

Office of Translational Alliances and Coordination



Beyond the Science: Entrepreneurial Support and Commercialization Resources

Stephanie Davis, PhD and Kathleen Rousche, PhD

Catalyze Webinar

4/25/22

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:

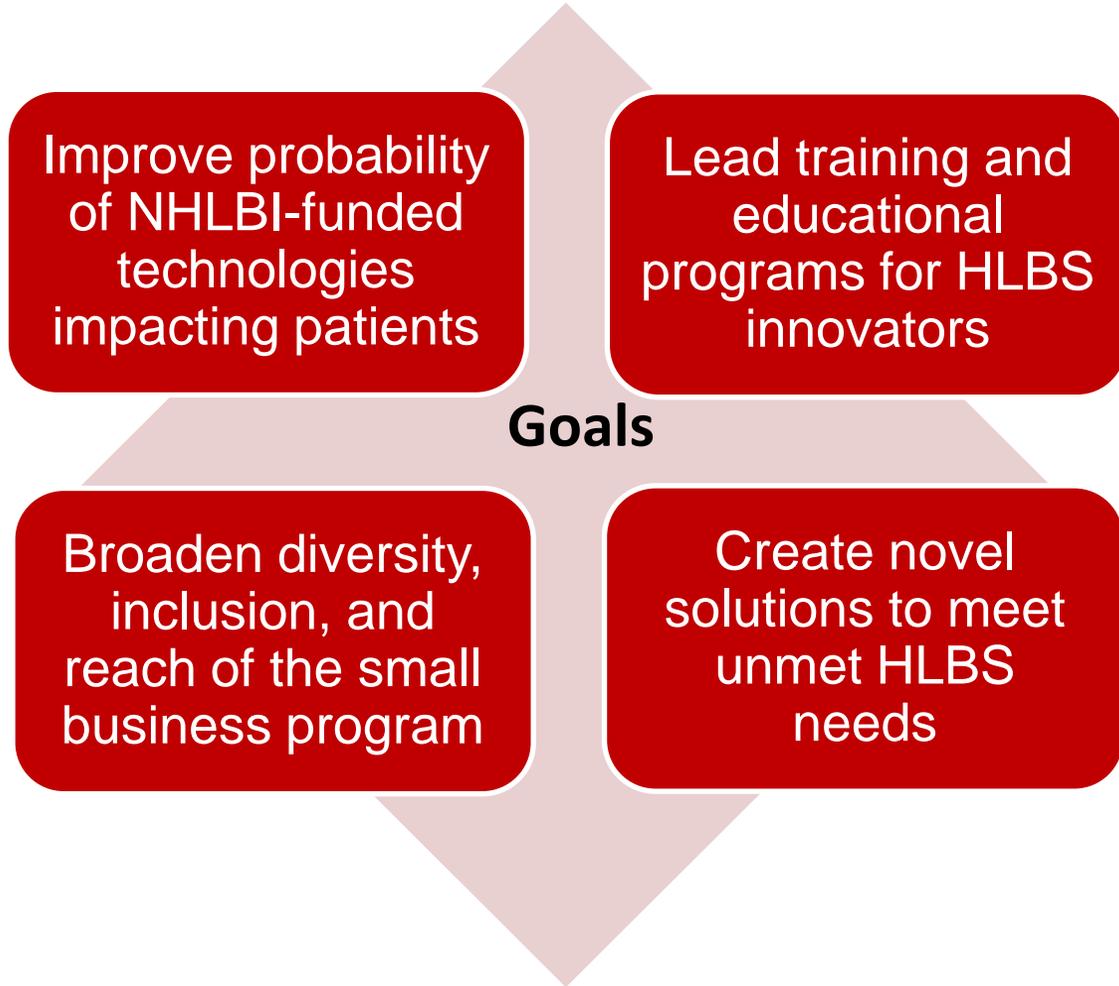
Understand
Human
Biology

Reduce
Human
Disease

Develop
Workforce &
Resources

Advance
Translational
Research

OTAC Mission



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)



**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**

NHLBI Mentor Network



**Both
Communities**

Advisory Experts at NHLBI



Renée Arnold, PharmD
Entrepreneur-In-Residence
Health Economics
Specialist



**Gautam Prakash,
PhD, JD**
Intellectual
Property Advisor



**Steve Flaim,
PhD, MBA**
Investor-In-Residence



Kwame Ulmer, MBA
Entrepreneur-In-Residence
Regulatory Specialist



Kimberly Martin, PhD
Entrepreneur-In-Residence
Clinical Trial Specialist

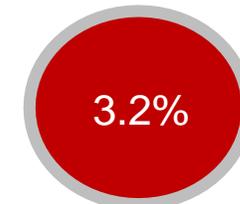
Small Business Grant Programs

Small Business Innovation Research (SBIR)

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

Federal agencies with an extramural R&D budget > \$100M

SET ASIDE

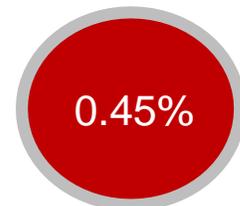


(FY21)

Small Business Technology Transfer Research (STTR)

