

NIH Support for Biomedical Product Development

Matt McMahon

Director

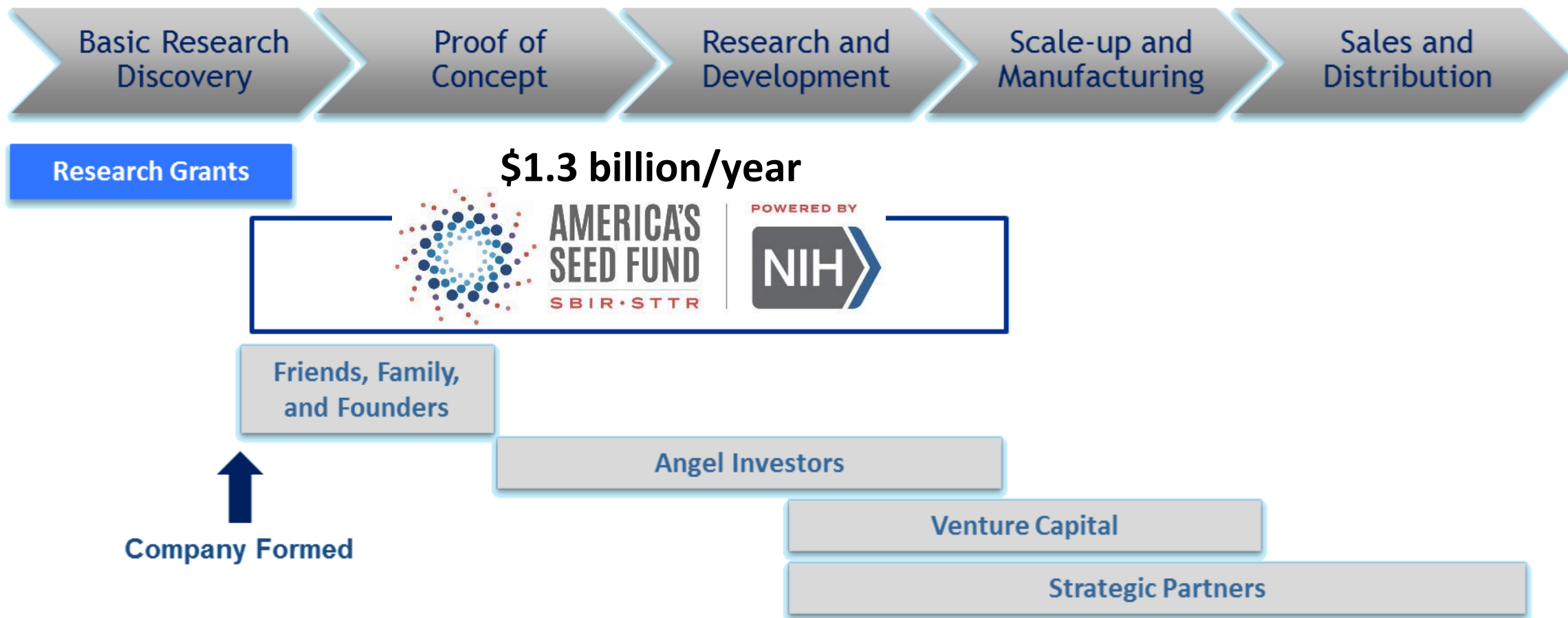
SEED (Small business Education & Entrepreneurial Development)

OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH



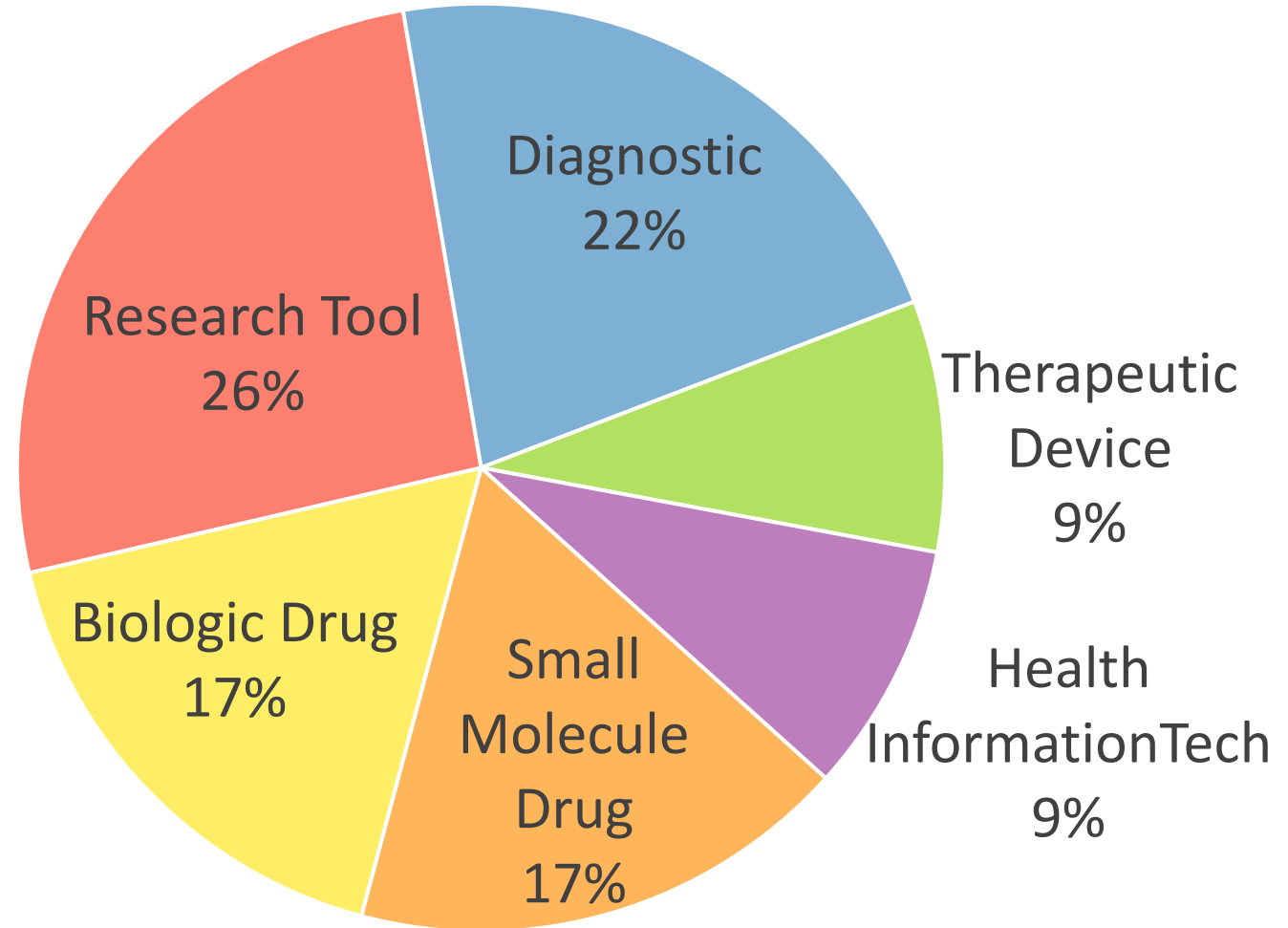
National Institutes of Health
Turning Discovery Into Health

NIH Small Business Programs are the largest sources of early-stage capital for life sciences in the U.S.



NIH Small Business Program Portfolio

supporting over 1,400 small businesses each year



MABSWITCH

kánnalife

Ternalys
THERAPEUTICS

STINGRAY
THERAPEUTICS

TIBARAY

IMMUNO
PHOTONICS

immunovia

CARI
Health

Cerulean
SCIENTIFIC

MOTIVITY

basepair

PA
therapeutics

OPSIN
BIOTHERAPEUTICS

Remmie



VINCERE

TRACE
BIOSCIENCES

NEUROSCOPE AI

ARTIAM
BIO

NeuroGeneces

Sur180
THERAPEUTICS



RESI
REDEFINING
EARLY STAGE
INVESTMENTS

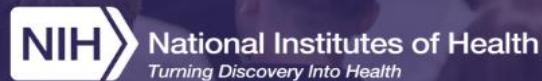
Presented by: LIFE SCIENCE
NATION
Connecting Products, Services & Capital

BIOTECH SHOWCASE™

JANUARY 8-10, 2024
SAN FRANCISCO, CA



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NIH Portfolio Success

Novartis snaps up rare disease biotech DTx Pharma in \$1bn deal

\$1.5M from NIH

The acquisition adds an siRNA delivery platform to Novartis's armament and a potential first-in-class treatment for Charcot-Marie-Tooth Disease.

