

# National Heart, Lung and Blood Institute



## Funding and additional product development resources for heart lung blood and sleep technologies

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NIH/NHLBI

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# Topics for Today

- ❖ NHLBI Mission and Goals
- ❖ NHLBI Innovation & Commercialization Office
- ❖ Support for Small Businesses and Academic innovators
  - Grant Programs
    - Congressional Small Business Program (SBIR/STTR)
    - NIH Academic Proof of Concept Center Programs (NCAI/REACH)
    - NHLBI Catalyze Program
  - Supplements to Awarded Grants
  - Tailored Innovator Resources

# NHLBI Mission

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a **research, training, and education** program to promote the **prevention and treatment of heart, lung, and blood diseases** and enhance the health of all individuals so that they can live longer and more fulfilling lives.

## NHLBI's Strategic Goals:

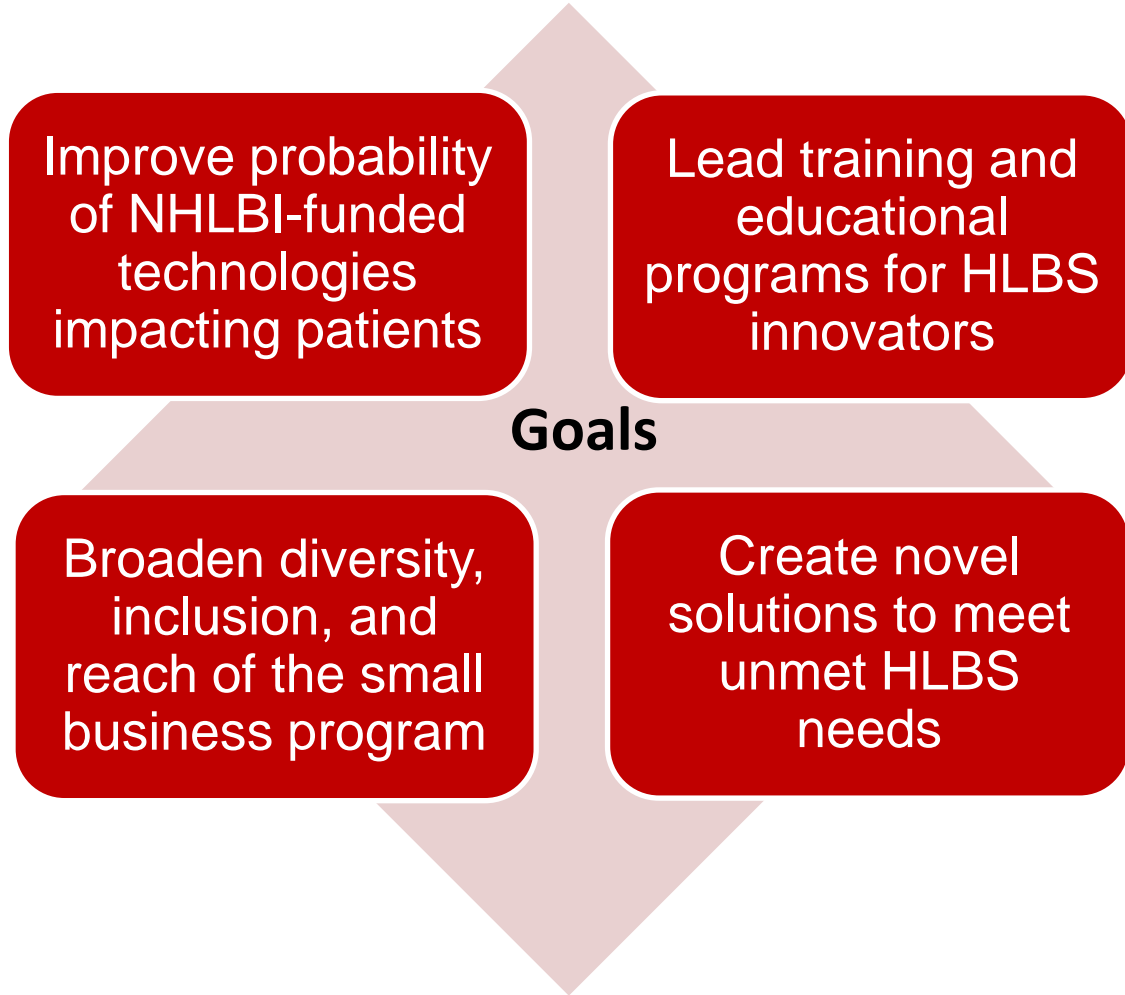
Understand  
Human  
Biology

Reduce  
Human  
Disease

Develop  
Workforce &  
Resources

Advance  
Translational  
Research

# NHLBI Innovation and Commercialization Office



## **MISSION**

*To accelerate the translation of discoveries and innovations into new biomedical products and services for heart, lung, blood and sleep diseases and disorders*

## **VISION**

*Development of a biomedical community that rapidly commercializes heart, lung, blood, and sleep technologies to improve public health*