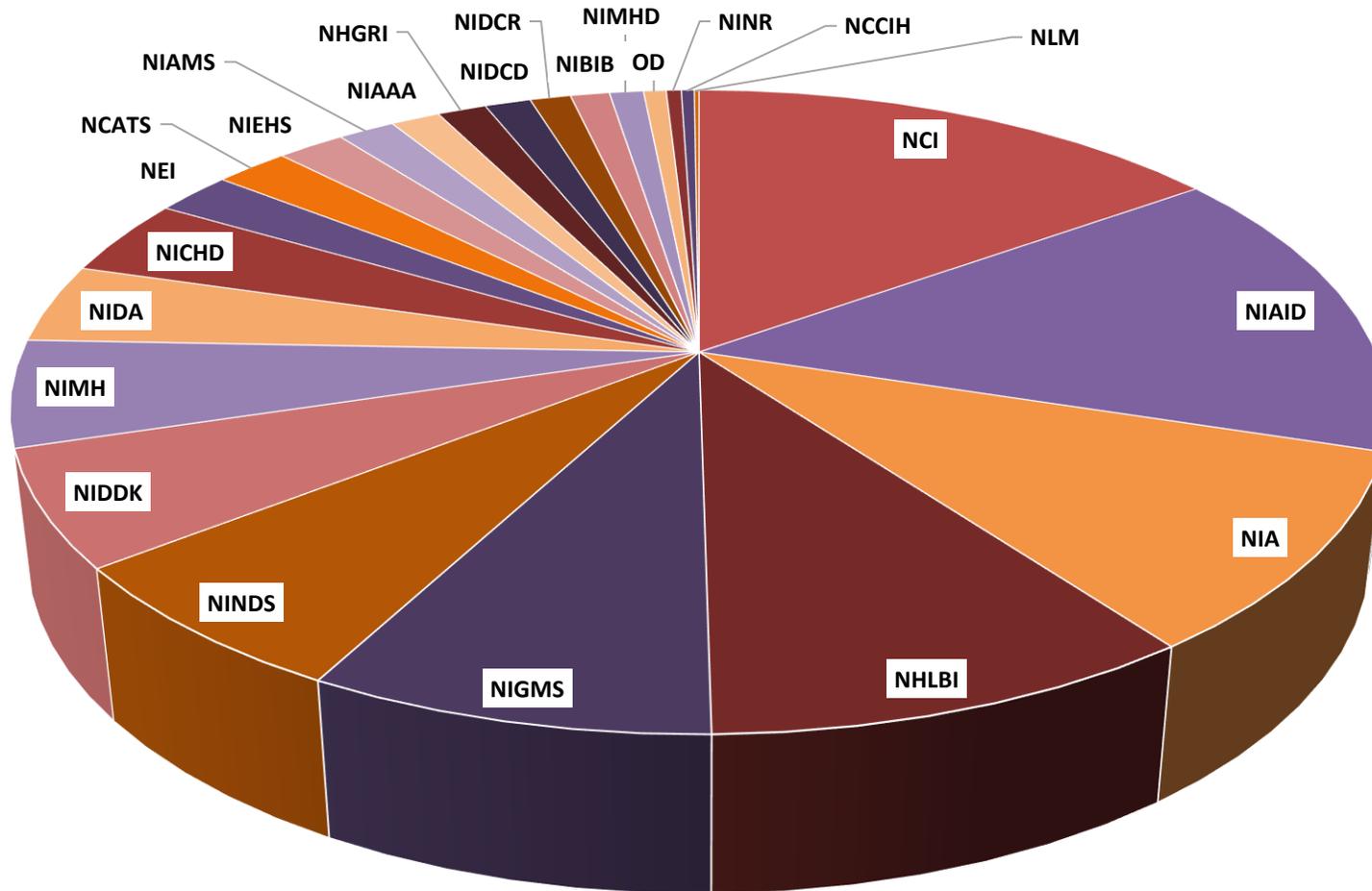
Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

Federal agencies with an extramural R&D budget > \$1B



(FY21)

NIH SBIR/STTR Budget Allocations FY2021



SBIR	\$1B
STTR	\$146M
Total	\$1.23 B

NHLBI: ~\$120M

SBIR/STTR Program Eligibility

- Organized for-profit U.S. business
- 500 or fewer employees, including affiliates
- Work must be done in the U.S. (with few exceptions)
- > 50% U.S.- owned by individuals and independently operated

**Award always
made to small
business**

OR

- > 50% owned and controlled by another (one) business concern that is
> 50% owned and controlled by one or more individuals in the U.S.

OR (SBIR ONLY)

- > 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

SBIR/STTR grant applications **and** SBIR contract proposals must be submitted **electronically**.

