



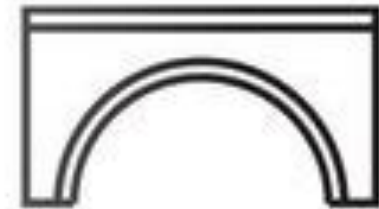
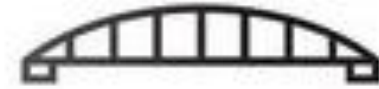
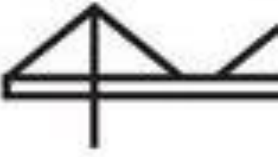
SBIR Bridge Award Program

RFA Concept Reissuance

Dec 7, 2022

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NCI SBIR Development Center



Congressionally Mandated Programs

Small Business Innovation Research (SBIR)

Engages small businesses in Federal R&D with commercialization potential. (FY21 Set-aside 3.2%)
Federal agencies with extramural R&D budget >\$100M

Small Business Technology Transfer (STTR)

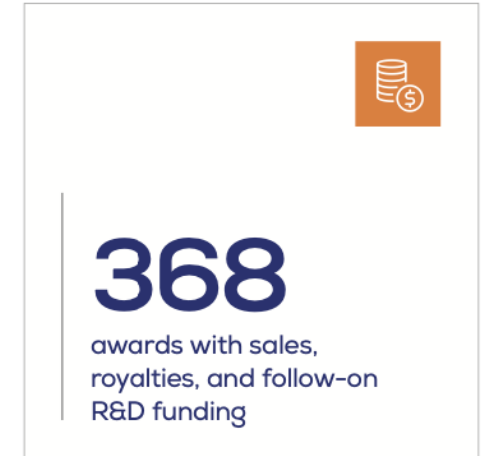
Facilitates R&D between U.S. research institutions and small businesses with commercialization potential. (FY21 Set-aside 0.45%)
Federal agencies with extramural R&D budget >\$1B

SBIR & STTR
Combined Budget
for FY22
\$1.2B at NIH
\$182M at NCI

- America's Seed Fund
- Main program to support innovative small businesses at the NIH
- Recently reauthorized for 3 more years

Economic Impact

- Pilot evaluation conducted by TechLink in 2018, in collaboration with the University of Colorado Boulder
- NCI SBIR/STTR Phase II grant awards made between 1998 and 2010 (690 awards)