# NHLBI Innovation and Commercialization Office Programs/Services

## Academic Innovation

Proof of Concept/Point of Care Programs

**Catalyze**  
(academic & small biz)

**CAPCaT**  
(academic & small biz)

**NCAI/REACH**  
(academic proof of concept)



**Academic  
Community**

## Small Business Innovation

SBIR/STTR and associated programs

**Commercialization  
Programs**

**Diversity  
Programs**

**Awards to  
Accelerate  
Commercialization**



**Small  
Business  
Community**

## Innovator Support

Unique expert staff

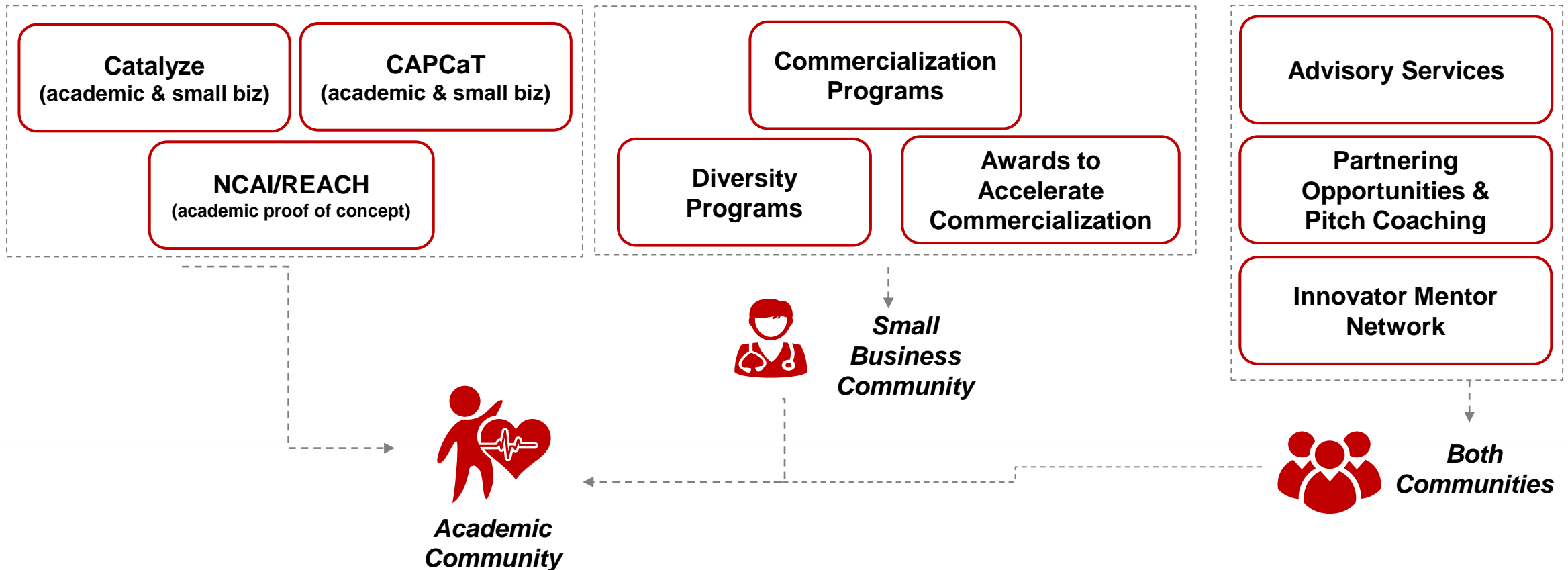
**Advisory Services**

**Partnering  
Opportunities &  
Pitch Coaching**

**Innovator Mentor  
Network**



**Both  
Communities**



# Congressionally Mandated Programs

**\$1.3 Billion Dedicated Funding via Set-aside from NIH's R&D Budget**



\$1.14 billion

## **SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

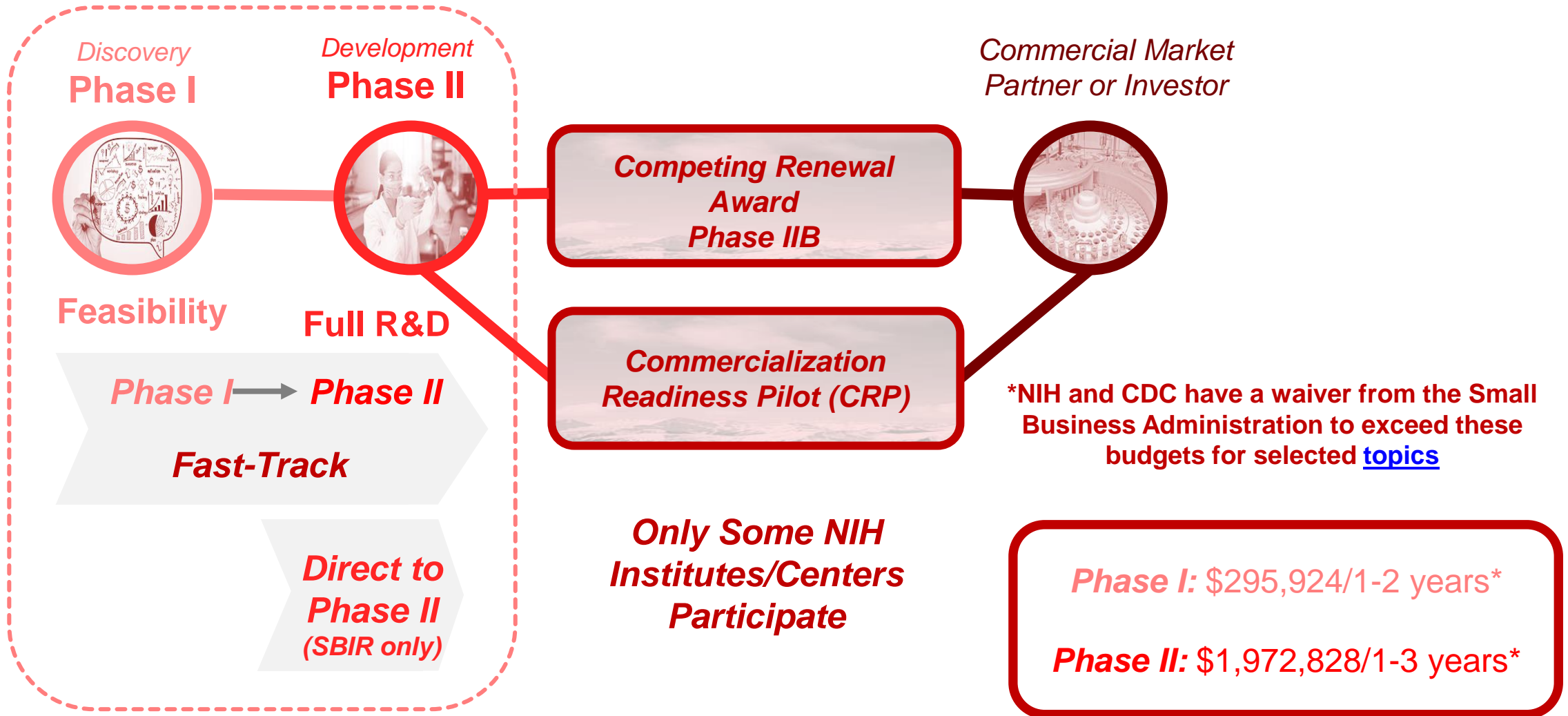


\$160 million

## **SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

# Phased Programs



# SBIR vs. STTR Programs

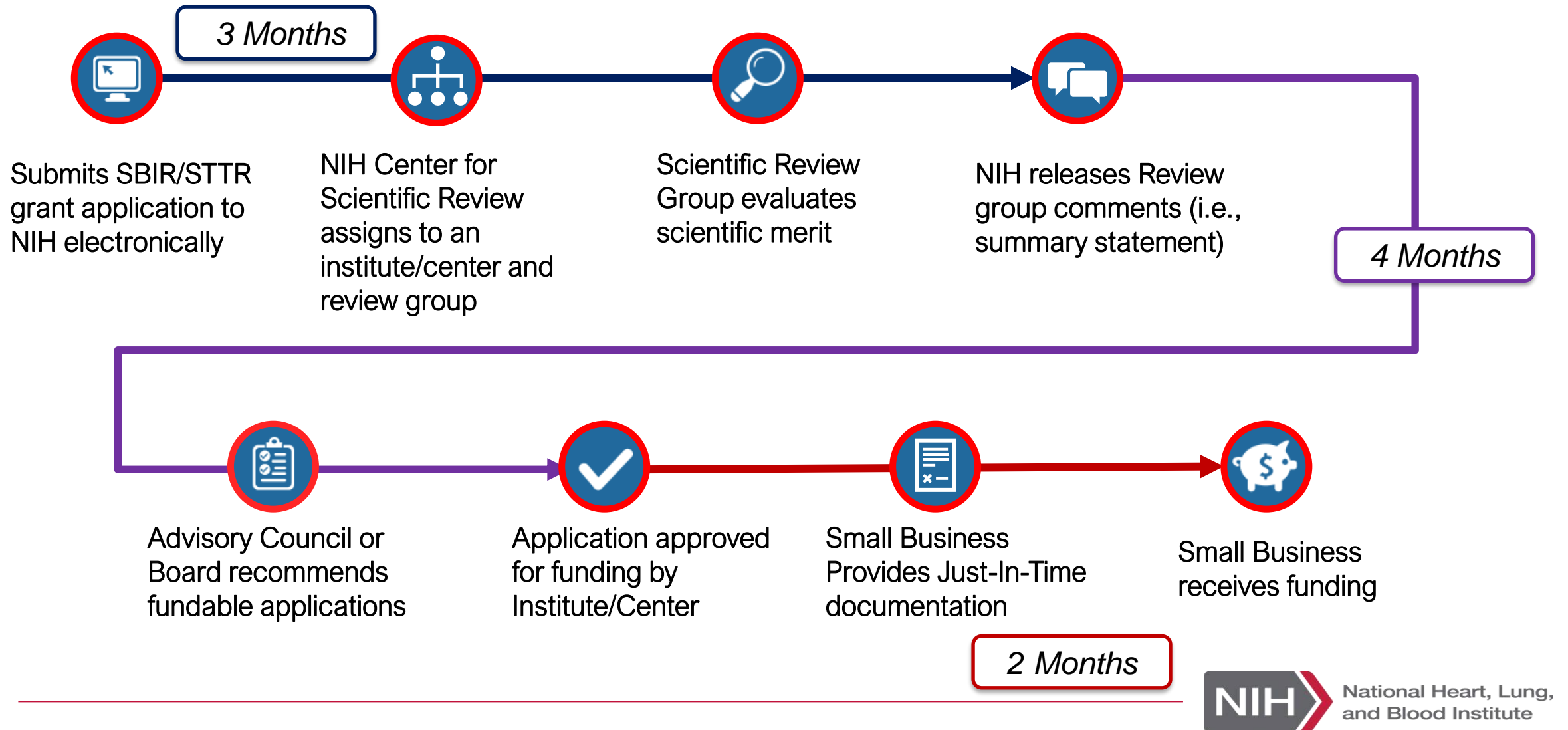
	SBIR	STTR
<b>Partnering</b>	<b>Permits</b> partnering	<b>Requires</b> a non-profit research institution partner