Sunbird Bio snaps up Glympse Bio for protein-based diagnostics

\$4M from NIH

\$90M+ in private funds

Adamis Pharmaceuticals Closes Merger with DMK Pharmaceuticals

Javelin Biotech Aims to Develop Industry-Leading
"Organ-on-a-Chip" Predictive Pharmacokinetics
Platform in Collaboration with Pfizer Inc.

A Seattle-based digital health business that created an app to **\$1.7M from NIH**

track breathing was secretly acquired by Google

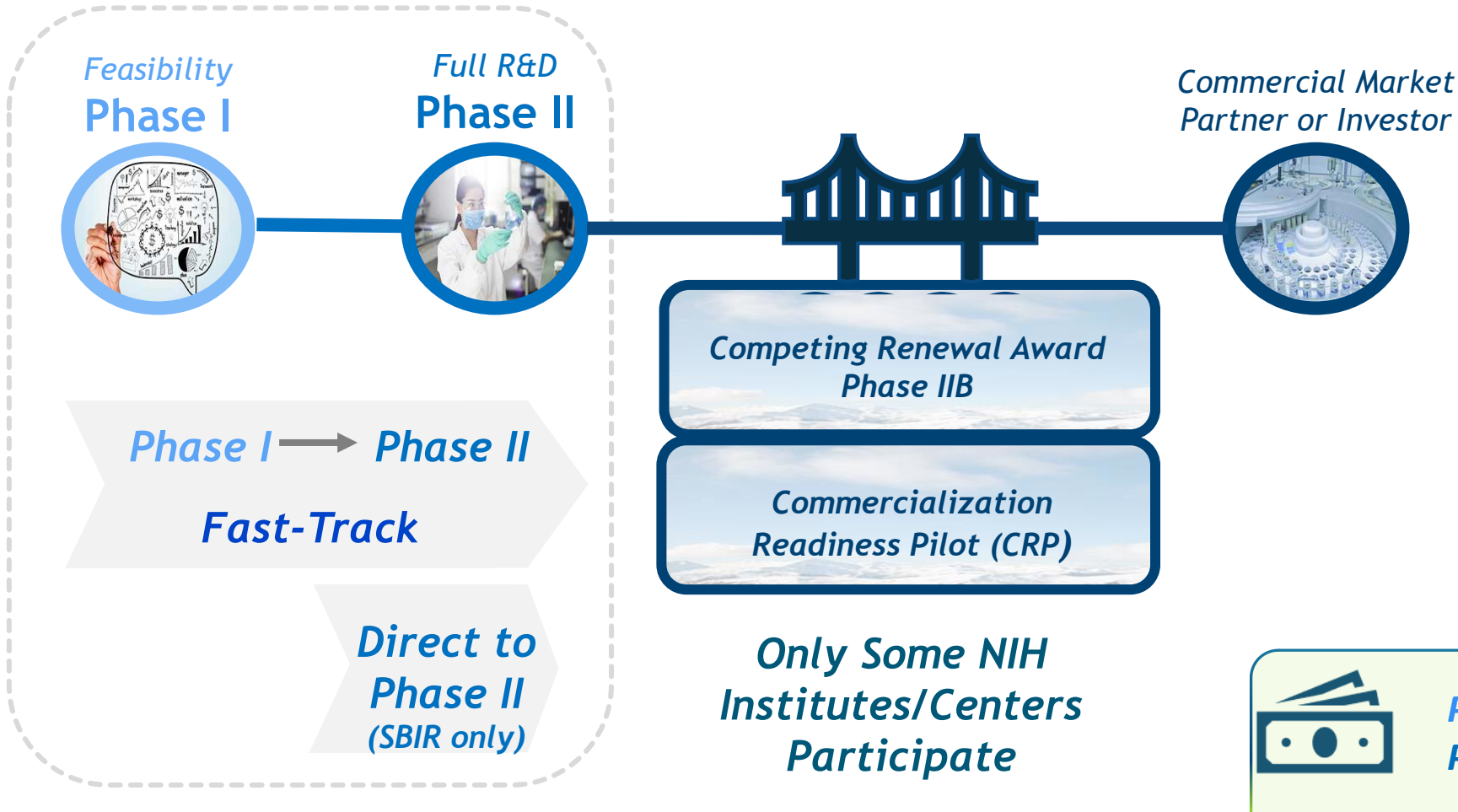
\$310K in private funds

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Small business R&D

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Cooperative R&D between small businesses and U.S. research institutions



*NIH and CDC have a waiver from the Small Business Administration to exceed these budgets for selected [topics](#)

