



Translational and Clinical Science Pilot Program

Pre-submission Webinar
March 10, 2025

**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





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Aims of the Pilot Program

- Enhance, broaden, and bolster NJ ACTS' research endeavors in translational science
- Propel clinical and translational science initiatives throughout NJ ACTS
- Provide resources to nurture projects

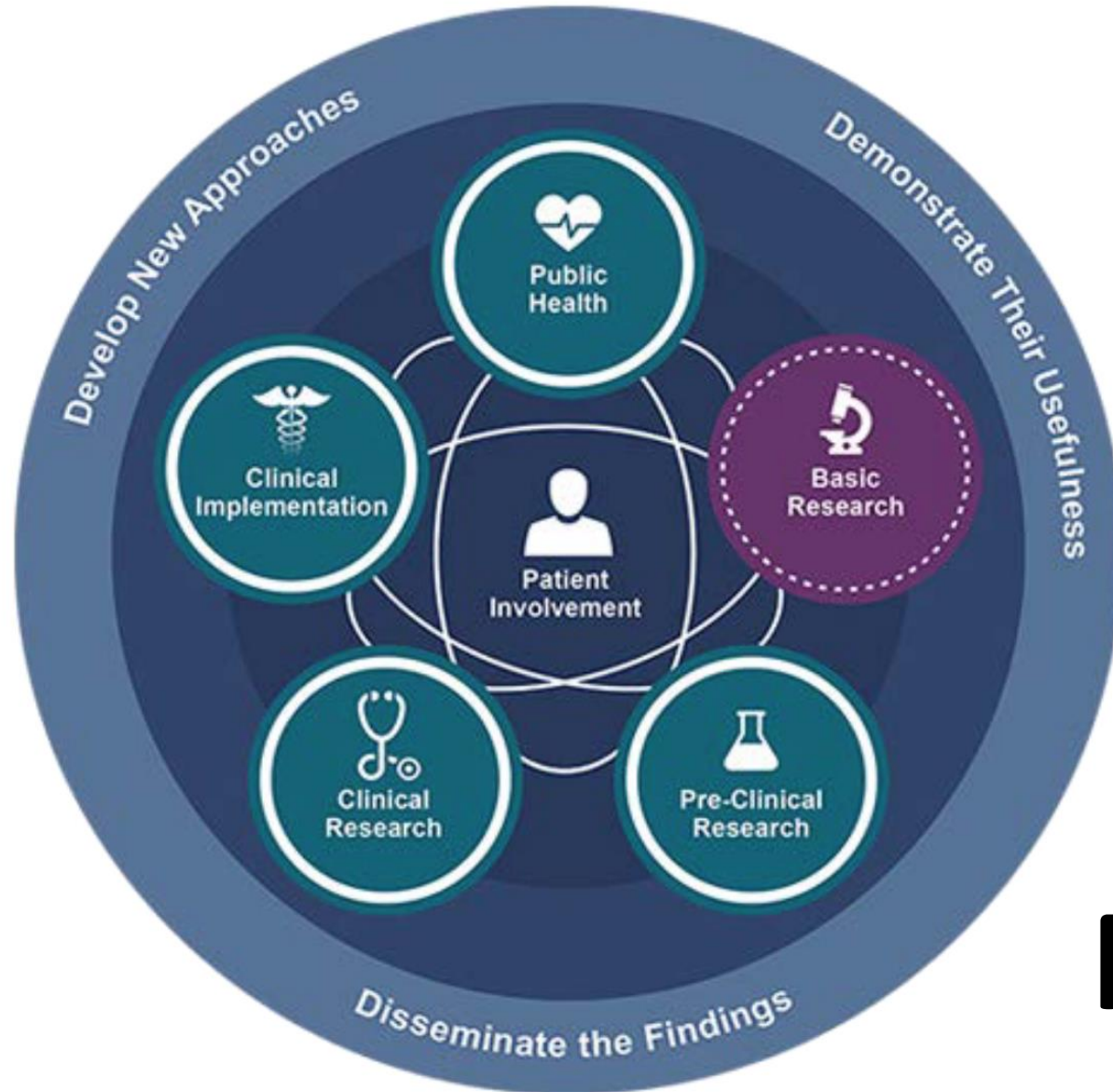


What is Translational Science?

- 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.

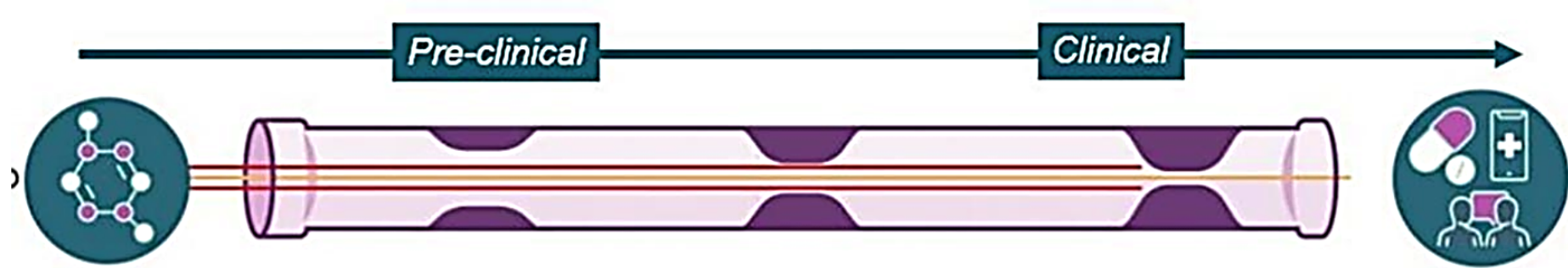


What is Translational Science?



