NIH x HJF Ecosystem:
NIH Program Overview

November 3, 2026

1:00 p.m. ET

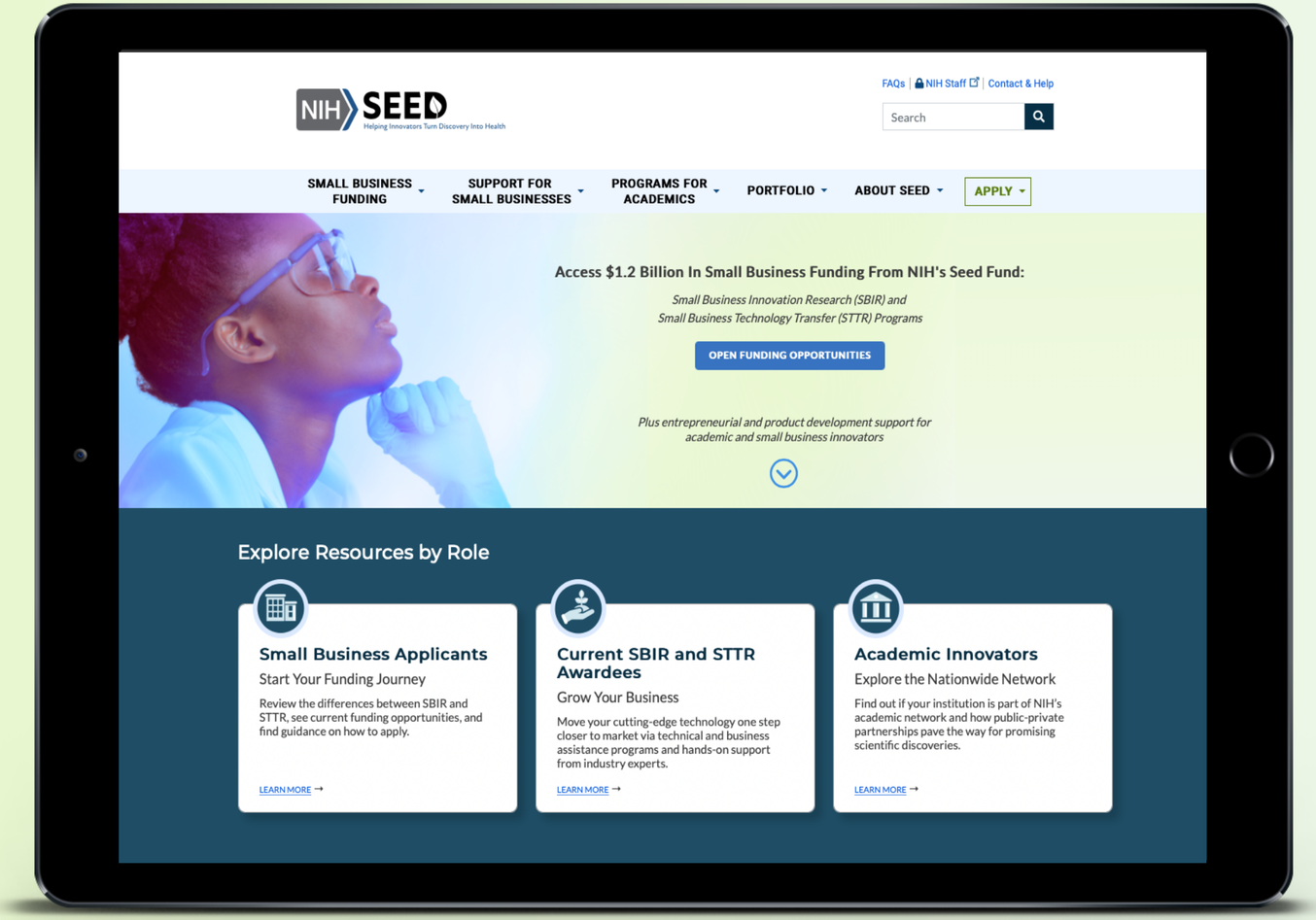
HJF Innovation Labs

NIH Speakers

NIH Small Business Program and NHLBI SBIR/STTR Overview	Stephanie Davis, Ph.D.
NINDS SBIR/STTR	Taryn Aubrecht, Ph.D.
NIGMS SBIR/STTR	Eddie Billingslea, Ph.D.
NIBIB SBIR/STTR	Stacie Gutowski, Ph.D.
NIAID SBIR/STTR	Kenneth Kim, M.S.
NIMH SBIR/STTR	Vasudev Rao, M.B.B.S., M.S.
NHLBI Catalyze Program	Rahul Thakar, Ph.D.
NIDDK SBIR/STTR	Marc Rigas, Ph.D.

NIH Small Business Program Overview

Small Business Program Website



seed.nih.gov

NIH Mission

National Institutes of Health
Turning Discovery Into Health

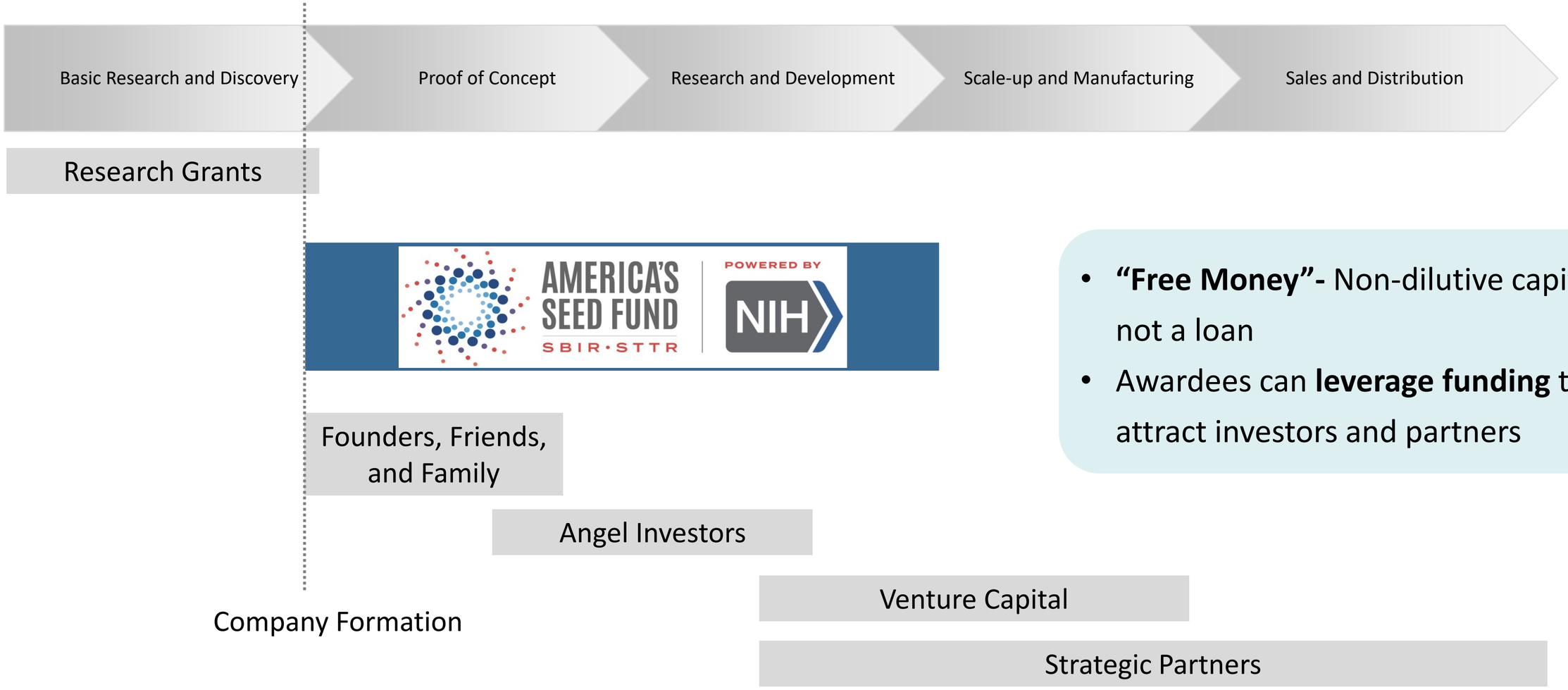





To seek fundamental knowledge about the nature and behavior of living systems and the ***application of that knowledge to enhance health, lengthen life, and reduce illness and disability****.*

