

SBIR · STTR
America's Seed Fund



The NHLBI SBIR/STTR Programs

Stephanie Davis, PhD

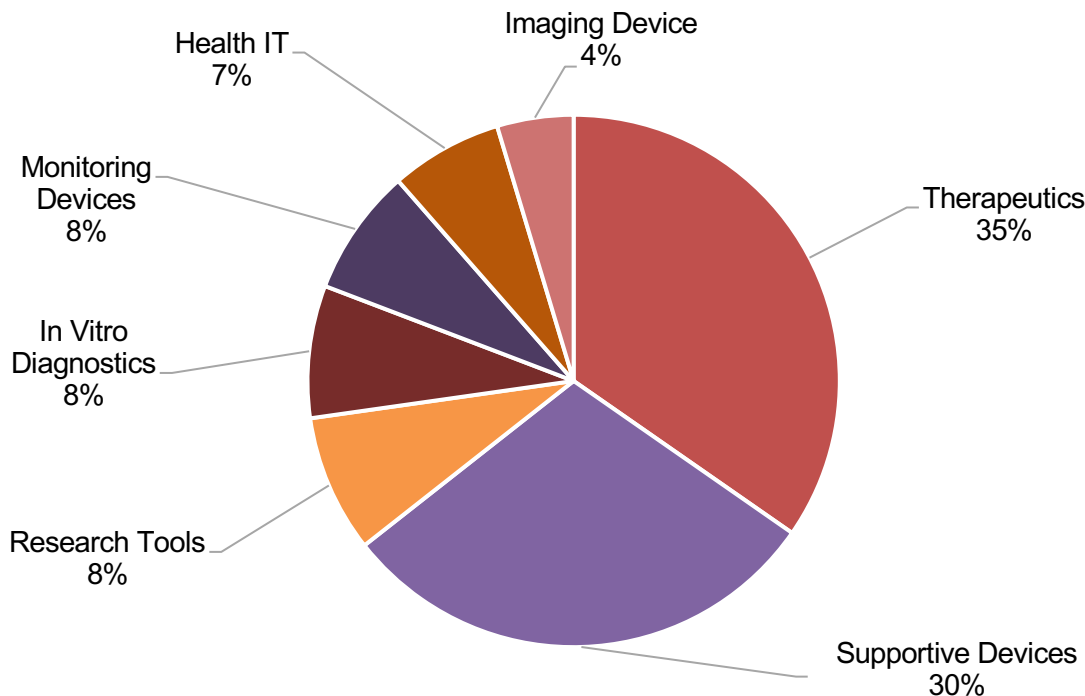
Small Business Program Coordinator

National Heart, Lung, and Blood Institute (NHLBI)

The NHLBI Small Business Program

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

Technologies Funded by NHLBI SBIR/STTR Program



~\$117M
Approximate annual
non-dilutive funds

~312
Active
projects

Omnibus FoAs

[PA-20-260](#)

R43/R44

No
Clinical Trial Allowed

[PA-20-262](#)

R43/R44

Clinical Trial Required

[PA-20-261](#)

R41/R42

Clinical Trial Required

[PA-20-265](#)

R41/R42

No
Clinical Trial Allowed

NHLBI Budget Specifics

	Phase I	Phase II
Guidelines	\$150K/6-12 months	\$1M/2 years
Hard Cap	\$256K/6-12 months	\$1.71M/2 years
→ NHLBI Waiver Topics	\$>256K/6-12 months	\$>1.71M/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)

