Translational and Clinical Science Pilot Program

And

Tri-Institutional Clinical and Translational Research Program

Pre-submission Webinar

February 12, 2026

New Jersey Alliance for Clinical and Translational Science:
A Platform for Translational Science in New Jersey
http://njacts.rbhs.rutgers.edu
An NCATS-funded CTSA Hub: UM1TR004789

Rutgers Institute for Translational Medicine and Science

Princeton University

RWJBarnabas Health

NJIT New Jersey's Science & Technology University

Pilot Programs Co-Leads

Arnold Rabson, MD
Laura Gallagher Chair of Developmental Biology and Director, The Child Health Institute of New Jersey and
Professor of Pharmacology; Pediatrics, and Pathology and Laboratory Medicine;
Rutgers Robert Wood Johnson Medical School

Samuel Wang, PhD
Professor
Princeton Neuroscience Institute
Princeton University

Jonathan Grasman, PhD
Assistant Professor
Department of Bioengingeering
New Jersey Institute of Technology

Joseph Jaeger, DrPH, MPH
AVP, Research RWJ Barnabas Health; Chief Academic Officer, Monmouth Medical Ctr; Professor, Family Medicine & Community Health & Assoc Dean, Monmouth Medical Ctr; Asst Vice Chancellor, Graduate Medical Education

Pilot Program Administrative Staff

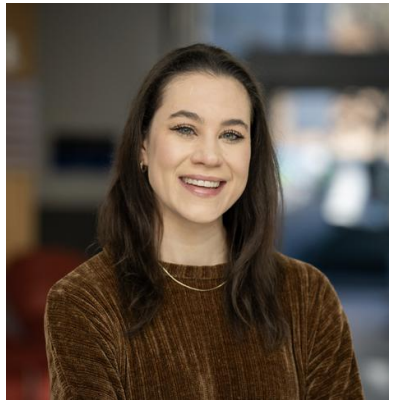
William Jester
Director of Administration

Casandra Burrows
CTSA Administrator

Judith Argon
Executive Lead Prog. Dev.

Pam Dahlen
Financial Assistant

Anthony Gonzalez
Regulatory and Compliance



Elizabeth Tawa
Princeton, Collaborative Research
Program Coordinator, NJ ACTS

Today's Goals

- Introduce both of the Alliance's Pilot Programs
  - Clinical and Translational Science Pilots
  - Tri-institutional Clinical and Translational Research Pilots
- Explain the differences between CTS and CTR
- Answer your questions so you can develop your letter of intent

What is the Same between the Programs?

- Both have a two-phase application process:
  - Letter of Intent
  - Full Application
- Application Requirements
- PI/Co-PI eligibility
- Review Criteria and Review Process
- Deadlines
- Must complete all regulatory requirements prior to funding
- Reporting requirements

What is the Main Difference?

