Beyond Research: Building a Business

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"Beyond Research: Building a Business"

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Office of the Director | Office of Extramural Research | National Institutes of Health

New Support for Awardees

Technical and Business Assistance (TABA)

TABA Needs Assessment → **TABA Funding** (requested in grant application)

Education

- I-Corps at NIH *Phase I
- Concept to Clinic: Commercializing Innovation (C3i) Program

Funding and Support

- CRP Funding *Phase II/IIB
- Regulatory & Business Development Consultants

Partnering and Investment Opportunities

- Company Showcase

BIO International Convention · RESI Redefining Early Stage Investments · LifeSciences Summit · The MedTech Conference · ACA Angel Capital Association

https://sbir.nih.gov/support-for-awardees

Purpose of TABA

The Technical and Business Assistance (TABA) Program helps small businesses identify and address their most pressing product development needs.

Enables companies to:

- Make better technical decisions
- Solve technical problems that are beyond the scope of the funded R&D
- Minimize technical risks
- Commercialize the product

TABA Funding

- Grantees may request TABA Funding as part of their grant or as a supplement (NOT-OD-21-062)
- TABA costs **may not** exceed:
  - $6,500 in additional funding **per year** for a Phase I
  - $50,000 in additional funding **per project period** for a Phase II

- Institutes/Centers can set individual budget and TABA guidelines
- Projects that are awarded TABA Funding **cannot** use centralized TABA Programs (TABA Needs Assessment) during that SBIR/STTR Project Phase

TABA Funding Guidelines

Support subcontractor or consultants for:

- 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 literature available through on-line databases.

Funding <u>cannot</u> support:

- Activities done by:
  - Recipient small business
  - Affiliates/investors
  - R&D subcontractor/consultant
- Contributions to the SBIR/STTR fee
- Activities outside the scope of the award
- Contingency costs or costs associated with the award R&D
- Audit or Bookkeeping services

TABA Needs Assessment

Help small businesses identify and address their most pressing product development needs.

TABA Needs Assessment Report

- ✓ Validates request for TABA funding
- ✓ Helps Company write a strong Phase II Commercialization Plan

- Summary Analysis/Company Summary
- Target Market Attractiveness
- Technology and Market Needs
- Regulatory/Clinical
- Business Model Profitability
- Reimbursement
- Competitive Advantages/Intellectual Property
- Market Access/Sales and Marketing Strategy
- Management Team
- Strategic Partners
- Funding Status
- Recommended Actions/Plan

110 companies participating since launch in November of 2020.

"Information received was critically helpful in our business plan."

"It is like having a professional roadmap."

https://sbir.nih.gov/support-for-awardees/taba-needs-assessment

TABA Needs Assessment

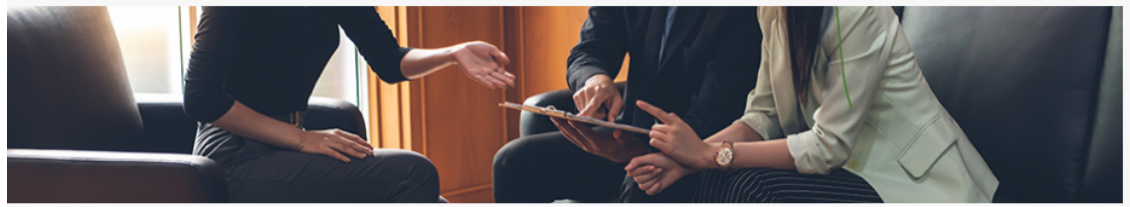
Eligibility:

SBIR or STTR recipients (grant or contract) with:

- Active NIH Phase I or Phase II OR
- Within two years of the completion of an NIH Phase I

- Projects that received Niche Assessment or TABA Funding in the Phase I are **ineligible**
- Participation in other Support Programs (e.g., I-Corps at NIH or C3i) **does not** make a company ineligible

Request Process



SBIR/STTR Home > Technical and Business Assistance - Needs Assessment

Technical and Business Assistance - Needs Assessment

The TABA Needs Assessment Report provides a third party, unbiased assessment of your progress in 10 technical and business areas that are critical to success in the competitive healthcare marketplace:

- Target Market Attractiveness
- Technology and Market Needs
- Regulatory/Clinical
- Business Model Profitability
- Reimbursement
- Competitive Advantage and Intellectual Property
- Market Access/Sales and Marketing Strategy
- Management Team
- Strategic Partners
- Funding Status

The report will also suggest the highest priority steps you can take to improve the commercial potential of your product or service. The TABA Needs Assessment is performed by Vikriti Management Consulting on behalf of NIH and a sample report may be found here. There is no cost for this report and the time commitment for participation is minimal - selected companies are required to participate in a small number of information gathering interviews with Vikriti's team of commercialization experts and a feedback session. Needs Assessment Reports will be completed in 2-3 months.