<b>Principal Investigator</b>	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business and devote at least 10% effort to the project
<b>Work Requirement</b>	Guidelines: May outsource up to 33% (Phase I), 50% (Phase II)	Minimum Work Requirements: 40% Small Business 30% Research Institution Partner



# NHLBI Application Cycles

Due Dates	Review meetings	Advisory Council Round	Earliest Project Start Date
January 5	March	May	July
April 5	June	October	December
September 5	November	January	April

# Timeline: Application to Award



# Review Criteria

## Scored Review Criteria (score 1-9)

- Application Phase Specific Considerations
- Significance (Real Problem/Commercial Potential)
- Investigators (Investigator and Team)
- Innovation (New or Improved?)
- Approach (Research Design, Feasible)
- Environment (Facilities/Resources)

## Additional Review Criteria (not scored individually)

- Application Phase Specific Considerations
- Protection of Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards

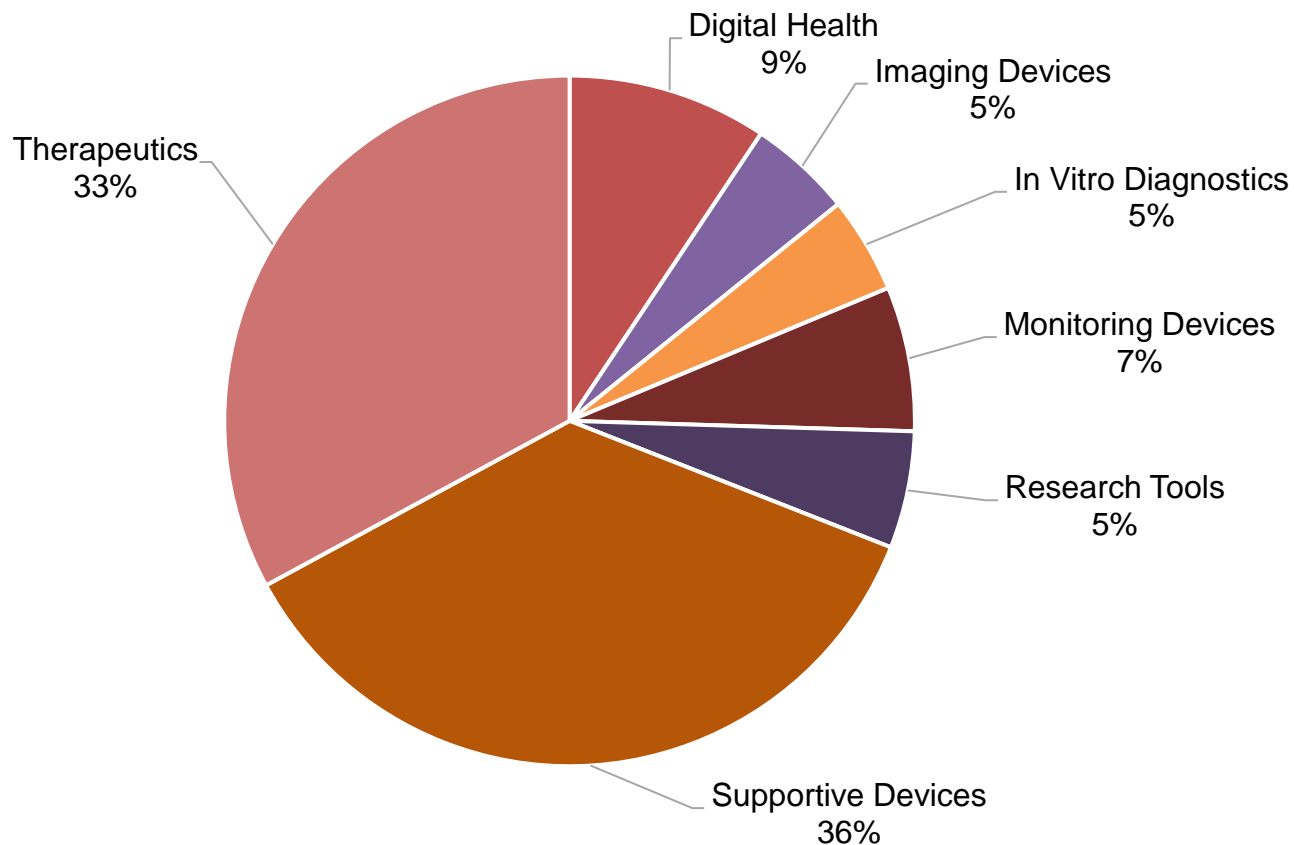
## Additional Review Considerations (not factored into the overall score)