Clinical and Translational **Science (CTS)**

Versus

Clinical and Translational **Research (CTR)**

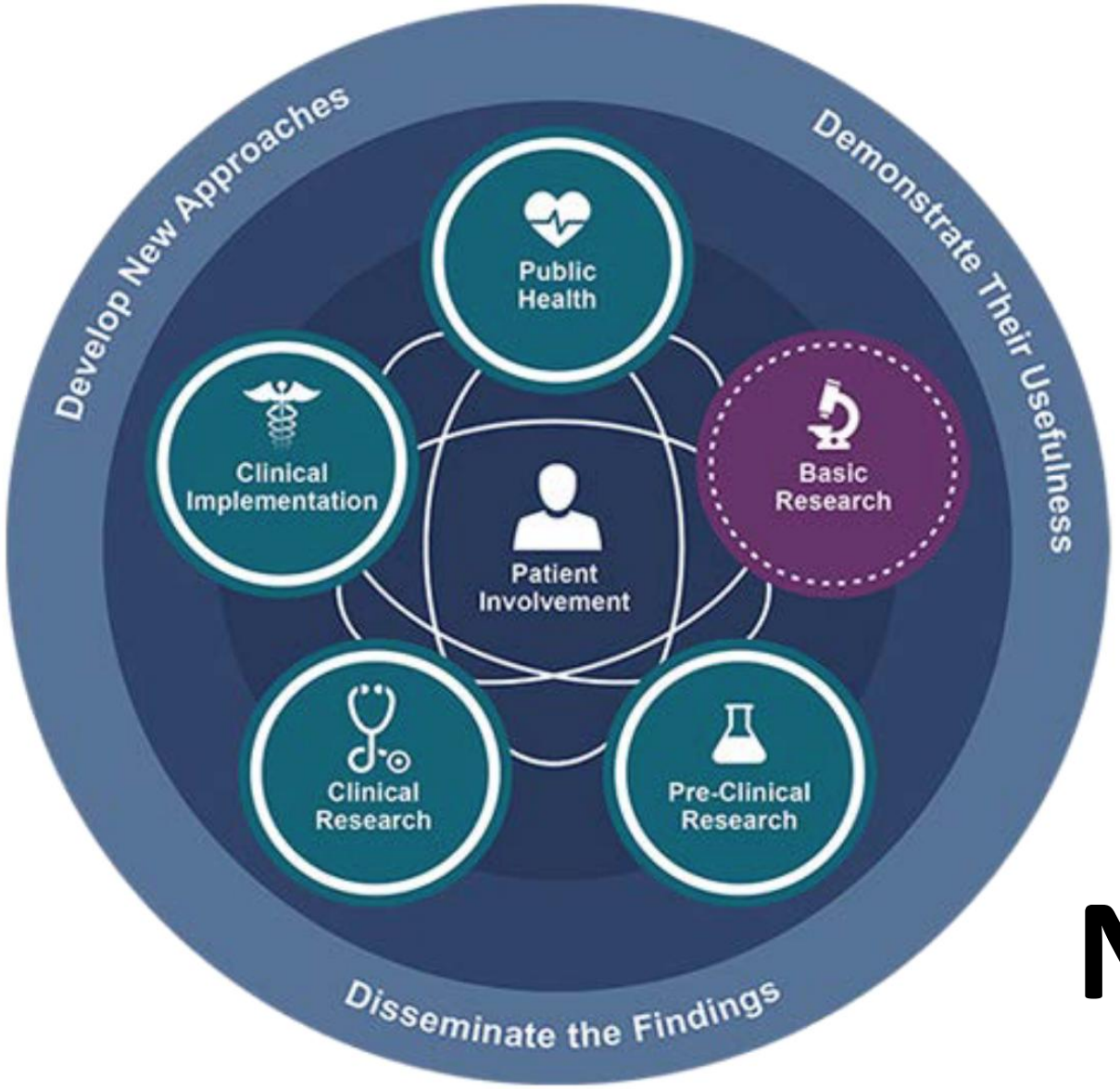
What is Translational Science?

- Focused on understanding the *scientific and operational principles* underlying each step of the translational process. (https://ncats.nih.gov/about/about-translational-science/principles)

- Catalyzes innovations that overcome longstanding challenges along the translational research pipeline, such as:

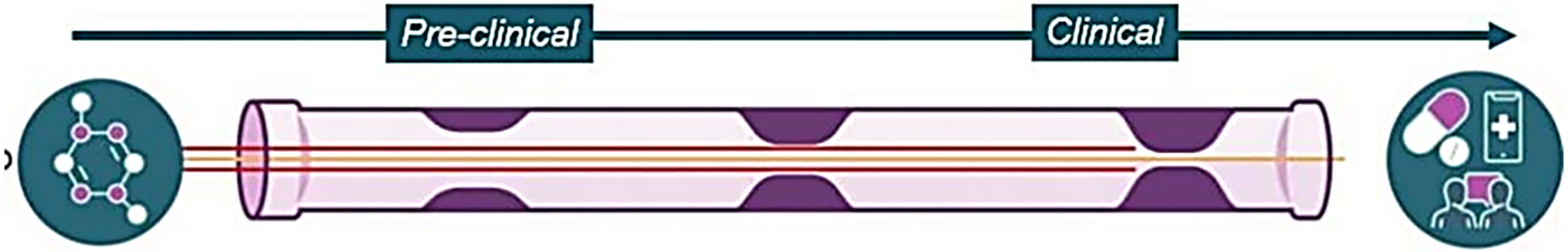
  scientific, operational, financial, and administrative innovations that transform the way that research is done, making it faster, more efficient, and more impactful.

