UNC | SCHOOL OF MEDICINE
North Carolina Translational and Clinical Sciences Institute

NC TraCS Clinical and Translational Science (CTS) Pilot Grant Program

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David Carroll, PhD – Director, Research Funding Development
Mary Beth Cassely – Director of TraCS Innovation Program
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Topics to be covered

- *Translational Research vs Translational Science*
- *Outline of CTS Pilot Program*
- *Q & A*

CTS Pilot Program – language from the CTSA FOA

"The CTS Pilot Module provides modest research support for new and innovative research projects relevant to CTS.

Pilot projects must be focused on translational science, i.e., focused on understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research."

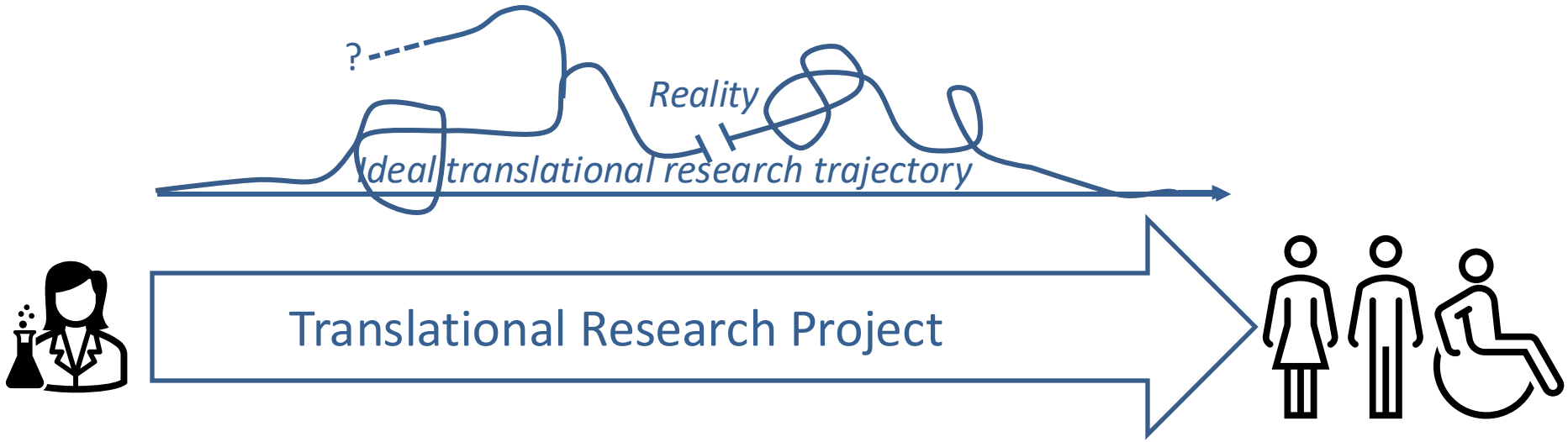
Translational research projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, ***are not allowed****."*

What is Translational Science?

- *Identifies barriers to the advancement of research across the translational spectrum*
- *Works toward a product or approach that overcomes or mitigates that barrier*
- *Generalizable across multiple diseases/conditions*

