National Center for Advancing Translational Sciences

NCATS SBIR AND STTR

Research Priorities

NCATS small business funding is designed specifically to transform the translational science process so that new prevention, detection and treatment technologies can be delivered to patients faster. NCATS supports the development of clinical technology, instruments, devices and related methodologies that may have broad application to research and improve patient care. Learn more about NCATS' SBIR and STTR research priorities.

Preclinical Drug Discovery and Development

Manufacturing and Bioengineering

- Methodologies and technologies to increase efficiency in manufacturing therapeutics, biomedical materials, medical devices, and diagnostics, such as:
  - Technologies to substantially improve efficiency and reduce costs in clinical-grade gene therapy vector manufacturing
  - Manufacturing approaches for N-of-1 gene therapy/gene editing to enable faster regulatory approvals accessible to all
  - New methods and tools for low-cost and accelerated bio-manufacturing and bioengineering
  - GMP production of exosomes and extracellular vesicles, including generation of producer cell lines
  - Bacteriophage-based therapeutics for disease and as modulators of the microbiome and its natural products
- New methods and tools for biologics production

Advanced Platforms and Interventions

- Interventions that target molecular pathways or mechanisms common to multiple diseases
- Platforms for non-antibody biologics, cell-based therapies, and gene therapy discovery
- Innovative technologies for non-small molecule delivery, such as:
  - Drug delivery methods with target tissue specificity
  - Technologies to allow therapeutic proteins other than lysosomal enzymes to be secreted and taken up by other cells via cross-correction
  - Technologies to deliver nucleic acid therapeutics to tissues other than the liver
- Innovative platforms for identification and prioritization of targets for therapeutic intervention with clear clinical impact, such as:
  - Targets that have been implicated for disease
  - Targets that have genetic variations that have been identified in functional regions of receptor targets
  - Targets that have high potential for biased signaling that would promote beneficial effects and reduce unwanted effects
- Novel "-omics" type of approaches that address bottlenecks in translational research and ultimately accelerate drug screening
- Volatile organic compounds (odors, scents) as biomarkers for disease

Research Tools and Approaches

- High-throughput technologies, such as:
  - Tools and technologies to enable high-throughput screening against currently "undruggable" targets
  - Improved tools for automation to increase the efficiency and capability of translational science platforms (i.e., screening, chemistry)
  - High-throughput epigenetics screening/ characterization tools and technologies
  - High-throughput Surface Plasmon Resonance devices for detecting protein small molecule interactions
  - New class of quantum-enabled sensing technologies for advancing translational sciences
  - Analytical lab instruments for smaller scale and higher throughput
  - Co-crystallization high-throughput screening techniques
- Tools and technologies that increase the predictivity or efficiency of optimization in medicinal chemistry, biologics, or other interventions
- AI (digital) and physical (lab) tools for predicting toxicity
- Novel strategies to reduce or eliminate immune responses to gene therapy
- Improved efficiency in genome editing and enzyme replacement therapy
- Development and validation of non-viral vectors for genetic therapy delivery
- Extracellular RNA-based biomarkers and therapeutics
- Approaches to targeting the human microbiome for therapeutic or diagnostic purposes
- Preclinical validation tools and methods for accurate prediction of clinical outcomes

Disease/Tissue Models and Assay Development

- Development of *in vitro* human tissue models (organs, 3-D printing) and microphysiological systems (MPS)/tissue chips
- 3-D printing technologies, including refinement of "disease-in a-dish"
- Phenotypic assay development and wider adoption for compound prioritization
- Stem cell technology platforms for human "disease-in-a-dish" applications and the evaluation of toxicity
- Fluorescence probes to replace antibodies for determination of cellular protein translocation

For More Information

Small Business Opportunities

ncats.nih.gov/funding/small-business-programs

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Biomedical, Clinical and Health Research Informatics