Eligibility: Companies that have held an active Phase I SBIR/STTR grant or contract within the past two years

Deadline: The Needs Assessment Program will be open throughout the year. Requests will be reviewed on a monthly basis with notification of status within 60 days of submission.

Learn more about the TABA Needs Assessment Rep

Register for the webinar today!

Request a Needs Assessment Report

- Open all year
- **MUST** submit a request at: https://sbir.nih.gov/support-for-awardees/taba-needs-assessment
- Requests are reviewed monthly
- Notification of status within 60 days of submission
- Report is completed in 2-3 months

April 28, 2021

I-Corps at NIH

MICHAEL WEINGARTEN
SBIR DEVELOPMENT CENTER
NATIONAL CANCER INSTITUTE

SBIR
DEVELOPMENT CENTER

I-CORPS AT NIH

- **Funding Opportunity Announcement (FOA) PA-19-029**

- Intensive *Entrepreneurial Immersion* course aimed at providing teams with skills and strategies to reduce commercialization risk
- Curriculum emphasizes *Reaching out to Customers* to test hypotheses about the market(s) for the technology
- Teams are expected to conduct over *100 interviews* in 8 weeks
- Format is focused on *Experiential Learning*
- NCI SBIR designed, launched, and manages the program for NIH
- 24 Institutes at NIH and CDC participate

I-CORPS at NIH

#ICorpsNIH

https://sbir.cancer.gov/icorps

TOP 10 STARTUP MISTAKES

100 First#Hits
www.100FirstHits.com

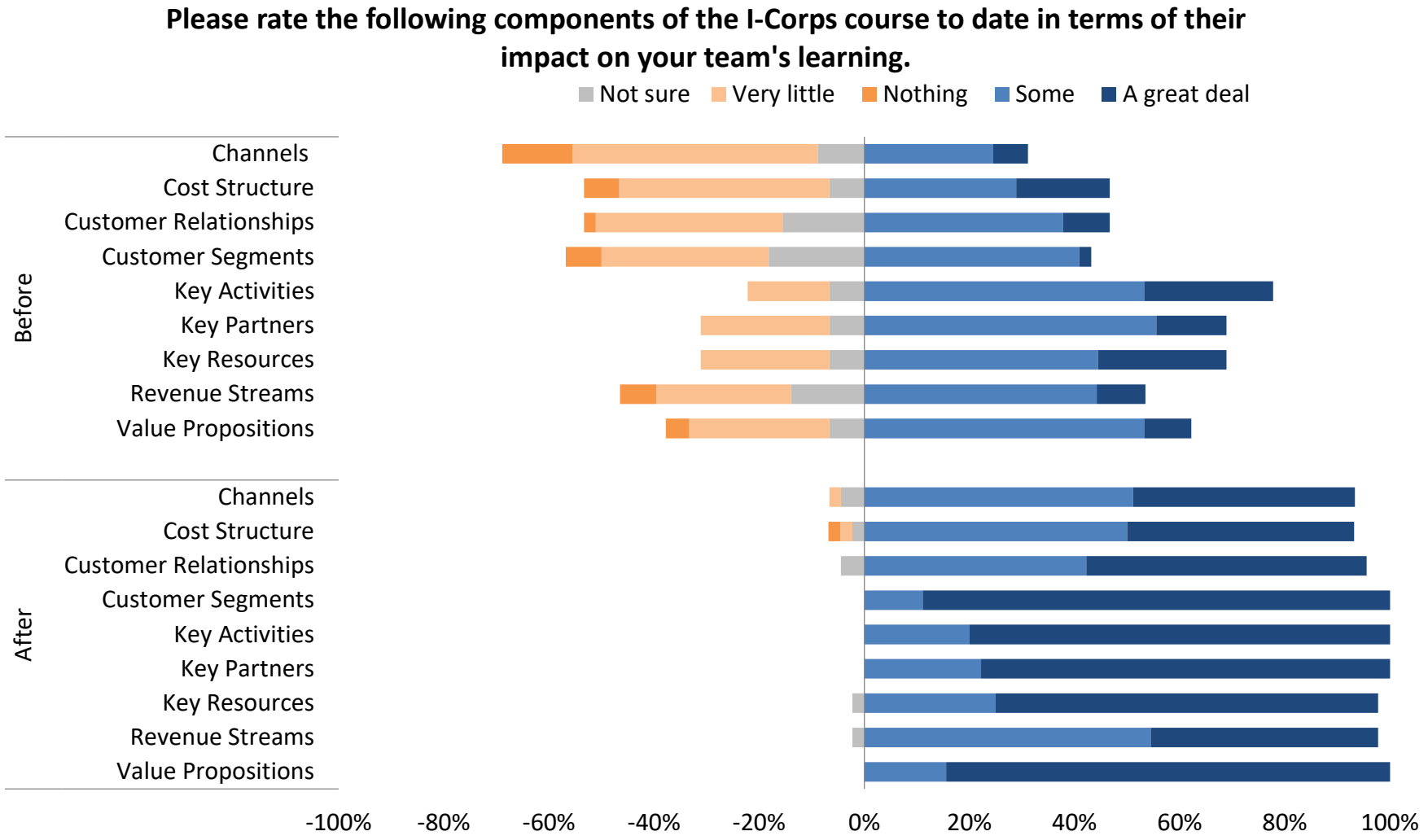
8. Spending Too Much Money **18** (2,1%)
9. Failing To Ask For Help **12** (1,4%)
10. Ignoring Social Media **6** (0,7%)
5. Not Having The Right Co-Founders **66** (7,9%)
6. Chasing Investors, Not Customers **45** (5,4%)
7. Not Making Sure You Have Enough Money **28** (3,3%)