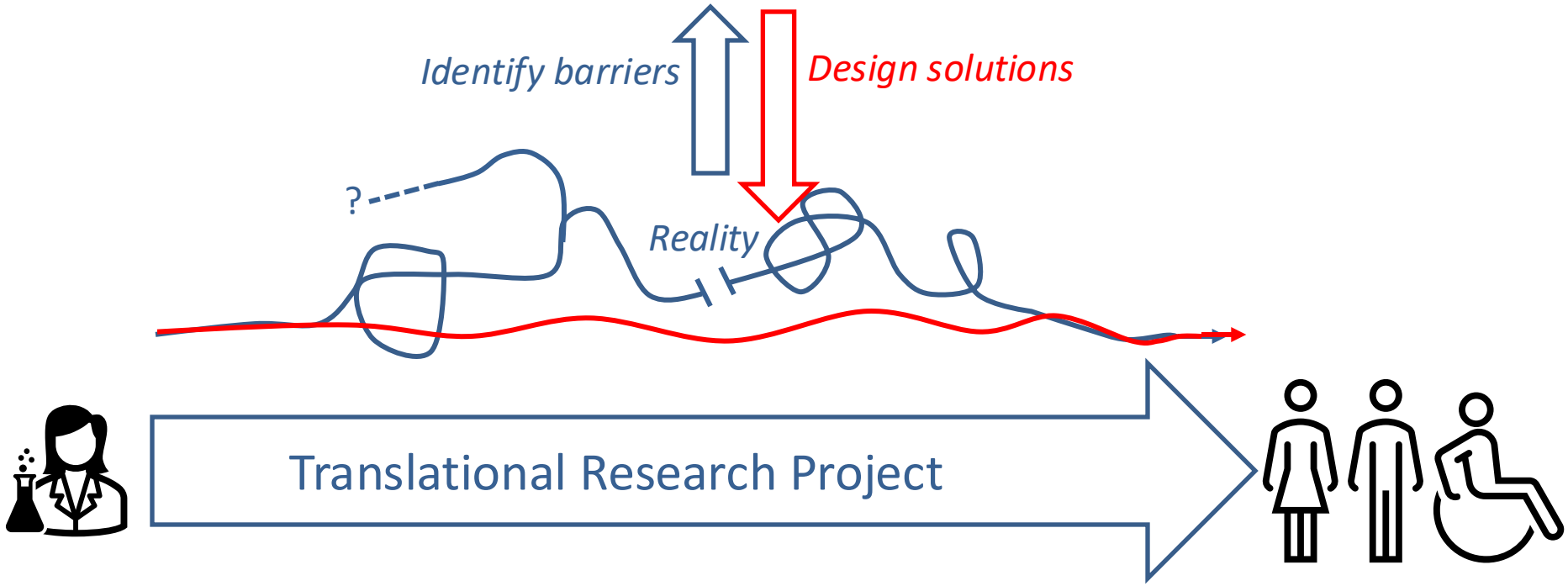
Translational *Science* vs Translational *Research*

Translational Research. *Turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and communities – from diagnostics, preventions and treatments, to medical procedures and behavioral changes*



Translational *Science* vs Translational *Research*

Translational Science *aims to accelerate the process of turning biomedical research discoveries into real-world applications that improve people's health, such as diagnostics, treatments and cures.*



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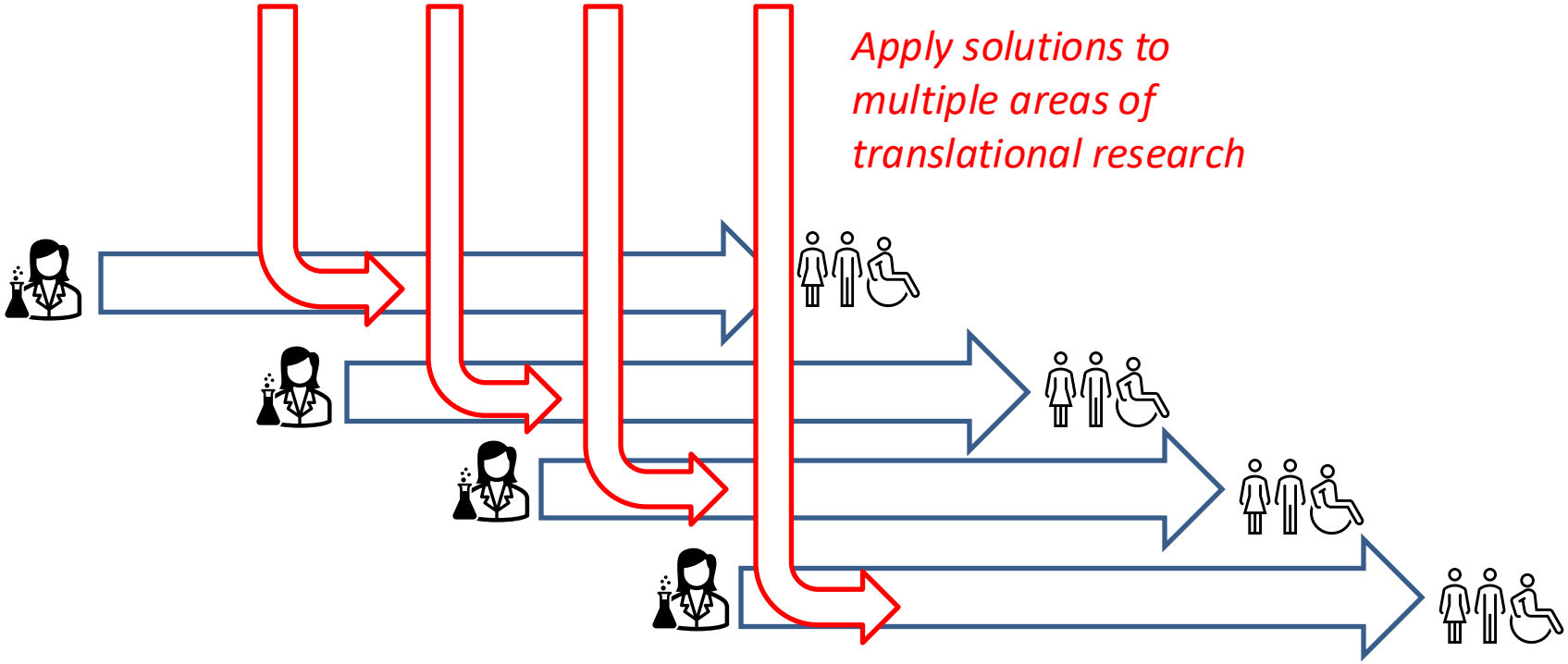
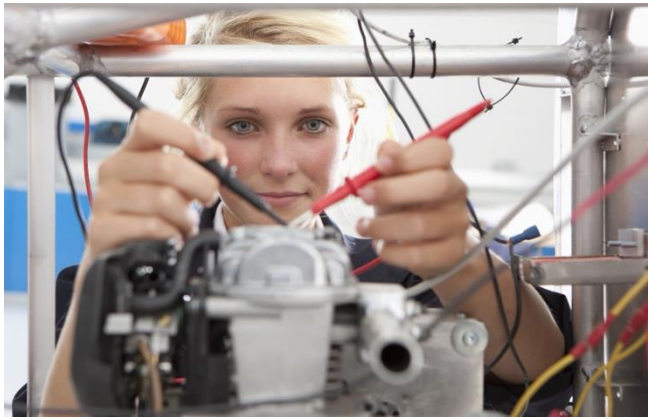


