Welcome!

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CCTS
Center for Clinical and Translational Science

Summary

- **Translational Science**

- **The Re-Frame**

- **Translational Barriers**

- **CCTS Partner Network Pilot Program**

Translational Science
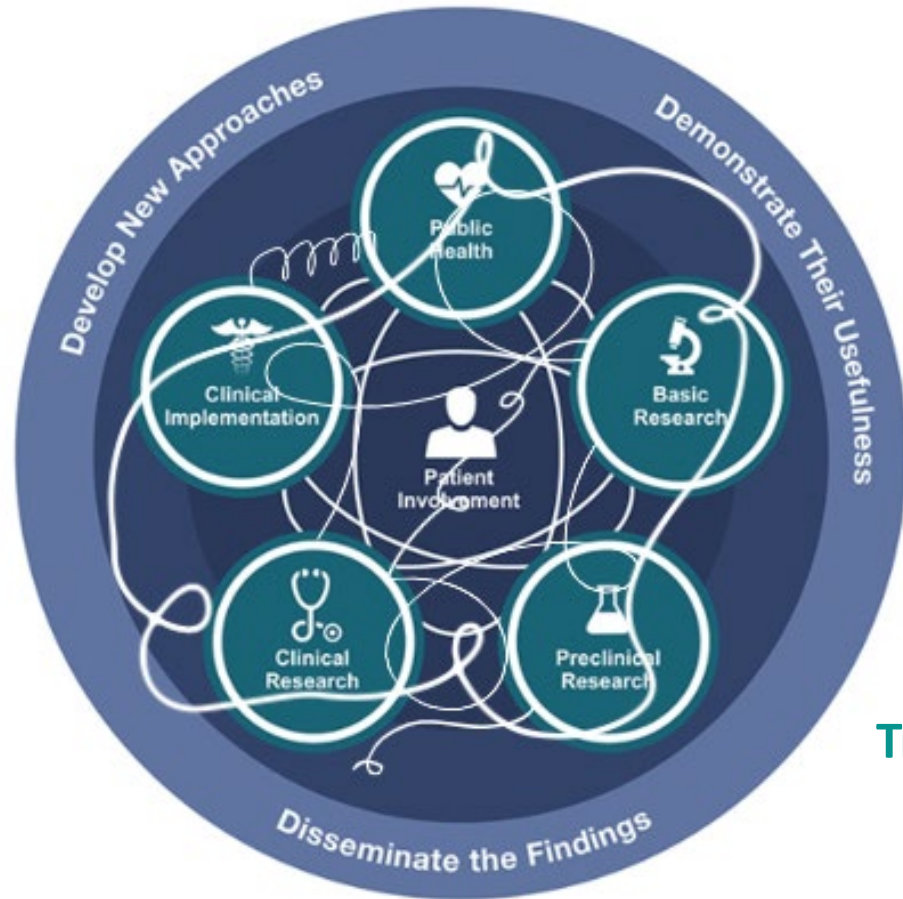
What is Translation?

