# Einstein-Montefiore CTSA Pilot Project Program

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
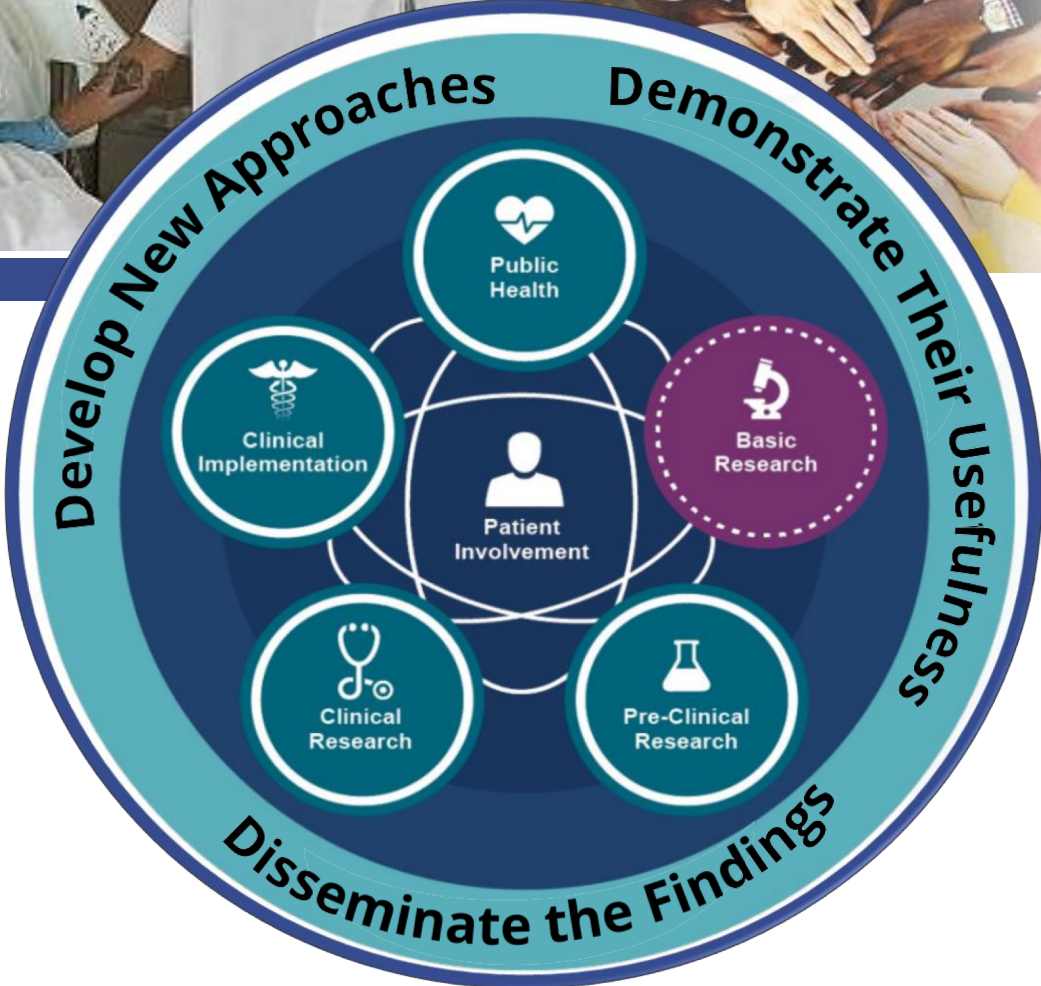
The Public Health Challenge