TR *vs* TS: The Detroit Example

Translational Research:
Designing a more efficient engine → more efficient car



Translational Science:
Using this new engine technology in multiple models – making *all* cars more efficient

TR *vs* TS: The University of Rochester Pie Example

Translational Research:
Baking a better pumpkin pie

Translational Science:
Designing a faster and more pastry-making technique, benefiting pie-makers everywhere

https://www.linkedin.com/posts/university-of-rochester-ctsi_translational-science-explained-easy-as-activity-7263173913285685248-op4k?utm_source=share&utm_medium=member_desktop

Is it CTS? Seven Characteristics of a CTS Study

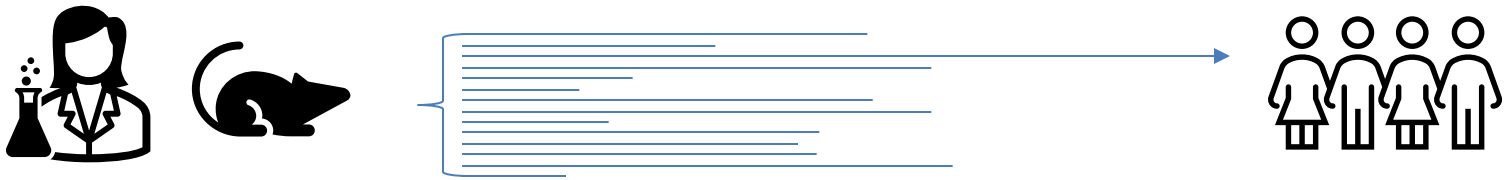
1. *This project encourages transformative ideas and risk taking toward achieving the overall goal of improving the translational process.*
2. *This project approaches research challenges and development of solutions by seeking commonalities across research on a range of diseases and conditions.*
3. *The knowledge gained from this project will be generalizable to a variety of diseases.*
4. *This project will develop and implement innovations in scientific approaches, methods and/or technologies to accelerate the pace of translational research.*
5. *This project addresses a common roadblock or bottleneck in translational research.*
6. *If successful, this project will improve translational research by making it more efficient and effective.*
7. *If successful, this project will yield information that will accelerate translational research.*

Schneider *et al.* (2023). Distinguishing between translational science and translational research in CTSA pilot studies: A collaborative project across 12 CTSA hubs. *J Clin Transl Sci*. **8(1):** e4. PMCID10877521.

Conclusions: Seven questions may be useful for informing deliberations regarding whether a study addresses a question that aligns with NCATS' vision of TS.