The process of turning observations into interventions to improve health
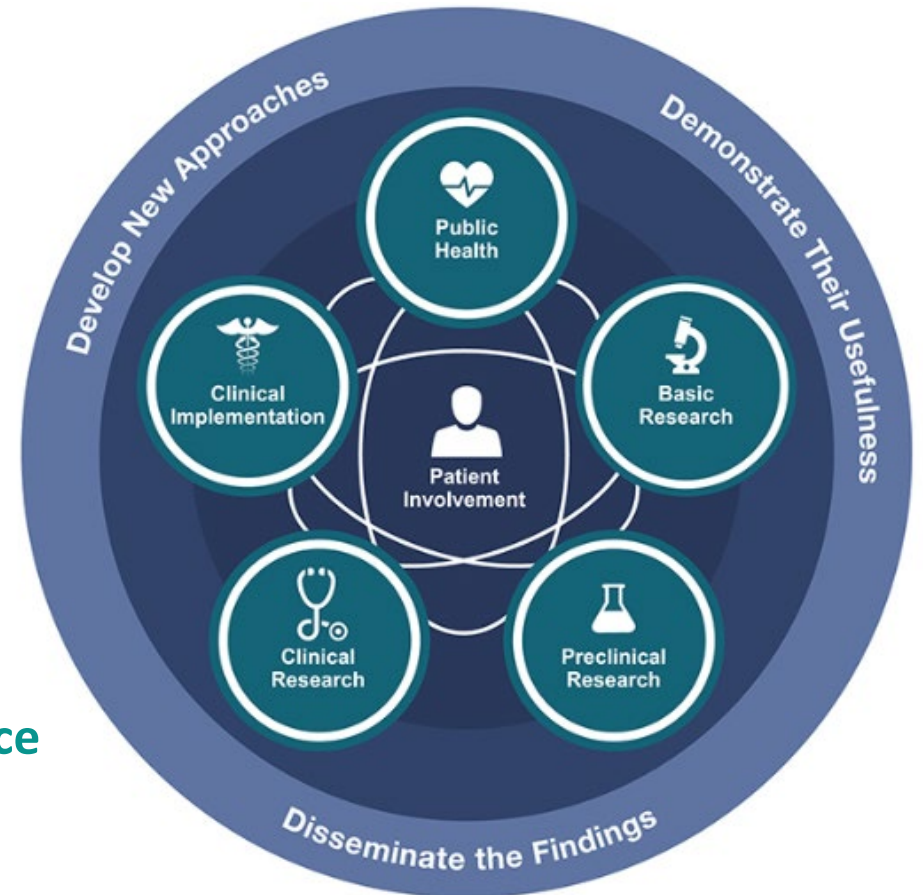
What is Translational Science?

Studying scientific and operational principles underlying each step of the translational process

- Identifying barriers to the advancement of research across the translational spectrum

- Developing a product or approach that reduces or removes the barrier

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Translational Science
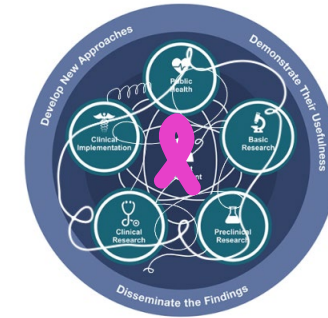
Translational Science

What is Translational Research?

Traversing a step of the translational process that applies to a specific target or disease
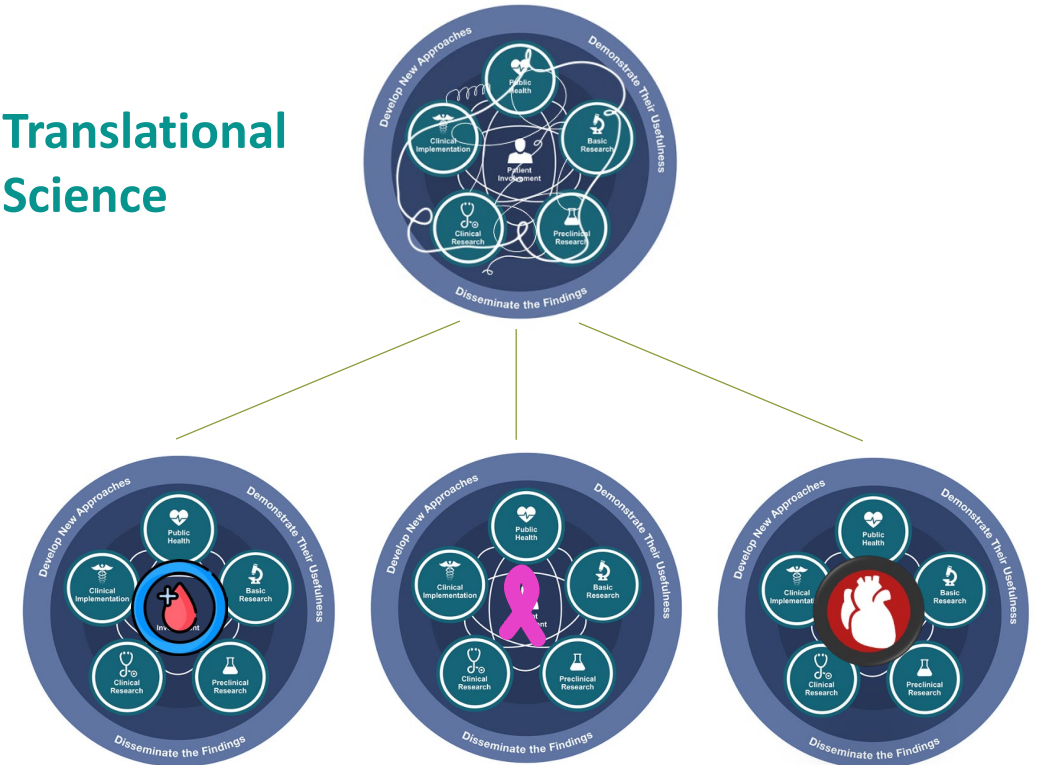
Translational Science vs. Research