Commercialization Plan – Business Model Canvas

I-CORPS at NIH

Key Partners	Key Activities	Value Propositions	Customer Relationships	Customer Segments
	Key Resources		Channels	
Cost Structure			Revenue Streams	

Business Model Canvas Knowledge



I-CORPS CASE STUDY - MEDABLE

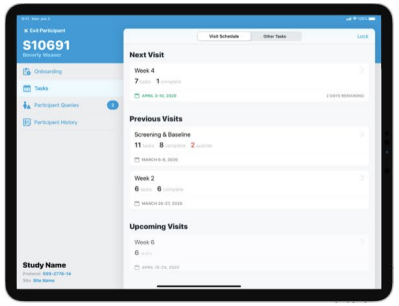
I-CORPS at NIH

MEDABLE

Ingrid Oakley-Girvan
SVP, Research and Strategy
I-Corps at NIH – 2018

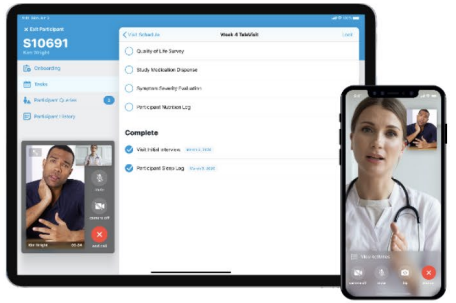
Informed consents with

Medable TeleConsent



Clinical Outcome Assessments with

Medable TeleCOA

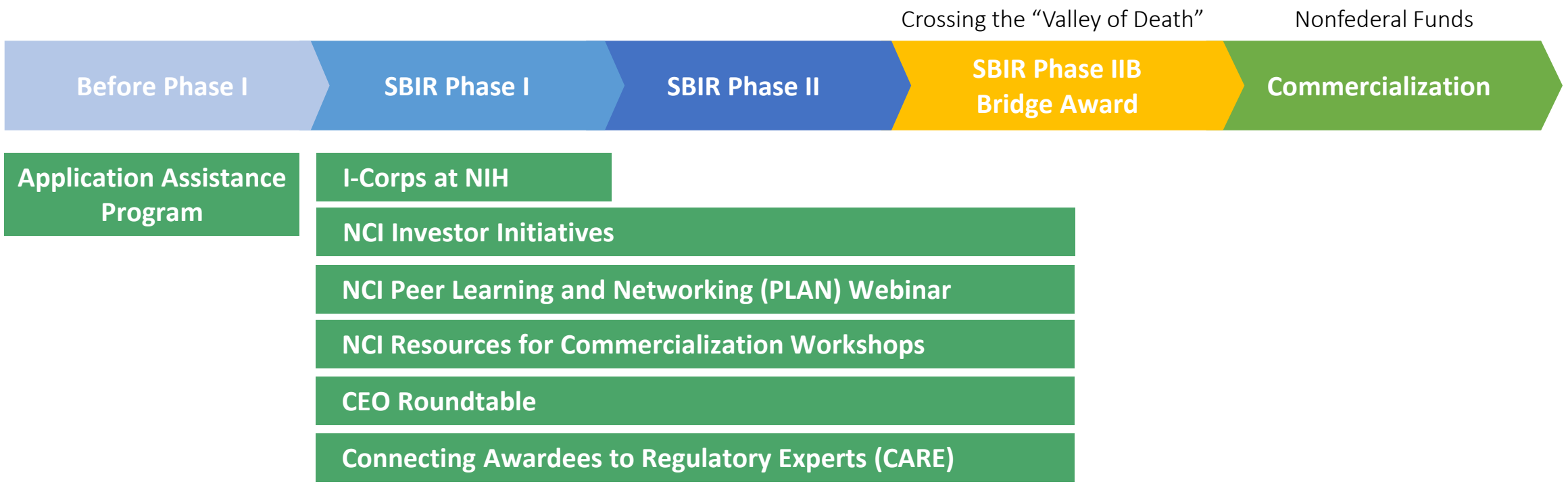


Onsite visits with

Medable TeleVisit

- Validated areas of unmet need as opportunities; 4+ new commercial apps
- New TeleVisit™ mobile app enables clinical trial research to progress in a social distancing setting and is used by leading biopharma sponsors and clinical research organizations worldwide
- Secured $91 million in Series C funding and has raised more than $136 million to date.

NCI SBIR ASSISTANCE



https://sbir.cancer.gov/resources