What is Translational Science?



NCATS

Bottlenecks in the Translational Research Pipeline



Examples of Bottlenecks

Basic /Preclinical Research

- Target qualification
- Predictive efficacy
- Predictive toxicology
- 'Risky' undruggable targets/ untreatable diseases

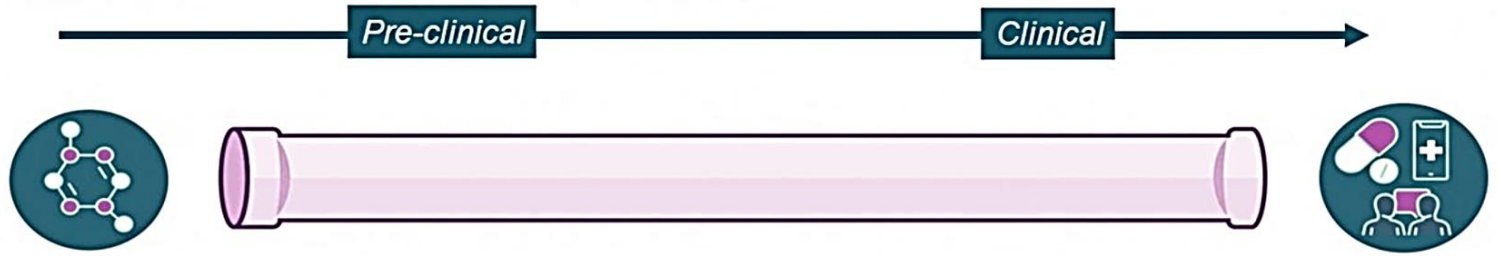
Clinical Research

- Data interoperability
- Inconsistent diagnostic and outcome criteria
- Clinical trial participant recruitment and diversity
- Clinical trial operational efficiency
- Administrative burdens (IRB)

Clinical Implementation/Public Health

- Time of intervention adoption
- Access and adherence
- Comparative effectiveness

Re-engineering the Translational Pipeline



Examples of Solutions to Overcome Research Bottlenecks

Operational	"One size fits all" approach • Adaptive and other novel trial designs	Low enrollment and diversity in clinical trials • Enhance community and informatics efforts
Administrative/ Training	Administrative burden for study start-up • Streamline regulatory processes	Shortage of qualified translational investigators and staff • Training and career development best practices
Scientific	Insufficient tools and technologies to predict toxicity and efficacy of new drugs • Platform-based (WGS for rare diseases, mobile tech for multiple diseases)	Incompatible databases to advance data science • Data, harmonization, interoperability and integration

Examples of Translational Science Projects

NOT Translational Science

- Testing a compound that was efficacious in an animal model of disease in a human model of disease
- Evaluating the toxicity of a newly developed compound to treat Alzheimer's disease
- Identifying early biomarkers of Multiple Sclerosis
- Recruitment of historically underrepresented groups into a clinical trial of breast cancer
- Generating a research database of patients with Diabetes in the Bronx

Translational Science

- Developing models/assays that can be better predictors of efficacy in humans than current cell/ animal models
- Development of new assay types based on human cells that can identify potential toxicities more accurately and efficiently than current animal testing methods
- Development of framework/models to identify biomarkers that change early in the course of intervention to gauge intervention efficacy
- Systematically studying barriers to enrollment of historically underrepresented groups in clinical trials
- Developing systems to merge clinical datasets from different sources accurately and efficiently

The key distinguishing features of a translational science project are (1) the focus on overcoming roadblocks to enhance the efficiency and speed translational research and (2) the generalizability of the solutions across a range of diseases and conditions.