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.**

Bottlenecks in the Translational Research Pipeline
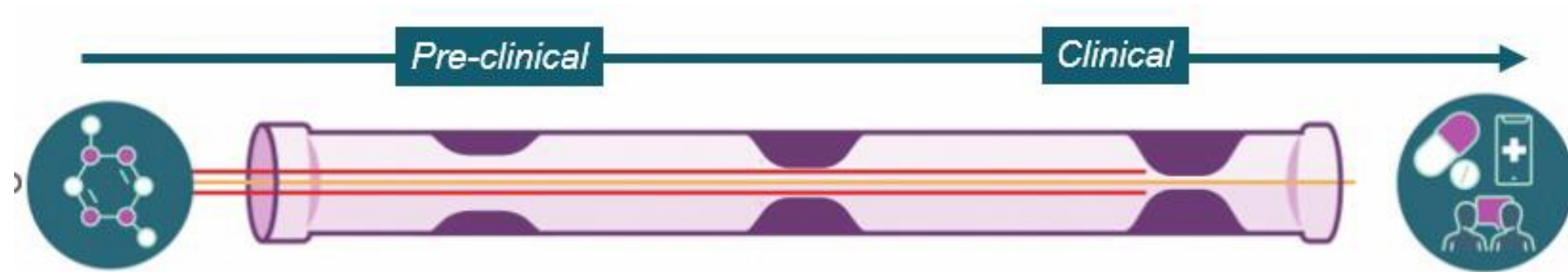
Examples of Bottlenecks

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

Pre-clinical → Clinical
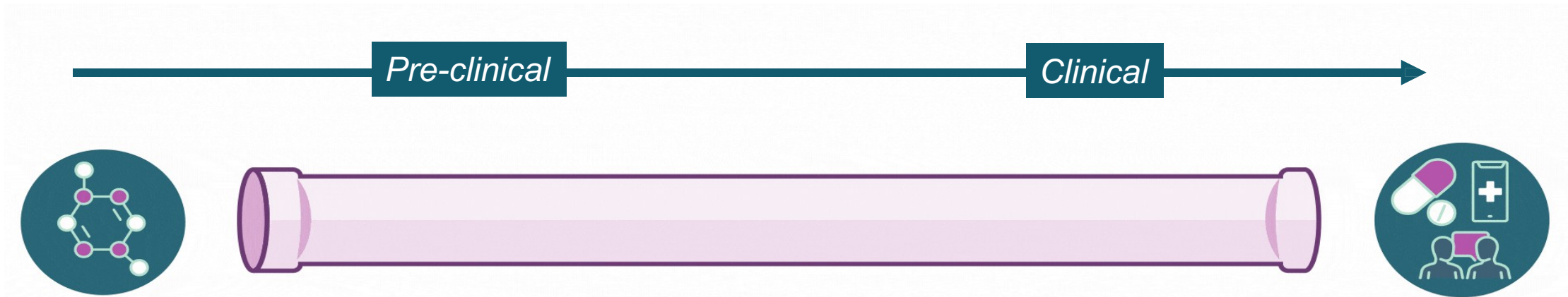
Examples of Solutions

Operational
"One size fits all" approach
- **Adaptive and other novel trial designs**

Low enrollment and diversity in clinical trials
- **Enhance community and informatics efforts**

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

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

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

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.**

2024 Einstein-Montefiore CTSA Pilot Project Awards

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

2024 Einstein-Montefiore CTSA Pilot Project Awards

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/

EINSTEIN-MONTEFIORE CTSA: ADVANCING TRANSLATIONAL SCIENCE

PILOT PROJECT PROGRAM

Apply for 2024 Pilot Project Award

2024 Request for Applications

2024 Einstein-Montefiore CTSA Pilot Project Awards

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)

2024 Einstein-Montefiore CTSA Pilot Project Awards

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 <u>MUST</u> be obtained prior to receiving funding

Questions?

1:1 Consultation requests?

ICTR Pilot Project Program Directors

Sofiya Milman, MD, MS
sofiya.milman@einsteinmed.edu

Sylvia Suadicani, PhD
sylvia.suadicani@einsteinmed.edu

ICTR Administrative Director

Elizabeth Castro
elizabeth.castro@einsteinmed.edu

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

https://grants.nih.gov/grants/guide/pa-files/PAR-24-042.html

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

https://grants.nih.gov/grants/guide/pa-files/PAR-24-054.html

Additional TS Funding Opportunities

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

Contact:

CTSA Program Directors:

Marla J. Keller, MD
marla.keller@einsteinmed.edu

Mimi Kim, Sc.D.
mimi.kim@einsteinmed.edu