2020 NEW OPPORTUNITY I: SMALL BUSINESS TRANSITION GRANT

FAST-TRACK

Phase I STTR

TRAINING
- SBC PI: Postdoc
- Mentoring plan required
  - Technical Mentor
  - Business mentor

TECHNICAL
- PI preps technology to move to SBC
- I-Corps at NIH required

Transition

PERSONNEL
- PI moves to SBC

TECH UPDATE
- R&D Milestones
- Commercialization plan
- IP agreement

Phase II SBIR

TRAINING
- Same PI (non-transferrable)
- Mentoring Continues
  - Contact type and frequency in mentoring plan

TECHNICAL
- Most research conducted at SBC site
- Small pivots allowed
  - No major scope changes

VISIT US ONLINE!

SBIR.CANCER.GOV

HHS Small Business Conference

Beyond Research: Building a Business

Kwame Ulmer
Entrepreneur-in-Residence

INNOVATION OFFICE
National Heart, Lung and Blood Institute

April 28, 2021

National Heart, Lung, and Blood Institute

NHLBI's 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:

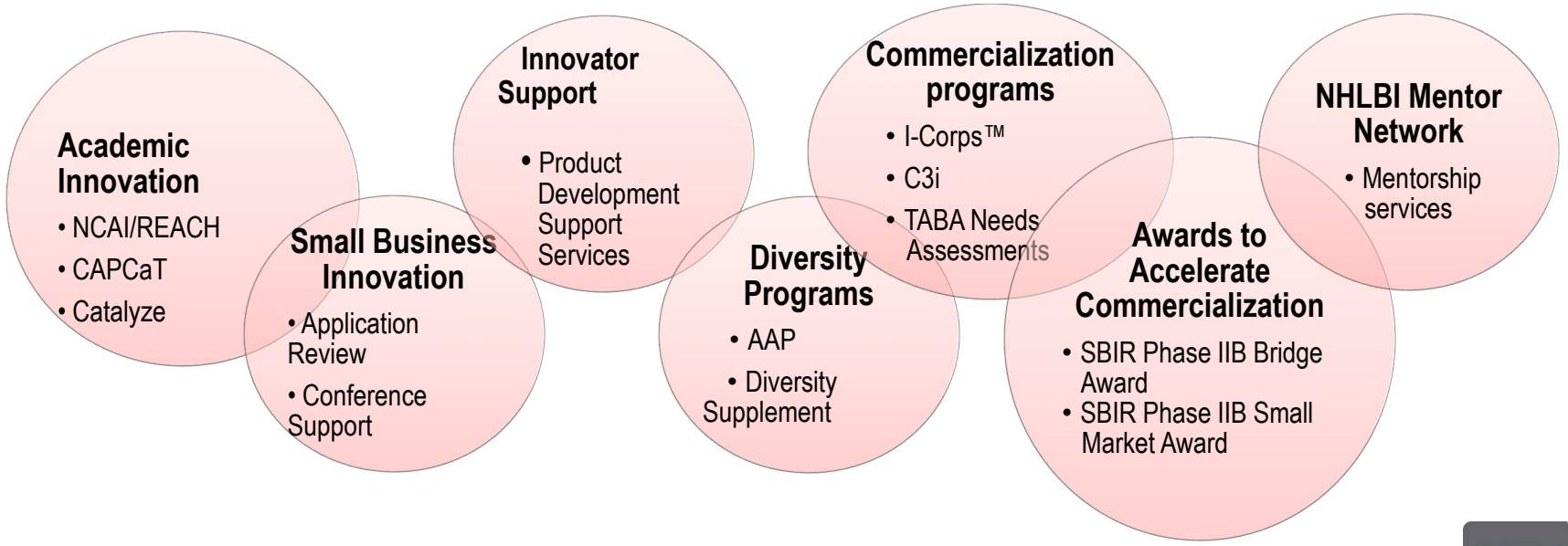
- **Understand Human Biology**
- **Reduce Human Disease**
- **Develop Workforce & Resources**
- **Advance Translational Research**

