Technology
- Area 4 - Workforce Development and Regulatory Science Training

National Center for Advancing Translational Sciences

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Overview of NOT-TR-23-026

Guadalupe (Lupe) Aquino, BA
Clinical Trial Specialist, Clinical Affairs Branch
Division of Clinical Innovation

December 4, 2023

- NOT-TR-23-026 Notice of Special Interest (NOSI): Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award (UG3/UH3) (Clinical Trial Optional) for Advancing Recruitment through Trial Innovation Network (AR-TIN)

NIH National Center for Advancing Translational Sciences

NOT-TR-23-026 - Advancing Recruitment through Trial Innovation Network (AR-TIN) NOSI

Purpose: to design, develop, demonstrate, implement, and evaluate digital and non-digital innovative tools and resources to improve participant recruitment in clinical trials

Research Objectives: The intent of the NOSI is to expand the TIN program both scientifically and geographically to provide more diverse collaborative opportunities for innovation across the CTSA consortium and an interest in tools and resources that advance decentralized methods to support rural and remote settings, as well as expand the recruitment of minorities, women, and members from rural-based communities in clinical trials.

Award recipients will be members of the Trial Innovation Network.

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NOT-TR-23-026 - Advancing Recruitment through Trial Innovation Network (AR-TIN) NOSI

Tools and resources of interest include, but are not limited to:

- Methods to improve disease progression modeling to advance the use of participant-based information that will inform safety and efficacy
- Tools and resources that advance the digitalization of clinical trials activities
- Innovative ways to incorporate clinical and demographic characteristics of intended populations in the absence of self-identification
- Improving rural inclusion in centralized and decentralized clinical trials
- User-friendly dynamic model on the inclusion/exclusion criteria and its impact on participant recruitment in clinical trials
- Proposals that explore the utilization of artificial intelligence (AI) and other digital-based technologies to increase and improve participant recruitment in clinical trials

NOT-TR-23-026 - Advancing Recruitment through Trial Innovation Network (AR-TIN) NOSI

National Human Genome Research Institute

Support the development of tools and resources for genomics in clinical trials.

Approaches that encompass the entire genome or are broadly applicable across variants, tissues, diseases, or function.

Priority areas are outlined in NHGRI's 2020 Strategic Vision and on the web pages for the research mission of NHGRI's Extramural Divisions and Offices.

Clinical trial tools and resources only relevant to a particular disease or organ system are not in scope with NHGRI.

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- **Additional Resources and NCATS, FDA and NIH Staff Contact**
- Questions and Answers

Additional Resources

- About Translational Science
  - https://ncats.nih.gov/about/about-translational-science
- Clinical and Translational Science Awards (CTSA) Program
  - https://ncats.nih.gov/research/research-activities/ctsa
- CTSA Program Applicant Information
  - https://ncats.nih.gov/research/research-activities/ctsa/applicant-information
- Accelerating Clinical & Translational Science Research Through Collaboration and Innovation
  - https://ncats.nih.gov/research/research-activities/ctsa/projects/ccia
- NIH's Definition of a Clinical Trial
  - https://grants.nih.gov/policy/clinical-trials/definition.htm
- Clinical Trial Specific Review Criteria
  - https://grants.nih.gov/policy/clinical-trials/review-criteria.htm
- Data Management and Sharing Policy
  - https://sharing.nih.gov/data-management-and-sharing-policy
- Data Management and Sharing Plan vs. Resource Sharing Plan
  - https://nexus.od.nih.gov/all/2023/03/20/data-management-and-sharing-plan-vs-resource-sharing-plan/

NCATS Staff Contacts

PAR-22-167

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NOT-TR-24-006

Scientific / Research Contacts

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Questions and Answers

NCATS Staff

December 4, 2023

Send questions regarding this funding opportunity to: CCIAFOAQuestions@mail.nih.gov

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NOT-TR-23-026: Common Questions

Are award recipients classified as a RIC or TIC within the TIN?

No. Award recipients are classified as members under AR-TIN within the TIN. Successful applicants, funded via this NOSI, will become members of the TIN and adhere to its governance model.

Can I submit an application to this NOSI for funding consideration for a tool that is not yet validated or evaluated?

Yes. However, your proposal must meet the requirements stated in the PAR-22-167.

What level of ownership will the TIN/CSTA Program have over the tools and or resources developed through AR-TIN?

Applications responsive to this NOSI will be expected to work collaboratively with members of the Clinical and Translational Science Award (CTSA) Program and the Trial Innovation Network (TIN), while also engaging the broader CTSA community, to achieve individual and consortium goals and objectives. Recipients will retain custody of and have primary rights to the data, software, tools and resources developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

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Questions and Answers

NCATS Staff

December 4, 2023

Send questions regarding this funding opportunity to: CCIAFOAQuestions@mail.nih.gov

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Presentations, slides, and Q&A will be posted on the NCATS website: CTSA Program Applicant Information

https://ncats.nih.gov/research/research-activities/ctsa/applicant-information

All questions and answers will be posted on the NCATS website including those not discussed during the live Q&A session of the TA Webinar.

Participants requiring a transcript of the webinar post recording should contact CCIAFOAQUESTIONS@mail.nih.gov.

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