TS Barriers and TS Approaches

- ***Barrier.*** *Many/most new drugs fail the transition from cell/animal model to human trials*



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Time

TS Barriers and TS Approaches

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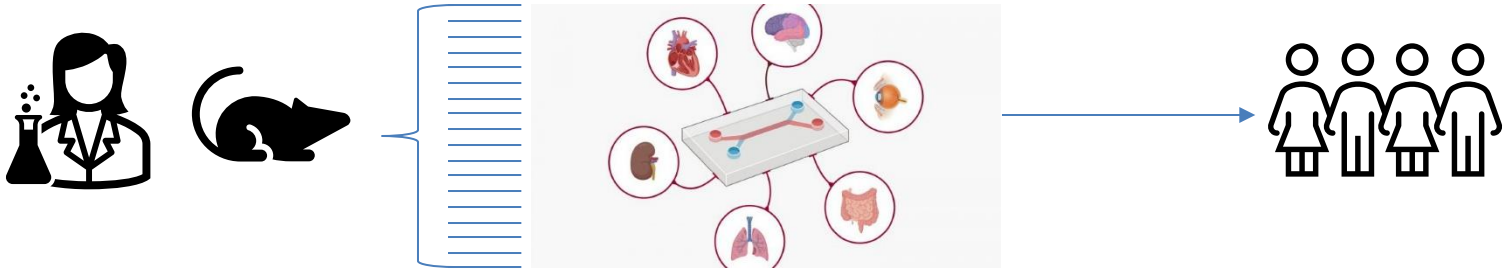


$$$$$$

Time

TS Solution. *Human organ on a chip, replicating human physiology and 3d structure*

Advantages. *Allows prescreening of larger numbers of candidate drugs faster and cheaper*

TS Barriers and TS Approaches

- ***Barrier.*** *Structured assessment windows in randomized trials disproportionately exclude those with barriers to participation (childcare, travel, work limitations)*

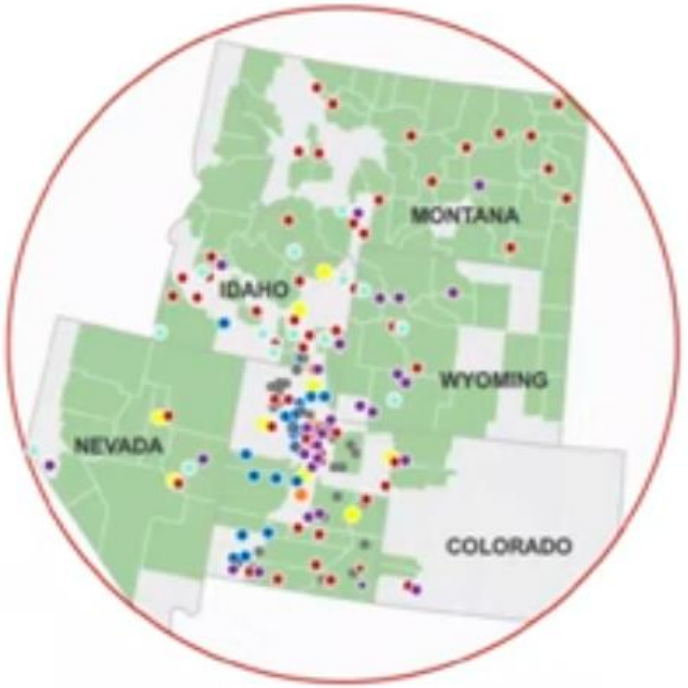
- ***TS approach.*** *New Statistical method allowing irregularly timed data to be used in analysis.*

- ***Advantage.*** *Clinical trials can be conducted with more flexible assessment timelines, improving inclusiveness while maintaining rigorous analytical plans*

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT*	$-t_1$	0	t_1	t_2	t_3	t_4	*etc*	t_x
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
(List other procedures)	X							
Allocation		X						
INTERVENTIONS:								
(Intervention A)			—	—	—			
(Intervention B)			X		X			
(List other study groups)			—	—	—	—		
ASSESSMENTS:								
(List baseline variables)	X	X						
(List outcome variables)				X		X	etc	X
(List other data variables)			X	X	X	X	etc	X

TS Barriers and TS Approaches

- ***Barrier.*** *Rural patients must drive far to undergo necessary regular research phlebotomy at university – impedes participation in studies*
- ***TS approach.*** *Rural research phlebotomy collective, based in local clinics*
- ***Advantage.*** *Reduces effort for rural population research engagement – participation generalizable across multiple studies*



TS Barriers and TS Approaches

- ***Barrier.*** *(i) Very low adherence to wearable monitors for PA/Sleep studies, (ii) Participant access to data through apps can bias results*
- ***TS approach.*** *Evaluate compact user-friendly and researcher-manageable PA/sleep tracker (Oura Ring) and compare with "gold standard" ActiGraph*