- Foreign Components
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Resources
- **Budget and Period of Support**

Center for Scientific Review  
<https://public.csr.nih.gov/>

# The NHLBI Small Business Program

Innovative and commercially-promising products to prevent, treat and diagnose **heart, lung, blood, and sleep (HLBS)-related diseases**



~\$130M

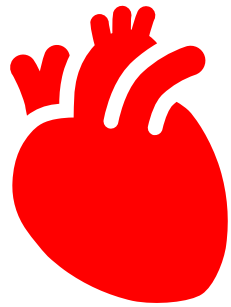
Approximate annual  
non-dilutive funds

>300

Active  
projects

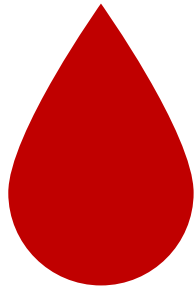
Technologies Funded by NHLBI SBIR/STTR Program

# NHLBI Mission Space



## Heart

- Arrhythmias
- Atherothrombosis
- Chronic Heart Failure
- Congenital Heart Defects
- Coronary Artery Disease
- Hypertension

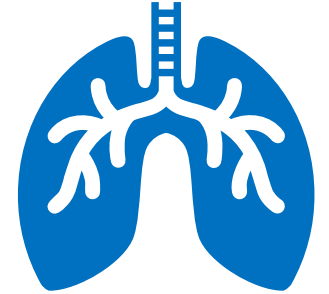


## Blood

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

## Lung

- ARDS
- Asthma
- Chronic Obstructive Pulmonary Disease
- Cystic Fibrosis
- Fibrotic Lung Disease
- Pulmonary Hypertension



## Sleep

- Circadian Disorders
- Insomnia
- Obstructive Sleep Apnea
- Sleep-Disordered Breathing



APPLICATION SERVICES

SMALL BUSINESS PROGRAM (SBIR/STTR) & AWARDEE OPPORTUNITIES

Basic & Early-stage Translational Research

Proof of Concept

Research & Development

Regulatory, Scale-up, and Manufacturing

Sales & Distribution

Proposal Guidance

Product Development Mentorship

Application Questions

Pitch Coaching & Conference Support

Digital Education & Online Resources

SBIR/STTR Phase I

SBIR/STTR Phase II

SBIR Phase IIB

REACH/NCAI

Catalyze, C3i

SBIR Diversity Supplement

AAP, ITEP

I-Corps

CRP

TABA

Services and Activities

Grant Programs/ Supplements

**SBIR** | Small Business Innovation Research  
**REACH** | Research Evaluation and Commercialization Hubs  
**NCAI** | NIH Centers for Accelerated Innovations  
**C3i** | Commercializing Innovation (C3i) Program

**AAP** | Applicant Assistance Program  
**ITEP** | Innovator to Entrepreneur Program  
**CRP** | Commercialization Readiness Pilot  
**TABA** | Technical and Business Assistance Programs  
**I-Corps** | Innovation Corps

Adoption by Patients & Providers

Public Health & Social Impact

# Omnibus Notices of Funding Opportunity

PA-23-230

R43/R44 Clinical Trial  
Not Allowed

PA-23-231

R43/R44 Clinical Trial  
Required

PA-23-232

R41/R42 Clinical Trial  
Not Allowed

PA-23-233

R41/R42 Clinical Trial  
Required

# NHLBI Targeted Notices of Funding Opportunity

Funding Opportunity	NOFO #
Phase IIB Bridge Awards	➤ <a href="#">RFA-HL-23-009</a>
Phase IIB Small Market Awards	➤ <a href="#">RFA-HL-23-008</a>
SBIR/STTR Commercialization Readiness Pilot (CRP) Program	➤ <a href="#">PAR-23-219</a> ➤ <a href="#">PAR-23-220</a>
HEAL Initiative: Technologies Directed at Enhanced Pain Management	➤ <a href="#">RFA-NS-23-006</a> ➤ <a href="#">RFA-NS-23-007</a>
NOSI: Small Business Initiatives for Innovative tools and Technologies for Improving Outcomes for Maternal Health	➤ <a href="#">NOT-EB-23-005</a>
Notice of Special Interest: Encouraging Small Businesses to Partner with Resource-Limited Institutions (RLIs) on Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Applications	➤ <a href="#">NOT-OD-23-179</a>
NOSI: Improving Patient Adherence to Treatment and Prevention Regimens to Promote Health	➤ <a href="#">NOT-OD-21-100</a>
NOSI: Validation of Digital Health and Artificial Intelligence Tools for Improved Assessment in Epidemiological, Clinical, and Intervention Research	➤ <a href="#">NOT-CA-22-037</a>
NOSI: Development of Functional Assay Sites to Evaluate Candidate -Omics Variants Associated with Heart, Lung, Blood, or Sleep Disease	➤ <a href="#">NOT-HL-23-066</a>
NOSI: Quantum Sensing in Biomedical Applications	➤ <a href="#">NOT-EY-23-009</a>