Identifying and addressing a broadly existing barrier is more likely to accelerate research than working on a barrier that exists in a silo.

Translational Research

Translational Science

Translational Science: The Re-Frame

Translational Research Project. Examine if an intervention improves a health-related outcome amongst diabetics.

Translational Research Approach.
Leverage established recruitment methods to enroll diabetics towards examining efficacy of the intervention.

Result. Establish the effectiveness of an intervention on health-related outcomes in diabetics.

Translational Barrier.
Achieving participant enrollment that is reflective of the affected population.

Translational Science Approach.
Identify barriers/facilitators towards equitable enrollment. Examine the feasibility of a novel recruitment approach.
Study may require a disease context (e.g. diabetes).

Result. Establish an equitable recruitment strategy.
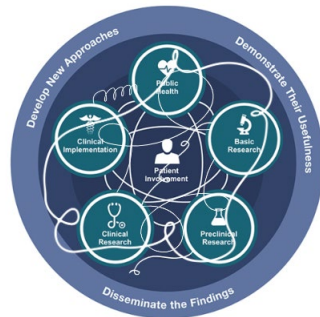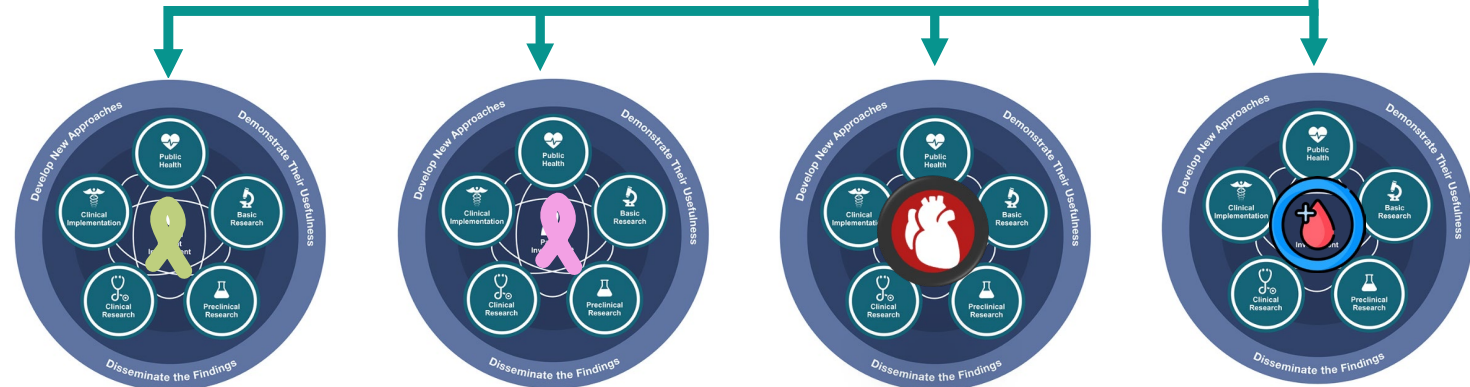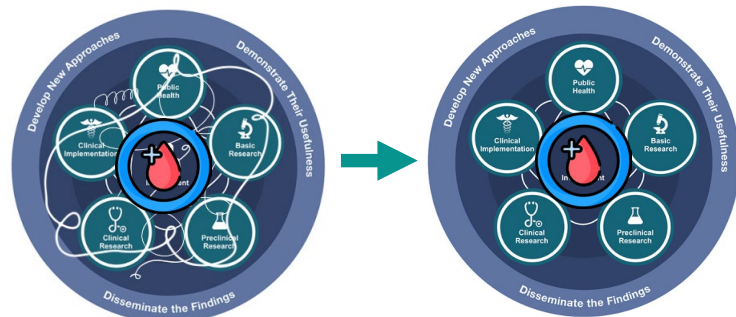
Translational Barriers