Advisory Experts at NHLBI



Renée Arnold, PharmD

Entrepreneur-In-Residence
Health Economics Specialist



Gautam Prakash, PhD, JD

Intellectual Property Advisor



Luis Gutiérrez, MBA

Entrepreneur-In-Residence



Steve Flaim, PhD, MBA

Investor-In-Residence

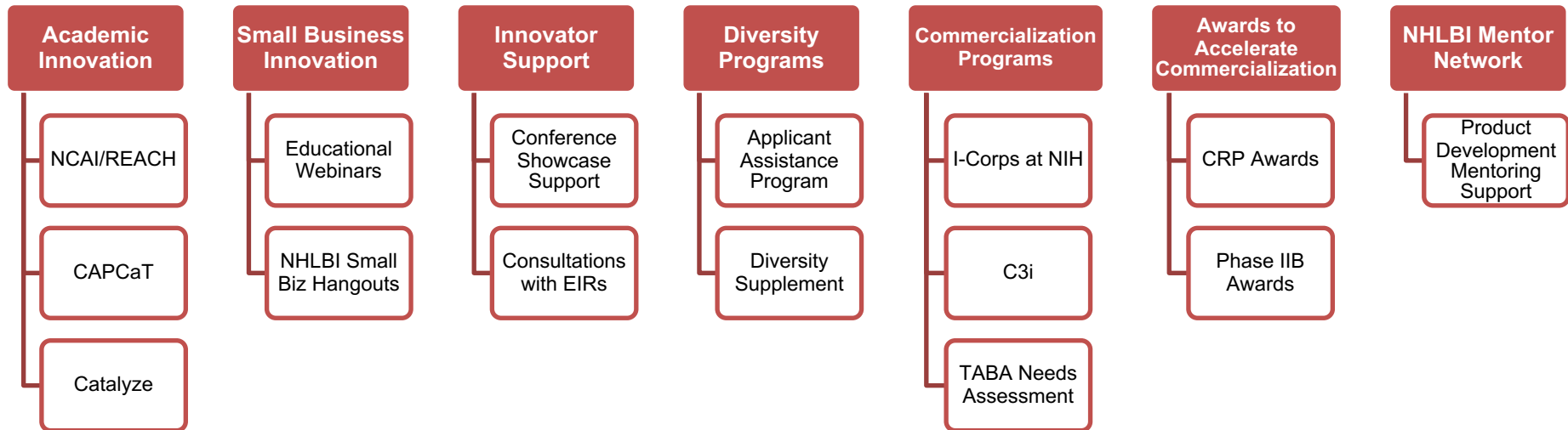


Kwame Ulmer, MBA

Entrepreneur-In-Residence
Regulatory Specialist

Private Investment
Small Business
Product Development
Pitch Coaching
Business Development
Intellectual Property
Regulatory
Reimbursement
Health Economics

NHLBI Innovation Office Programs and Resources



NIH Applicant Assistance Program (AAP)

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

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 20th, 2021

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

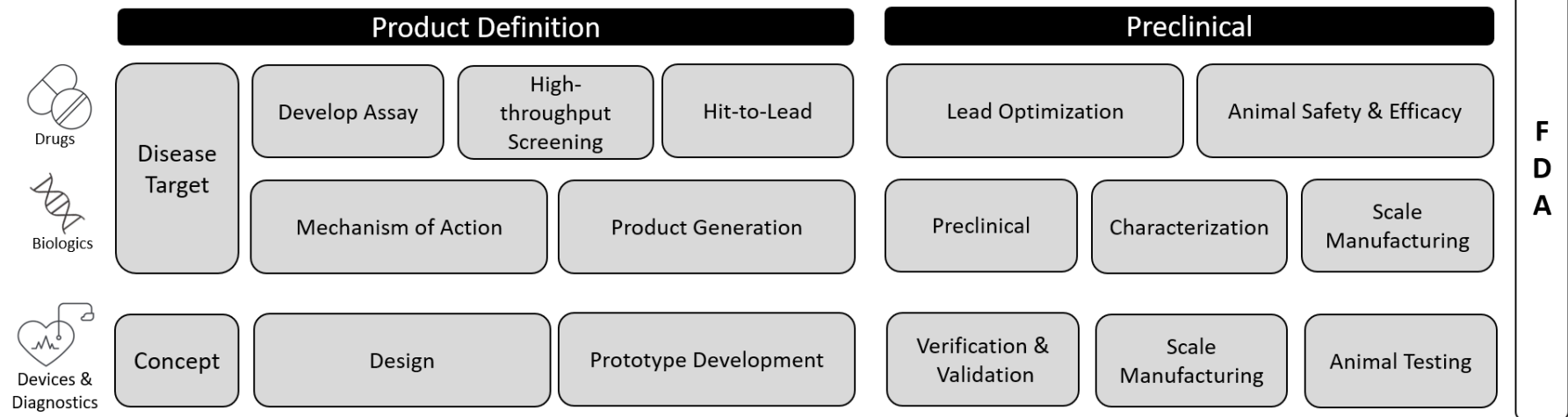
Evaluation and oversight to adjust program and projects based on trends, challenges, and to share best practices

For more information email NHLBI_Catalyze@mail.nih.gov



Activities Supported by Catalyze

Early Translational Research Supported by Catalyze*



* The Catalyze Program does not support clinical trials or engagement with the FDA.

<https://www.nhlbi.nih.gov/grants-and-training/funding-opportunities-and-contacts/NHLBI-Catalyze-Program>

Current Catalyze Program Funding Opportunities

Next Application Deadline: March 9, 2021

Devices

- Prototype Design and Testing, Diagnostic Disease Target Identification, Assay Development and Research Tool Dev. ([RFA-HL-20-024](#))
- Prototype Testing and Design Modification, Diagnostic Disease Target Assay Development, and Design Characterization, and Research Tool Testing and Validation ([RFA-HL-20-028](#))

Small Molecules and Biologics

- Target Identification and Validation, Preliminary Product/Lead Series Identification ([RFA-HL-20-023](#))
- Preliminary Product/Lead Series Identification ([RFA-HL-20-027](#))

Enabling Technologies

- Enabling Technologies and Transformative Platforms for HLBS Research ([RFA-HL-20-022](#))

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



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

Resources and Tips for Applicants

■ Resources


- [NIAID Small Business Grant Sample Applications](#)
- [Writing a Good Commercialization Plan](#)
- [NIA Sample SBIR Grant Application](#)
- [SF424 SBIR/STTR Application Instructions](#)
- [Annotated Form Set for NIH SBIR Grant Applications](#)
- [SBIR/STTR Application Process Infographic](#)
- [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