- ***Advantage.*** *Enables collection of non-biased PA/HRV/sleep data while reducing need to participants to travel to central lab setting. Applicable to a variety of PA-based studies and interventions*

Translational Research as CTS Use Case

*"Translational research projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, **are not allowed**."*

TS Barrier. *Minority communities are underrepresented in clinical trials*

TS goal. *Understand the barriers to equitable recruitment to trials*

TS approach. *Design a recruitment approach that captures truly representative study population*

TR Project. *Test whether a new drug improves outcomes T2D patients*

Use Case. *Test the new recruitment approach in the T2D study*

Result. *The insights gained during the course of the T2D study recruitment address the overarching TS question: "Is the new recruitment strategy effective?"*

Translational Research as CTS Use Case

"Translational research projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, ***are not allowed****."*

In this instance, the T2D study (Translational Research) acted as a "use case" to test the TS recruitment approach and address the broader TS barrier

This is acceptable as long as the TR use case is placed in the context of the overarching TS question

Remember that this is still a Pilot Program…

Projects are intended to:

1. *explore possible innovative new leads or new directions for established investigators;*
2. *stimulate investigators from other areas to lend their expertise in research in CTS; and*
3. *provide initial support to establish proof of concept.*
4. *generate preliminary data to support subsequent applications for external funding*

TraCS CTS Pilot Program Basics

- *4-8 grants, awarded annually.*
- *$25k – $50k grants.* ***No match allowed***
- *Use of TraCS services is encouraged*
- *1 year funding period, extending from April 1 – March 31 -* ***No budget extensions***
- *PI eligibility essentially the same as that for NIH "R" funding*
- *PI from any TraCS partnership institution (UNC, NC A&T, NC State)*

Using TraCS Services for Pilot Projects

- *For example:*
  - *Biostatistics*
  - *FastTraCS*
  - *Regulatory*
  - *Team Science*
  - *Informatics and Data Science (IDSci)*
  - *Clinical and Translational Research Center (CTRC)*
  - *Patient and Community Engagement in Research (PaCER)*
  - *Inclusive Science Program (ISP)*
  - *Research Recruitment and Retention (R&R)*

- *Visit NC TraCS website, see what TraCS offers*
- *Consult with individual Service reps*
- *Address Service usage in application*
- *TraCS services are available at reduced rates to Pilot awardees*
- *Use of TraCS services must be discussed with, and agreed upon with service reps, and described in the Service Agreement attachment in the application (one agreement form per TraCS service to be used)*

“Cooperative Agreement” vs Grant

- *Ongoing Pilot Program input and support:*
- *Navigator assigned to research team*
  - *Advise on CTS aspects of research*
  - *Liaise between team and TraCS services*
  - *Future plans and funding opportunities*
- *Regular meetings*
- *6- and 12-month progress reports*

Key Dates/Timeline – Cycle 5

FOA Release Date	*March 1, 2025*
FAQ Sessions (2)	*April 24, 2025 (Registration link)*
	April 29, 2025 (Registration link)
**Meeting with Pilot Staff*	*March - June, 2025*
***Meeting(s) with TraCS service reps*	*March - June, 2025*
Application Due Date	*July 8, 2025*
Anticipated Funding Announcement	*October 2025*
Completing Regulatory Approvals (IRB, IACUC, NCATS)	*March 1, 2026*
Funding Period	*April 1, 2026–March 31, 2027*

**Required for all prospective applicants*
***Required only for applicants intending to use TraCS services*

Proposal Submission and Review

- *Due July 8, 2025 through the NC TraCS online pilot submission system*
- *Application comprises a set of uploaded PDFs describing Research Plan, CTS Relevance, Timeline, Budget, Biosketches etc*
- *Applications will be reviewed "NIH-style" – assigned to a small set of reviewers and subsequently discussed in Study Section.*
- *Funding decisions will be announced October, 2025, and all applicants will receive written feedback*

Program Staff/Contacts/Information

General Questions? email pilots@unc.edu

Contacts:

- *David Peden, MD, MS - Module Leader*
- *David Carroll, PhD - Lead Navigator (for questions re: topic suitability and application process)*
- *Mary Beth Cassely – Director of TraCS Innovation Program (for questions re: applicant eligibility)*
- *Laura Cowan – QA/QC Manager, Pilot Program*

Funding Announcement, FAQs, Application Portal:
https://tracs.unc.edu/index.php/services/pilot-program/cts

NCATS Translational Science Resources:
https://ncats.nih.gov/translation/translational-science-resources

Questions/Discussion