2024 NJ ACTS CTS Pilots Awardees

- A Testing Platform for Probing the Role of Dendritic Structural Plasticity in Neuropsychiatric Disorders
- Ultrasound Responsive Therapeutic Gas Microbubbles for Localized Treatment of Cardiac Injury
- Preconception Care: An Ounce of Prevention
- Assessing Engagement and Recruitment Messaging Using Kiosk Videos

2025 NJ ACTS CTS Pilots Awardees

- Rapid, low-cost SNP detection with occluded Cas13
- Decoding Pain Modulation in the Motor Cortex: A Multimodal Approach Using Transcranial Magnetic Stimulation, Electroencephalography, and a Biosensor for Pain Quantification
- Bridging Decades: Developing Data Architecture to Link Historical Cohort with Contemporary Electronic Health Records
- An optical contrast agent to enable in vivo imaging of immune cell activation in response to immunotherapy

Clinical and Translational Science Projects ($40,000)

- Addresses how we improve the processes that facilitate and support research
- Tests two or more approaches to solving a challenge.
- Is hypothesis-driven
- Identifies a roadblock to translational research
- Demonstrates relevance for others doing research

Clinical and Translational Science Themes

Projects should:

- Focus on challenges, roadblocks and approaches and processes to address them
- Be disease agnostic
- Align with one of these themes:
  - Creating Efficiencies by Integrating Knowledge, Creating Partnerships, or Working Across Diseases
  - Expanding Patient and Community Engagement
  - Exploring Bold Scientific Approaches
  - Training and Education
  - Organizational Environment

Expanding Patient and Community Engagement

- Develop and test new and innovative ways to involve impacted patients, communities, and community organizations as research collaborators
- Implement evidence-informed practices for patient- and community-engaged research
- An example might be testing novel recruitment strategies or testing different modes of patient communication to determine which is more effective

Exploring Bold Scientific Approaches

- Explore ambitious research goals that have the potential to produce major advances and/or paradigm shifts.
- Research Priority Setting: Include diverse perspectives in research priority setting, such as through partnerships with new collaborators, so research investments address population and patient health needs.
- Research Design, Implementation and Data Analysis: Pose innovative research questions and develop and implement innovations in research methods.
- Research Processes and Structures: Develop and implement innovations in research team interactions.

Training and Education

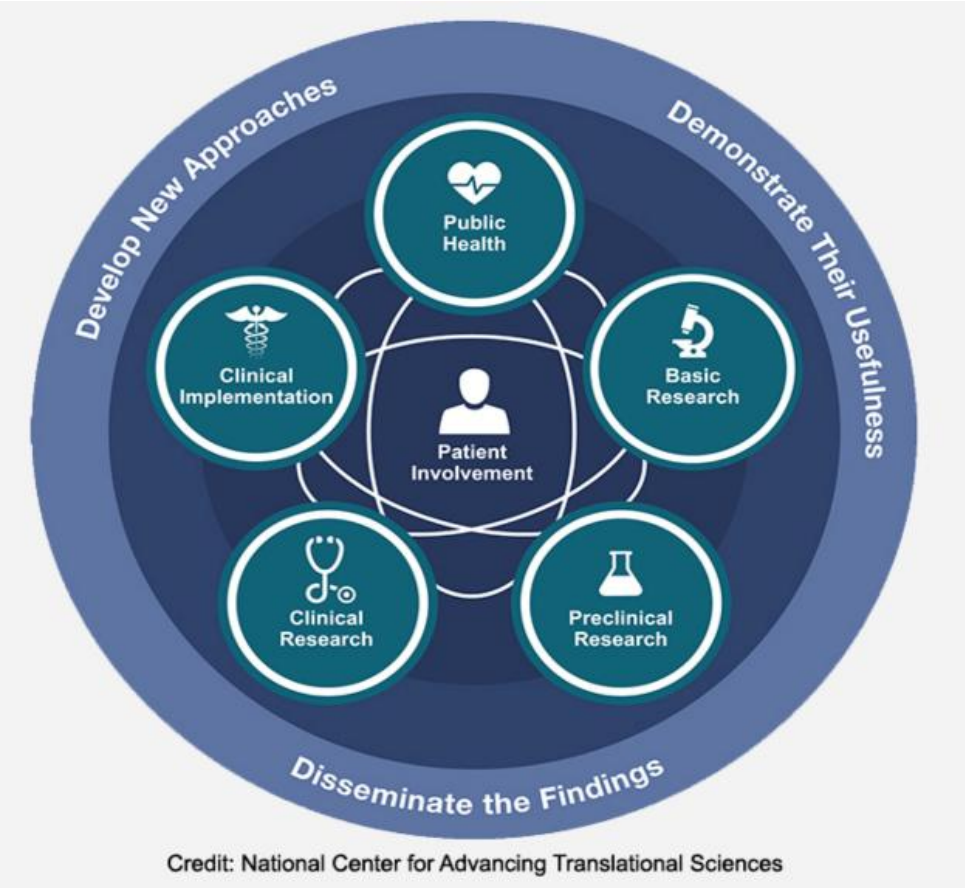
- Workforce Development: Develop and test the effectiveness of new training mechanisms and/or modules for any component of the research workforce.