Cyber/Data Security

- Cybersecurity for greater integration of artificial intelligence in health
- Data security and data linkage approaches (AI/ML)
- Tools that allow for persistent identifier and attribution for data contributors while ensuring that shared data has not been altered
- Tools and environments that enable facile interrogation of publicly available data

AI and Machine Learning Tools

- Expanding the use and capabilities of computational research
- Tools to assess algorithms developed with artificial intelligence and/or machine learning
- Cloud-based tools and methods for meaningful sharing, re-use, and integration of research data
- Tools and technologies that leverage AI and real-world data for enhanced product evaluation and surveillance that could be leveraged for rapid response to public health needs

Innovative Technologies

- Nanotechnology, such as nanoneedles and nanoparticles, to help improve early disease detection and targeted therapeutic delivery
- Telemedicine platforms and tools that facilitate/enhance translational research, medicine, and access to care in rural populations
- Digital tools to support unmet translational science and healthcare operational needs, such as:
  - Generalized disease registry template platforms that can be reused for multiple diseases
  - Searchable access to information about research resources, facilities, methods, cells, genetic tests, molecules, biologic reagents, animals, assays and/or technologies with evidence about their use in research studies
  - Novel platforms and tools for including and integrating patient-reported data
  - Software platforms for electronic health records and personalized health records targeting data accessibility and interoperability for community medical centers and physician-owned health providers with modularity to assess AI algorithm performance pre-deployment and longitudinally post-deployment
  - Personalized phenotypic profiling and intervention based on patient-centered integration of data from multiple data sources and devices

Clinical, Dissemination and Implementation Research

Clinical Trials

- Tools for decentralized clinical trials and design of pivotal trials
- Computational or web-based health research methods, such as:
  - Platforms for generally applicable and scalable multi-disease registries and natural history studies
  - Clinical trial designs and analyses (e.g., for pragmatic clinical trials)
- Novel ways to develop new biomarkers that can be used to reduce existing barriers or bottlenecks in clinical translation
- Tools and technologies that increase the efficiency of human subjects' research by facilitating:
  - Rapid diagnosis
  - Clinical trial recruitment and subject tracking, including patient eligibility analysis and retention tracking
  - Institutional Review Board evaluation
  - Regulatory processes and regulatory decision support

Community Engagement

- Tools, technologies, and other strategies that address and improve community engagement to develop innovative health approaches
- Telemedicine or digital health applications that focus on research in rural populations
- Patient empowerment tools/apps that allow users to compare their treatment and outcomes to existing treatment guidelines and outcomes for normative populations
- Strategies to enhance quality and accelerate performance of dissemination and implementation research

Innovative Digital Tools and Technology

- Development of marketable digital health applications
- Tools and technologies that enhance the quality, safety, efficiency, and effectiveness of new innovations in community settings
- Tools, technologies, and other strategies that address medication adherence in clinical settings
- Implementation tools for clinical decision support algorithms in more than one hospital system
- Tools and technologies that help characterize human disease states and assist in assessing the impact of interventions

Rare Disease and Unmet Needs

Drug Discovery and Development

- Diagnostics or useful drug targets for rare diseases using Pangenome data
- Assays for high-throughput screening of rare disease-related targets
- Novel technologies for enzyme replacement therapies (e.g., new cell culture/expression system) to solve major bottlenecks in rare diseases research
- Prioritization scale for repurposing generic drugs for rare diseases (design interactions for clinical trials)
- Improved tools and technologies for biomarker development in rare diseases

Clinical Diagnosis and Disease Management

- Tools and technologies that address the rapid diagnosis and/or clinical management of rare diseases
- New diagnostics for rare diseases including quantum-based diagnostic methods/techniques
- Processes for streamlining ICD codes for rare diseases (or new ways to classify as ICD-code adjacent)
- Digital twins for rare disease research, diagnosis, and treatment

Note on Clinical Trials:

NCATS will not accept SBIR/STTR applications that propose clinical trials; all projects within the topics listed here must be for projects that do not propose clinical trials.