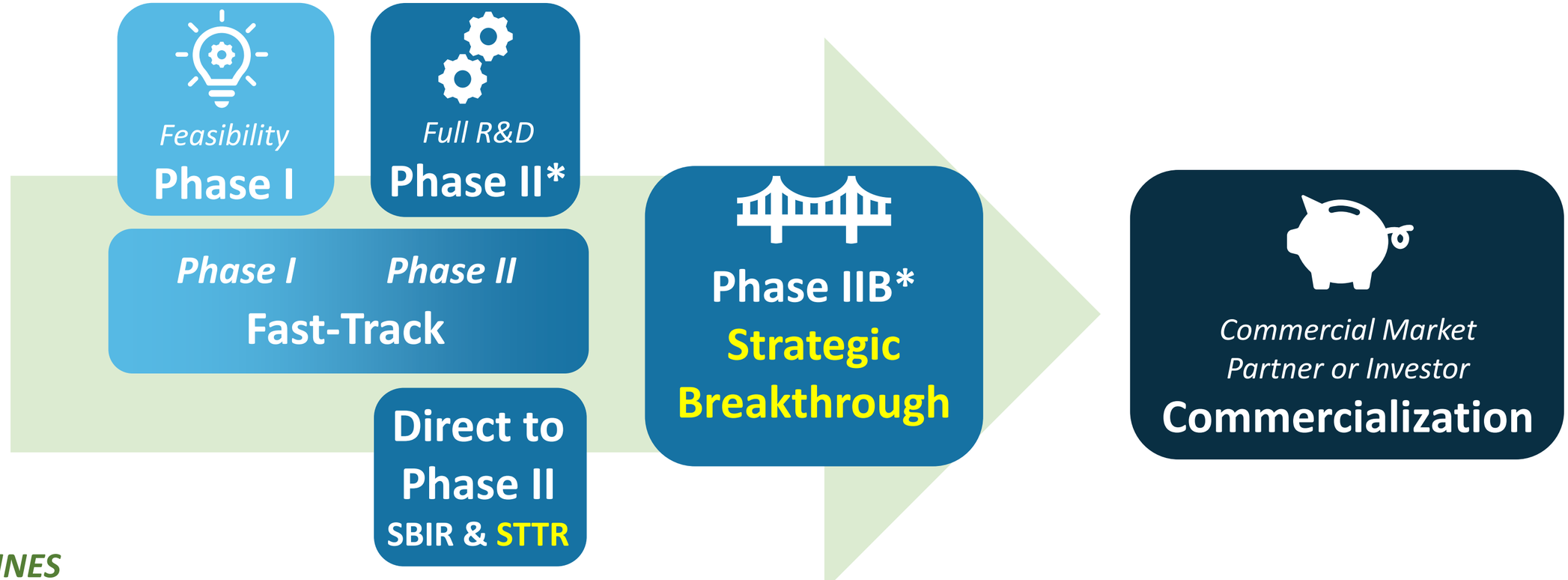
The Small Business Program helps NIH accelerate discoveries from bench to bedside

Benefits of NIH Funding



- **"Free Money"-** Non-dilutive capital and not a loan
- Awardees can **leverage funding** to attract investors and partners

Phased Programs



BUDGET GUIDELINES

Phase I: $335,937 funding 1-2 years

Phase II: $2,239,578 funding 1-3 years

NIH, CDC, ARPA-H can exceed these budgets for selected topics

Commercialization Readiness Program (CRP)*

**Only available to SBIR and STTR recipients*

Funding Opportunities



Parent Notices of Funding Opportunity (NOFOs)

- Parent SBIR: PA-27-100
- Parent STTR: PA-27-102
- Phase IIB Strategic Breakthrough (SBIR): PA-27-101
- Commercialization Readiness Pilot (CRP): PAR-27-098

Review the Small Business Funding Considerations and Contacts Webpage!

SBIR and STTR Critical Differences

Award is always made to the small business

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g., university)
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	Guidelines: Primary employment (>50%) with the small business	Employed by either the research institution partner or small business

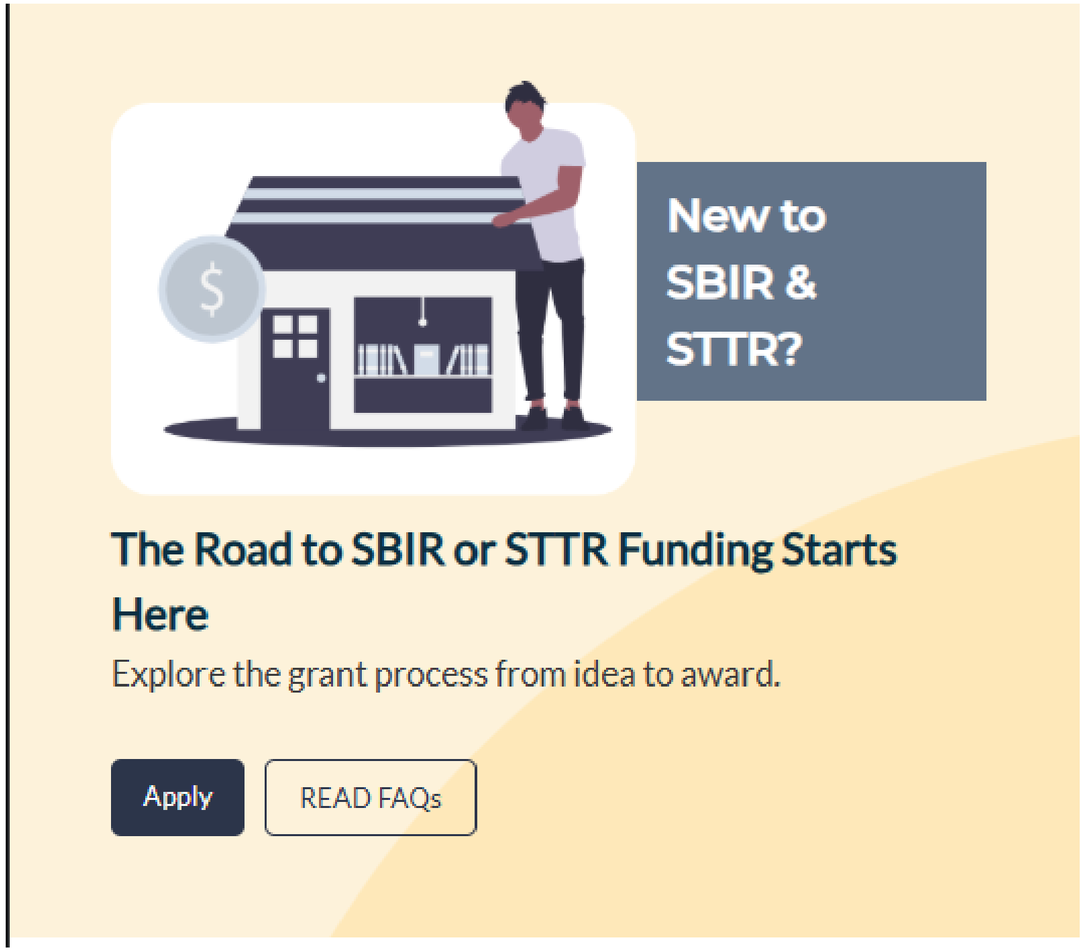
Eligibility Criteria

Determined at the time of award

SBA eligibility guide: sbir.gov/apply

- Organized as for-profit US business
- Small: 500 or fewer employees, including affiliates
- Individual Ownership:
  - Greater than 50% US-owned by individuals and independently operated <OR>
  - Greater than 50% owned and controlled by other business concerns that are greater than 50% owned and controlled by one or more individuals, an Indian tribe, ANC or NHO (or a wholly owned business entity of such tribe, ANC or NHO) <OR>
  - **SBIR ONLY**: Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these
- Work must be done in the US
  - Foreign Subawards/subcontracts: Only unfunded international collaborations or foreign components will be considered

Application Resources



Prepare Your Application (seed.nih.gov/howtoapply)

- Application Instructions
- Annotated Form Set
- Sample Applications
- State Resources through SBA FAST Program

Most Important Piece of Advice



24 of the NIH's Institutes fund small business R&D projects through the SBIR and STTR Programs.

Learn More

Talk to a Program Officer at least a month before the application deadline!

Small Business Funding Considerations and Contacts

Small Business Funding Considerations and Contacts

The information found in the Small Business overview applies across all NIH institutes, centers, and offices (ICOs). This page provides ICO-specific interest areas, due dates, and contacts related to small business.

Expand All

- National Center for Advancing Translational Sciences (NCATS) +
- National Center for Complementary and Integrative Health (NCCIH) +
- National Cancer Institute (NCI) +
- National Eye Institute (NEI) +

Not sure who to contact?

- Program Official
- Awarding IC Funding Contact
- Email: SEEDinfo@nih.gov

Connect with SEED

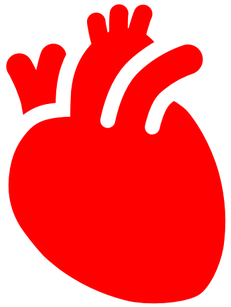
seed.nih.gov/

SEEDinfo@nih.gov



NIH Central Resource for Research Grants and Funding Information:
grants.nih.gov

NHLBI Mission Space

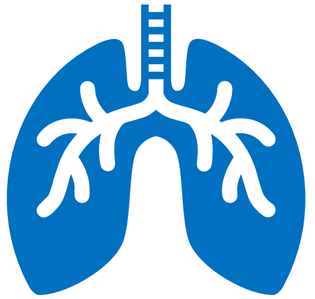


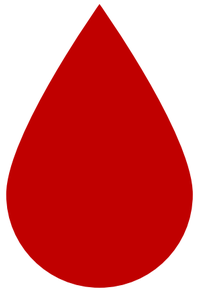
Heart

- Arrhythmias
- Atherothrombosis
- Heart Failure
- Congenital Heart Defects
- CAD
- Hypertension

Lung

- ALI/ARDS
- Asthma
- COPD
- Cystic Fibrosis
- Fibrotic Lung Disease
- Pulmonary Hypertension