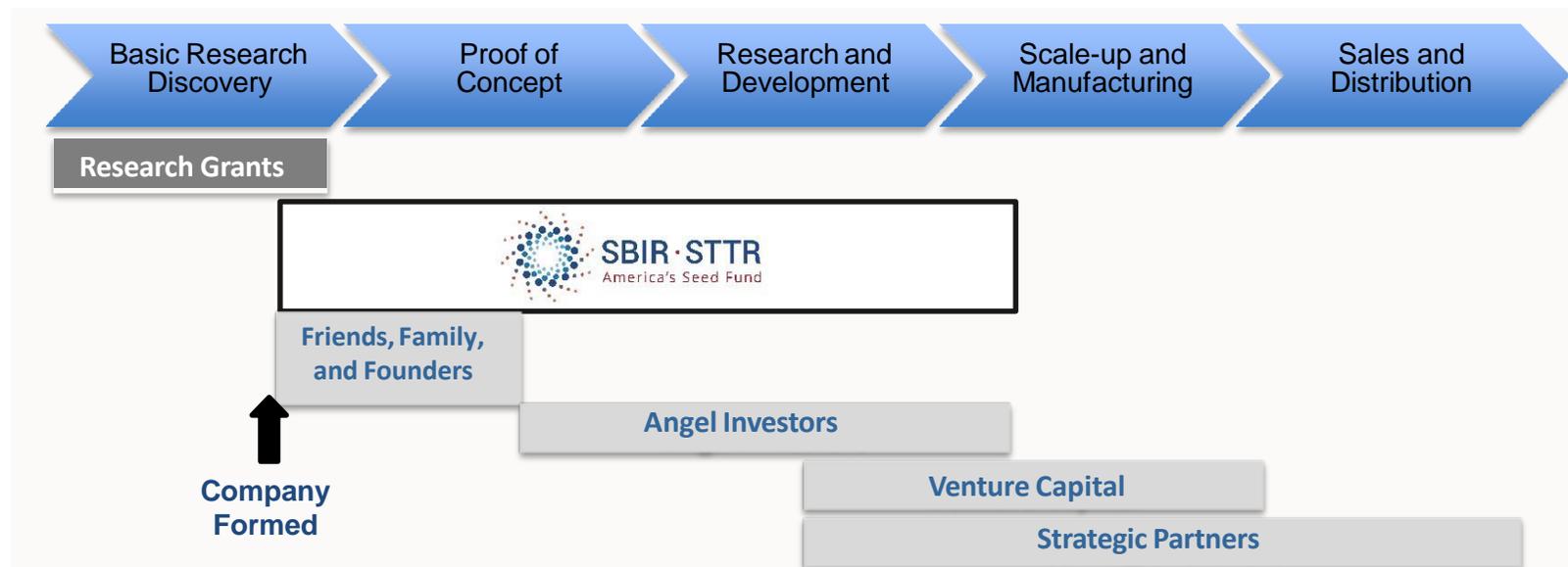
REQUIRED REGISTRATIONS

- DUNS Number (Company)
- System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov
- Grants submit via ASSIST or Grants.gov Workspace
- For contracts, submit proposals with [electronic Contract Proposal Submission](#) (eCPS) website



Why Seek SBIR/STTR Funding

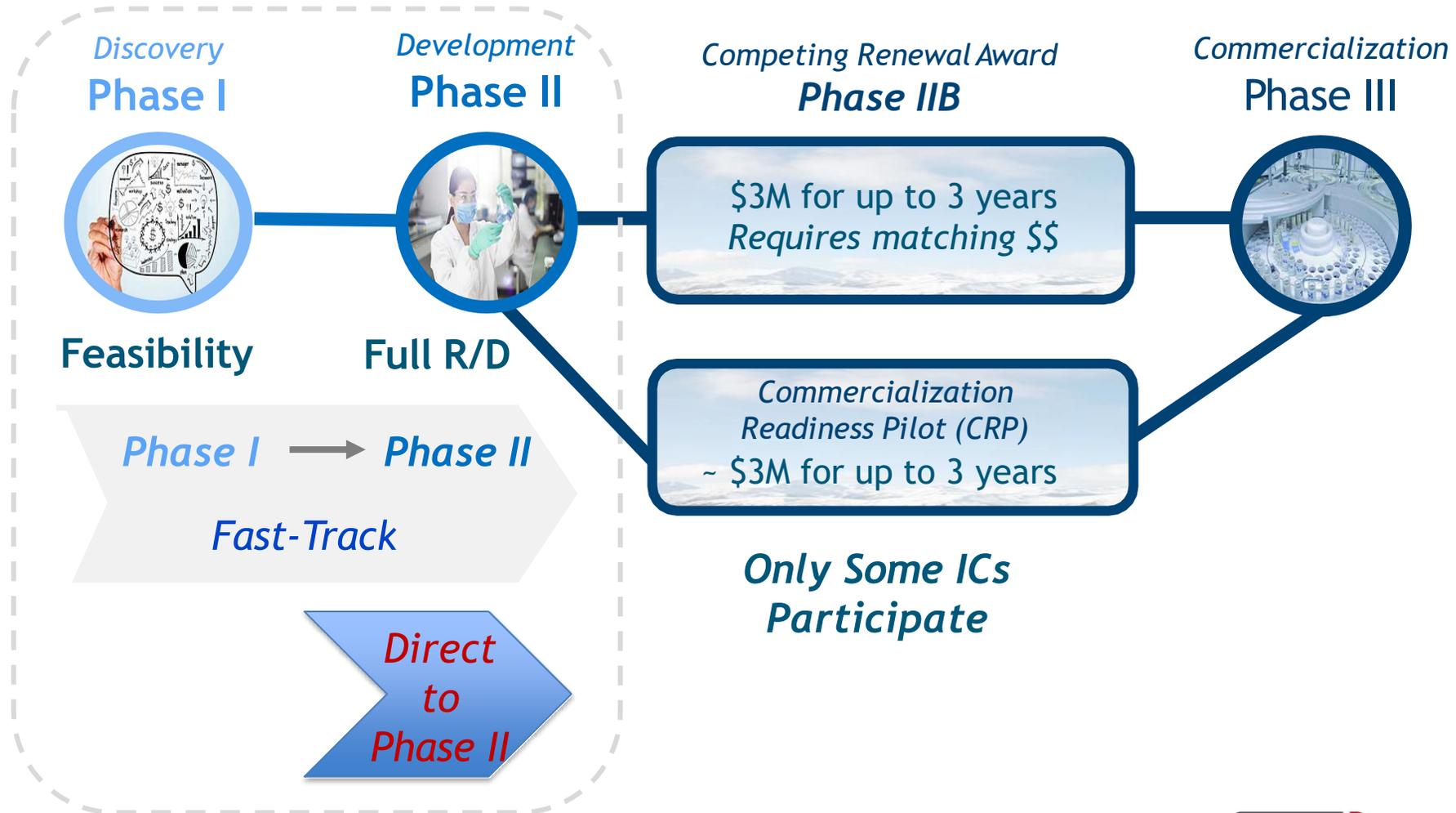
- Provides **seed funding** for innovative technology development
- One of the **largest funding sources of early stage life sciences** in the US
- No repayment required; **Not a loan** = non-dilutive **capital**
- IP rights are normally retained by the small business
- Provides recognition, verification, and visibility
- Can provide leverage to attract other funding and collaboration (e.g., venture capital, strategic partner)