Innovation office supports advancing translational research

NHLBI Continuum of Support

Funding and Support for NHLBI Innovators

- Supports the NHLBI innovator community to validate and advance discoveries to products that improve patient care and health.
- Develop relationships with strategic partners and build opportunities for NHLBI innovators to further their product development efforts.

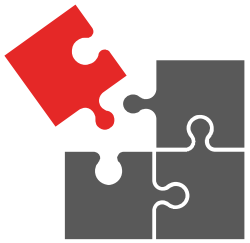


NHLBI Innovation Office Support Services

One on One Advisory Services

Contact NHLBI specialists with specific questions:

- *SBIR/STTR applications*
- *Regulatory*
- *Business development*
- *Intellectual property*



Product Development Support Services

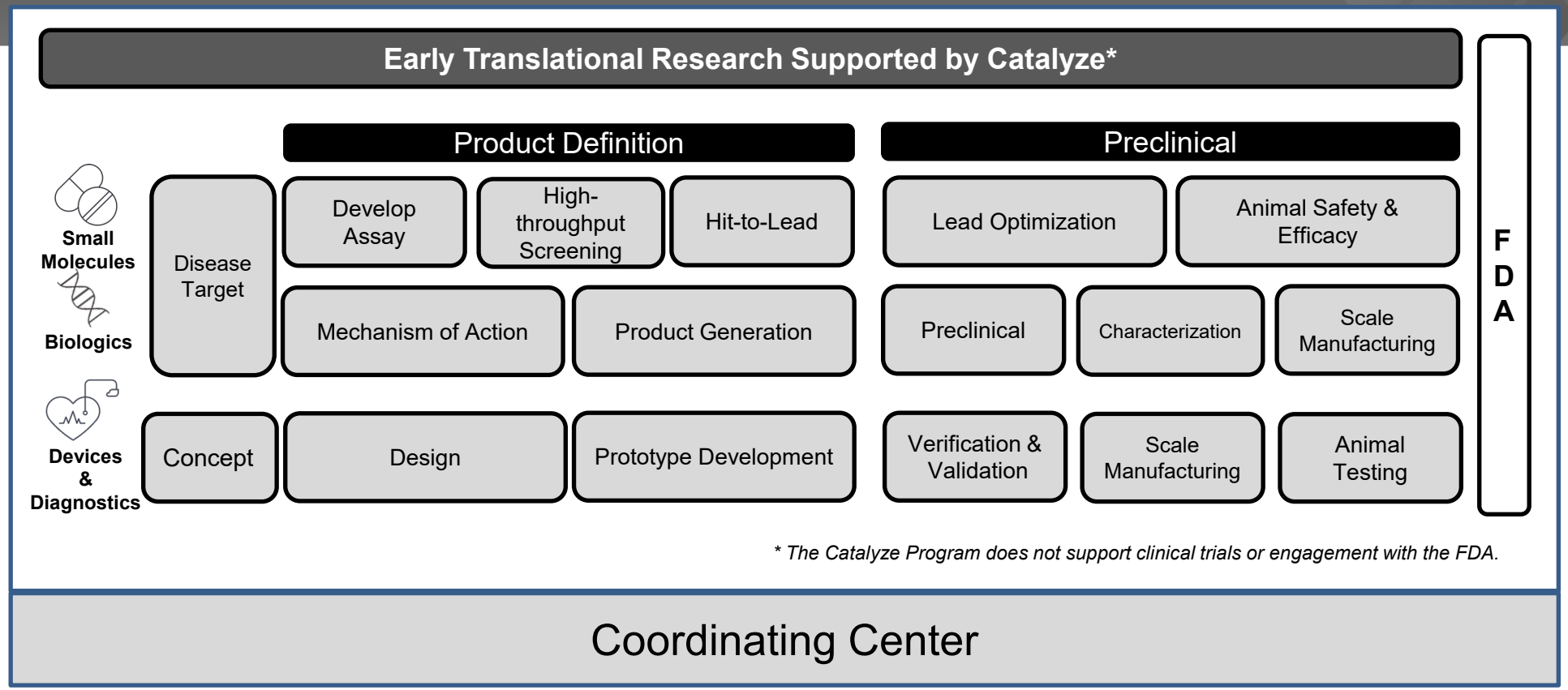
- *National Mentor Network – targeted company support*
- *Showcase Events - offers conference registration fees to industry partnering and investor meetings*
- *Pitch coaching for Showcase Events*

