



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*

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*Laura Cowan – QA/QC Manager, Pilot Program*

# Topics to be covered

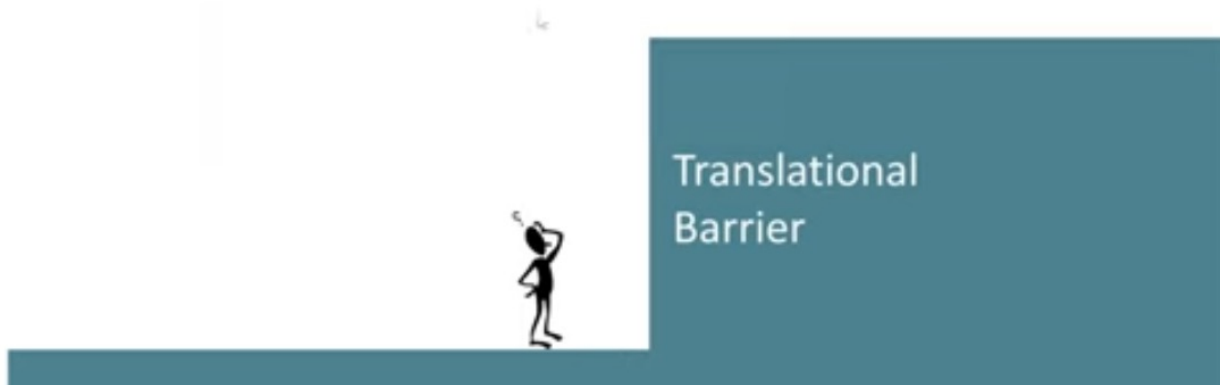
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- *Translational Research vs Translational Science*
- *Outline of CTS Pilot Program*
- *Q & A*

# What is Translational Science?

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- *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*



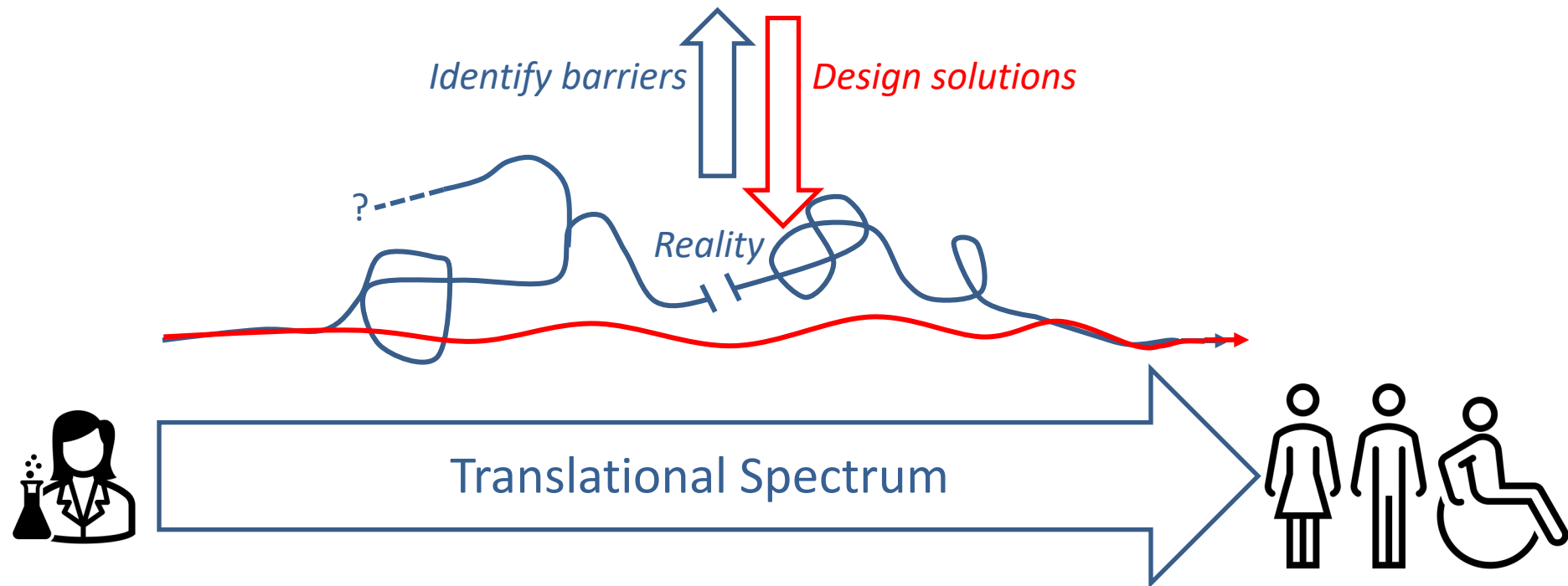
# Translational *Science* vs Translational *Research*

**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.



# CTS Pilot Program – language from the CTSA FOA

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*“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.**”*