Data interoperability
- Leverage secondary analysis of existing data (e.g. use registries and natural history studies, biomarker qualification, pharmacoepidemiological studies, comparative effectiveness trials, adaptive clinical trial design, National COVID-19/Clinical Cohort Collaborative – NC3)
- Integrate access, transparency and interoperability of data across clinical care and research
- Develop generalizable digital health technologies and predictive applications
- Hone AI/ML and technology-driven solutions

Preclinical research methodologies
- Test solutions aimed at improving the transition from preclinical models (cell/animal) to human trials (e.g. predictive efficacy, predictive toxicology, disease models)
- Target elements that are common across diseases (e.g. drug target)
- Examine methods to address limitations created by chemistry, manufacturing and controls (CMC)

Clinical study and trial design
- Address medical needs
- Define and validate novel endpoints
- Target elements that are common across diseases (e.g. social determinant(s) of health)
- Engage community and stakeholder engagement and outreach
- Develop sustainable strategies for patient and community collaborations
- Clinical trial networks
- Contemporary clinical trial design

Clinical adoption
- Dissemination and implementation science

Regulatory processes
- Integration of project management
- Collaborative structures, agreements, IP management
- Organizational structure to support cross-institutional collaboration
- Leverage Single IRBs and Reliance Agreements

Translational Science – Pilot Sized

Development of a novel Bayesian covariate-adjusted response-adaptive (BCARA) design for Phase II randomized clinical trials with a continuous outcome.

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

Translational Innovation. 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.

Translational Science – Pilot Sized

Testing the adherence and reliability of a physical activity monitor.

Translational Barrier. (i) Very low adherence to wearable monitors for PA/Sleep studies, (ii) Participant access to data through apps can bias results.

Translational Innovation. Evaluate compact, user-friendly and researcher-manageable Physical activity monitor compared to a gold standard

Advantage. Enables collection of non-biased physical activity while reducing need to participants to travel to central lab setting. Applicable to a variety of PA-based studies and interventions.

Translational Science – Pilot Sized

Assessment of the impact of clinical pharmacogenomics on real and potential medication use in Veterans with mental health illness.

Translational Barrier. Access to patient information at the point of care is a barrier to clinical adoption.

Translational Innovation. Develop a method to make patient information available to the provider at the point of care.

Advantage. Enabling providers access to patient information improves clinical adoption and enables outcome evaluation.

Translational Science – Pilot Sized

Examples of activities that may be supported:

- Demonstration in a particular use case(s) that the new methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient

- Feasibility/proof of concept studies to support future CTS projects

- Development of new research methodology and/or new technologies/tools/resources that will advance CTS and thus increase the efficiency and effectiveness of translation

- Dissemination of effective tools, methods, processes, and training paradigms

- Early-stage development of new therapy/technology with generalizable application to an identified translational roadblock

- Secondary analysis of existing data (e.g., National COVID Cohort Collaborative (N3C))

Translates to…

- **Clinical Research Acceleration Projects** that increase efficiency and effectiveness of testing and delivery of new treatments

- **Data Science, Informatic, AI/ML Projects** that increase data congruence, interpretation or utilization towards improving health outcomes

- **Dissemination and Implementation Projects** that inform how innovations, discoveries or interventions become a standard of scientific, healthcare or community routines. health care or community

- **Predictive Efficacy and Toxicology Projects** that develop model systems that more closely resemble human physiology to improve drug candidate ID, basic biology of disease or testing platforms

- **Network Capacity Building Projects** that build or engage collaborative approaches to fast-track promising translational research projects equitably

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CCTS Partner Network Pilot Program

- **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

- Projects may demonstrate advances in translational science (making one or more steps of the translational process more effective/efficient) via a translational research project (see prior slide regarding "Re-Frame").

