

# NCI SBIR Innovative Concept Award

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RFP Concept Review\_BSA  
(Reissuance)  
November 30, 2023



**WILLIAM BOZZA, PhD**  
**NCI SBIR Development Center**

# Congressionally Mandated Programs

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## 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 FY23  
\$1.3B at NIH  
**\$203M at NCI**

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

# Concept Award: Overview

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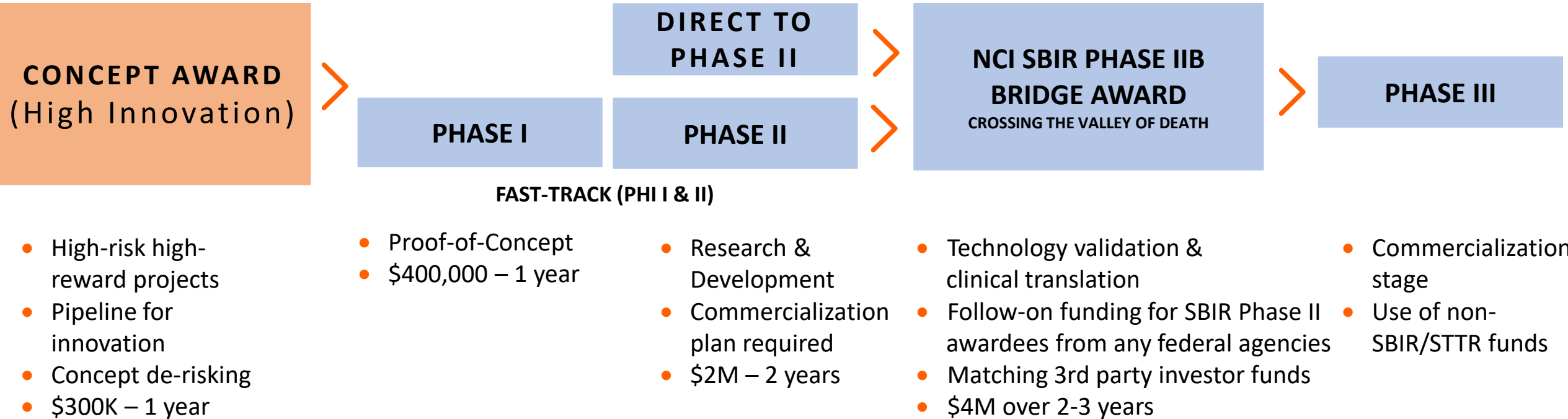
**3-year pilot launched in 2021**

- High-risk/high-reward projects
- Focus is on Innovation
- Transformative technologies to address rare and pediatric cancer
- \$300K SBIR Contract Funding (one year of funding)
- No preliminary data is required
- Fund experiments to obtain initial de-risking and proof-of-concept data

Program created in response to an external working group convened by the National Cancer Advisory Board (NCAB). Top working group recommendation was to create a “high-risk/high-reward Concept” award to promote paradigm-shifting innovation.

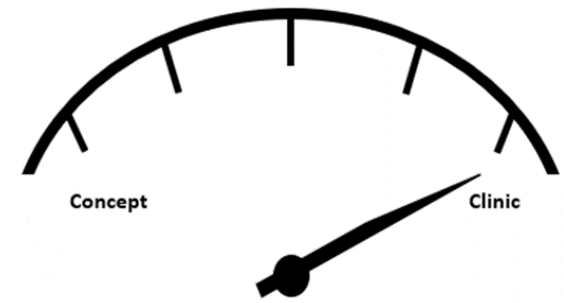


# Concept Award: Overview



# Concept Award: Purpose and Objectives

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## Portfolio Innovation

Increase early-stage innovation & high-risk high-reward projects in NCI SBIR portfolio

## Rare & Pediatric Cancer Focus

Bridge rare and pediatric cancer portfolio gaps

## High Response & New Stakeholders

Achieve high responses, engage new small business customers, and streamline review/award process