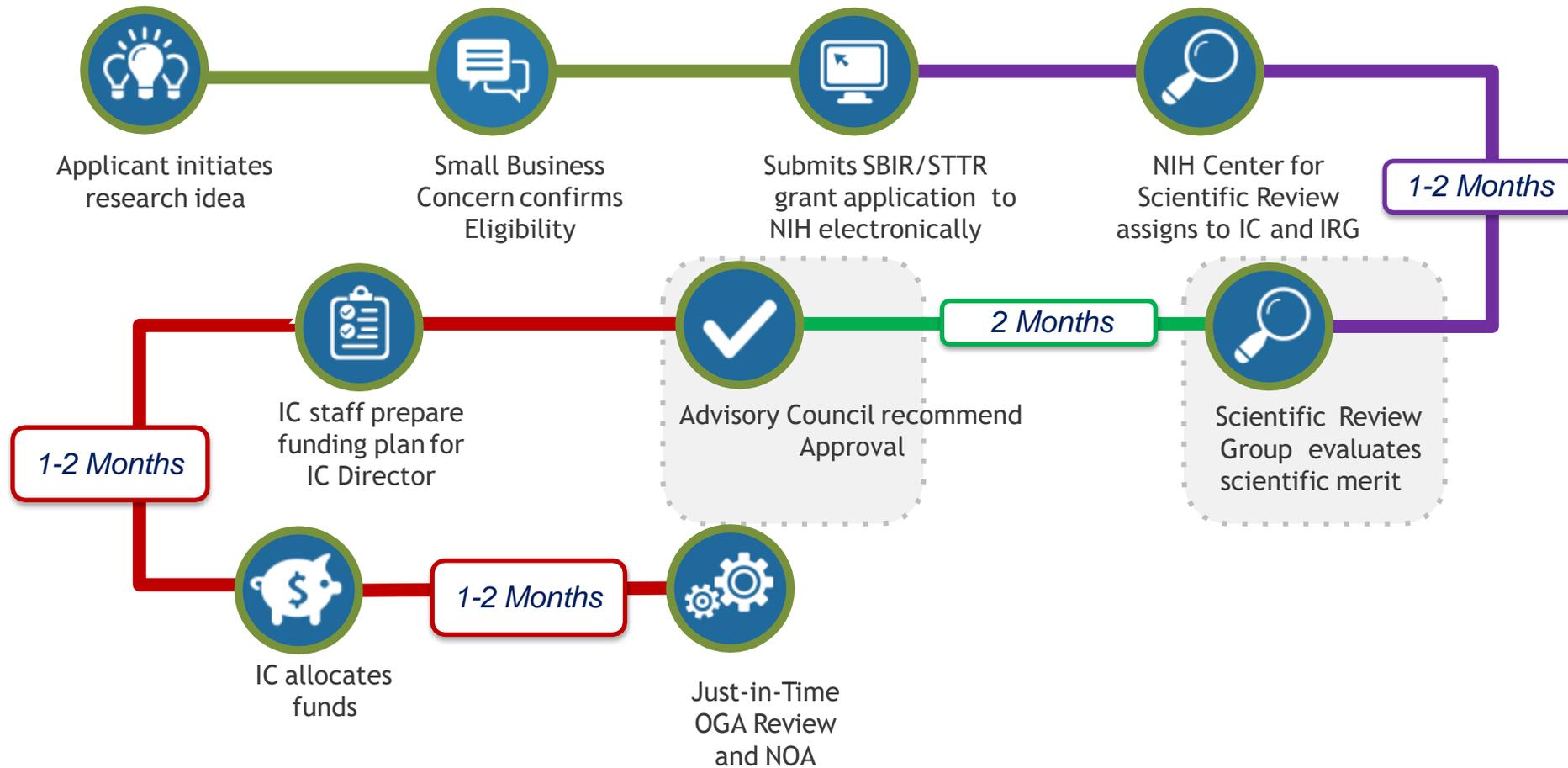
SBIR vs. STTR Programs

	SBIR	STTR
Partnering	Permits partnering	Requires a non-profit research institution partner
Principal Investigator	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
Work Requirement	Guidelines: May outsource up to 33% (Phase I), 50% (Phase II)	Minimum Work Requirements: 40% Small Business 30% Research Institution Partner