"Small Biz Hangouts" YouTube Playlist

- *Series of videos regarding common issues that biomedical innovators face.*
- *Go to bit.ly/SmallBizHangouts*

Website: sbir.nih.gov/nhlbi

NHLBI Catalyze Program



Funding

Leverage federal investment with non-federal match

Coordinated Approach

Seamless continuum of funding programs from validation through first-in-human trials

Individualized Support

Milestone-driven project management

Technical support to mitigate technical risk

Program Flexibility

Evaluation and oversight

Identify and share best practices

NIH National Heart, Lung, and Blood Institute

For more information email NHLBI_Catalyze@mail.nih.gov

NHLBI Innovation Subject Matter Experts

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

Kwame Ulmer, MBA
Entrepreneur-In-Residence
Regulatory Specialist

Gautam Prakash, PhD, JD
Intellectual Property Advisor

Luis Gutiérrez, MBA
Entrepreneur-In-Residence

Steve Flaim, PhD, MBA
Investor-In-Residence

NIH Support for Innovators

Chris Sasiela, PhD, RAC
Innovator Support Team Lead / Senior Regulatory Specialist
Small business Education and Entrepreneurial Development (SEED) Office

Online Resources – Application Preparation

Preparing an application

- Sample Applications [NIAID]
  - https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44)
- Sample Applications [NIA]
  - https://www.nia.nih.gov/research/osbr/nia-small-business-sample-applications
- Understanding Per Review [CSR]
  - https://www.youtube.com/user/CSRNIH

Online resources – Commercialization

Building a business

- Small Business Workshops [NIA]
  - https://www.nia.nih.gov/research/osbr/archived-small-business-events
- Business Finances [NIBIB]
  - https://www.nibib.nih.gov/entrepreneurial-finance-course
- Pitching Your Company [NHLBI]
  - https://www.youtube.com/watch?v=6QkIlDS_aPE&list=PL_ntiNjc6Gvksm4mQxmGh0iHM946PXEu0&index=3
- Intellectual Property Portfolios [NHLBI]
  - https://www.youtube.com/playlist?list=PL_ntiNjc6Gvksm4mQxmGh0iHM946PXEu0

NIH SBIR/STTR Diversity Supplement

PA-18-837

Administrative Supplement to Promote Diversity in Research and Development Small Businesses

Purpose: Improve the diversity of the research workforce

- Small Businesses with active small business awards (SBIR/STTR)
- Recruit and support individuals from underrepresented groups in health-related research

Career Level:

- Undergraduate
- Graduate
- Degree Holders
- Postdoctoral
- Developing Independent Career

Amount:

$5,000- 100,000*

*Depending on candidate career level

Rolling Deadline

National Institutes of Health
Office of Extramural Research

Concept to Clinic: Commercializing Innovation

- C3i program

Entrepreneurial education that teaches teams (innovator, entrepreneurial lead, mentor) methods to assess the commercial value, validate the market need, and develop a compelling pitch for their biomedical technologies.

- Available to academic and small business awardees.

SEED Innovator Support Team

- Available to NIH awardees
- Business, regulatory, payment, IP SME focused consults
- **Connect through your NIH Program Officer**

- Send us an email (SEEDinfo@nih.gov)
- Info to include in your message:
  - Award number and NIH Program Officer name
  - Brief background about your project
  - Topic you want help with and specific questions

Questions