# Phase IIB Bridge (HL-23-009) and Small Market (HL-23-008) RFAs

## Purpose of the Programs

- Provide innovators who are developing technologies focused on heart, lung, blood, or sleep-related condition with support to meet **regulatory milestones and connect with investors/strategic partners**
- Bridge Program designed for all technologies that fall under the NHLBI mission
- Small Market Program designed for technologies that address **rare diseases and/or pediatric indications**

## Budget

- Up to \$3M total costs over 3 years
  - 1:1 Matching Funds Expected for Bridge Awardees
  - 1:3 Matching Funds Expected for Small Market Awardees

## Approximate Number of Awards Per Year

- Five (5) Bridge Awards
- Two (2) Small Market Awards

Next Receipt Date: **February 28<sup>th</sup>, 2024**

# Phase IIB Program Informational Webinar

January 25, 2024  
1:00 p.m. ET

Register via QR Code Below



# Targeted and Supplemental Programs & Tailored Product Development Resources

## Commercialization Programs

I-Corps at NIH, C3i, CARE, & TABA

## Awards to Accelerate Commercialization

Phase IIB Awards & Commercialization Readiness Pilot (CRP)

## Diversity Programs

Diversity Supplements, Applicant Assistance Program, ITEP

## Early-Stage Product Development

Catalyze, NCAI/REACH

## Tailored Advisory Services

Conference Showcase Support, Mentor network, & Consultations with EIRs

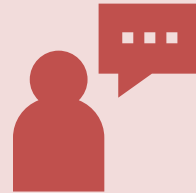
# Connecting Awardees with Regulatory Experts (CARE)

*NIH and FDA collaborate to connect small businesses with FDA and support communications during early-stage product development.*



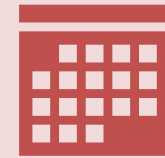
## Who Is This Program For?

- Early-stage companies that have not discussed their technology with FDA or participated in the CARE program previously



## What Does It Entail?

- Companies submit their application containing regulatory questions to NCI SBIR
- NCI SBIR reviews and directs to correct FDA Center
- Companies receive informal responses from discipline specific experts at the relevant FDA center



## When/How Can I Apply?

- Applications are due in 2024, check the program link below for up-to-date information.
- Submit your application on the CARE Program website [here](#)

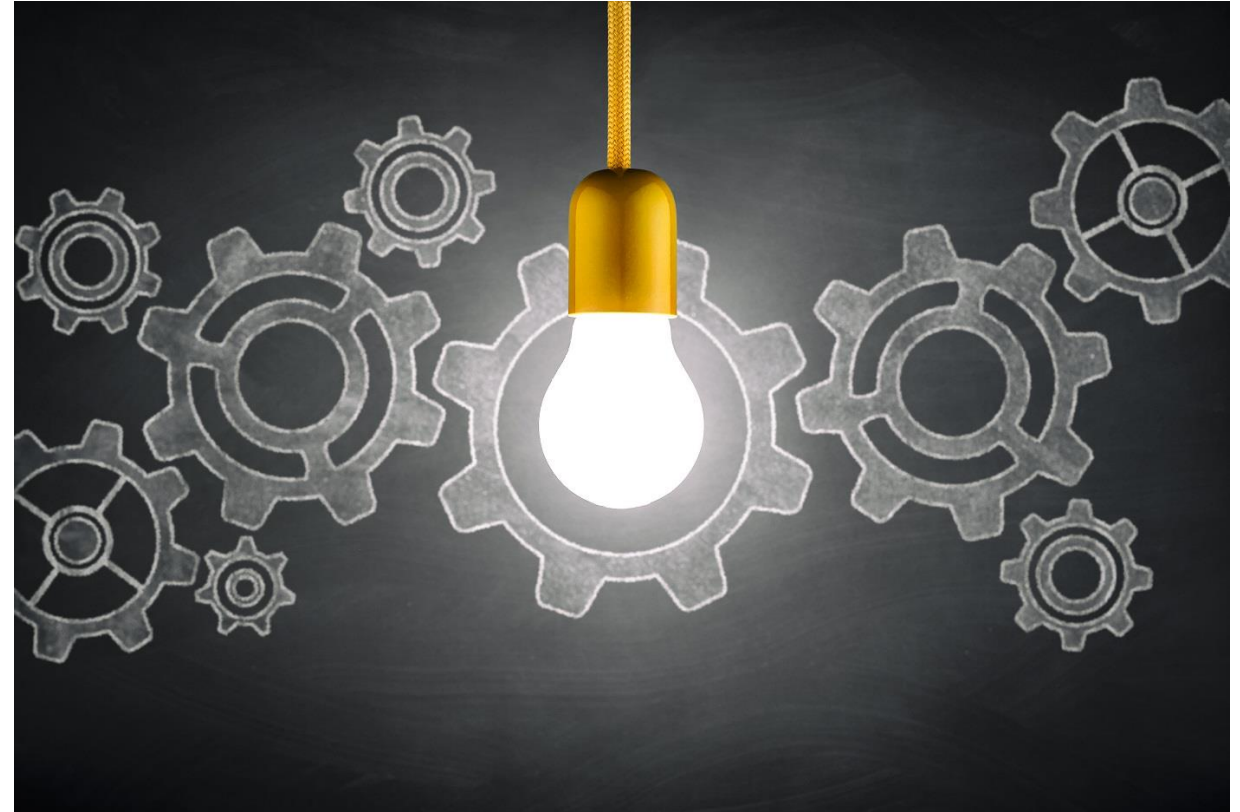
# Innovation Corps (I-Corps) at NIH™ (PAR-22-073)

- Launched at the NIH in 2014 as a program based on the Lean Startup Methodologies
- Promotes customer discovery experience by requiring participants to conduct ~100 interviews over eight weeks
  - Content from interviews helps refine proposed business model
  - “You cannot commercialize something that nobody wants
- Open to current Phase I and early stage Fast-Track SBIR/STTR awardees
- Two receipt dates per year
  - **Next due date January 31, 2024**
- Selected companies may receive up to \$55K for course registration and travel expenses



# Concept to Clinic: Commercializing Innovation Programs (C3i/e-C3i)

- The NIBIB C3i and e-C3i programs provide medical device innovators with the tools and frameworks that are required to commercialize their technologies
- Education (e-C3i)
  - Ten (10) weeks of entrepreneurial training
  - Open to **only non-SBIR/STTR grantees**
- Validation/Execution
  - Twenty-four (24) weeks of entrepreneurial training
  - Open to **SBIR/STTR and non-SBIR/STTR grantees**