- **Translational research projects are not allowed**, i.e. <u>those focused on</u> crossing a particular step of the translational process for <u>a particular target or disease</u>

CCTS Partner Network Pilot Program

Pilot projects are intended to (be pilot-sized):

- Explore possible innovative new leads or new directions for established investigators;
- Stimulate investigators from other areas to lend their expertise in research in clinical translational science
- Provide initial support to establish proof of concept
- Projects must be feasible within the proposed timeframe, have high methodological and scientific quality, and answer important scientific questions

Pilot projects are <u>not intended</u> for large projects by established investigators that would otherwise be submitted as separate research grant applications.

CCTS PARTNER NETWORK PILOT PROGRAM
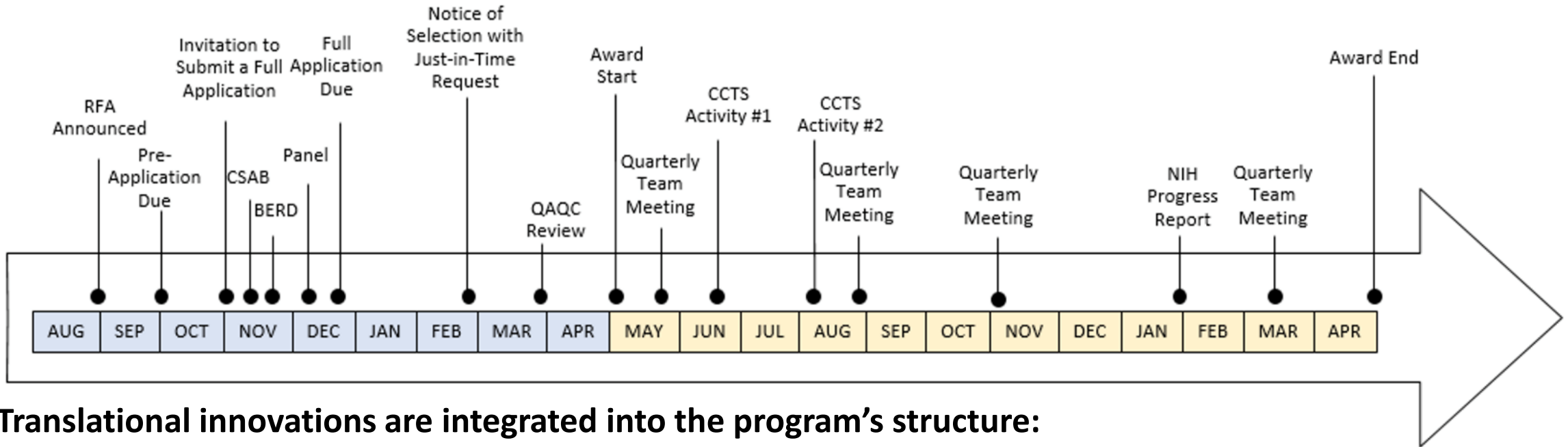
Translational innovations are integrated into the program's structure:

- Leverage Cross-Disciplinary Team Science (Team Meetings)
- Utilize Boundary Crossing Partnerships (CCTS Panels, Peer-Review)
- Prioritization of Diversity, Equity, Inclusion and Accessibility (CSAB)
- Bold and Rigorous Research Approaches (BERD, Panel, CCTS Consultations)
- Crosscutting Solutions for Common and Persistent Challenges (CCTS Capacities)
- Enhance the Speed of Translational Research (CCTS Capacities)
- Emphasize Creativity and Innovation (CCTS Events)

CCTS PARTNER NETWORK PILOT PROGRAM

Byron Lai, PhD, MS
Asst. Professor
Pediatric Rehabilitation Medicine
UAB
2022 Pilot

Sara Cooper, PhD
Faculty Investigator
HudsonAlpha Institute for Biotechnology
2021 Pilot

Translational Science – Pilot Sized

Testing the validity and reliability of a replicable tele-monitored physical fitness battery that is inclusive of adults with and without physical disabilities.