Phased Program



Timeline: Application to Award



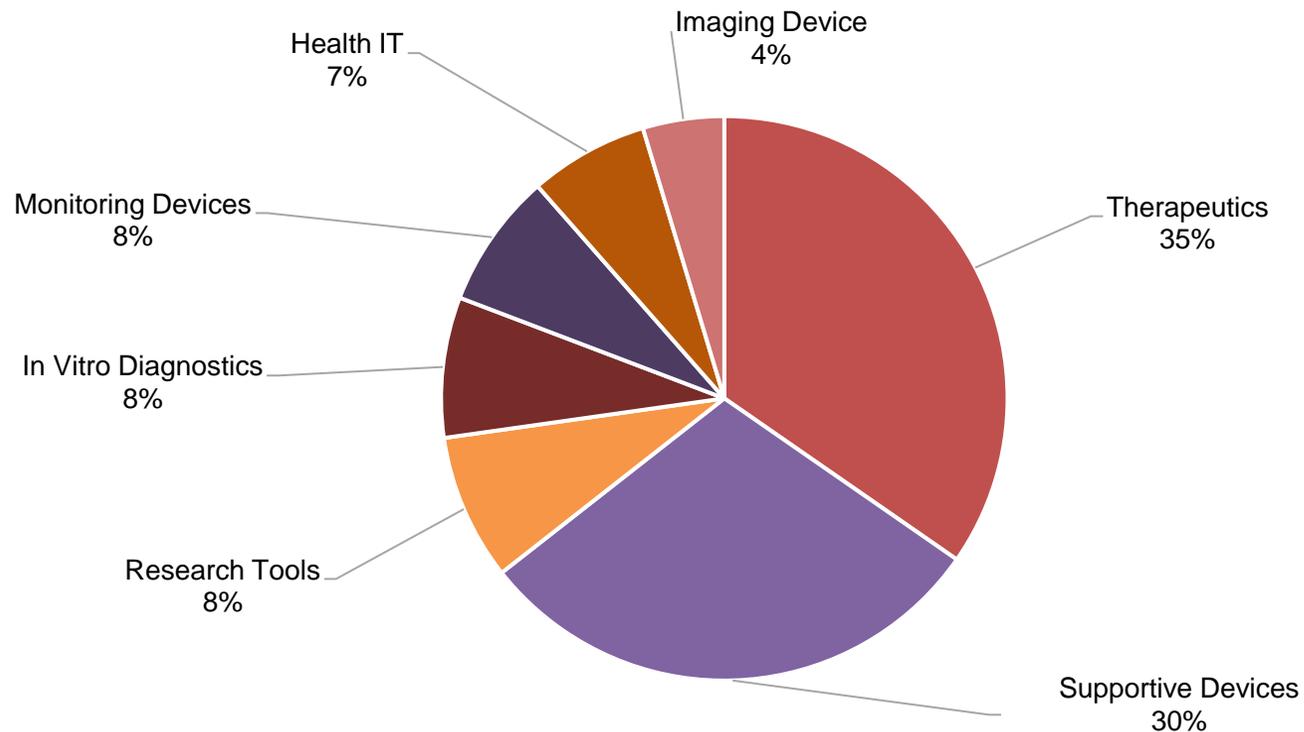
NHLBI Application Cycles

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

The NHLBI Small Business Program

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

Technologies Funded by NHLBI SBIR/STTR Program



~\$120M

Approximate annual
non-dilutive funds

~312

Active
projects

NHLBI Mission Space

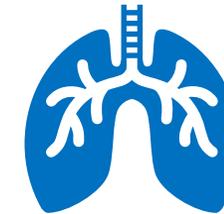


Heart

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

Lung

- Acute Respiratory Distress Syndrome
- Asthma
- Chronic Obstructive Pulmonary Disease
- Cystic Fibrosis
- Fibrotic Lung Disease
- Pulmonary Hypertension



Blood

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

Sleep

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



NHLBI Budget Specifics

	Phase I	Phase II
Guidelines	\$150K/6-12 months	\$1M/2 years
Hard Cap	\$275K/6-12 months	\$1.83M/2 years
→ NHLBI Waiver Topics	\$>275K/6-12 months	\$>1.83M/2 years

[NIH Topics for Budget Waivers](#)

SBIR Budgets are defined by **total cost** and subcontracting is limited. Know the rules and the criteria.

Check Budget allowance in each FOA

Can request a 7% Fee

- Company Profit
- Of total budget

Fee for Service (*Can Vary by IC): CRO-type activities can count as small business costs providing that:

1. It is a commercially available service
2. All analysis is done by small business
3. Fee per basis (no indirect costs by fee for service providers)

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

Omnibus Funding Opportunity Announcements

[PA-21-259](#)

R43/R44 Clinical Trial
Not Allowed

[PA-21-260](#)

R43/R44 Clinical Trial
Required

[PA-21-261](#)

R41/R42 Clinical Trial
Required

[PA-21-262](#)

R41/R42 Clinical Trial
Not Allowed

Targeted SBIR/STTR FOAs



Innovations for Healthy Living SBIR RFA (MD-22-004)

- Funds the development of devices, diagnostic tools, and other technologies specifically designed for use in patients with HLBS conditions from NIH-designated Health Disparity Populations