# Technical and Business Assistance (TABA)

## Discovery Phase I



### Feasibility

**\$6.5K for Technical and Business Assistance-related expenses**  
(Request during application or through NOT-OD-21-062)

NIH-Administered [TABA Needs Assessment Program](#)

## Development Phase II



### Full R/D

**\$50K for Technical and Business Assistance-related expenses**  
(Request during application)

NIH-Administered [TABA Consulting Services](#)

## Examples of activities supported by TABA Funds

Assistance with product sales

Intellectual property protections

Market research and/or validation

Development of regulatory plans

Development of manufacturing plans

Access to technical and business databases

# Administrative Supplements to Promote Diversity (PA-21-345)

- Provides financial support for SBIR/STTR awardees to hire early-career scientists to **enhance the diversity of the NIH-supported workforce**
- Allows candidate to receive
  - Entrepreneurial training
  - Scientific training
  - Real-world experience
- Covers the following expenses
  - Salary Support
  - Travel
  - Supplies
- Eligibility Criteria
  - Must have an active SBIR/STTR award
  - Candidate **must** be a U.S. Citizen or a permanent resident





# NIH Applicant Assistance Program

AAP is a FREE Application preparation ASSISTANCE program for new and previously-unsuccessful Phase I SBIR/STTR grant applicants

## PROGRAM GOAL

- Provide a **mentor** for applicants with great technology, but little NIH experience and limited NIH experience in their network
- **10-week program aiming to:**
  - ↑ number of applications
  - ↓ number of errors

## APP PROGRAM FREQUENCY

- **3-cycles**

## Next Due Date:

- Anticipated May 2024

<https://sbir.cancer.gov/aap>

AAP Provides	AAP Does Not Provide
Phase I SBIR/STTR application preparation support and review	Grant writer
Specific Aims review and advice	Research plan development
Submission process coaching	Small business registration of NIH application submission services

# NIAID/NHLBI Innovator to Entrepreneur Program (ITEP)

**ITEP assists participants with program development, application development, SBIR/STTR training, grantsmanship training, entrepreneurial training, one on one consulting, and marketing/outreach activities.**

## **PROGRAM GOAL**

- To establish a support program designed to assist participants in making the transition from innovator to entrepreneur
- **5-month program aiming to:**
  - ↑ number of qualifying applications from underrepresented groups
  - ↓ number of errors

## **PROGRAM ELIGIBILITY:**

- Innovation within NIAID or NHLBI Mission space
- Be an individual inventor or represent the established small company
- Inexperienced entrepreneur
- Haven't previously received an SBIR/STTR award

## **ITEP PROGRAM FREQUENCY**

- **2-cohorts**
- Rolling

# Innovator Education: Tailored Product Development Support

## ■ 1:1 Consultations

- IP, Regulatory, Reimbursement, Clinical Trial Design, Investability, Health Economics, Commercialization Strategy, Business Development



## ■ Mentor Network

- External Product Development Experts
- Launched Mentor Webinar Series



## ■ Partnering Opportunities and Pitch Coaching

- Conference Attendance Registration
- Pitch Coaching leading up to the event
- NHLBI Innovation Showcases