Eligibility

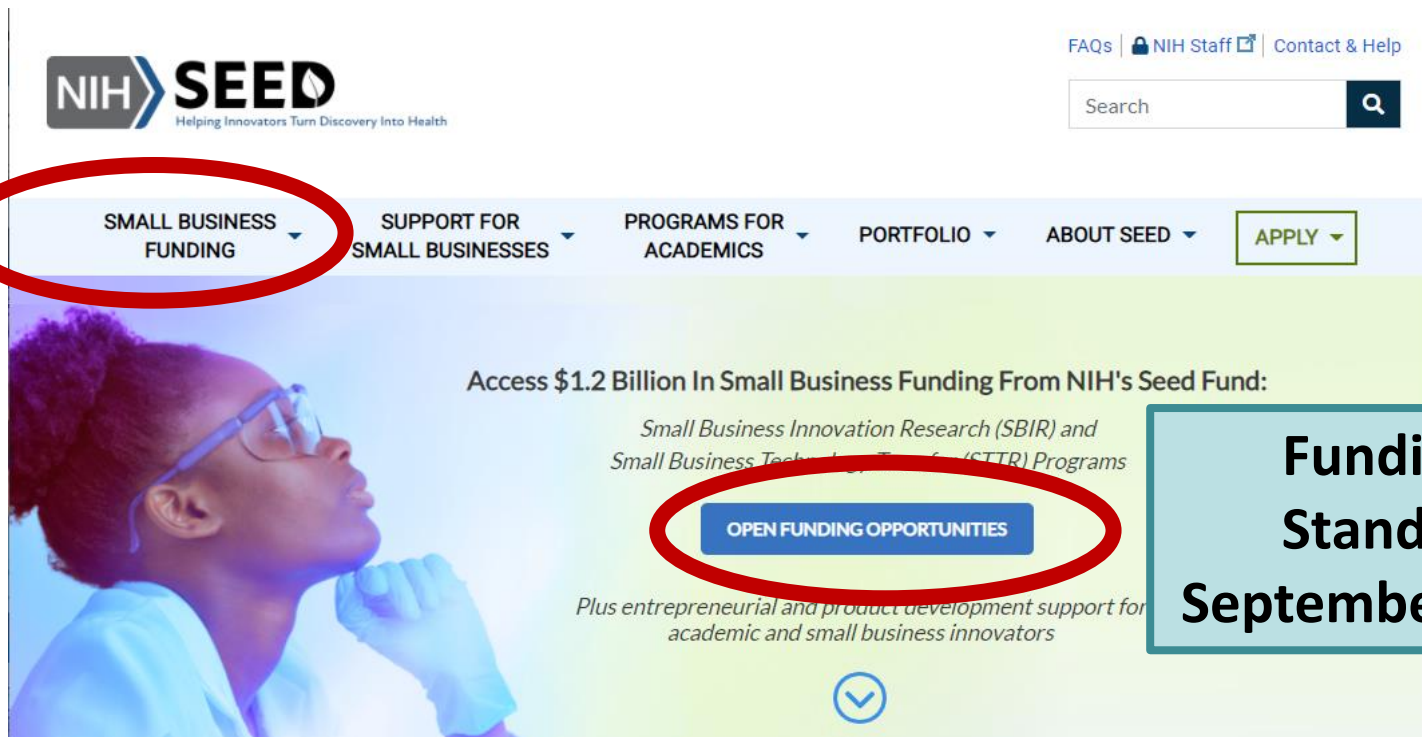
SBIR and STTR Differences

Application & Review Process

Grants Policy

SBIR Contracts

Sample Applications



Funding Opportunities:
Standard receipt dates:
September 5, January 5, April 5

Most Important Piece of Advice

NIH SEED
Helping Innovators Turn Discovery Into Health

FAQs | NIH Staff | Contact & Help

Search

SMALL BUSINESS FUNDING | SUPPORT FOR SMALL BUSINESSES | PROGRAMS FOR ACADEMICS | PORTFOLIO | ABOUT SEED | APPLY

Access \$1.2 Billion In Small Business Funding From NIH's Seed Fund:
Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

OPEN FUNDING OPPORTUNITIES

Plus entrepreneurial and product development support for academic and small business innovators

New to SBIR & STTR?

Learn How to Apply for SBIR or STTR Funding
Find step-by-step instructions on how to apply for more than \$1 billion in funding.

LEARN MORE | READ FAQ

Small Business Research Areas

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

Select an Institute to learn more about their mission and how they support small business.

Select Funding Institute | Learn More

INSTITUTE-SPECIFIC SBIR AND STTR CONTACTS

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

Not sure who to contact?

Research Portfolio Online Reporting Tools (RePORT):
<https://report.nih.gov/>

Email: SEEDinfo@nih.gov

Be Prepared to Resubmit



MARY POTASEK, PH.D.

President and Co-founder
NCI Awardee

<https://www.simphotek.com/>



LAVERNE MORROW CARTER,
PH.D.

President and Co-founder
NCI Awardee

<https://www.simphotek.com/>



“ SBIR is a tough route, and people should be aware of that. The reviewers are not concerned about feelings. But take the criticism seriously, correct the things that need correcting and be prepared to resubmit. Don't give up because of a depressing review.”

“ [SBIR] has been a long, trying, but worthwhile journey...from multiple submissions that were not discussed...to applications that scored below the funding levels...to concurrent applications (one Phase II and a Phase I) emerging from the rigorous peer review process with impact scores in the “Excellent” range.”

Entrepreneurial & Product Development Support