Blood

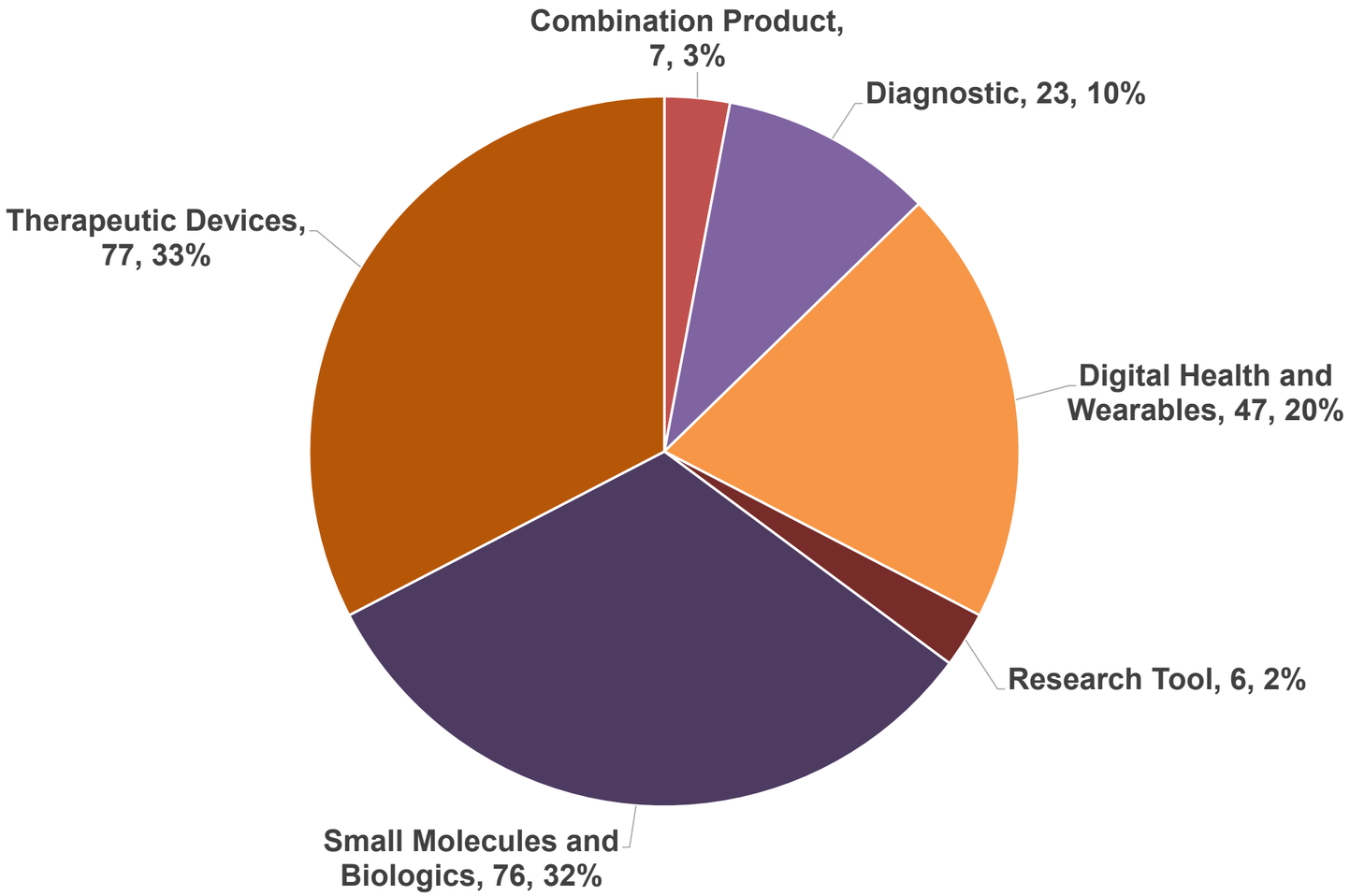
- Bleeding Disorders
- Anemia
- Myeloproliferative Disorders
- Sickle Cell Disease
- Thrombotic Disorders
- Transfusion Medicine

Sleep

- Circadian Disorders
- Insomnia
- OSA
- Sleep-Disordered Breathing



NHLBI Small Business Program Portfolio



~$130M Annual budget

>230 Active Projects

NHLBI Budget

Mechanism	Max Budget	Project Period
Phase I SBIR (R43) Phase I STTR (R41)	$400,000 total costs	1 – 2 years
Phase II SBIR (R44) Phase II STTR (R42)	$3,000,000 total costs	2 – 3 years
Strategic Breakthrough Phase IIB SBIR	$4,500,000 total costs	3 – 4 years
Commercialization Readiness Pilot (SB1)	$500,000 total costs	1 – 2 years

Please contact us before applying if you anticipate your budget exceeding these limits

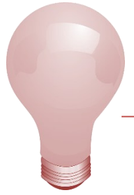
NHLBI Small Business and Product Development Support

NHLBI Innovation & Commercialization Office

Application Services



- Outreach and Education
- Proposal Guidance
- Application Questions
- Applicant Assistance Programs





Technology & Innovator

NHLBI Funding

- SBIR/STTR (>$130M)
  - Phase I,II, IIB, CRP
- Other translational programs

Academic and Small Business Innovation

Awardee Opportunities

Product Development Guidance

Entrepreneurs-in-Residence
- 1:1 Consults
  - IP, Regulatory, Reimbursement, HEOR, Business Development
- **Entrepreneurial Education**

Supplemental Support

- **Customer Discovery**
- **Technical and Business Assistance**
- **Commercialization Readiness**

Partnership & Investment Initiatives

- **Pitch Coaching/Conference Access**
- **Opportunity to connect with investors and partners**
- **AI-driven partnering platform**



Adoption & Health Impact

Connect with Us!



Sign up for our Newsletter

https://bit.ly/438X8XD

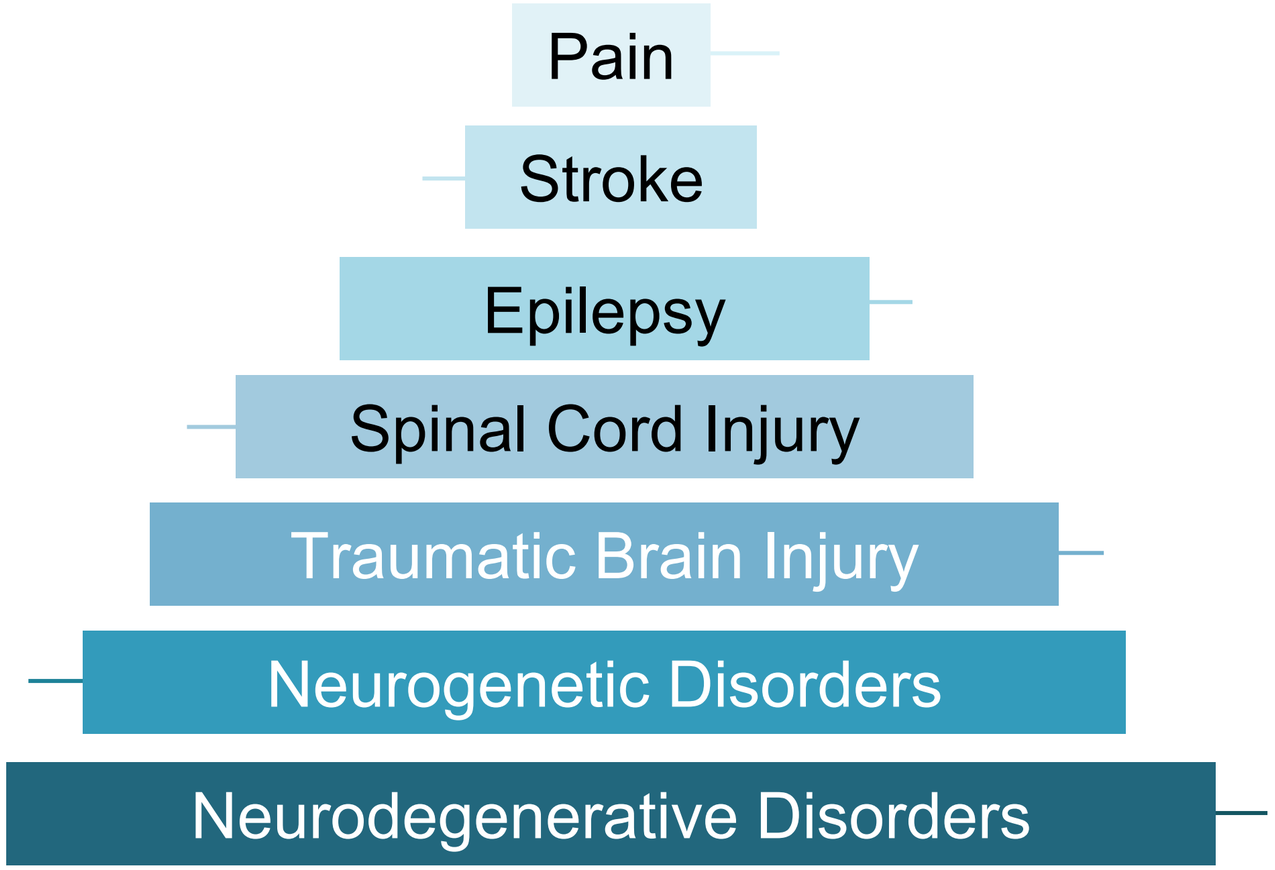
Email us at NHLBI_SBIR@mail.nih.gov

NIH National Heart, Lung, and Blood Institute

NINDS Mission

To seek fundamental knowledge about the brain and nervous system and use that knowledge to **reduce the burden** of neurological disease for **all people.**

The NINDS mission space encompasses hundreds of neurological disorders



NINDS Small Business Funding Overview

All technology modalities

- Small Molecules
- Biologics
- Medical Devices
- Diagnostics
- Digital Health
- Clinical Tools
- Research Tools

Broad range of development stages

drug discovery → prototyping → *in vitro* testing → preclinical development → clinical research → early-stage clinical trials



All neurological indications within the NINDS mission space

$100M per year
(includes HEAL, BRAIN, AD/ADRD)

*Largest source of seed funding for neuroscience companies

Program Priorities:

New Companies	New Technologies	Strong Commercial Potential and Market Fit	Unmet Needs and Small Markets