ANGEL CAPITAL ASSOCIATION

# Advisory Experts at NHLBI

**Renée Arnold**



Entrepreneur in  
Residence

**Health Economics,  
Outcomes  
Research  
&  
Reimbursement**

**Steve Flaim**



Investor-In-Residence

**Investing**

**Kwame Ulmer**



Entrepreneur in  
Residence

**Regulatory**

**Kimberly Martin**



Entrepreneur in  
Residence

**Clinical Trials**

**John Hsu**



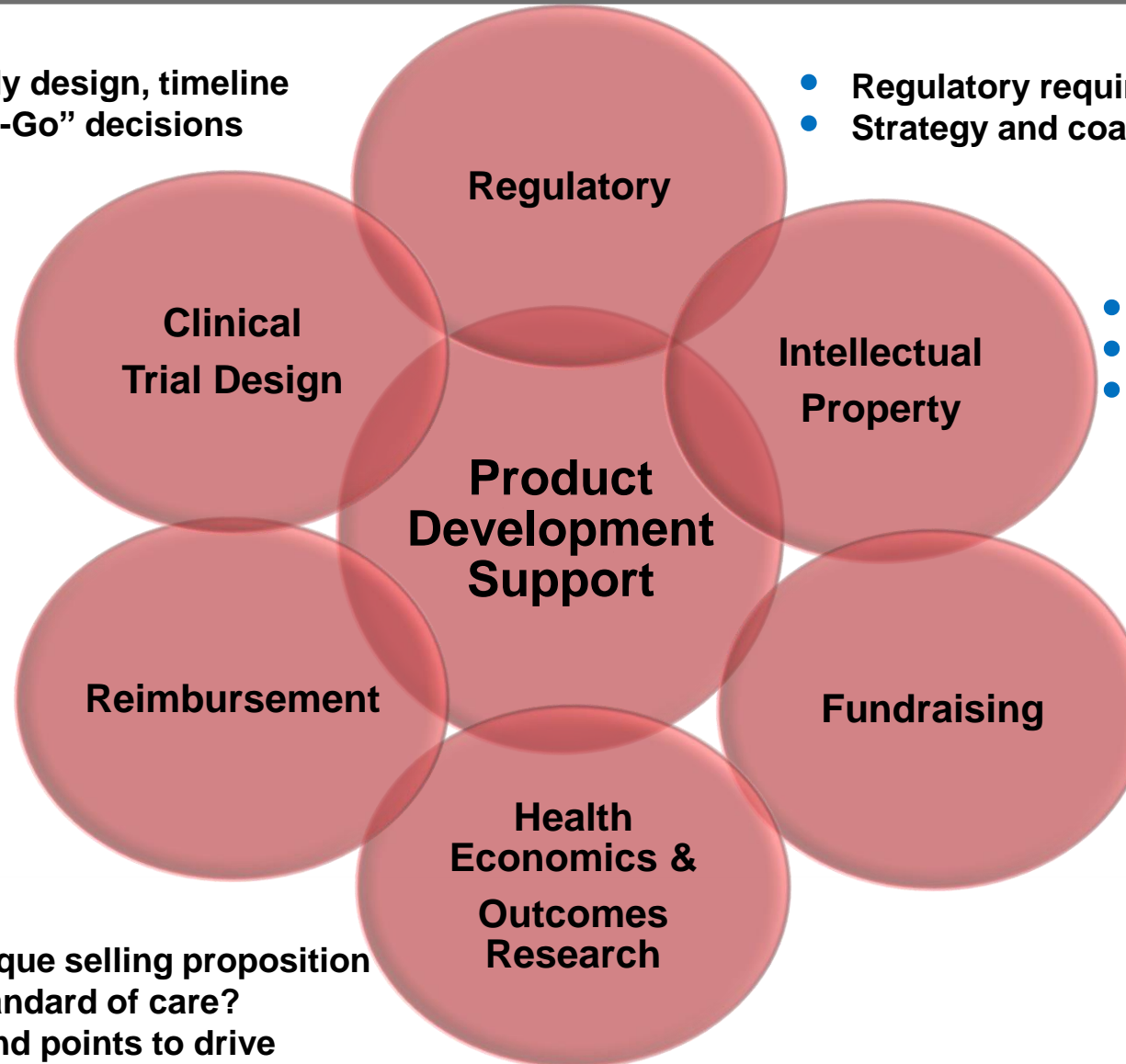
Intellectual Property  
Advisor

**Intellectual Property**

# Entrepreneurial & Product Development Expertise

- Clinical strategy, study design, timeline
- POC trials for “Go/No-Go” decisions

- Regulatory requirements & health authority viewpoints
- Strategy and coaching for regulatory interactions



- IP Strategy
- Types of IP - patents, trademarks etc.
- US vs. X-US

- Who is the end user?
- Setting?
- Insurance Coverage
- New/existing code(s)

- Positioning for M&A / VC investments
- Company structure, C-Suite team
- Pitch Coaching & Mentoring

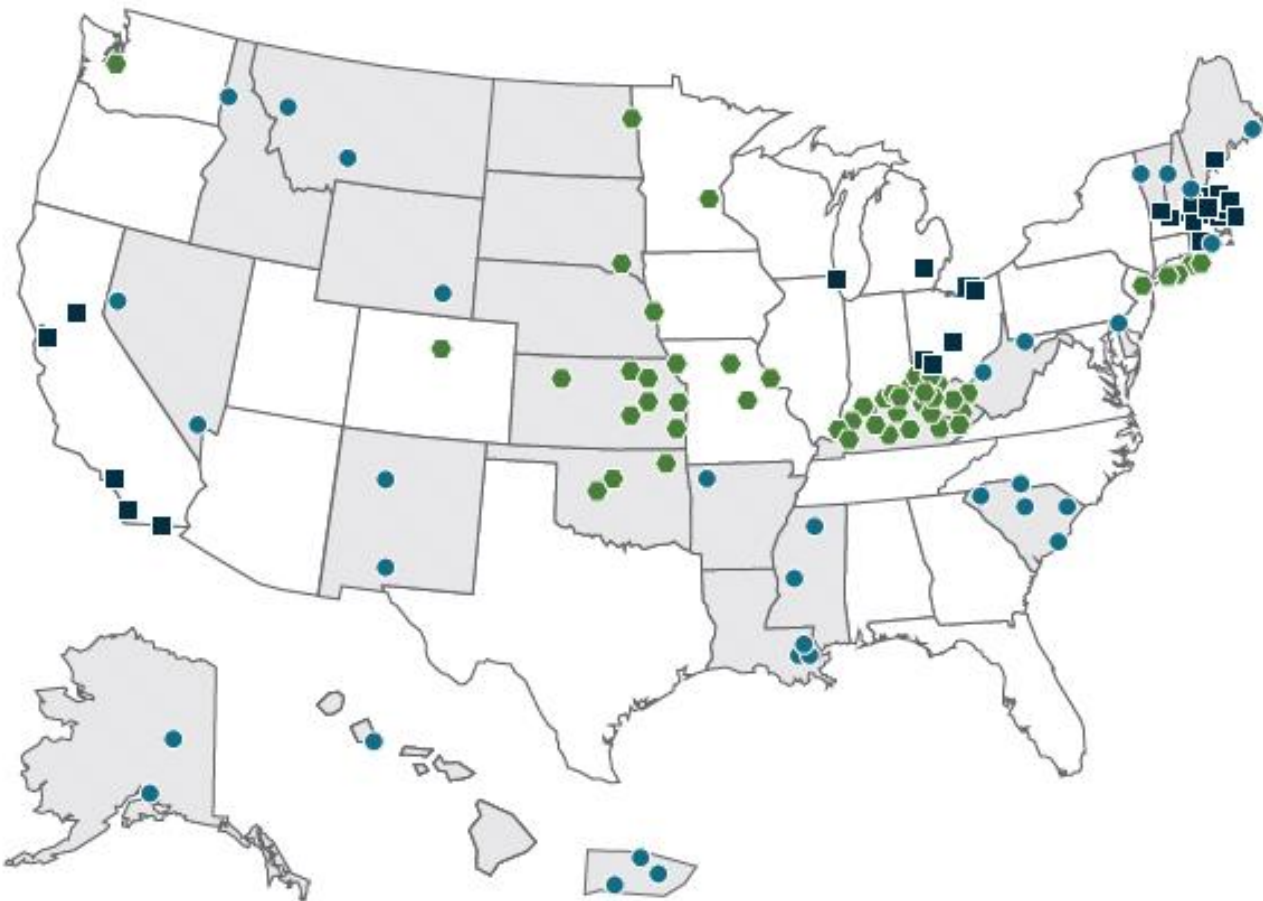
- Define the TPP or unique selling proposition
- Change to current standard of care?
- Design clinical trial end points to drive HEOR

# Leveraging NIH Support: KaloCyte, Inc.

\*Easy-to-use, shelf-stable red blood substitute available anywhere and at any time



# NIH Academic Proof of Concept Network



Developing a scalable model and best practices for accelerating academic discoveries into products that improve health

## NIH Centers for Accelerated Innovation (NCAI) - 2013

- Heart, Lung, Blood, and Sleep focused
- 3 centers - 28 institutions in 7 states

## Research Evaluation And Commercialization Hubs (REACH) – 2015 and 2019

- Trans-NIH
- 3 hubs - 6 institutions in 3 states
- 5 hubs – 42 institutions in 10 states

## NIGMS IDeA States Regional Technology Transfer Accelerator Hubs – 2018

- Develop innovative entrepreneurial training resources
- 4 hubs – partnership between 4 small businesses and 48 institutions in 23 states and Puerto Rico

**NCAI, REACH, NIGMS Hubs**

# NCAI/REACH: Unique Program Offerings

- NHLBI-led NCAI and REACH 2015 Pilot Programs served as a model for current REACH 2019/2023 Programs
- Established best practices for effective technology translation