Translational Barrier. Reproducibility of a remote data collection is a barrier to research adoption.

Translational Innovation. Validate a robust remote data collection scheme.

Advantage. Future clinical studies can incorporate and rely on a robust remote data collection method, reducing the barrier of reporting to a laboratory for study visits/data collection in future clinical studies.

Translational Science: The Re-Frame

Translational Research Project. Examine the feasibility of a tele-assessment fitness test battery designed for individuals with mobility disabilities.

Translational Research Approach. Leverage established recruitment methods to enroll disabled individuals towards examining feasibility of the test.

Result. Establish the feasibility of the test for individuals with mobility disabilities.
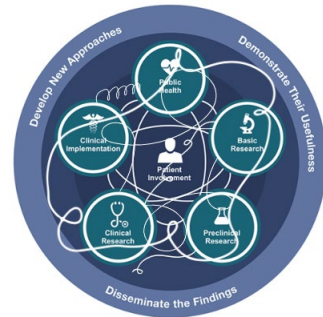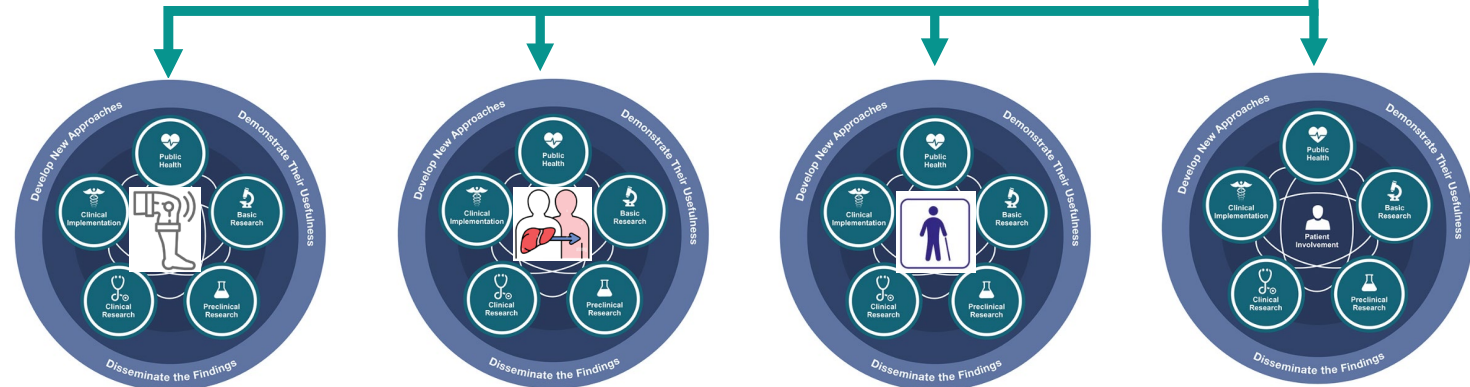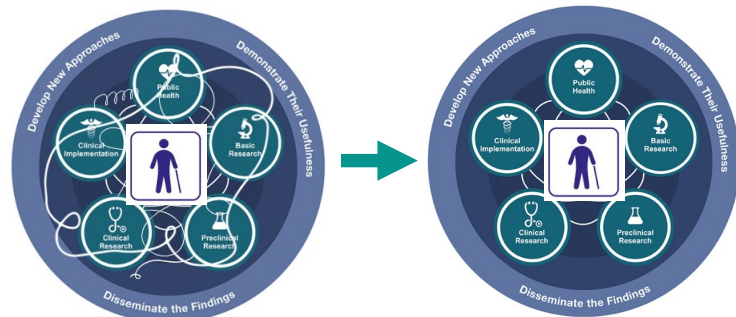
Translational Barriers.
- Fidelity of remote data collection.
- Development of an inclusive test that may be applied to many disease contexts.

Translational Science Approach.
- Compare the feasibility of the test in clinical laboratory and simulated tele-assessment.
- Assess the agreement of tests between healthy individuals and those with mobility disabilities.