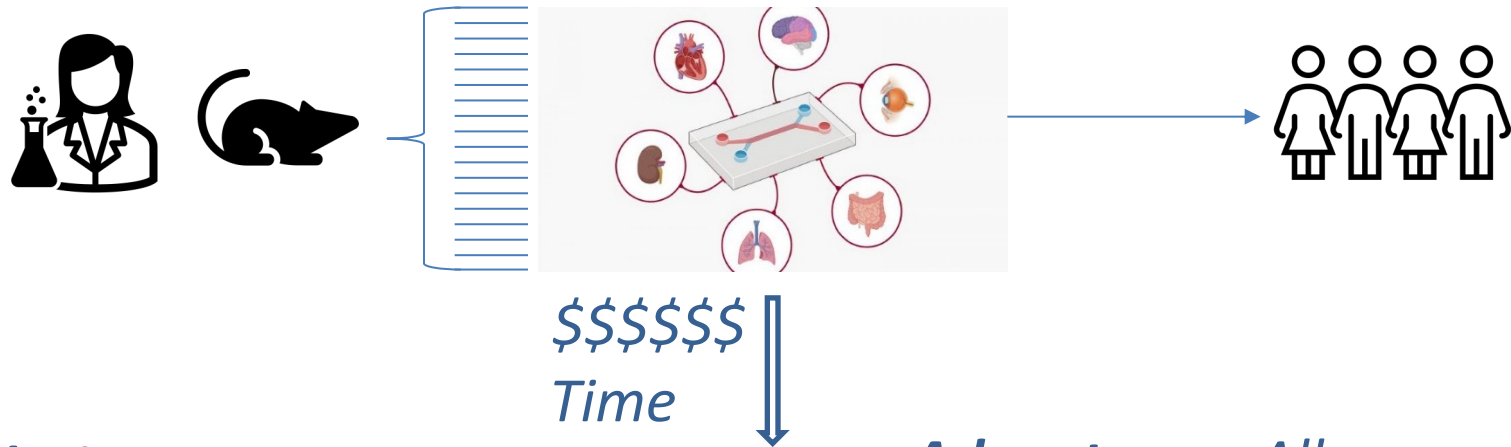
# TS Barriers and TS Approaches

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



# TS Barriers and TS Approaches

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



**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

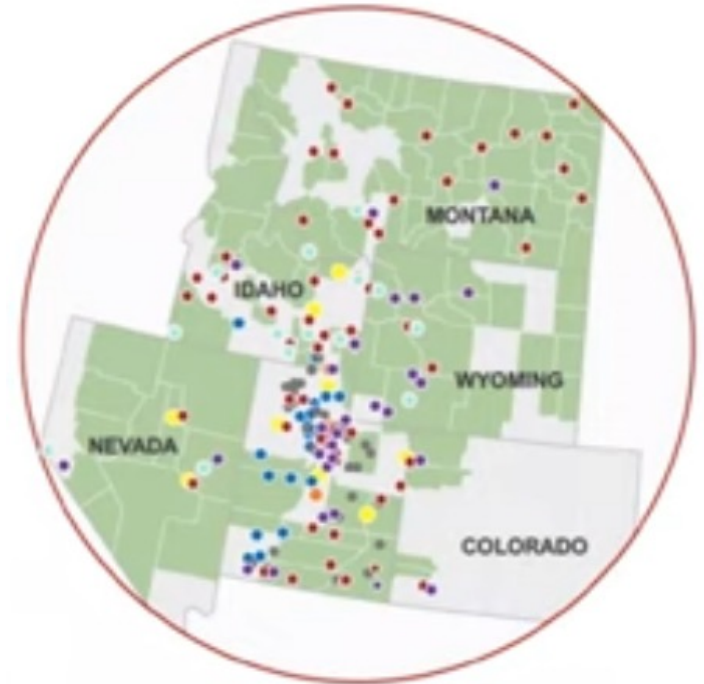
- **Barrier.** Structured assessment windows in randomized trials disproportionately exclude those with barriers to participation (childcare, travel, work limitations)
- **TS approach.** New Statistical method allowing irregularly timed data to be used in analysis.
- **Advantage.** Clinical trials can 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	$t_x$
<b>ENROLMENT:</b>								
Eligibility screen	X							
Informed consent	X							
(List other procedures)	X							
Allocation		X						
<b>INTERVENTIONS:</b>								
(Intervention A)			←————→					
(Intervention B)			X		X			
(List other study groups)			←————→					
<b>ASSESSMENTS:</b>								
(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 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...

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- *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*

# CTS Pilot Program Basics

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- *4-8 grants, awarded annually.*
- *\$25k – \$50k grants. **No match requirement***
- *Use of TraCS services is expected/encouraged*
- *1 year funding period, extending from April - April*  
**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

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- *For example:*
  - *Biostatistics*
  - *Clinical and Translational Research Center (CTRC)*
  - *Community and Stakeholder Engagement (CaSE)*
  - *FastTraCS*
  - *Informatics and Data Science (IDSci)*
  - *Inclusive Science Program (ISP)*
  - *Recruitment and Retention*
  - *Regulatory*
  - *Team Science*
- *Visit [NC TraCS website](#), see what TraCS offers*
- *Consult with Pilot Program staff*
- *Consult with individual service reps*
- *Address Service usage in application*
- *“Reasonable” level of TraCS service assistance free to pilot awardees*



# “Cooperative Agreement” vs Grant

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- *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 3

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<i>FOA Release Date</i>	<i>September 22, 2023</i>
<i>FAQ Sessions (2)</i>	<i>October 11 &amp; 13, 2023</i>
<i>*Meeting(s) with TraCS service reps</i>	<i>September 25, 2023 – November 10, 2023</i>
<i>Application Due Date</i>	<i>November 14, 2023</i>
<i>Anticipated Funding Announcement</i>	<i>January 19, 2024</i>
<i>Anticipated Funding Start</i>	<i>April 1, 2024</i>

*\*required only for applicants intending to use TraCS services*

# Proposal Submission and Review

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- *Due November 14, 2023 through the NC TraCS online pilot submission system*
- *Application comprises a set of uploaded PDFs describing Research Plan, 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 ~January 19, 2024, and all applicants will receive written feedback*

# Program Staff/Contacts/Information

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- *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*