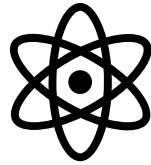
## Project De-Risking

De-risk early-stage innovation & foster follow-on funding opportunities

# Overview of Awards to Date



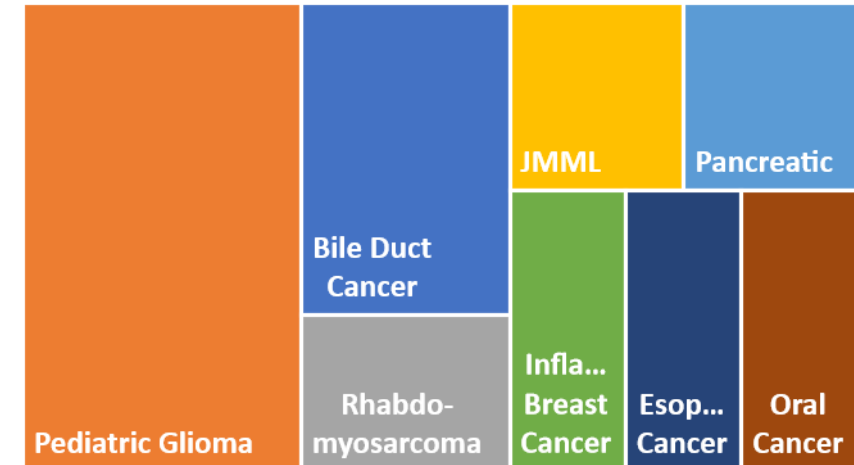
- Launched in 2021
- 13 Awards
- \$3.9M NCI Funding
- 38 % of awards represent women and/or unrepresented minorities



- Project types



- Cancer indications



# External Evaluation Committee & Methodology

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**Mel Billingsley (Chair)**

Former President and Chief Executive Officer,  
Life Sciences Greenhouse  
Professor Emeritus, Pennsylvania State  
University College of Medicine

**Keith Marmer**

Chief Innovation &  
Economic Engagement Officer  
University of Utah

**Nakia Melecio**

Founder & Director  
MedTech Center of Excellence  
Georgia Institute of Technology

**Molly Wasko**

Professor & Associate Dean  
University of Alabama at Birmingham  
Collat School of Business  
UAB I-Corps Program Director

**Sam Mazin**

Founder & Chief Technology Officer  
RefleXion Medical

**Deepa Narayanan**

Business Development Program Manager  
Amazon Web Services (Healthcare)

**Peter Kuhn**

Professor, University of Southern  
California  
Founder, Epic Sciences  
Founder, Cansera

- NCI SBIR Executive Secretary presented Concept Award overview and update
- NCI SBIR provided written documentation of program metrics and non-confidential project information
- Evaluation Committee reviewed the information and generated a written Evaluation Report detailing findings and recommendations
- Evaluation Report included in renewal documentation

# Did the Program Help Accomplish Key Objectives?

High Response & New Stakeholders

	FY22			FY23			FY24		
	Total	Applied/ Never Awarded	New to NCI SBIR	Total	Applied/ Never Awarded	New to NCI SBIR	Total	Applied/ Never Awarded	New to NCI SBIR
White Papers	96	33	33	70	28	29	100	44	45
Full Proposals	46	6	21	25	14	9	50	20	23
Awards	6	0	3	7	4	2	TBD	TBD	TBD

- 70-100 white papers each fiscal year
- 80% of white papers and 69% of awards represent companies new to NCI SBIR funding
- All Concept Awards were made in 6 months or less



# Did the Program Help Accomplish Key Objectives?

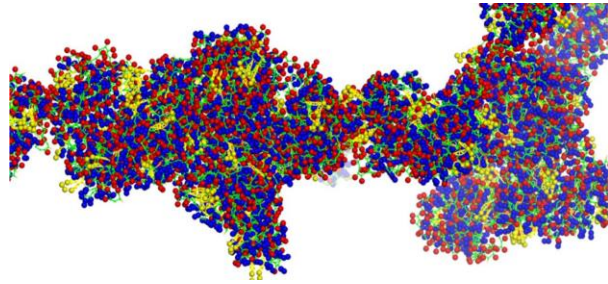
Rare & Pediatric  
Cancer Focus

Concept Awardee	Technology	Indication	Underrepresented Indication In NCI SBIR Portfolio
UbiquiTx	Therapeutic	Intrahepatic Cholangiocarcinoma (CCA)	✓ (1 Award)
DCLK1 LLC	Therapeutic	Cholangiocarcinoma (CCA)	✓ (1 Award)
Petri Bio	Therapeutic	Diffuse midline glioma (DMG)	✓ (3 Awards)
Gencyte Therapeutics	Therapeutic	Juvenile myelomonocytic leukemia (JMML)	✓ (0 Award)
NomoCan Pharmaceuticals	Therapeutic	Pancreatic	
Columbus NanoWorks	Diagnostic	Inflammatory breast cancer (IBC)	✓ (0 Award)
Genomic Expression	CLIA Test	Rare cancer	
NovoMedix	Therapeutic	Rhabdomyosarcoma	✓ (1 Award)
Adelphi Technology	Device	DIPG	✓ (4 Awards)
Captis Diagnostics	Diagnostics	Low-grade glioma	✓ (1 Award)
ImmunoTarget Therapeutics	Therapeutic	Esophageal cancer	✓ (7 Awards)
Coordination Pharmaceuticals	Therapeutic	Oral cancer	✓ (9 Awards)
Nzumbe	Therapeutic	Glioma	

