

# Making the Most of Your NIH Phase II Small Business Award

*Chris Sasiela, PhD, RAC:* Director, SEED Innovator Support Services  
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NIH Phase II awardees

*Ana Moreno, PhD:* Founder and CEO Navega Therapeutics

*Mo Chen, MBA, PhD:* Founder and CEO WNT Scientific

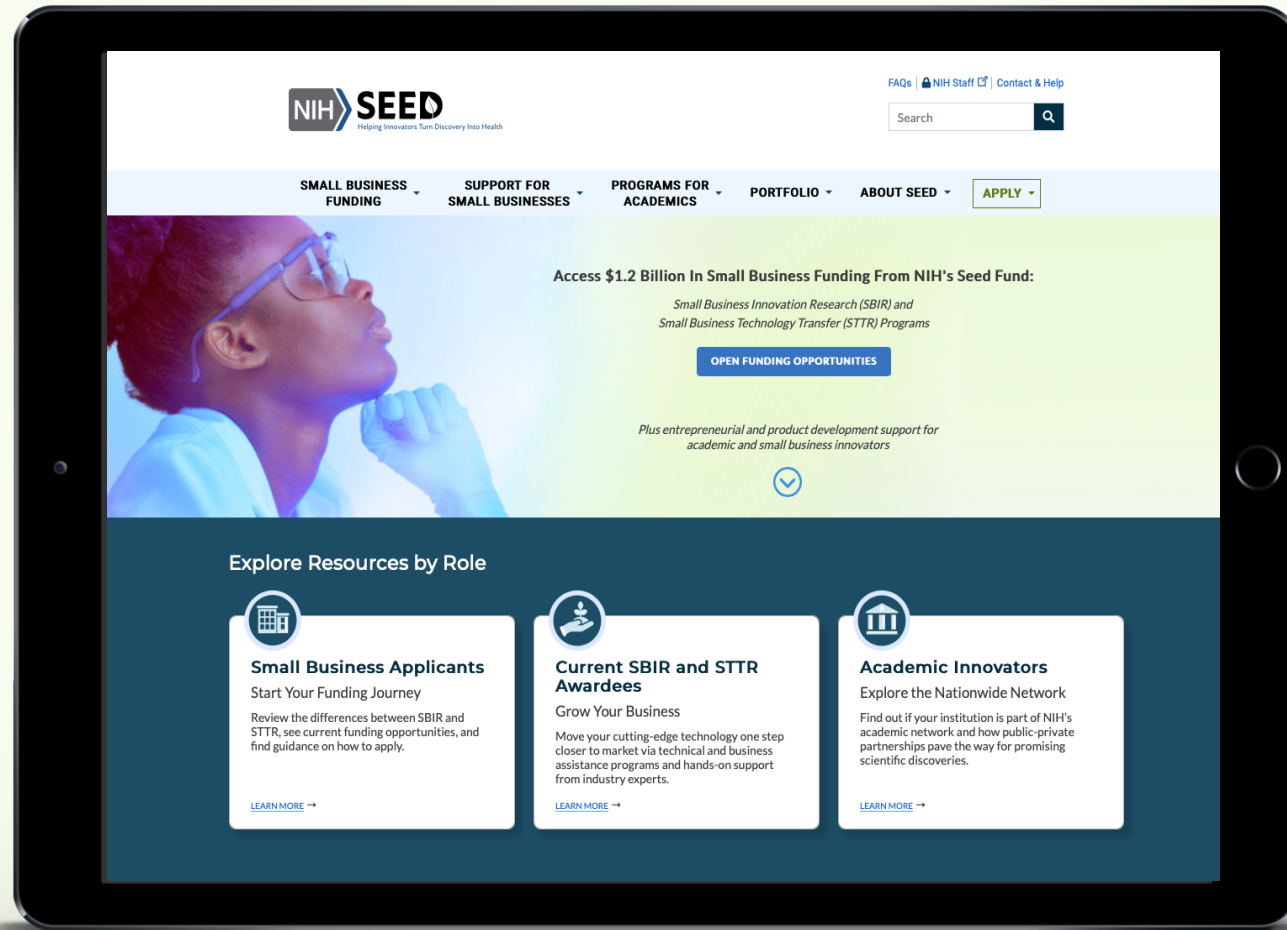
OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH

This presentation may include presenter's notes.

# Webinar Housekeeping

- **Note: This webinar is being recorded.** The recording and materials will be made available to participants 7 business days after the session.
- Please submit all questions in the Q&A box located in your control panel.