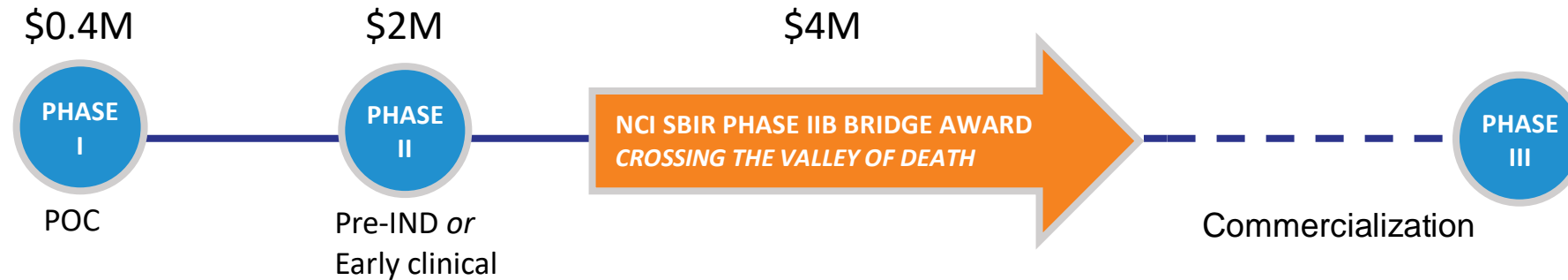


SBIR Funding Overview



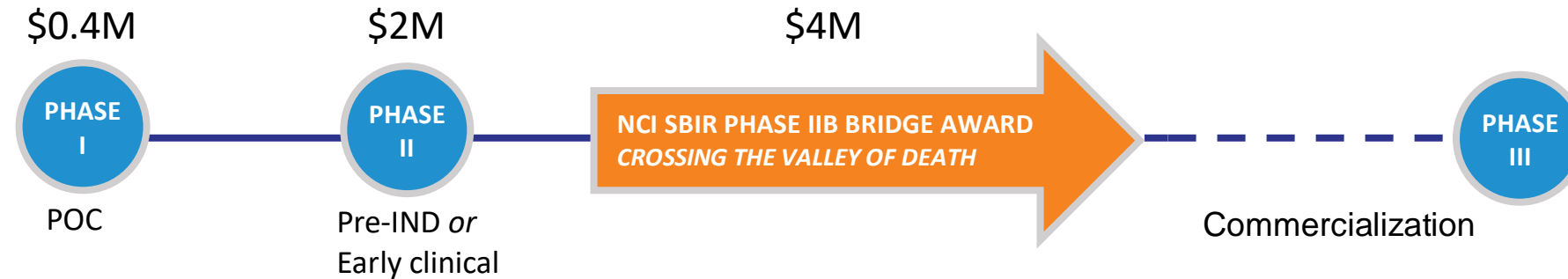
- Phase I: Proof of Concept studies; \$400k max (10% success rate)
- Phase II: Pre-IND/Early Clinical Studies; \$2M max (16% success rate)
 - Direct-to-Phase II and Fast-Track options
- Phase I and II grants can only take companies so far...
 - Many promising technologies face a funding gap to reach next key value inflection points
 - Challenging for many early stage companies to attract investment
 - Without further funding technologies can wither or face significant delays

Bridge Award: Crossing the Valley of Death



- Bridge Award addresses this challenge by providing companies with additional funding and by requiring them to raise matching funds ($\geq 1:1$ match)
 - First NIH SBIR program of its kind, launched in 2009
 - Investors: Support technologies vetted by peer-review and de-risked with NCI funds
 - NCI: Support technologies that have undergone rigorous due diligence and can attract investment.

Bridge Award: Crossing the Valley of Death



- Provides up to \$4M (total cost) over 2 to 3 years
- Technology validation and clinical translation (all portfolio areas)
- Companies that have completed Phase II from any Federal Agency are eligible
- Clinical trials optional

Bridge Award: Purpose and Objectives



Milestones

Enable awardees to accomplish critical milestones toward commercialization by providing continued funding to companies that recently completed Phase II SBIR or STTR project



Partnerships

Promote partnerships between awardees and third-party investors and/or strategic partners to facilitate and accelerate the capital-intensive steps that are required for commercialization



Investment

Leverage federal funding to attract private investment that equals or exceeds NCI funds

Awardees are required to raise matching funds

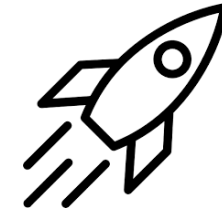
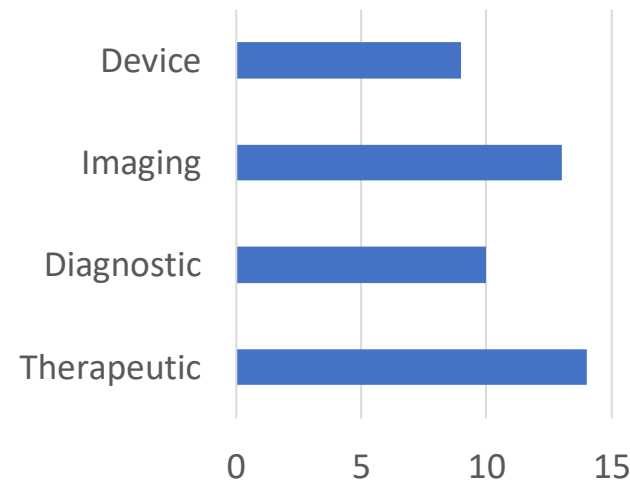
Overview of Awards to Date