Next Due Date: TBA



HEAL INITIATIVE: Development of Therapies and Technologies Directed at Enhanced Pain Management SBIR/STTR RFAs (NS-20-008, NS-20-009, NS-20-010, NS-20-011)

- Funds the development of technologies and non-addictive therapeutics that may improve pain management in patients with HLBS conditions as well as technologies and therapeutics to minimize HLBS complications of analgesic use

Next Due Date: September 6th, 2022



Notice of Special Interest (NOSI): Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health (NOT-EB-21-001)

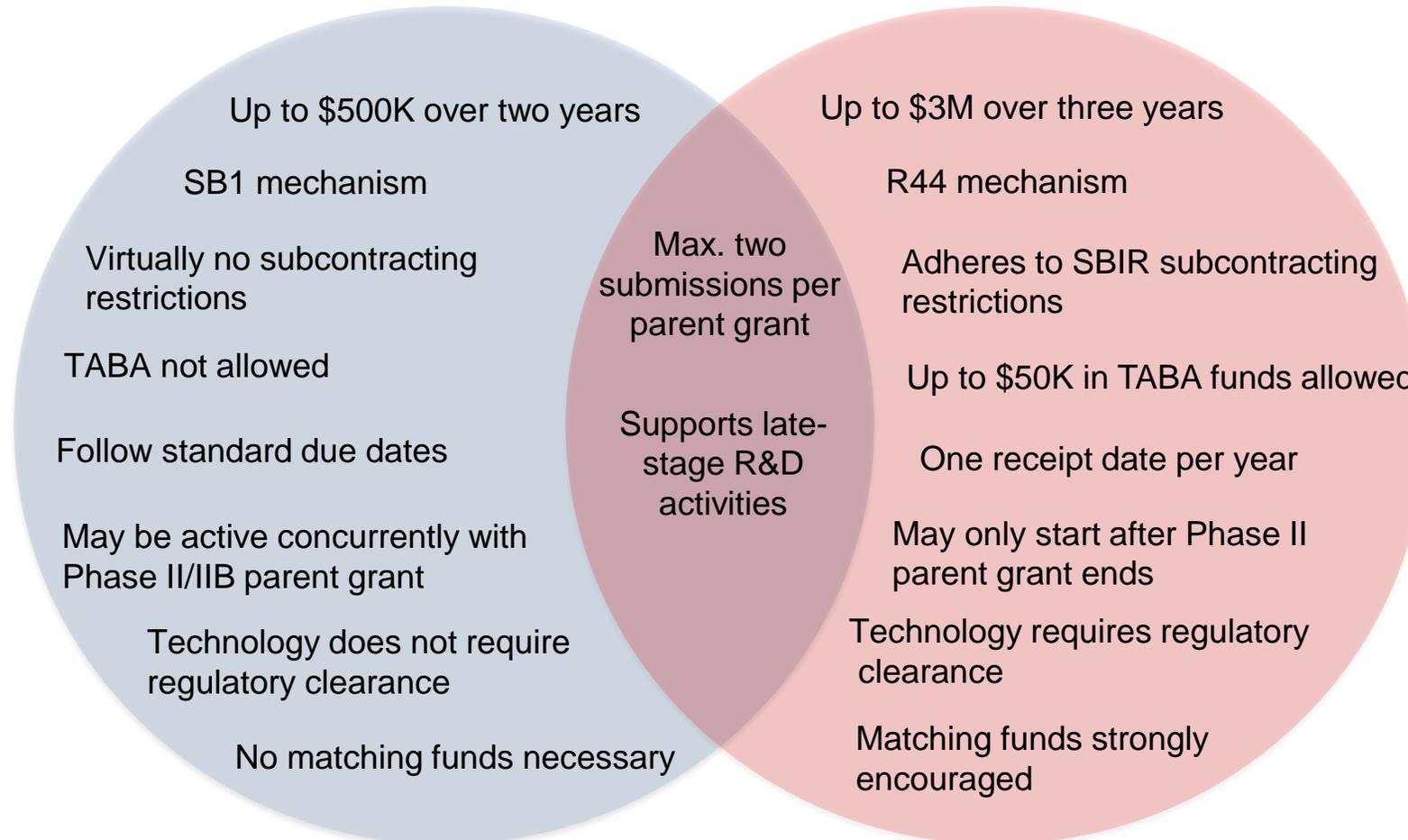
- Funds the development of tools, technologies, and devices for the diagnosis of pregnancy-related HLBS conditions

Standard Due Dates

Late-Stage Support for NHLBI Grantees

Commercialization Readiness Pilot Program (PAR-20-128, PAR-20-129, PAR-20-130)