- Rigor and Reproducibility: Create novel training in Rigor and Reproducibility.

- Regulatory Knowledge: Evaluate new approaches to regulatory knowledge and compliance across the spectrum of clinical and translational research.

What is Translational Research
(*v* Translational Science)

Translating discoveries from laboratory to bedside to populations



Credit: National Center for Advancing Translational Sciences

What is Translational Research
(*v* Translational Science)

Translational research is a continuum:

- Develop new approaches and the transfer of applying discoveries from basic research
- Demonstrate their usefulness through clinical trials and studies
- Disseminate the findings to enhance best practices in the community and to impact policy to improve human health.

Important Notes

- All pilot proposals must demonstrate clinical relevance
- Number of awards is flexible depending on the number and quality of proposals
- Collaboration across institutions is encouraged but not required

Application Types

Clinical and Translational Research Projects:

- Anywhere along the entire range of the translational research continuum (T0-T4)
- Laboratory-based, clinical, health services, epidemiology, community engagement, and diversity research
- Projects that focus on novel aspects of the heterogeneity of disease and response to therapy are encouraged.

PROPEL Projects

- High-risk, high-reward
- Catalyze scientific discovery by supporting proposals to explore novel ideas, adding new technologies or research methods to a project
- Enable clinical data acquisition, purchase of small equipment, or licenses to data sets.

Application Types

Valued Partner Projects

- Support team research and build liaisons with key partners in industry, government, non-profits, other CTSAs, and/or insurance companies.
- Must leverage institutional support with partner in-kind services or funding.
- Proposals must include a detailed description of the in-kind support and a letter of support from the partner organization.

2024 Awardee Projects

- Sterilization and In Vivo Testing of an Addressable Microfluidics Device for Commercial Applications
- Quantifying Change Readiness and Its Impact on Psychotherapy Outcomes
- Wildfire-borne Particulate Matter: Effect on Bronchodilation
- Exploring Youth Perspectives on Positive Childhood Experiences and Mapping Community Assets That Foster Them
- Exploring a Neuropathic Basis for Acute Pulpal Pain – A Clinical Pilot

Other Differences/Similarities?

	CTS	CTR
Eligible Lead Institiion	Rutgers, Princeton, NJIT and RWJBH	Rutgers and NJIT Princeton and RWJBH may serve as collaborators
Funding Source	CTSA award from NCATS	Rutgers, Princeton and NJIT institutional Funds
Required Approves	Regulatory Approvals Requires NCATS Approval	Regulatory Approvals
Clinical Trial	Not Permitted	Not Permitted
No. of Award	4-6 Awards Direct Costs only	2-3 Awards Direct Costs only
Amount of award	~$40,000	$50-$100,000
Length	12 months or less, depending on NCATS approval date	12 months
Start-date	Depends on regulatory review/approval requirement completion and NCATS approval	Depends on regulatory review/approval requirement completion
No Cost Extension	Not allowed	12 month extension allowed