NIH Technical and Business Assistance Program

Phase I

Request a Needs Assessment Report

Identifies gaps in commercial readiness
to help companies strategize for their project's next steps

Phase II

Budget \$50k for TABA Vendor Services in Phase II Application

Hire a vendor to address your most pressing product development need

<https://seed.nih.gov/TABA>

Gap Analysis by Independent Third Party



Market and Competitive Awareness

- Do you need a market analysis?
- Has the value proposition been pressure tested?



Business Model Profitability

- Do you have a pricing and reimbursement strategy?
- Do you have a roadmap to profitability?



Manufacturing, Regulatory, and/or Clinical Plan

- How will you meet manufacturing requirements?
- Have you identified a clear regulatory pathway?
- What clinical data will be required?



Intellectual Property / Barriers to Entry

- Do you have a solid IP strategy?
- Do you have freedom to operate?

Phase II TABA Funding

Scope of Work Consultation

At some point, all innovators need to outsource some aspect of their product development and commercialization work. Whether this outsourced work is standardized testing, manufacturing, product distribution, market analysis, legal issues, or regulatory filings -- the first step to acquiring a desired end product is the clear communication of your needs.

SEED SOW Development Consults assemble a team of appropriate subject matter experts to help you clarify your needs, required and ideal deliverables, and consider what qualities and experience are important in a potential vendor. After this consult, companies will have an overall understanding of how to identify potentially qualified vendors, a strong draft SOW document for their use in soliciting proposals from possible vendors, and a framework for evaluating the attributes of each proposal received.

This consult is highly recommended for SBIR/STTR Phase I awardees who plan to request TABA Funding in their Phase II application.

[Request a Scope of Work Consult](#)

Sample SOWs include:

- IP Strategy
- Market Analysis
- Reimbursement
- Regulatory
- Pre-IND
- IND Sample SOW

What can you get for \$50k?