NINDS Budget Limits

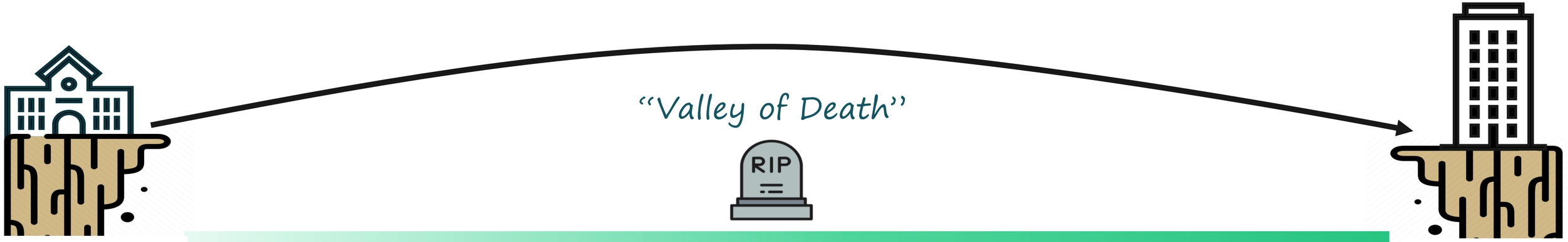
	Total Funding Support	Duration
Phase I	$700K	6-24 months
Phase II	$3 Million	12-36 months
Phase IIb	$3 Million	12-36 months
CRP	$2 Million	12-36 months

* *Award amounts reflect SBA-approved hard cap waiver. Applies to only specific topics*

NINDS SMALL BUSINESS PROGRAM

More than a check:

Supporting companies on their journey from bench to bedside



BASIC RESEARCH FUNDING

NINDS Small Business Funding

PRIVATE FUNDING/ REVENUE

- REACH Hubs
- NIH I-Corps
- CRO support
- Executive Roundtables
- Business Assistance Supplements
- NINDS Dolphin Tank
- Company Showcase Events
- Commercialization Readiness Program
- SBIR/STTR Outreach
- C3i Concept to Clinic
- Company Needs Assessment
- Consultant support
- Business Experts
- Pitch Coaching
- Business Advising
- Investor and Industry Network
- Embedded Entrepreneur Program

NINDS SMALL BUSINESS PROGRAM



National Institute of General Medical Sciences

Eddie Billingslea, PhD

Small Business Strategy Coordinator

NIGMS Small Business program: At a glance

NIGMS Mission

- NIGMS supports tools and technologies focused on:
  - basic research that lays the foundation for advances in disease diagnosis, treatment, and prevention.
  - research in specific clinical areas like sepsis, anesthesiology, and wound healing
  - efforts to build research capacity

NIGMS SBIR/STTR Topics of Interest

- **Technology & Data:** Scientific instrumentation, computational technologies, data science, and platform technologies for basic research.
- **Pharmacology & Health:** Platform technologies for drug discovery, medicinal chemistry, anesthesiology, wound healing, and sepsis.
- **Capacity Building & Education:** Products to enhance scientific research capacity and science education.

Key NIGMS pipeline programs

- **Technology Development Program (R01):** A "feeder" program supporting the creation of new technologies.
- **Research Evaluation and Commercialization Hubs (REACH):** Provides funding, training, and project management to help scientific discoveries become promising healthcare solutions.

Small business programs: By the numbers

- **Annual Budget:** ~$100M
- **Phase I SBIR/STTR budget:** up to $700k
- **Phase II SBIR/STTR budget:** up to $3M
- **Applications Received:** ~350 per year
- **Success rate:** ~28%

National Institute of Biomedical Imaging and Bioengineering

Technologies to Shape the Future of Health

NIBIB Small Business Program



November 3, 2026

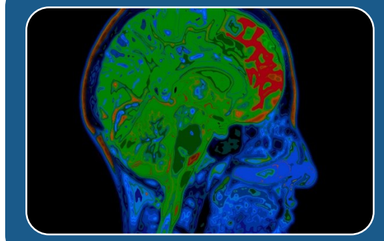
Stacie Gutowski, PhD
Program Director | NIBIB
NIBIB-SBIR@mail.nih.gov

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

NIBIB Mission:

*To **transform, through technology development**, our understanding of disease and its prevention, detection, diagnosis, and treatment.*

*NIBIB supports new tools and technologies to **improve human health** within its internal laboratories and through grants, collaborations, and training.*



Division of Applied Science and Technology (Bioimaging)

- Bio-Electromagnetic Technologies
- Bioanalytical Sensors
- Image-Guided Interventions
- Magnetic Resonance Imaging
- Nuclear Medicine
- Molecular Probes and Imaging Agents
- Optical Imaging and Spectroscopy
- Photoacoustic/Optoacoustic Technologies
- Ultrasound: Diagnostic and Interventional
- X-ray, electron, and Ion Beam



Division of Discovery Science and Technology (Bioengineering)

- Bionics
- Medical Devices
- Medical Simulators
- Robotics
- Physiomimetic Materials
- Nanomaterials
- Biomolecular Technologies
- Cellular and Multicellular Technologies
- Living Materials
- Manufacturing and Biomanufacturing Tools
- Screening and High-Throughput Tools
- Molecular Materials



Division of Health Informatics

- Artificial Intelligence, Machine Learning , and Deep Learning
- Digital Health- Mobile Health and Telehealth
- Biomedical Informatics
- Point of Care Technologies – Diagnostics
- Image Processing, Visual Perception and Display
- Bioanalytical Sensors

Technology Development

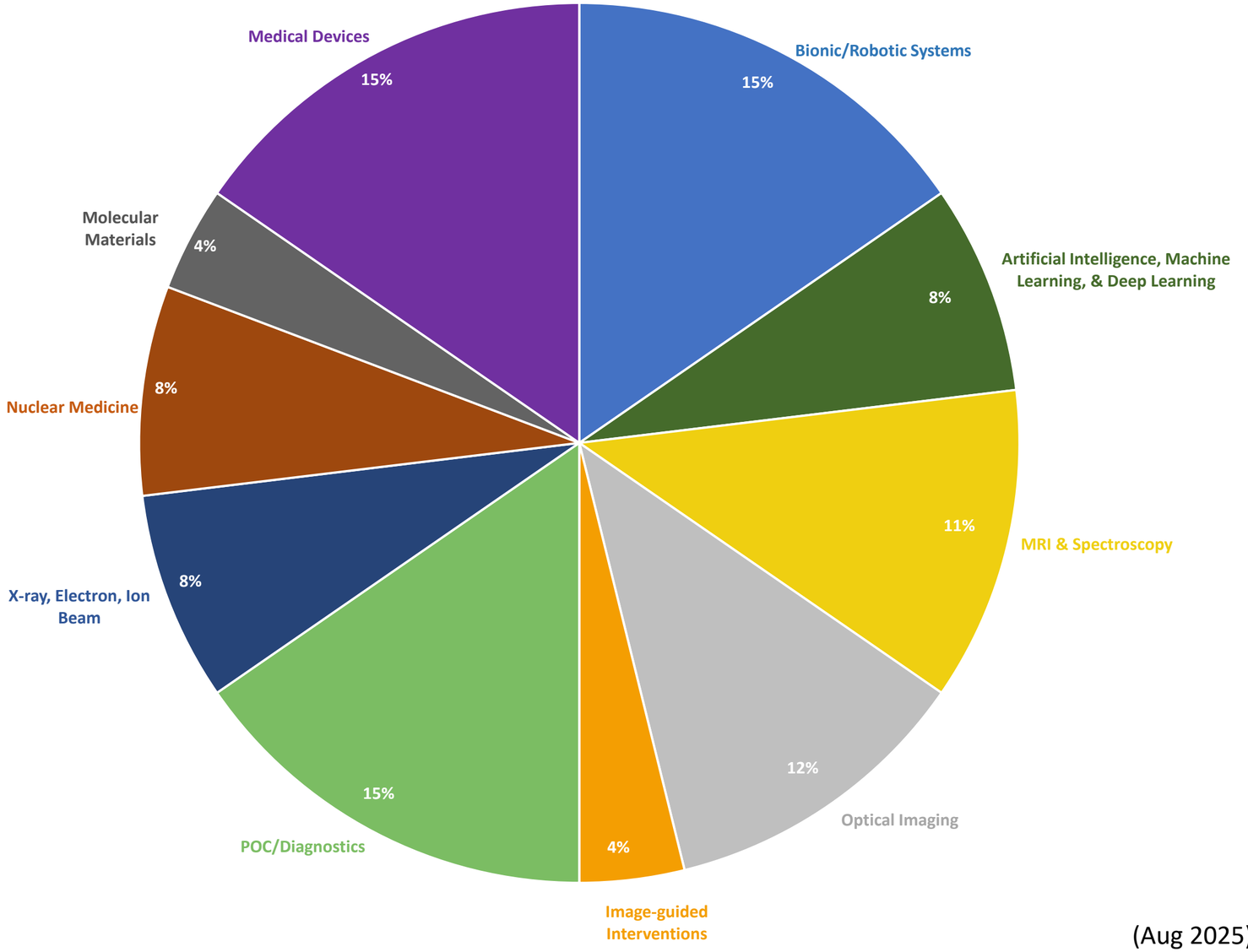
Broadly Applicable

Advancing Human Health

NIBIB Small Business Overview

Support innovative technologies through various stages of commercial research and development

- ≤ 1 yr for Phase I
- ≤ 2 yrs for Phase II
- SBA Budget Guidelines
  - $335,937 for Phase I
  - $2,239,578 for Phase II
- Early stage/feasibility CTs (NOT-EB-21-005)
- NIBIB does not participate in Phase IIB