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

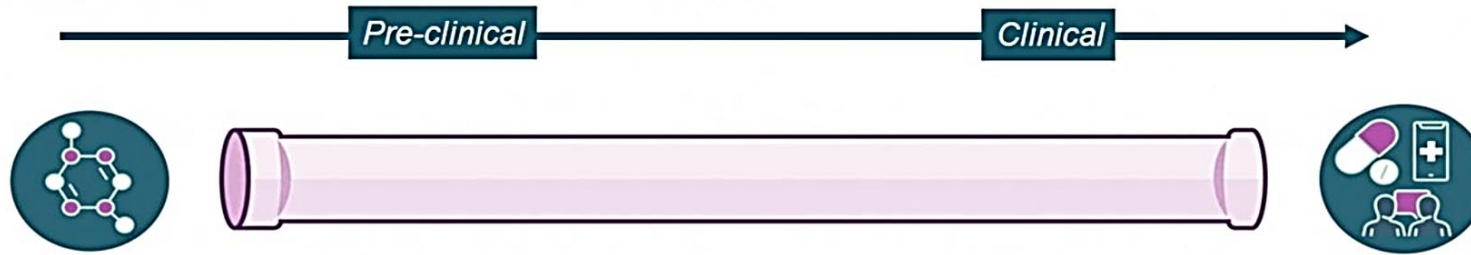
- Data interoperability
- Inconsistent diagnostic and outcome criteria
- Clinical trial participant recruitment and diversity
- Clinical trial operational efficiency
- Administrative burdens (IRB)

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	<p>“One size fits all” approach</p> <ul style="list-style-type: none"> • Adaptive and other novel trial designs 	<p>Low enrollment and diversity in clinical trials</p> <ul style="list-style-type: none"> • Enhance community and informatics efforts
Administrative/ Training	<p>Administrative burden for study start-up</p> <ul style="list-style-type: none"> • Streamline regulatory processes 	<p>Shortage of qualified translational investigators and staff</p> <ul style="list-style-type: none"> • Training and career development best practices
Scientific	<p>Insufficient tools and technologies to predict toxicity and efficacy of new drugs</p> <ul style="list-style-type: none"> • Platform-based (WGS for rare diseases, mobile tech for multiple diseases) 	<p>Incompatible databases to advance data science</p> <ul style="list-style-type: none"> • 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



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.



Budget and Project Length

Up to \$40,000

Project Duration: 9 months

- NOTE: given length of project and funds available, do not be overly ambitious in project aims

Start-date:

- Depends on regulatory review/approval requirement
- NCATS approval

Carryover of funding is prohibited as are no cost extensions



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 March 14, 2024 (5:00 pm)

LOI Form available at: <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 March 18 if deemed eligible or not



Application Components

Program Specific Form

Title

Abstract: up to ½ page

Specific Aims: up to ½ page

Research Strategy: up to 3 pages

- Background/Preliminary Data
- Research Plan
 - Objective
 - Approach
 - Milestones
 - Deliverables
 - Describe the use of the NJ ACTS Modules and Cores
 - Anticipated Impact

How will project promote independent funding: up to 1 page

Project Timeline by Month: up to 1 page



Application Components, cont.

References

Other Support Information for Co-PIs

Detailed Budget

NIH Biosketch for Co-PIs and Key Personnel

Letters of Support



Application Review Process

Due: April 11, 2025 (5:00 pm)

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**



Application Process: Due April 11th

	Page Limits
NJ ACTS Pilot Application Form	REDCap Form
Program Application Form	REDCap Form
Additional elements to be submitted as a single PDF in this order:	
Project Abstract	Up to ½ page
Specific Aims (note: abstract/specific aims should equal 1 page)	Up to ½ page
Research Strategy	Up to 3 pages
Background/Preliminary Data	
Research Plan: <ul style="list-style-type: none"> • Objective • Approach • Milestones • Deliverable • Anticipated impact 	
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 Format)	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 I/Institution
Co-PI's NIH-formatted biosketch	Up to 5 pages
Key personnel NIH formatted biosketches	Up to 5 pages
Letters of support from affiliates, partners, or others	Up to 1 page each



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



When Will We Hear? How Soon Can We Start?

Notification: May/June 2025

Actual Start Date and Release of Funds Depend On:

- Project that do not involve 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)
 - Requires NCATS review and approval



How Long is the Project?

Project Period

- 9 months
- Actual project length depends on regulatory and NCATS approvals

Are No Cost Extensions Grants Allowed?

- NCEs are not allowed due to the nature of the CTSA funding



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



Q&A