What is the CTSA?

- Clinical and Translational Science Award
- NIH grant from National Center for Advancing Translational Sciences (NCATS)
- CTSA has provided continuous funding for the Einstein-Montefiore ICTR since 2008
- 63 US medical research institutions receive CTSA funding, called “hubs”
- Einstein-Montefiore CTSA grant funding 2023-2030
NCATS’ Mission

Turn research observations into health solutions through translational science
The Public Health Challenge

10,000 Diseases

and only

500 Treatments or Cures

Time from early development to the medicine cabinet takes 10-15 years

9 out of 10 that enter clinical trials fail

Average of 17 years for research evidence to reach clinical practice
What is Translational Science?

The NIH/NCATS define:

- ‘Translation’ is the process of 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 research’ is the endeavor to traverse a particular step of the translational process for a particular target or disease.

- ‘Translational science’ is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Translational science is “disease universal” - it focuses on the scientific and operational bottlenecks that are common to translational research for most or all diseases.

https://ncats.nih.gov/translation/spectrum
Austin CP. Clin Transl Sci 2021
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 Clinical Translational Pipeline

Operational
“One size fits all” approach
• Adaptive and other novel trial designs

Administrative/Training
Administrative burden for study start-up
• Streamline regulatory processes

Scientific
Insufficient tools and technologies to predict toxicity and efficacy of new drugs
• Platform-based (WGS for rare diseases, mobile tech for multiple diseases)

Examples of Solutions
Low enrollment and diversity in clinical trials
• Enhance community and informatics efforts

Shortage of qualified translational investigators and staff
• Training and career development best practices

Incompatible databases to advance data science
• Data, harmonization, interoperability and integration (N3C, INSIGHT)
Examples of Projects

**Translational RESEARCH**

- 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.
- 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.
- Systematically studying barriers to enrollment of historically underrepresented groups in clinical trials.
- Developing systems to merge clinical datasets from different sources accurately and efficiently.
Additional Examples of TS

Novel methods and technologies for:

- **Community engagement**: increase efficiency and effectiveness of intervention development, measuring impact on health outcomes.

- **Implementing clinical research studies and trials**: e.g., digital health, telehealth, data science/AI/ML for site selection/activation, recruitment/retention, patient reported outcomes, biomarker identification/validation, data collection/analysis, risk communication, clinical monitoring, data and safety monitoring, interoperability of EHR systems and data management systems.

- **Engaging understudied /underreported populations** in research and trials.

- **Diagnosing patients** using clinical, genetic or ML methods.

- **Identifying molecular underpinnings of genetic diseases and potential targets** for therapeutics development (e.g., computationally-assisted modeling).

- **Making data more meaningful, open, and accessible** using data science, informatics tools, AI/ML (predictive modeling, algorithms, simulation technologies, creation and dissemination of knowledge networks).

- **Reducing time to adoption of an intervention**.
Projects in Translational Science (TS)

• Address challenges in TS in all areas and stages of the translational process

• **All Faculty** at Einstein and Montefiore

• **$40,000** per project, **1-year duration**, up to 4 projects per year

• **Applications due January 31st, 2024, 5 pm ET**

• **Award notifications mid-February; start date March 1st, 2024**
Support

• Generation of preliminary data, demonstration of study feasibility, refinement of research strategies → extramural grant applications in translational science.

• Early-stage development of new research methodologies, therapies, tools and technologies with generalizable applications.
ICTR Cores and Resources available to Applicants / Awardees

**Biomarker and Biorepository**
Provides sample processing, analyses and banking for biologic fluid and tissue specimens

**Biostatistics, Epidemiology & Research Design**
Assists with study design, biostatistical analyses, novel trial designs and methodologies

**Clinical Research Resource**
Provides dedicated staff and space, regulatory knowledge and support, recruitment tools

**Community Collaborative**
Provides consultations and collaborations with the Bronx community and healthcare partners

**Health Research Implementation**
Design and implement research to efficiently improve the gap between evidence and practice

**Health Informatics**
Provides infrastructure and tools to optimize collection and integration of data, and advanced analytics (AI/ML and predictive modeling)
2024 Einstein-Montefiore CTSA Pilot Project Awards

Application Information

ICTR website: [https://www.einsteinmed.edu/centers/ictr/pilot-projects/](https://www.einsteinmed.edu/centers/ictr/pilot-projects/)
Proposal components:

- Title and Abstract (500 words maximum)
- Project proposal (3 pages maximum) containing the following sections:
  - Background
  - Significance
  - Specific Aims
  - Approach
- Principal Investigator (PI) and other key personnel NIH biosketches
- PI and key personnel other research support (in NIH format)
- Budget justification and itemized budget (use NIH PHS 398 form)
Proposal must clearly describe:

• The translational barrier(s) / roadblock(s) that will be addressed

• Expected generalizability of study outcomes (i.e., to other disease areas, patient cohorts, etc.)

• Future directions and long-term impact

If required, **IRB** or **IACUC** approval **MUST** be obtained prior to receiving funding
Questions?

1:1 Consultation requests?

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Additional TS Funding Opportunities

R03
• Small Grant Program for the NCATS CTSA Program (PAR-24-042)
  • KL2/K12 scholars (former and current) and recipients of diversity and re-entry supplements.
  • Support research projects that can be carried out in a short period of time with limited resources and that provide preliminary data to support submission of a subsequent R01, or equivalent, application.
  • LOI due: January 19, 2023; Earliest submission date: February 20, 2024.
  • Budget: $50,000

RC2
• Limited Competition: High Impact Specialized Innovation Programs in Clinical and Translational Science for UM1 CTSA Hub Awards (PAR-24-054)
  • Support the development of research platforms and/or resources to address critical gap areas and/or roadblocks in clinical and translational science at institutions funded by the NIH CTSA.
  • LOI due: 30 days prior to submission; Earliest submission due: January 12, 2024.
  • Budget: $500,000/yr for up to 5 years
Additional TS Funding Opportunities

For additional information and eligibility to apply for a R03 and RC2 funding opportunity in TS

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