# Small Business Program Website



<http://seed.nih.gov>

# NIH Mission



*To seek fundamental knowledge about the nature and behavior of living systems and the **application of that knowledge to enhance health, lengthen life, and reduce illness and disability.***

*The Small Business Program helps NIH accelerate discoveries from bench to bedside*

# Benefits of NIH Funding

The largest sources of early-stage capital for life sciences in the US



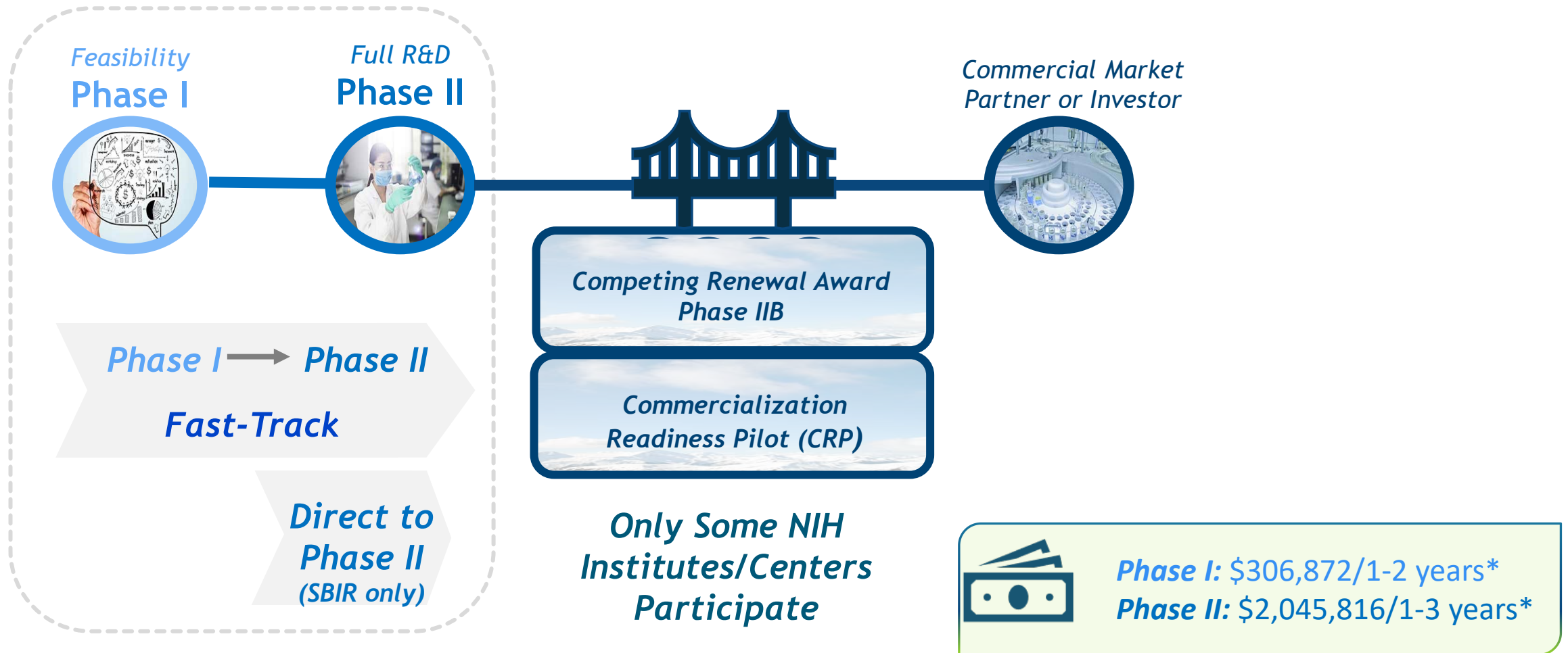
Research Grants



- **“Free Money”** - Non-dilutive capital and not a loan
- Awardees can **leverage funding** to attract investors and partners



# Phased Programs



\*NIH, CDC, ARPA-H have a waiver from the Small Business Administration to exceed these budgets for selected [topics](#)

# Phase IIB vs. CRP

## Competing Renewal (Phase IIB)

- After Phase II award only
- Phase II out-sourcing guidelines
- Accepted Through Omnibus (if allowed by IC) or specific funding opportunities
- Encourages matching funding

## Commercialization Readiness Pilot (CRP)

- Concurrent with or after Phase II award
- Significant out-sourcing is allowed
- Through specific Funding Opportunities ONLY

Trans-NIH Funding Opportunities:

