

NCATS SBIR & 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 & STTR research priorities.



Preclinical Drug Discovery and Development

- Innovative platforms for identification and prioritization of targets for therapeutic intervention with clear clinical impact; such as those that are: implicated for disease, have genetic variations that have been identified in functional regions of receptor targets, and/or have high potential for biased signaling that would promote the beneficial effects of receptor signaling and reduce the unwanted effects
- Tools and technologies to enable highthroughput screening of compound activity on currently "nondruggable" targets
- Assays for high-throughput screening of rare-diseases-related targets
- Co-crystallization high-throughput screening techniques
- Fluorescence probes to replace antibodies for determination of cellular protein translocation
- Phenotypic assay development, including stem cell technology platforms for human "disease-in-a-dish" applications and the evaluation of toxicity
- Interventions that target molecular pathways or mechanisms common to multiple diseases
- Platforms for non-antibody biologics, cellbased therapies and gene therapy discovery
- Small molecule and biologics analytical characterization
- Accelerated bioengineering approaches to the development and clinical application of biomedical materials, devices, therapeutics and/or diagnostics
- Development of novel technologies for enzyme replacement therapies (e.g., new cell

culture/expression system) to solve major bottlenecks in rare diseases research

- Innovative methods to determine alternative uses for existing therapeutic interventions for high priority areas, such as rare diseases and pain
- Tools and technologies that increase the predictivity or efficiency of medicinal chemistry, biologic or other intervention optimization
- Technologies to deliver nucleic acid
 therapeutics to tissues other than the liver
- Methodologies and technologies to increase
 efficiencies of manufacturing therapeutics
- Development of novel high-throughput technologies that focus on making translational research more efficient
- GMP production of exosomes/extracellular vesicles
- Generation of producer lines for large scale production of exosomes/extracellular vesicles
- Extracellular RNA-based biomarkers and therapeutics of human diseases
- Approaches to targeting the human microbiome for therapeutic or diagnostic purposes
- Scale-up, manufacturing and characterization of IPS cells
- 3D printing technologies
- Technologies to substantially improve the efficiency and reduce the cost of clinical grade gene therapy vector manufacturing
- Development of in vitro human tissue models (organs, 3D printing)
- Technologies to allow therapeutic proteins other than lysosomal enzymes to be

secreted and taken up by other cells via cross-correction

- Novel strategies to prevent deleterious immune responses to gene therapy, to improve efficiency in genome editing and/or enzyme replacement therapy
- Establishing more robust phenotypic screens that may help prioritize candidate compounds for further testing
- Innovative technology for non-small molecule delivery
- High-throughput epigenetics screening/ characterization tools and technologies
- Microphysiological systems (MPS)/Tissue Chips, including MPS/Tissue Chips that incorporate known functional variants (e.g., ACMG 59 or CPIC A alleles), for study comparison using the same derived genetic background across a set of tissue chips with the functional variant
- Volatile organic compounds (odors, scents) as biomarkers for disease
- Bacteriophage-based therapeutics for disease and as modulators of the microbiome and microbiome natural products
- High-throughput Surface Plasmon Resonance devices for detecting protein small molecule interactions
- New class of quantum-enabled sensing technologies for advancing translational sciences (e.g., point-of-care ultrasensitive high-throughput technologies for diagnostics, and miniaturized benchtop technologies for chemical/bioanalyte characterization)

) Biomedical, Clinical & Health Research Informatics

- 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
- Cloud-based tools and methods for meaningful sharing, re-use and integration of research data
- Novel platforms, technologies and tools for: (1) enabling clinical and translational research, particularly those with mechanisms for inclusion of patient-reported data and (2) integration of patient data collected from multiple devices and multiple/ diverse clinical studies
- Development of personalized phenotypic profiling (as well as personalized intervention) based on patient-centered integration of data from multiple data sources, including social media
- Development of predictive models for translational science
- Digital applications and tools (including telemedicine platforms) that facilitate/ enhance translational research and medicine in rural populations
- Generic Disease Registry template platforms that can be reused for multiple diseases
- Mobile device validation tools to ensure data from different brands or versions have compatible results

- Tools to assess with algorithms developed with artificial intelligence, machine learning
- Tools that allow for persistent identifier and attribution for data contributors that give credit to the data producers while ensuring that shared data has not been altered
- Patient Mobile Tool Platforms that facilitate tool developers to build "apps" that integrate into their medical records
- Tools and environments that enable an easy interrogation of publicly available data
- Innovative approaches like nanoneedles and nanoparticles to help improve early disease detection and targeted therapeutic delivery

Clinical, Dissemination and Implementation Research

- · Tools and technologies that:
 - Increase the efficiency of human subjects research, that facilitate the rapid diagnosis and/or clinical trial recruitment and subject tracking, institutional review board evaluation and/or regulatory processes
 - Evaluate and improve the process of informed consent
 - Address medication adherence in clinical settings
 - Address and improve community engagement
 - Address the rapid diagnosis and/or clinical management of rare diseases
 - Help characterize human disease states and assist in assessing the impact of interventions
 - Support unique approaches to advance diversity, equity and inclusion
 - Mine published data and generate usable knowledge and analytics to advance research
- Increased efficiency of clinical research conduct, including but not limited to regulatory decision support, patient eligibility analysis and recruitment and retention tracking
- Educational tools for clinical and translational science
- Computational or web-based health research methods, including:
 - Platforms for generally applicable and

scalable multi-disease registries and natural history studies

- natural history studies Clinical trial designs and analyses
- (e.g., for pragmatic clinical trials)
- Approaches, tools, platforms and environments that:
 - Integrate data in novel ways for development of new biomarkers that can be tested in translational research paradigms for which there are barriers or bottlenecks
 - Engage prospective research participants who are from under-represented communities and impacted by disparities and the digital divide
- Strategies to enhance the quality of and accelerate the conduct of dissemination and implementation research
- Sustainable solutions for effective tools and environments in translational research
- Development and validation of patient reported outcomes, clinician-reported outcomes and biomarkers for rare diseases that are not already supported by a disease-specific NIH Institute or Center
- Patient empowerment tools/apps that allow users to compare their treatment and outcomes to normative populations-existing treatment guidelines
- Telemedicine or digital health applications that focus on research in rural populations

Note on Clinical Trials:

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

For More Information

Small Business Opportunities ncats.nih.gov/smallbusiness

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National Center for Advancing Translational Sciences

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