(Aug 2025)

NIBIB Support for Small Businesses

Funding

- **SBIR (R43/R44):**
  - PA-27-100 - Clinical Trial Optional
- **STTR (R41/R42):**
  - PA-27-102 - Clinical Trial Optional
- **Commercialization Readiness Program (CRP) (SB1):**
  - PAR-27-098 – Clinical Trial Optional
  - NIBIB does **NOT** accept clinical trials under the CRP
- **Small Business Transition Grant for New Entrepreneurs**
  - STTR (R41/R42): PAR-27-040* - CT Optional
  - SBIR (R43/R44): PAR-27-039* - CT Optional

*Forecasted on Grants.gov

Other Support

- **Commercialization Enhancement Programs**
  - *Concept to Clinic Commercializing Innovation (C3i) Program*
  - Regulatory and Business Development Consultations
  - Partnering and Investment Opportunities
- **NIH Technical and Business Assistance (TABA)**
  - TABA Funding
  - Needs Assessments

Concept to Clinic: Commercializing Innovation (C3i) Program



Provides specialized **business frameworks** and essential tools for **successful translation** of biomedical technologies from the lab (**concept**) to the market (**clinic**)

- ✓ Assess unmet market need
- ✓ Assess the commercial viability
- ✓ Customized curriculum
- ✓ Tailored Mentoring

Program Partners

- NIBIB
- NHLBI
- NIDDK
- NINDS
- NIMH
- NIA
- NICHD
- NIGMS
- NCI
- NINR
- NIH BRAIN Initiative

https://www.nibib.nih.gov/research-program/c3i-program

C3i Program Overview

EDUCATION

eC3i
12 weeks
Jun-Aug

- Online curriculum, virtual training course
- Tailored access to experienced Business Advisors (BA) and Project Managers (PM)
- Stakeholder Interviews
- Final presentations on value proposition
- Teams can be selected for participation in C3i Program

VALIDATION & EXECUTION

C3i
24 weeks
Oct-Apr
In-person Boot Camp (Feb)

Phase 1
- Needs Statement
- Stakeholder Analysis/Interviews
- Value Proposition
- Business Rationale
- Weekly calls with BA/PM
- Homework Presentations
- Final Business Rationale Presentations

Phase 2
- Regulatory/Reimbursement
- Killer Experiment
- Healthcare Economics
- Intellectual Property
- Sales and Marketing
- Milestones and Valuation
- Manufacturing and Logistics
- Pitch Coaching
- Final Presentations

ACCELERATION

C3i Accell
12 months
Jun-Jun

- Supports academic teams who successfully completed C3i
- ≤1 year and ≤$150k total costs
- Milestone-driven, proof-of-concept studies
- Continued BA and PM support
- Business formation, strategic partnerships, licensing
- Preparation of SBIR/STTR grant application

Concept to Clinic: Commercializing Innovation (C3i) Celebrates 10 Years

Goal:
Provide NIH grantees with essential business frameworks and specialized mentoring for successful translation of biomedical technologies from lab (concept) to market (clinic)

Objectives:
- Validate an unmet market need
- Validate a viable business opportunity
- Build a compelling pitch to secure support from investors and partners

Outcomes:

- **223** Teams Trained
  - 115 Academic (RPG) Teams
  - 108 Small Business Teams
  - **>540** Individuals
- **54%** Phase I to Phase II conversion rate (~2x the NIH Phase II success rate)
- **>$600M** in Private Funding Raised*
- **>40** Successfully Launched Products

*PitchBook Data. (n.d.). Retrieved May 29, 2024, from https://pitchbook.com/

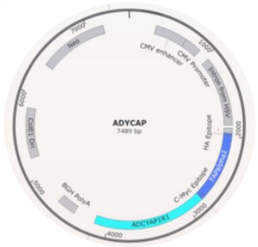


https://www.nibib.nih.gov/research-program/c3i-program

Sample Products on the Market



TriLambdaXRM-30
Sigray



FAP-tagged GPCRs
SpectraGenetics, Inc.



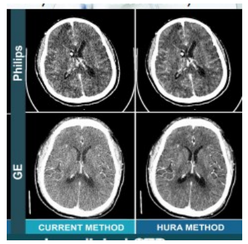
Accuro
Rivanna Medical



Vayu Oxygen Blender System
Vayu Global Health Innovations



Magellan
Orthocare Innovation



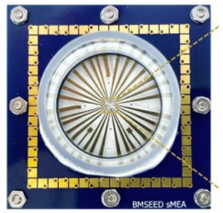
Hura CPT
Hura Imaging



ActivSight
Activ Surgical



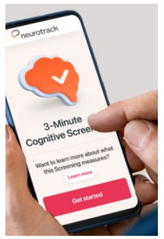
AnemoCheck
Sanguina



Stretchable MicroElectrode Array
BMSeed



Retitrack
C. Light Technologies



Neurotrack App
Neurotrack Technologies

RADx® Health Technology Development

- NIBIB RADx® program supports rapid development of health technologies
- Not SBIR funding, utilizes contracts with federal partners; includes wrap-around support
- New funnels launching late 2026

MIDLIFE

Advancing non-hormonal approaches to diagnose, monitor, and treat midlife-related conditions in women.

https://cimit.org/midlife/

Pediatric Medical Device Pilot

Accelerating point of care and digital health technologies for neonates and infants.

https://cimit.org/pediatricmedicaldevices/

Contact Us!



Kari Ashmont, PhD
Translational Team Lead



Stacie Gutowski, PhD
Program Director



Todd Merchak
Director, Office of Program Evaluation and Strategic Partnerships

- www.nibib.nih.gov/programs/small-business-programs
- Subscribe to the SBIR/STTR Listserv:

  Email LISTSERV@LIST.NIH.GOV with the following text in the message body: **subscribe SBIR-STTR your name**

NIBIB-SBIR@mail.nih.gov

NIAID Small Business Programs



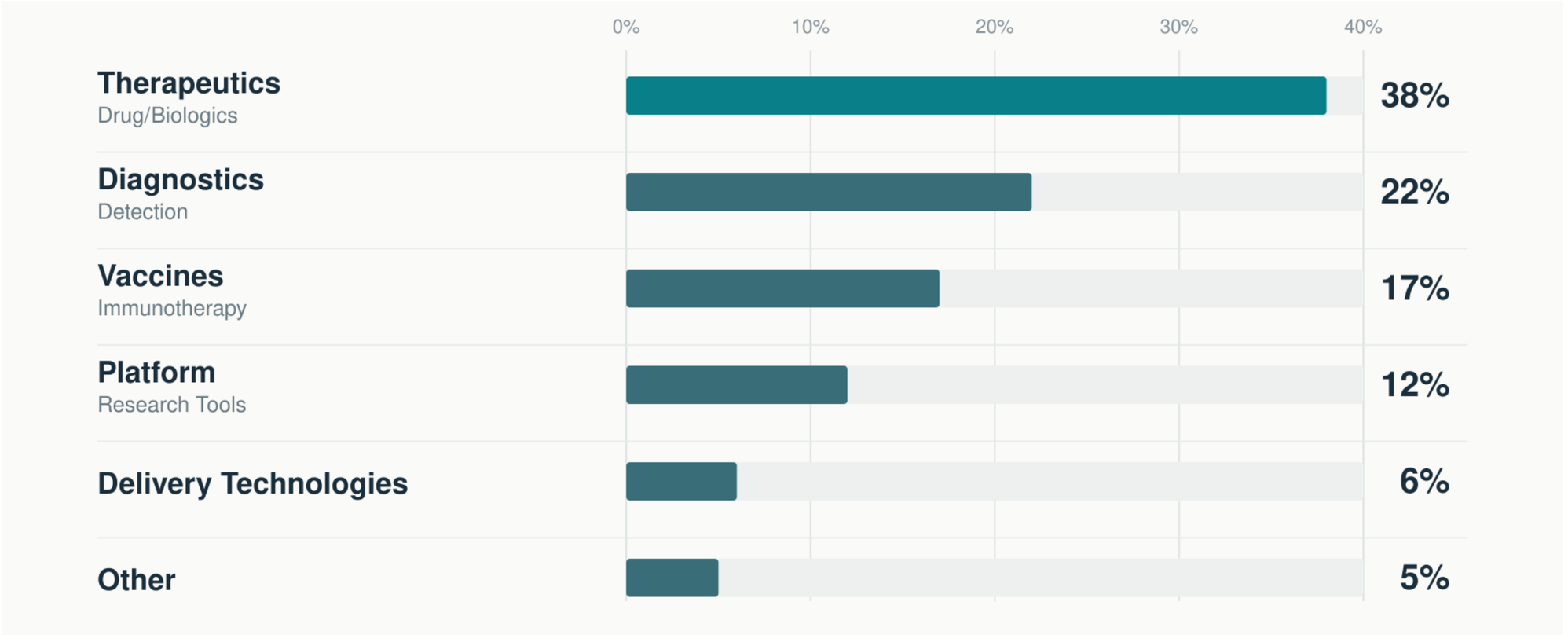
Kenneth Kim
Acting Small Business Program Manager
November, 2026

NIAID Mission

- The NIAID Mission is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.