**PAR-23-219:** Clinical Trial Not Allowed

**PAR-23-220:** Clinical Trial Required

*Only Some NIH Institutes/Centers Participate*

**Contact Program Staff BEFORE submission!**



# NIH SBIR/STTR Diversity Supplement

## PA-21-345 Administrative Supplement to Promote Diversity in Research and Development Small Businesses (NIH and CDC)

Purpose: Enhance the diversity of the research and entrepreneurial workforce

- Small Businesses with active small business awards (SBIR/STTR)
- Recruit and support individuals from diverse backgrounds



**Supported >100 Individuals to Date**

### Career Level

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

[https://seed.nih.gov/diversity\\_supp](https://seed.nih.gov/diversity_supp)



# Technical and Business Assistance (TABA) Programs

## Phase I and Phase II

### TABA Funding

Grant funds to use your own vendors for Technical and Business Assistance

- \$6,500 per year for a Phase I
- \$50,000 per project for a Phase II

Follow Instructions to request funds in the application

## Post-Award TABA Programs

### Phase I

#### TABA Needs Assessment\*

Provides a third-party, unbiased assessment of areas that are critical to success in the competitive healthcare marketplace

### Phase II

#### TABA Consulting Services\*

Available to *limited number* of awardees in the areas of Intellectual Property, Market Analysis, Regulatory Affairs, or Reimbursement Planning.

# TABA Funding Request Best Practices

- Must use a third-party vendor – cannot support company personnel
- All instructions in the [SF424 \(R&R\) Application Guide](#) must be followed.
  - Label the requested cost “Technical Assistance” on one of the lines from 8-10.
  - Include a detailed description of the technical or business assistance that your vendor will provide, including the name of the vendor and the expected benefits and results of the technical or business assistance provided in the Budget Justification.
- Budget request needs to be justified
  - Develop a **Scope of Work Document\*** describing your desired deliverables
  - Solicit multiple bids
  - Evaluate all vendor responses before committing
- \*SEED’s Innovator Support Team can help with SOW development.
  - [Reimbursement Sample SOW](#)
  - [Intellectual Property Sample SOW](#)
  - [Market Analysis Sample SOW](#)

# Entrepreneurs in Residence



NIH [Entrepreneurs in Residence](#) (EIRs) provide business development guidance and counsel to assist awardees with progress toward commercialization objectives and ensure market success. Each EIR brings unique expertise and experience from their prior and current careers.

- ✓ Fortune 200 companies
- ✓ Corporate/Private Venture Funds
- ✓ C-suite leadership
- ✓ Entrepreneurs (serial)

[Request a Consult](#)

# Subject Matter Experts



- NIH Subject Matter Experts (SMEs) provide *ad hoc* consultations for NIH awardees focused on regulatory and reimbursement topics . Each SME brings unique expertise and experience from their prior and current careers. SMEs have worked in government agencies, healthcare settings, and life science industry.

- ✓ Understanding coding & payment
- ✓ Interactions with FDA
- ✓ Strategy / best practices

[Request a Consult](#)



# Investor conference opportunities



**BIOTECH  
SHOWCASE™**



ANGEL CAPITAL ASSOCIATION



100+ companies/year  
January/June matching

[Request Form](#)



Pre-event webinar  
Templates  
Pitch Coaching  
Onsite EiR

# 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

Small Businesses: Review this important update about [changes to the Internal Revenue Code on R&D Expenses \(Section 174\)](#)

Access \$1.3 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 businesses.

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](mailto:SEEDinfo@nih.gov)

List of SBIR Program Managers:  
<https://seed.nih.gov>

Hear from your Peers



# Phase II Awardees



- Ana Moreno, CEO of Navega Therapeutics
- Navega is developing a patented, non-permanent gene therapy to target pain that is non-addictive, highly specific and long-lasting.
- NINDS: Phase I, Phase II, CRP, Diversity Supplement
- NCI: Phase I, Phase II, Diversity Supplement
- SEED: 3 EiR consults, 2 regulatory consults, BIO attendance support (2x)



- Mo Chen, CEO of Wnt Scientific
- Wnt is developing therapeutic products for musculoskeletal disorders.
- NIAMS: Phase I
- NIA Phase I
- NIDCR: Phase I, Phase II, CRP
- SEED: TABA Needs Assessment, TABA Consulting Services, BIO attendance support (1x)



# Connect with SEED



## Online

<http://seed.nih.gov/>



## Email us

[SEEDinfo@nih.gov](mailto:SEEDinfo@nih.gov)



## @nihseed

<https://twitter.com/nihseed>



## NIH SEED

<https://www.linkedin.com/company/nihseed>

## Sign up for NIH and SEED updates:

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

## The NIH Guide for Grants and Contracts:

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