Result. Increase the enrollment and retention of healthy and disabled participants in remotely delivered exercise studies

Translational Science – Pilot Sized

Screening for Hereditary Cancer Risk in African Americans

Translational Barrier. Access to patients is a barrier to clinical implementation.

Translational Innovation. Assess the efficacy of a novel patient recruitment method.

Advantage. Inform the development of future clinical implementation strategies.

Translational Science: The Re-Frame

Translational Research Project. Examine the risk of breast cancer in a population via genetic screening.

Translational Research Approach.
Leverage established recruitment methods to enroll participants in breast cancer screening.

Result. Establish the risk of breast cancer in a population.

Translational Barrier.
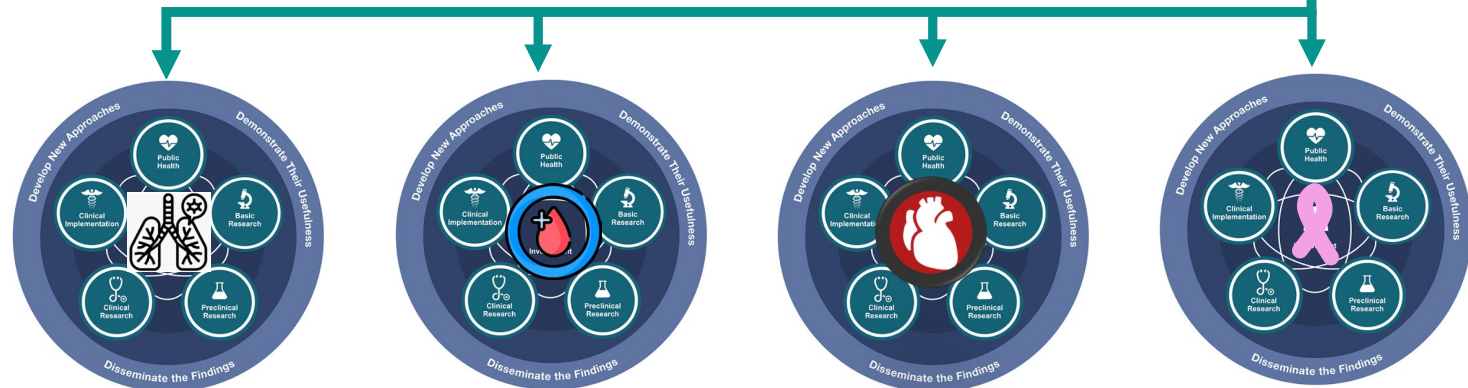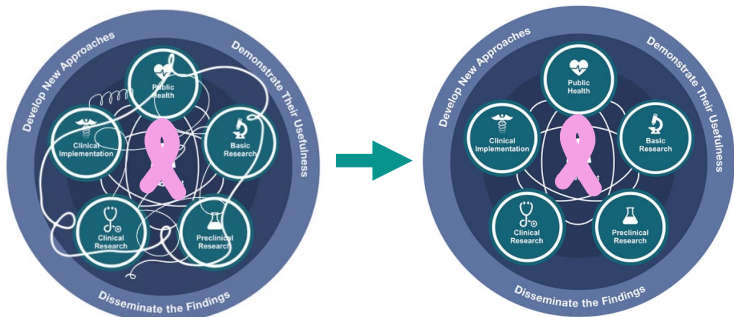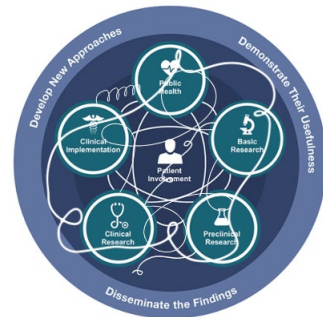Achieving participant enrollment that is reflective of the affected population.

Translational Science Approach.
Identify barriers/facilitators towards equitable enrollment. Examine the feasibility of a novel recruitment approach.
Study may require a disease context (e.g. breast cancer).

Result. Establish an equitable recruitment strategy.

Questions

CCTS PARTNER NETWORK PILOT PROGRAM

FAQs:

- **Is it true that investigators engage in translational science but don't recognized it?**
  YES!