- $195M annual SBIR/STTR budget supports product development and commercialization in:
  - The immune system, microbe biology, and host-microbe interactions
  - Diagnostic and prevention strategies
  - Treatment and cure strategies

NIAID SBIR/STTR Portfolio by Technology Type



NIAID SBIR/STTR Waiver Budget Limits & Clinical Trials

Phase	Budget Limit Total Cost	Support Years	Accepts Clinical Trial SBIR	Accepts Clinical Trial STTR
Phase I SBIR & STTR	$700K	1-2	✓	✗
Phase II SBIR & STTR	$3M	1-3	✓	✗
Phase IIB Strategic Breakthrough SBIR Only	$3M	1-3	✓	N/A
Commercialization Readiness Program SBIR Only	$2M	1-3	✗	N/A

Approved Waiver Topics

NIH National Institute of Allergy and Infectious Diseases

NIAID

Important Advice

- Start and submit your application early
- Applicants are STRONGLY encouraged to talk with a Program Officer at least one month before the application deadline
- Please send a one-page, non-confidential abstract that includes specific aims to

NIAIDSBIR@mail.nih.gov

National Institute of Allergy and Infectious Diseases

NIAID

National Institute of Mental Health (NIMH)

SBIR/STTR Programs

For more info:

Neurotechnologies

Improve Functional Measurement and Visualization of CNS

- Microscopy
- Electrophysiology
- Brain Imaging
- Clinical CNS Activity/ Function Measures
- Clinical Grade Processing/ Analysis Pipeline

Interventions

Novel, Targeted to Improve Clinical Function

- Drug Discovery & Development
  - Novel CNS Targets
  - Unbiased Screening, Formulation
- Medical Devices
- Digital Health Technologies
  - Screening, Assessment, Treatment, Clinical Decision Support

Biomarkers

Objective Measure of Subject Function

- CNS measures
- Subject Level Data
- Developmentally Sensitive
- Composite Measures
- Standardization of Data
  - Collection, Processing, Analytics
- Clinical Grade and FDA cleared

HIV/AIDS

Basic, Behavioral and Implementation Science

- CNS Co-morbidities & CNS Viral Reservoir
  - Understanding, Prevention & Diagnosis
- Tools for the Clinic
  - Prevention, Testing, ART Adherence
  - Management & Alleviation of Mental Illness
  - Reduction of Violence, Stigma & Trauma Related to HIV

Mission: *To transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure.*

NIH National Institute of Mental Health

CATALYZE
Accelerating Translation

NHLBI Catalyze: An Overview for NIH

Rahul G. Thakar, Ph.D. Acting Scientific Director, Catalyze

Tuesday, November 3, 2026

NIH National Heart, Lung, and Blood Institute

Catalyze Background

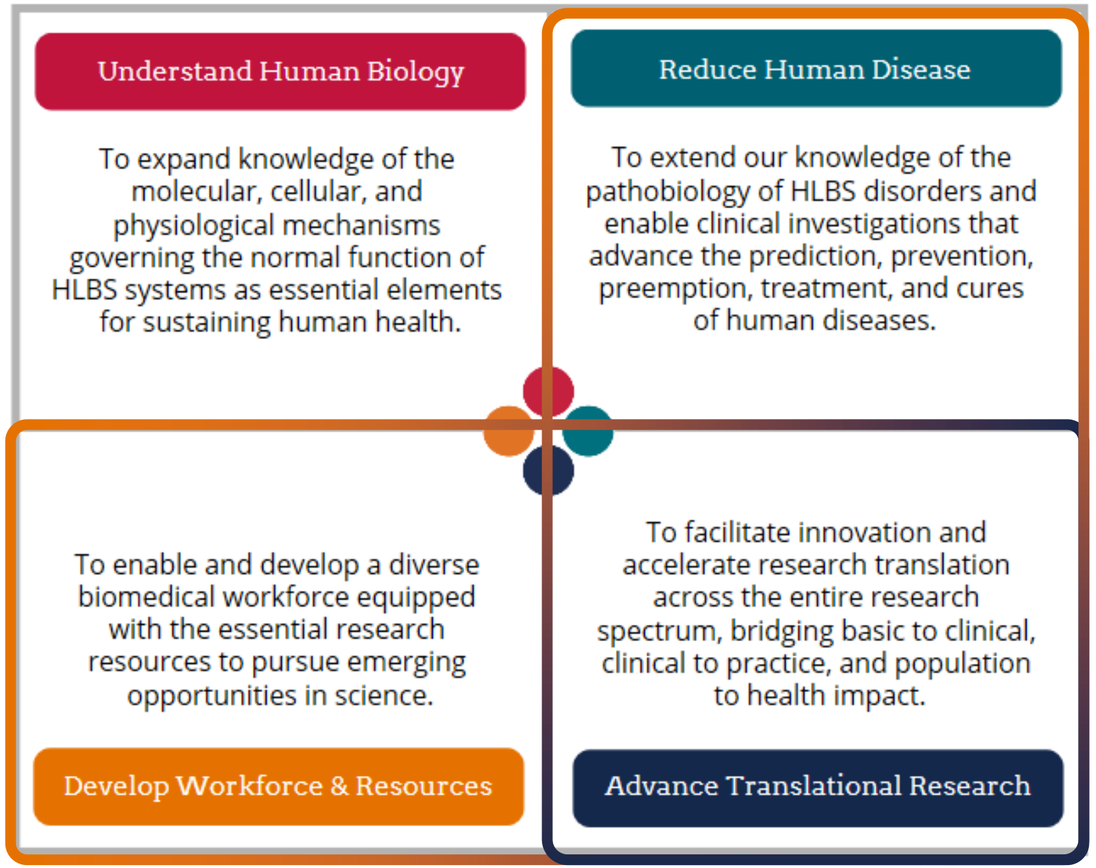
NHLBI Strategic Vision

4 Mission-Driven Goals

NHLBI Catalyze Program

Provides a bridge from basic to clinical research across the entire Heart, Lung, Blood, Sleep research spectrum

Trains a diverse scientific workforce fluent in product development and entrepreneurship



Two Decades of NHLBI Translational Programs

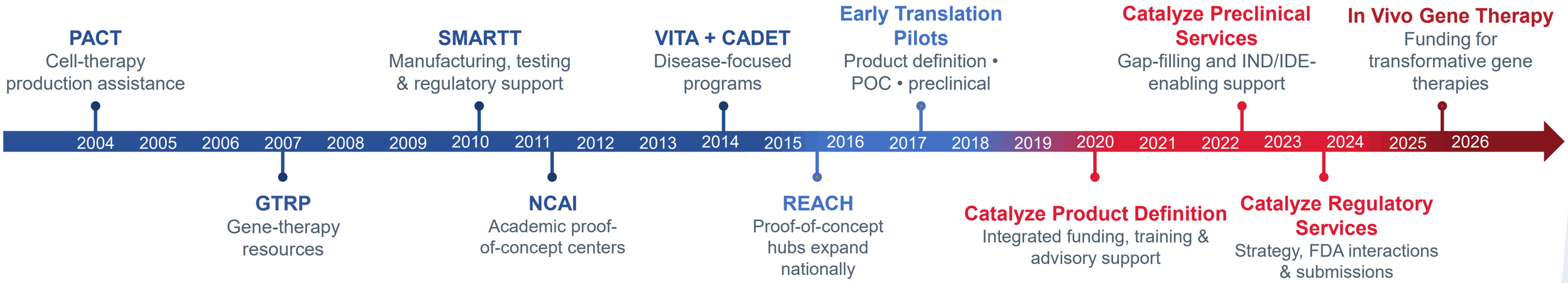
From specialized translational resources to an integrated, end-to-end Catalyze platform

Foundational Programs — Specialized product-development resources

Integration Pilots — Early translation portfolio

Catalyze — Coordinated translational continuum

Gene Therapy



What changed with Catalyze

A portfolio of targeted programs evolved into a coordinated pathway spanning validation, product definition, preclinical development and regulatory readiness.

1 Coordinated Funding

Grant mechanisms plus flexible service support

2 Milestone-driven Delivery

Individualized plans and project management

3 Integrated Expertise

Scientific, technical, regulatory & commercialization

4 Workforce Development

Training, mentorship & entrepreneurship

Specialized resources → **Integrated translational platform**

NHLBI Catalyze Program Mission & Strategy

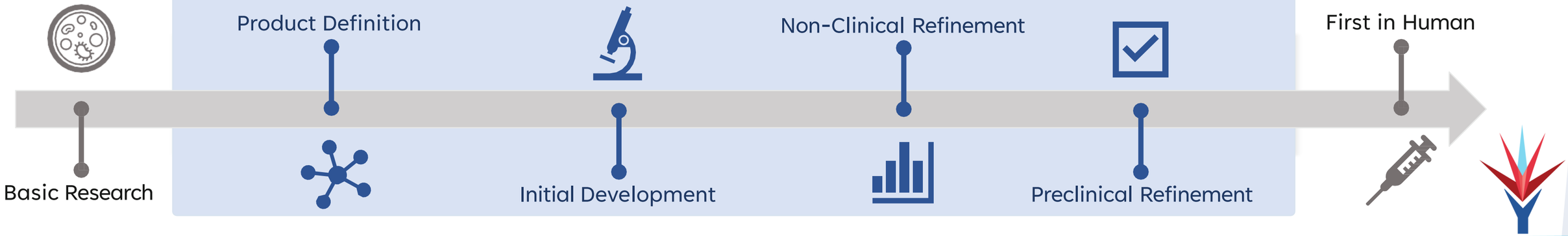
MISSION

To *accelerate* promising biomedical discoveries into therapeutics and devices by equipping teams **to advance toward first-in-human testing** and training a translational workforce fluent in product development and entrepreneurship.