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



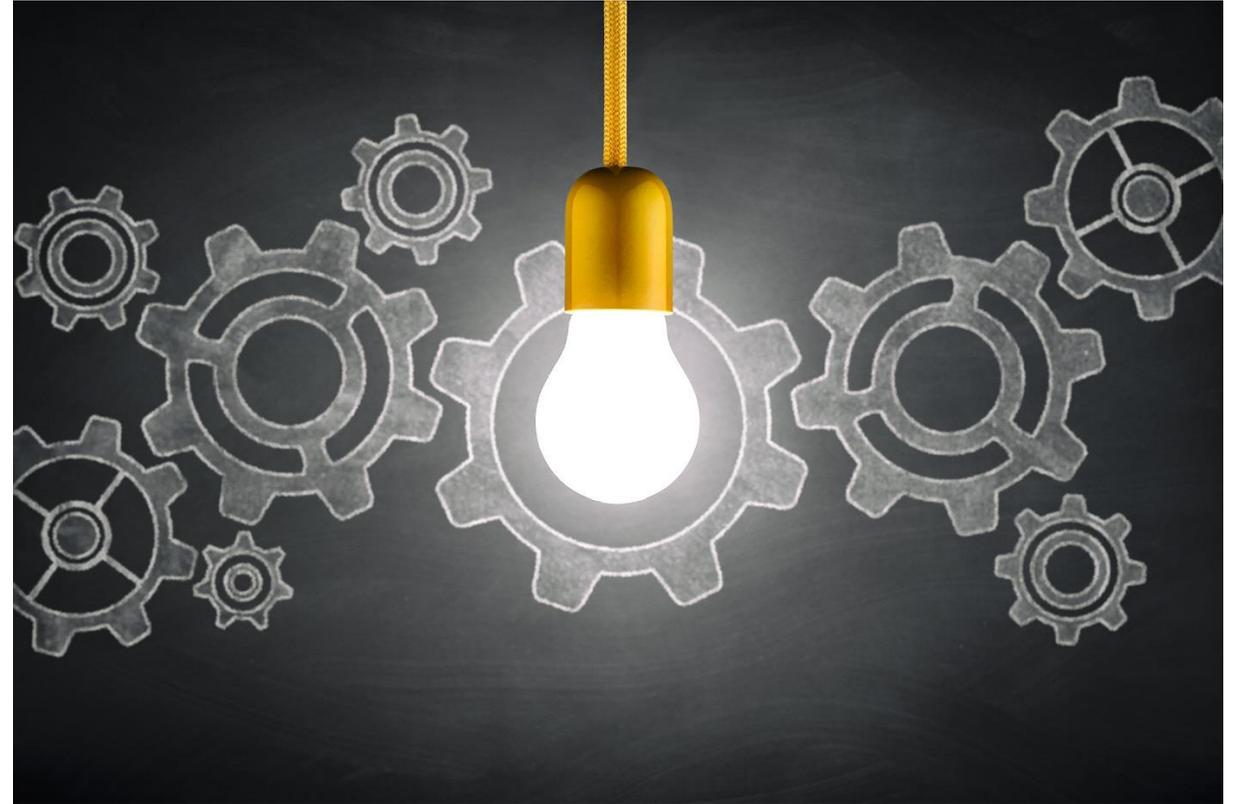
Innovation Corps (I-Corps) at NIH™ (PAR-22-073)

- 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 November 15th, 2022
- Selected companies may receive up to \$55K for course registration and travel expenses



Concept to Clinic: Commercializing Innovation Program (C3i)

- The NIBIB C3i program provides medical device innovators with the tools and frameworks that are required to commercialize their technologies
- Validation/Execution
 - Twenty-four (24) weeks of entrepreneurial training
 - Open to SBIR/STTR and non-SBIR/STTR grantees
 - Due date August 5th, 2022



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



Partnering Opportunities & Pitch Coaching

- Connects NHLBI-funded companies to potential investors and strategic partners
 - Pitch Coaching from office advisory team
 - Free registration
1. American Heart Association (AHA) Conference, Nov 2020
 2. Redefining Early-Stage Investments (RESI), Jan 2021
 3. Biotech SEED Showcase, Jan 2021
 4. Redefining Early-Stage Investments (RESI), Mar 2021
 5. American College of Cardiology (ACC) Innovation Showcase, Apr 2021
 6. Angel Capital Association (ACA) Annual Meeting, May 2021
 7. BIO Annual Meeting Digital, June 2021
 8. CaPCAT Showcase, Jun 2021
 9. Digital Redefining Early-Stage Investments (RESI), Sep 2021
 10. BioPharm America Digital, Sep 2021
 11. NIH Innovation Conference (NIC)(SEED/OER)
 12. Life Science's Summit (LSS), Nov 2021

12
Events

27
Company
Registrations

41
Pitch-coached
companies

NIH Applicant Assistance Program (AAP)

- FREE ten-week coaching program for new and previously-unsuccessful Phase I SBIR/STTR grant applications
- Participating ICs: **NHLBI**, NCI, NINDS, NIA, NCCIH, NIEHS, NCATS, NINR, NIAAA, NICHD

NIH AAP	NOT PROVIDED
Phase I Preparation Support/Review	Grant Writer
Review of Specific Aims Page	Development of Research Plan
Submission Process Coaching	Completion of submission or registration processes for you

Goal of the AAP

Provide a mentor for applicants with great technology but little NIH experience and limited NIH experience in their network, including businesses owned and led by **women** and/or **historically underrepresented individuals**

For more information, visit the [AAP Webpage](#)

Next Due Date: May 23rd, 2022

Catalyze Program

Enhancing Support for Translational Research

Catalyze provides a comprehensive suite of support and services to **academic investigators and small businesses** to facilitate the **translation of basic heart, lung, blood and sleep discoveries** into **viable therapeutics, devices and diagnostics ready for human testing**.