- Market entry & launch strategy report
- Patent protection report & draft patent application
- Regulatory strategy with focus on requirements for successful NDA
- Pricing model & reimbursement strategy
- Regulatory roadmap & pre-IND meeting with FDA
- Competitive landscape report
- Exclusive license agreement negotiation & IP landscape analysis
- Payer market access strategy
- Marketing plan with customer landscape and marketing materials

SEED Innovator Support Team

Entrepreneurs in Residence



EiRs provide business development guidance to help portfolio companies meet their commercialization objectives and ensure market success.

Subject Matter Experts



SMEs provide *ad hoc* consultations focused on regulatory and reimbursement topics. SMEs have worked in government agencies, healthcare settings, and life science industry.

Partnering and Investment Opportunities

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Convention

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INVESTMENTS
4D Drugs
Devices
Diagnostics
Digital Health
MEETS AI

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INNOVATION**

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MEDTECH
CONFERENCE**
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MedTechColor **vive**

ACA

ANGEL CAPITAL ASSOCIATION

Landmark Angels



~ 100 companies
supported each year

NIH PORTFOLIO COMPANY SHOWCASE

The NIH Company Showcase program prepares SBIR/STTR-funded small businesses to present their value proposition to potential investors and strategic partners. Each company receives one-on-one coaching from industry experts and support to pitch at high profile industry partnering events.



Filter [Clear All](#)

Showcase Event ⓘ

Select ▼

- Angel Capital Association
- BIO
- Landmark Angel Forum
- Life Sciences Summit
- MedTech Color
- RESI/LifeScience

Technology Type ⓘ

Select ▼

- Diagnostic
- Digital Health
- Drug
- Medical Device
- Platform
- Research Tool
- Select All

State

Select ▼

- Connecticut
- Delaware
- Florida
- Georgia
- Hawaii
- Idaho
- Illinois



3Helix

3Helix commercializes labeled collagen hybridizing peptide (CHP) that specifically binds to such unfolded collagen chains, enabling unlimited laboratory applications in pathology, biomechanics, cell biology, regenerative medicine, and more. 3Helix is advancing its compounds to enable new pathways to achieving diagnostic and therapeutic objectives.

Contact Name: Yang Li
Contact Email: yli@3helix.com
Website: <https://www.3helix.com/>
City, State – Congressional District: Salt Lake City, UT – 2
Technology: Diagnostic
Primary NIH Institute: Research Infrastructure (ORIP)
NIH Projects: [NIH RePorter for 3Helix](#)
Sponsored Event(s): Life Sciences Summit 2021
Success Story: [Utah Company Develops Research Tool To Detect Diseases Earlier And More Accurately](#)

Entrepreneurial Support Programs



BIO-Entrepreneurship Capstone Program

<https://seed.nih.gov/bioecapstone>

Cohort based training on lean startup fundamentals, customer discovery, and more for students, postdocs, and early career faculty.



Helps medical device innovators translate biomedical technologies from the lab (concept) to the market (clinic).

<https://seed.nih.gov/support-for-small-businesses/commercialization-enhancement-programs>



Phase I SBIR/STTR teams conduct 100 interviews over 8 weeks to develop a business model canvas.

Funding for Small Businesses to Diversify the Entrepreneurial Workforce



Request additional funding to support a candidate from a diverse background

Small businesses with active NIH SBIR or STTR award can apply for an administrative supplement to support research and entrepreneurial experiences.

Candidates from all career levels are eligible.

Supplements range between \$5,000 and \$100,000 depending on the candidate's career level.

✓ For more information and resources, seed.nih.gov/diversity_supp.



Patient Impact



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Research News

FDA Approval of AGAMREE® (vamorolone) for Duchenne Muscular Dystrophy Granted to Santhera Pharmaceuticals

October 26, 2023

World's first non-invasive home anemia test from Sanguina



Linshom Medical raises Series A to launch non-invasive, portable respiratory monitor



Bone Health's OsteoBoost Vibration Belt Receives Breakthrough Device Designation



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<https://seed.nih.gov/subscribe>

The NIH Guide for Grants and Contracts:

<http://grants.nih.gov/grants/guide/listserv.htm>