Strategy

- Network of Translation Expertise
- Leveraged Federal Investments
- Milestone-Driven Support
- Risk Mitigation and Program Flexibility

CATALYZE COORDINATING CENTER SUPPORT



Catalyze CC Resources

Product Development Support

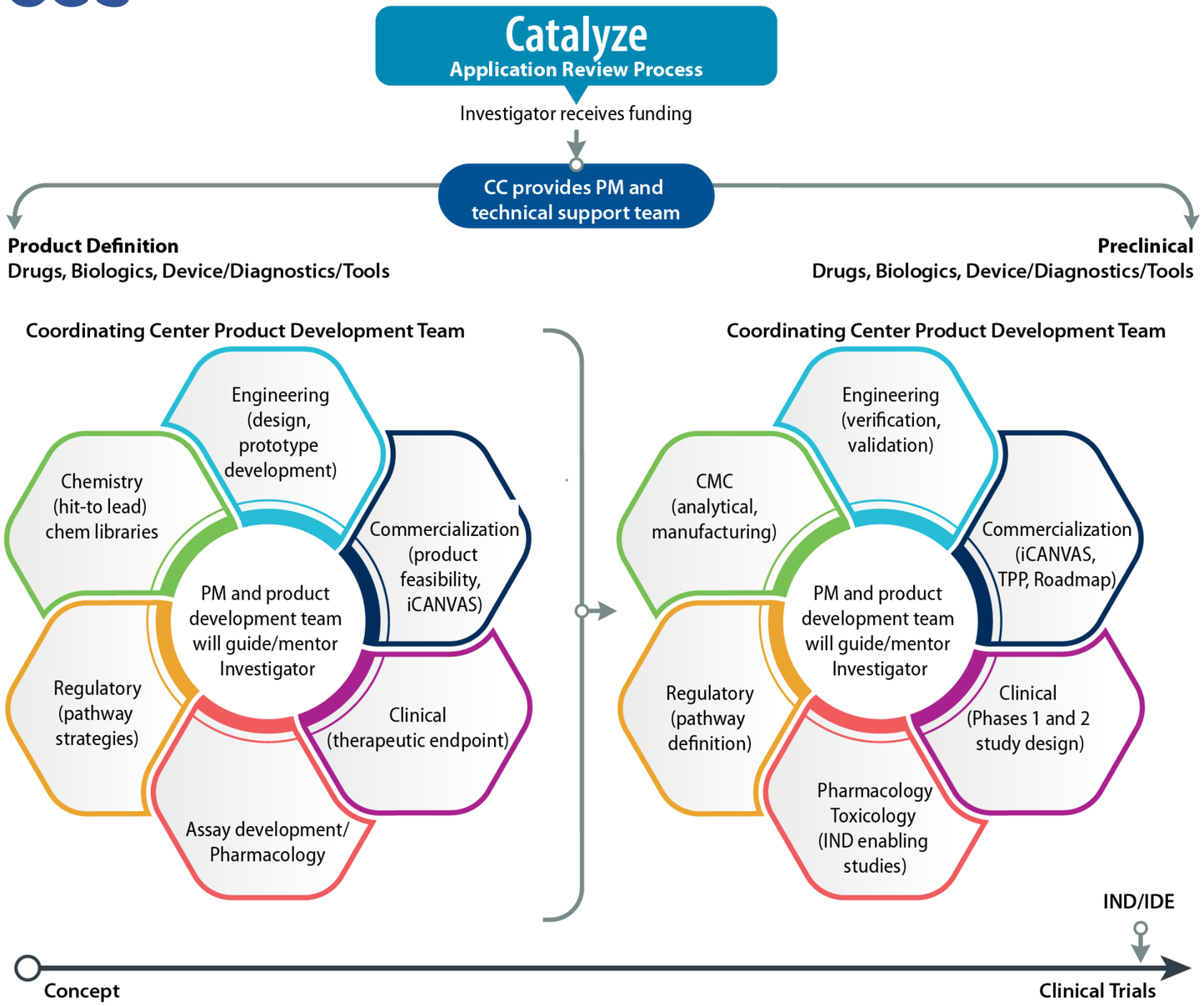
- Therapeutics
  - Chemistry
  - Pharmacology
  - Assay development
  - Toxicology
- Engineering support
  - Prototype development
  - Design verification and validation
- Regulatory Affairs
  - Strategy development
  - FDA Submissions

Commercialization Support

- Technology readiness
- Feasibility
- Intellectual property

Skills Development

- Courses, workshops



Catalyze Is Producing Measurable Translational Outcomes

Six years of operating experience – this is not a pilot concept.



$88.9 M

Follow-on funding raised

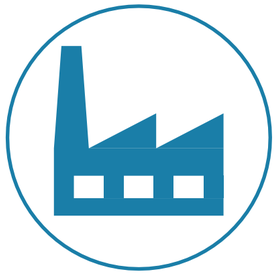
1.16× NIH investment



24

SBIR/STTR awards

39 applications



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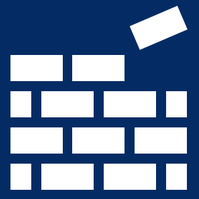
Start-ups formed



Catalyze is generating follow-on capital, new companies, and downstream NIH investment across its translational portfolio.

The Catalyze Framework Successfully Supports a Broad and Evolving Technology Portfolio

Flexibility across technologies. Breadth across science.

TECHNOLOGY PORTFOLIO — ALL CATALYZE PROJECTS (n = 99)*

Product Definition & PreClinical

Medical Devices	Drugs	Cell & Gene Therapy	Biologics (Non–Cell/Gene)	Research Tools	Combination Products
31	29	10	13	12	4
Projects	Projects	Projects	Projects	Projects	Projects

Catalyze supports a diverse range of technologies and platforms from molecules to devices, cell and gene therapies, tools, and combination products to address complex translational challenges.

BREADTH ACROSS NHLBI SCIENTIFIC AREAS — ALL CATALYZE PROJECTS (n = 99)*

HEART	LUNG	BLOOD	SLEEP
48	27	21	3
Projects	Projects	Projects	Projects

Different technologies. Different scientific priorities. Different development challenges. One flexible framework.

* n=99 portfolio, June 2026

NHLBI CATALYZE PROGRAM

IN VIVO GENE THERAPY INITIATIVE

TARGET AUDIENCE

U.S. Academics, Non-Profits & Small Businesses

In Vivo Gene Therapy: Scope, Key Barriers & Application Process

PROGRAM SCOPE & FUNDING

High-Risk, High-Reward (TRL 1–2)

NHLBI explicitly funds early-stage concepts considered "too early or too risky" for conventional mechanisms to break translational bottlenecks.

Proof-of-Concept Framework
12–18 month milestones designed to validate biological feasibility and translatability.

Therapeutic Focus
Starting with Hematopoietic Stem Cells (HSCs) in Sickle Cell Disease; expandable across blood disorders.

Priority Platforms
Novel viral vectors, targeted LNPs, non-viral delivery, and immune-evasive gene editing systems.

BOTTLENECKS ADDRESSED

Four Key Biological Barriers

Proposals must directly target at least one foundational field-wide barrier defined from community consensus workshops:

1. **In Vitro vs. In Vivo Mismatch**
   Discordance between laboratory cell assays and in vivo delivery efficacy.
2. **Model Translatability**
   Uncertainty in how humanized mouse models predict human clinical outcomes.
3. **Immune Tolerance**
   Poorly understood host immune responses to newly expressed therapeutic proteins.
4. **Niche Intercellular Crosstalk**
   Lack of systems modeling complex bone marrow stem cell microenvironments.

HOW TO APPLY

3-Stage Application Funnel

A streamlined intake process designed to rapidly vet disruptive concepts prior to full external peer review:

1. **Expression of Interest (EOI)**
   Submit ≤1,000-word concept form online. Covers IP status, barrier alignment, and preliminary aims.
   Deadline: Sept 20, 2026
2. **NIH Pitch Day (Invite-Only)**
   Required 1-day in-person presentation at NIH (Bethesda, MD). Travel reimbursed via GSA per diem.
   Date: November 5, 2026
3. **Full Application & Review**
   Prioritized concepts invited to submit complete proposals for external scientific evaluation.

NHLBI_catalyze@mail.nih.gov nhlbicatalyze.org/invivo

Catalyze Is a Flexible, Adaptive Platform

Catalyze meets technologies where they are.

MULTIPLE ENTRY POINTS

PRODUCT DEFINITION

Define and de-risk the product concept

- Feasibility
- Target product profile
- Prototype/assay development

PRECLINICAL DEVELOPMENT

Generate evidence needed for regulatory advancement

- Safety/efficacy
- Manufacturing/CMC
- Engineering validation

TOWARD FIRST-IN-HUMAN

Prepare technologies for the next stage of development

- Regulatory strategy
- IND/IDE readiness
- FDA engagement

SUPPORT SCALES AND ADAPTS AS PROJECT NEEDS EVOLVE

Technical Expertise
Project-specific SMEs and consultants

Regulatory Support
Strategy, submissions, and FDA engagement

Commercialization Support
IP strategy, market insights, and pathways to follow-on capital

Milestone-Driven Management
Progress tracking, risk management, and go/no-go decisions