## Program Funding

- Identify projects
- Up to \$400K in project funding  
(1:1 *non-federal match required*)



## Training and Resources

- Business development
- Regulatory planning
- Financing and partnerships



## Educational Coaching

- Project management and coaching by industry experienced mentors



## Personalized feedback

- FDA, CMS, NSF, USPTO
- Kaiser Permanente
- Life science industry experts



## OUTCOMES

- 435 projects
- 125 startups
- >\$2B follow-on \$
- > 3000 academic innovators trained





CBC-  
HITES

UM-BILD



UNIVERSITY OF  
MONTANA



N



SIHI-  
REACH



HEALTH SCIENCE CENTER  
TEXAS A&M UNIVERSITY

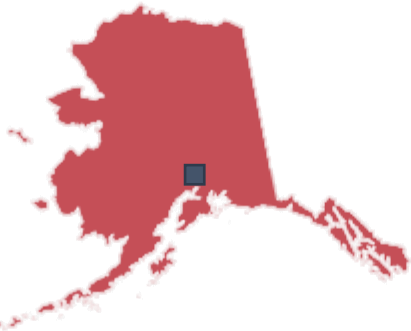


RICE



JSU | JACKSON STATE UNIVERSITY  
1877

Mid-  
South  
REACH



utmb Health

GCC-  
REACH



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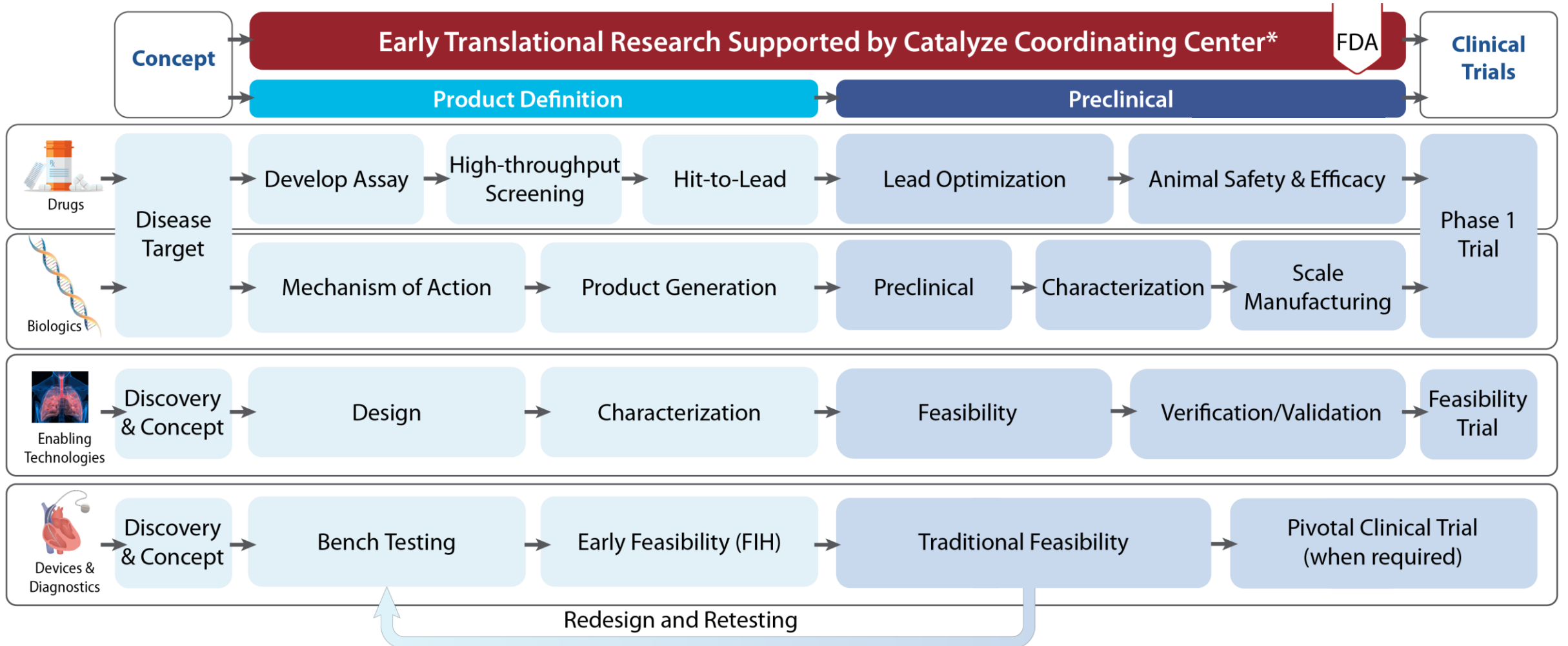
Website: [www.nhlbicatalyze.org](http://www.nhlbicatalyze.org)

Email: [NHLBI\\_catalyze@mail.nih.gov](mailto:NHLBI_catalyze@mail.nih.gov)

## Mission

The mission of **Catalyze** is to provide a comprehensive suite of support and services to facilitate the transition of basic science discoveries into viable diagnostic and therapeutic candidates that have been cleared for human testing, and to develop a translational research workforce fluent in product development and entrepreneurship.

# Catalyze Program Components



NHLBI Catalyze

# Product Definition Funding Opportunities

## Application Deadlines

February 21 | July 21 | November 21

### Enabling Technologies

- Enabling Technologies and Transformative Platforms for HLBS Research R33 ([RFA-HL-23-010](#))

### Small Molecules and Biologics

- Target Identification and Validation, Preliminary Product/Lead Series Identification R61/R33 ([RFA-HL-23-011](#))
- Preliminary Product/Lead Series Identification R33 ([RFA-HL-23-012](#))

### Devices and Diagnostics

- Prototype Design and Testing, Diagnostic Disease Target Identification, Assay Development and Research Tool Dev. R61/R33 ([RFA-HL-23-013](#))
- Prototype Testing and Design Modification, Diagnostic Disease Target Assay Development, and Design Characterization, and Research Tool Testing and Validation R33 ([RFA-HL-23-014](#))

US-based academic, non-profit institutions, and US-owned for-profit institutions are eligible to apply

# Connect with Us!

- Follow us on Twitter at [@NHLBI\\_SBIR](https://twitter.com/NHLBI_SBIR)
- Email us at [NHLBI\\_SBIR@mail.nih.gov](mailto:NHLBI_SBIR@mail.nih.gov)

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# Thank you!



National Heart, Lung,  
and Blood Institute