- **Are Dissemination or Implementation projects eligible?**
- **Are projects seeking future support towards commercialization (e.g. SBIR/STTR) eligible?**
- **Are basic/bench research projects eligible?**
- **Are clinical research projects eligible?**
- **Are rare disease projects eligible?**
  Yes, provided that applications are framed as translational science projects (i.e. framed as addressing a translational barrier).

- **Are projects that exclusively focus on Type Two Diabetes eligible?**
- **Are projects that exclusively focus on a single rare disease eligible?**
- **Are projects that exclusively focus on Triple Negative Breast Cancer eligible?**
  No. Please connect with the CCTS Pilot Program (anneruss@uab.edu).

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CCTS PARTNER NETWORK PILOT PROGRAM

FAQs:

- **What is the maximum award?** $30,000 (direct).

- **Are only faculty members eligible to apply?** Yes. And. If an applicant anticipates a faculty position by the award start, be prepared to provide a Letter of Support from the Department Chair (or equivalent) attesting to a faculty appointment beginning before the start of the award (May 1, 2024). Clinical research staff professionals, health system administrators and trainees may play essential roles on pilot teams, including Multiple PD/PI (MPI), assuming a faculty member serves as the communicating MPI.

- **Can applicants reapply?** Yes, resubmissions have been funded but are not provided special consideration and must be framed as translational science projects.

- **Do applicants need to coordinate consults?** Required consults (BERD, Panel, CSAB) are coordinated by the CCTS program. Investigators are encouraged to consult with other CCTS capacities (e.g. Clinical Research Unit, Biorepository, Bionutrition, Clinical Regulatory Support Program) free of charge. If recruiting participants, consultation with CRSP makes you eligible for a Gold Star Award.

- **Are applicants required to use CCTS services?** Use of CCTS capacities is highly encouraged.

CCTS PARTNER NETWORK PILOT PROGRAM

FAQs:

- **Is cosponsorship required or allowed?** Our sponsor does not allow co-sponsorship, cost-sharing, matching.

- **Is the support offered by the CCTS Pilot Program internal or external support?** Support for this program flows from the NIH's National Center for Advancing Translational Science to the CCTS "Hubbed" at UAB. The CCTS selects projects; however, projects are subjected to NCATS Prior Approval that is akin to a "Just in Time" process, where information is supplied to the NIH for approval before the project can start. Therefore, support for this program is viewed as *internal* in some contexts and *external* in other contexts.

- **Should I include indirect in the budget?** Indirect costs are part of the award at institutions' agreed upon indirect rate.

- **What if my institution/department requires that my budget contains indirect costs and my application logged by its Office of Sponsored Programs?** Investigators are encouraged to connect administrators with the CCTS Pilot Program (anneruss@uab.edu).

CCTS PARTNER NETWORK PILOT PROGRAM

FAQs:

- **Is the lay summary a scientific abstract?** No. Lay summaries are leveraged to facilitate, as applicable, communications with the CCTS Community Scientific Action Board (CSAB), identifying reviewers and promotion of your work. Since the lay summary is leveraged in several ways, applicants enter the summary in the online application form instead of their PDF application.

- **What are operational suggestions for applicants?**
  If invited to submit a full application, consider discussing and drafting your human subject research protocol with the CCTS, institutional IRB and/or collaborators as early as possible, especially if IRB approval is required at more than one institution, proposing an NIH Clinical Trial or Greater than Minimal Risk study.

- **What kind of applications fair well during review?**
  - Applications that identify and address a translational barrier.
  - Applications that communicate how the proposed work is part of a longer-term research plan.

Translational Science – Pilot Sized

Assessment of the impact of clinical pharmacogenomics on real and potential medication use in Veterans with mental health illness.

Translational Barrier. Access to patient information at the point of care is a barrier to clinical adoption.

Translational Approach. Develop a method to make patient information available to the provider at the point of care.

Advantage. Enabling providers access to patient information improves clinical adoption and enables outcome evaluation.

In this instance, mental illness amongst Veterans acted as a "use case" to test the TS approach and address the TS barrier. This is acceptable, as long as the translational research case is placed in the context of the overarching translational science question.

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