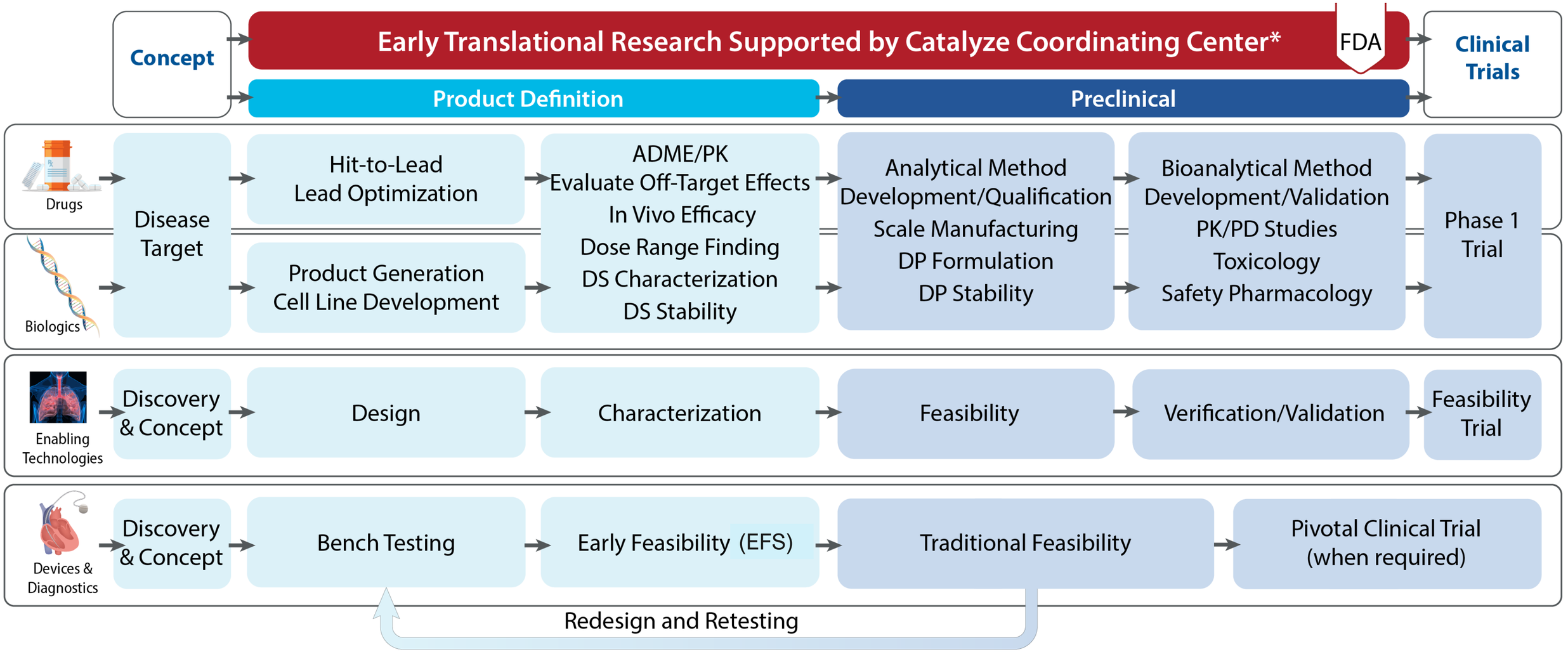
One platform. Different entry points. Support tailored to project needs.

CATALYZE
Accelerating Translation

You have questions?

I have answers!

Catalyze supports translation through clinical trials



Catalyze In Vivo Gene Therapy Development Program

The Catalyze infrastructure is adaptable to emerging scientific needs

Early proof of concept for in vivo HSC gene therapies, starting with sickle cell disease

Four barriers to translation identified

1. In vitro results poorly predict in vivo delivery performance
2. Humanized mouse models have uncertain translational relevance
3. Immune tolerance to newly expressed proteins remains unclear
4. Experimental models miss interactions in the HSC niche

Approaches sought

- Novel vector platforms
- Nonviral delivery systems
- Immune evasion technologies
- Translational models or assays

Other approaches that overcome these barriers are welcome.

Program scope

Initial focus

HSC targeting, with emphasis on SCD

Project stage

High-risk concepts at TRL 1–2

Project duration

12–18 months for proof of concept

Builds on the Cure Sickle Cell Initiative (2018) and the CIRM & Gates Foundation partnership (2019).

https://nhlbicatalyze.org/invivo

National Institute of Diabetes and Digestive and Kidney Diseases

NIDDK Small Business Programs

Marc Dawson Rigas, Ph.D.

Program Officer

Division of Diabetes, Endocrinology, and Metabolism (DEM)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

National Institute of Diabetes and Digestive and Kidney Diseases

NIDDK Mission Statement

The NIDDK Mission is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.



The Small Business Program helps accelerate discoveries from bench to bedside

National Institute of Diabetes and Digestive and Kidney Diseases

What Type of Science Does NIDDK Support?

Diabetes (T1D and T2D)
Obesity
Endocrine and Metabolic Diseases
- **Diseases of thyroid function**
- **Metabolic bone disease**

Digestive Diseases
Liver Diseases
Nutritional Disorders
Pancreatic Disease

Kidney Diseases
Urological Diseases
Hematologic Diseases

Diabetes, Endocrinology, and Metabolism

Digestive Diseases and Nutrition

Kidney and Urological Health



NIH National Institute of Diabetes and Digestive and Kidney Diseases

Scientific Portfolios NIDDK/ DEM Division

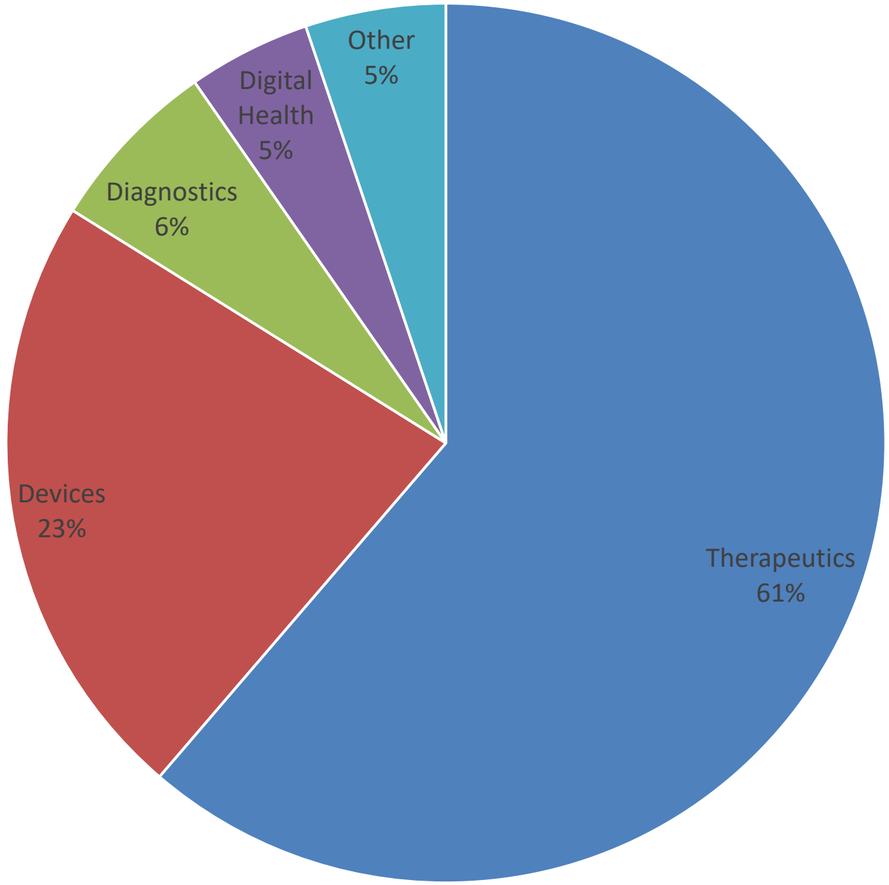
Basic Science → **Translational** → **Clinical**

- Hepatic metabolism
- Islet regeneration
- Thyroid physiology and function
- Gestational diabetes
- Protein trafficking and secretion
- Exocrine pancreas role in diabetes
- Health equity in diabetes research
- Muscle metabolism
- Neuroendocrinology
- Cystic fibrosis
- Diabetic peripheral neuropathy
- Islet developmental biology
- Metabolic imprinting
- T1D genetics
- Digital technology in T2D
- Adipose tissue remodeling
- Bone and mineral metabolism
- Diabetic foot ulcers
- Behavioral research in diabetes
- Insulin resistance mechanisms
- Molecular and functional imaging
- Data science
- Diabetes epidemiology
- Adipose tissue remodeling
- Precision medicine and drug discovery
- T2D in pediatrics
- Functional metabolomics
- Diabetes control technologies
- Computational biomodelling
- T1D prevention
- T1D pathogenesis
- Islet transplantation program
- Inborn errors of metabolism
- T1D therapy
- T2D pathogenesis
- Circadian rhythms in metabolism
- Neurobiology of obesity
- Intrauterine environment

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

NIH National Institute of Diabetes and Digestive and Kidney Diseases

NIDDK SBIR Portfolio



Active SBIR/STTR Awards: 155

National Institute of Diabetes and Digestive and Kidney Diseases

Budget Guidelines

Project Type	Total Funding Support	Award period
Phase I SBIR or STTR	Normally may not exceed $400,000	Normally may not exceed 1 year
Phase II SBIR or STTR	Normally may not exceed $2,500,000	Normally may not exceed 2 years
Phase IIB Strategic Breakthrough	Normally may not exceed $3,000,000*	Must not exceed 4 years
Commercialization Readiness Pilot (CRP)	$2,000,000	Must not exceed 3 years

*Applicants must secure 100% third-party matching funds for the proposed Phase IIB Strategic Breakthrough award project.

For a list of Approved Topics for Awards Over Statutory Budget Guidelines, visit: https://grants.nih.gov/funding/find-a-fit-for-your-research/nih-institutes-centers-offices/NIDDK?category=small-business

National Institute of Diabetes and Digestive and Kidney Diseases

Thank You!

Please contact us

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National Institute of Diabetes and Digestive and Kidney Diseases

Q&A