Funding

Unique funding strategy to leverage federal investment with matching commitments and flexibility to adjust to technical challenges

Individualized Support

Milestone-driven project management and technical support to mitigate technical risk

Coordinated Approach

Seamless continuum of funding programs to advance promising heart, lung, blood and sleep technologies from validation through first-in-human trials

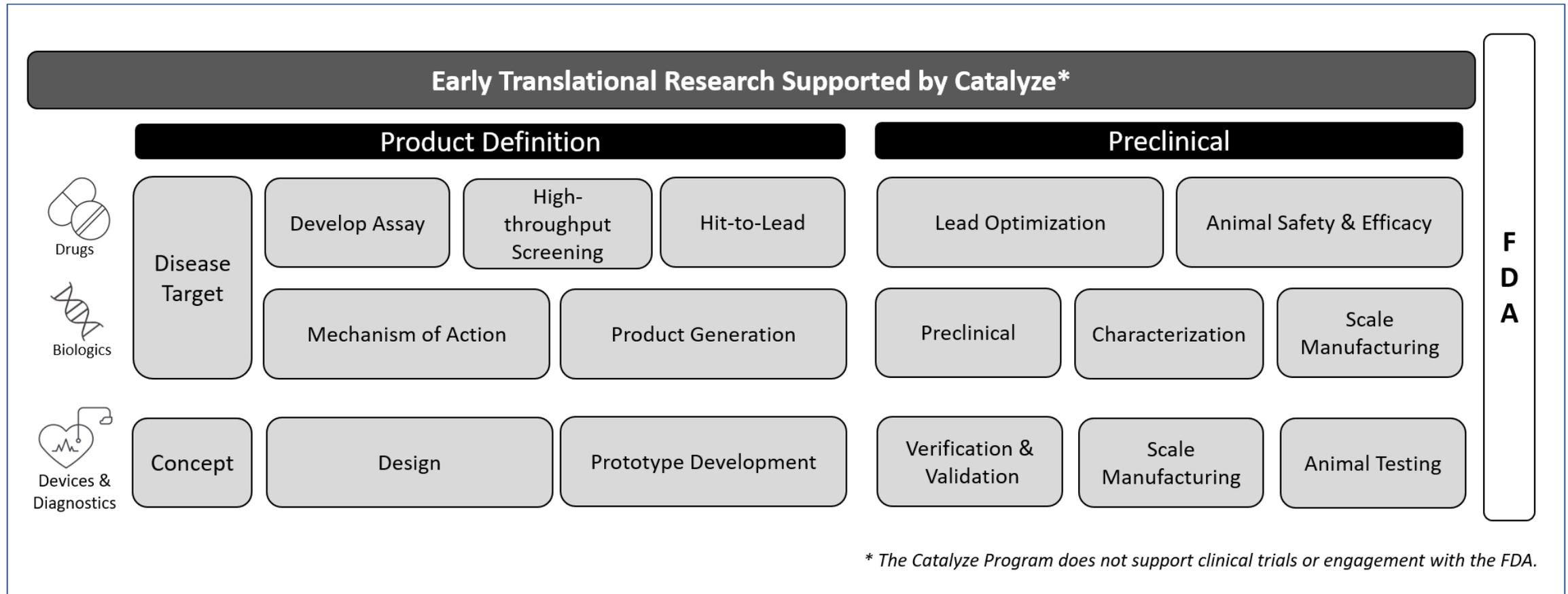
Program Flexibility

Evaluation and oversight to adjust program and projects based on trends, challenges, and to share best practices

For more information email NHLBI_Catalyze@mail.nih.gov



Activities Supported by Catalyze



Visit the [Catalyze Website](#) for more information

Catalyze Program Funding Opportunities

Next Application Deadline: July 21st, 2022

Devices

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

Small Molecules and Biologics

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

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

Enabling Technologies

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



NHLBI Small Biz Hangouts



[NHLBI Playlist](#)

Regulatory

- Navigating the FDA Website
- "First Contact" with FDA
- Finding the Right Regulatory Consultant
- Developing a Target Product Profile

Commercialization

- Writing your Phase II Commercialization Plan
- Identifying and Connecting With Your Customer
- How Pharma Evaluates New Therapeutic Opportunities

Intellectual Property

- Intellectual Property Basics for the New Innovator
- Making Your Mark: The Use and Care of Trademarks
- Patent Litigation: Basics, Defense, and Offense – Parts 1 & 2

Helpful Resources For Applicants

- [2021 HHS Small Business Conference Playlist](#)
- [Writing a Good Commercialization Plan](#)
- [Writing a Competitive Commercialization Plan \(NIA\)](#)
- Sample Applications
 - [NIAID SBIR/STTR Grant Applications](#)
 - [NIA Sample SBIR Grant Applications](#)
 - [NCI Sample SBIR/STTR Grant Applications](#)
- [SF424 SBIR/STTR Application Instructions](#)
- [Annotated Form Set for NIH SBIR Grant Applications](#)
- [SBIR/STTR Application Process Infographic](#)
- [SBIR/STTR Study Section List](#)
- [CSR Assisted Referral Tool](#)
- [NIH RePORTER](#)
 - Database of NIH-supported Research
 - [Matchmaker](#): find similar projects or program officials



Connect with Us!

Connect with the NIH

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

Connect with the NHLBI

- [NHLBI Small Business Inquiry](#)
-  @NHLBI_SBIR
- Sign up for our NHLBI Newsletter [HERE](#)
- **Email:** NHLBI_SBIR@mail.nih.gov

Thank you!



National Heart, Lung,
and Blood Institute