- Launched in 2009
- 49 Awards
- \$126M NCI Funding
- \$501M in matching funds
- Sources include top VC, strategics and Angel Groups



- Project types



- 19 Products Launched



Bridge Award - Case Study



- 2018 Bridge Award
- Small molecule targeting DRD2 and ClpP
- Phase II clinical trial of ONC201 for gliomas
- Fast-Track and Orphan FDA status
- Acquired by Chimerix

Family of 'miracle' girl surviving aggressive cancer raising money for research



Carolyn Muyskens
The Holland Sentinel



Emerson Hoogendoorn, age 9, plays with modeling clay at her grandmother's house in Park Township. Carolyn Muyskens/Holland Sentinel

- Diagnosed with DIPG at age 6
- Not expected to survive the year
- 1% 5-year survival
- 3 years later Emerson thriving
- Tumor stable at 12% original size

“Her family attributes her survival to the experimental medicine she takes as part of a clinical trial. The drug is called ONC201, and it is being tested as a treatment for brain tumors like Emerson's and even some other forms of cancer.”

Evaluation: Findings and Recommendations



- Bridge Award Program has successfully met program goals
 - Awardees completed significant milestones
 - Established key partnerships
 - Attracted private investment (1:5 ratio; FY2016-2020)
- Matching fund requirement key program feature
 - Pushed companies to seek investment (vs. rely on grants)
 - NCI funds helped entice private investment
 - *Prestige and validation as important as funds*

“[The Bridge Award tells] investors that they are backing something that makes a lot of scientific and commercial sense... NCI backing helped the VCs connect the dots and determine that it was a bet they were willing to take. The Bridge was the de-risking they needed at that moment, and they ended up putting in a lot more than a 1:1 match. Having the Bridge gave the confidence that raising additional funding was possible” Sean Mackay (Isoplexis CEO and Co-founder)

Evaluation: Findings and Recommendations



- Bridge Award Program supports key early development activities that are beyond the scope of Phase II SBIR grants
 - Private investment critical but difficult to attract
 - “Valley of Death”
- Companies facing increased costs due to inflation
 - Important that Bridge Award accounts for this so that companies can continue to accomplish goals
 - Recommend modest increase in award size
- Maintain number of Bridge Awards per year
 - Last 5 years: 3-6 awards per year
 - Aim for set aside to support higher end of new awards

Proposed RFA Reissuance

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

National Cancer Institute (NCI)

Funding Opportunity Title

SBIR Phase IIB Bridge Awards to Accelerate the Development of Cancer-Relevant Technologies Toward Commercialization (R44 Clinical Trial Optional)

Activity Code

R44 Small Business Innovation Research (SBIR) Grant - Phase II only

Announcement Type

Reissue of RFA-CA-20-033 - SBIR Phase IIB Bridge Awards to Accelerate the Development of Cancer-Relevant Technologies Toward Commercialization (R44 Clinical Trial Optional)

Related Notices

None

- Last renewed in 2017 (5 years)
 - Increased award size from \$3M to \$4M
- 2022 Reissuance Request:
 - Request 5 year approval
 - Clinical Trials optional
 - Increase award size to \$4.5M
 - Anticipate funding ~6 awards/year
 - First year set aside \$12M (\$60M over 5 years)
- Evaluation Committee recommend program renewal

RFA Justification

- The RFA set-aside funds signals NCI's strong commitment to this program and helps encourage the participation of SBIR awardees, private investors, and strategic partners
- Importance of recruiting reviewers with strong industry backgrounds and business domain expertise to evaluate applications due to an increased focus and special review criteria that address commercialization strategy
 - Special review criteria: balanced consideration of technical and commercial merit; IP and regulatory strategy; fundraising plan
 - Bridge Award SEPs have recruited an average of around 40% Industry panel members, compared to about 25% for regular SBIR/STTR Study Sections

THANK YOU

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