PI/Co-PI Eligibility

- Be well suited to the project
- Can devote sufficient effort to complete the proposed aims
- Appropriate experience and training to lead this project
- Demonstrated an ongoing record of accomplishments in their field(s).
- If the project is collaborative or multi-PD/PI, the investigators should have complementary and integrated expertise
- PI(s) must:
  - Have a primary affiliation with the Alliance Partners of NJ ACTS (Rutgers, Princeton, NJIT, or RWJ Barnabas Health)
  - Hold a faculty or equivalent position
  - Postdoctoral fellows, residents and clinical fellows may serve as Co-I's, provided their mentors are from one of the four partnering institutions.
- PIs/Co-PIs are limited to one application per cycle.
  - The sole exception is clinicians who may have a specific expertise or patient populations and be relevant to more than one proposal. Eligibility for this exception should be clearly described in both the LOI and the application.

Application Process: Letter of Intent

Required

Due February 20, 2026 (midnight)

LOI Form available at:

- CTR: https://redcap.rutgers.edu/surveys/?s=REFN3K3AX3DT9DY8
- CTS: https://redcap.rutgers.edu/surveys/?s=JWT39TWX3L8JXY48

REDCap Form: Title, Co-PIs, Draft Abstract and Draft Specific Aims

Purpose:

- Ensure match between RFA and project
  - Specifically ensure responsiveness as Translational Science and not Translational Research
- Assess competitiveness
- Allow leaders to start matching reviewers to projects

Institutional sign-off: Not required for LOI

Notification by February 27, 2026 if deemed eligible or not

Application: Due March 13th

	Page Limits
Clinical and Translational Research Pilot Application Form	REDCap Form
Clinical and Translational Science Pilot Application form	REDCao Form
Additional elements to be submitted as a single PDF in this order:	
Research Strategy	6 pages
• Project Abstract	Up to ½ page
• Specific Aims (note: abstract/specific aims should equal 1 page)	Up to ½ page
• Background/Preliminary Data	Up to 2 pages
• Research Plans	Up to 3 pages
How will Pilot Program funding lead to independent or sustainable funding?	Up to 1 page
Project Timeline by month	Up to 1 page
References	As needed
Other Support Information for Co-PIs (NIH Current and Pending Common Form)	As needed
Detailed Budget (NIH PHS 398): 1 for each participating institution and Budget Justification (1 for each participating institution), plus cumulative Budget	As needed for each PI/Institution
Co-PI's NIH Common Form Biosketches	Up to 5 pages
Key personnel NIH Common Form Biosketches	Up to 5 pages each
Letters of support from affiliates, partners, or others	Up to 1 page each

Application Review Process

Due: March 13, 2026 (midnight)

Levels of Review:

- Administrative Review
- Initial Review:
  - Review by the Co-leads/Program Leadership
  - Additional reviewers selected from:
    - Academy of Mentors
    - Previous pilot awardees
    - Prominent scientists in the field
- Final review and funding decision by Program Leadership from the Alliance partners

Review Criteria

- Impact
- Use of NJ ACTS resources (Cores and Modules)
- Collaboration-building potential
- Potential to generate reproducible findings and high-quality
- Excellence of the science
- Potential for translation
- Likelihood of success
- Use of RWJBH data, facilities or patients (requires RWJBH sign-off)
- Potential for:
  - Publications
  - NIH funding
  - Adoption of outcomes by health system

Institutional Sign-off

Not required for LOI

Application:

- May be required – depends on institutional policy
- See RFA for details
- If collaborating across NJ ACTS affiliates or other entities, a separate budget and sign off is required

Where do we go for help?

Does my project fit the RFA:

- Pilots Co-leads

Identifying potential Co-PIs

- RFA contains a helpful list

Budgets, Subcontracts, NCATS Approvals

- Email: njacts@rbhs.rutgers.edu

When Will We Hear?
How Soon Can We Start?

Award Notification: April 2026

Actual Start Date and Release of Funds Depend On:

- Not involving human subjects or vertebrate animals or foreign components:
  - As soon as any modifications required by the committee are received
- Involving human subjects or vertebrate animals or foreign components:
  - Institutional regulatory approvals required (animals/humans)
- For CTS proposals, NCATS approval
- Earliest Start Date: May, 2026

Where do we go for help?

Does my project fit the RFA:

- Pilots Co-leads

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Q&A