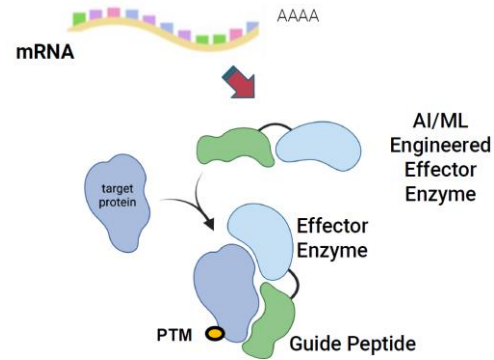
✓ = Less than 10 base project awards in QVR in the last 5 years

- 85 % of awards made were for indications heavily underrepresented in NCI SBIR portfolio

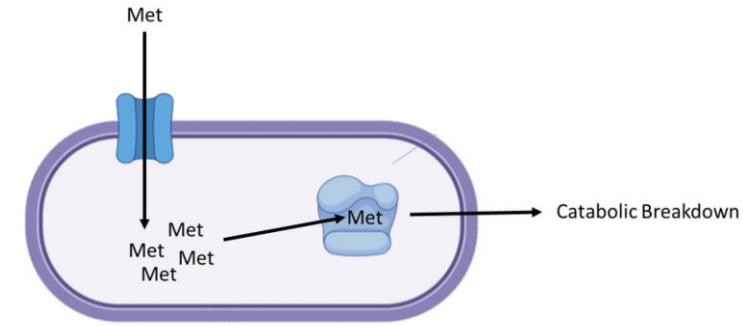
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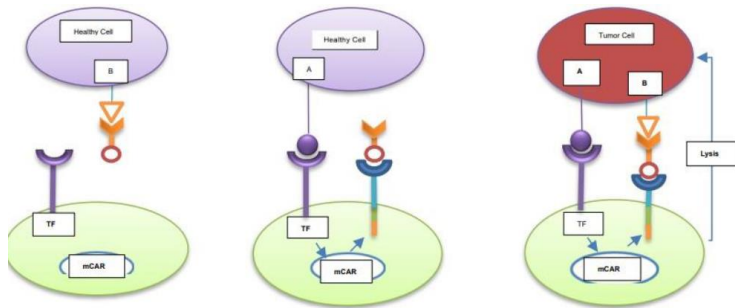
Supramolecular Nanosponges



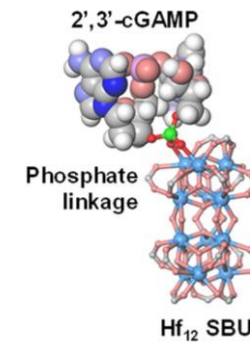
Protein silencing with Ubiquibodies



Genetically modified microbes for methionine depletion



Second generation CAR Ts w/logic gated adaptor systems



Nanoscale Metal-Organic Frameworks as X-ray activatable Vaccines

# Did the Program Help Accomplish Key Objectives? - Case Study

Project De-Risking



## Innovative Technology

Coordination is developing nanoscale metal-organic frameworks (nMOF) containing immune modulators as X-ray activatable cancer vaccines for treatment of oral cancer. Technology class is unrepresented in NCI SBIR portfolio.

## Disruptive Clinical Impact

Significant unmet medical need was identified in the current lack of immunotherapy options for metastatic and recurrent oral cancer patients. The technology has the ability to change standard of care.



## Project De-Risking/Achievements

- Technology de-risked through Concept Award aims
- IND-enabling studies completed by company after award
- IND submitted to FDA and currently under review
- First-in-human clinical trials expected for Q1 2024

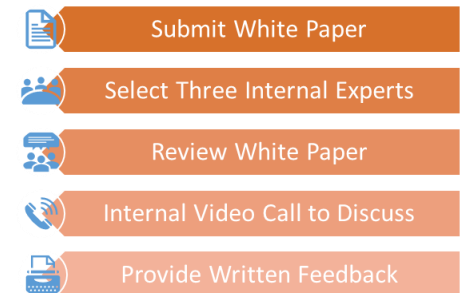
# External Evaluation Findings

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- Concept Award has successfully met all evaluation metrics
  - Disruptive and innovative approaches are being developed for pediatric and rare cancers
  - High response rates were achieved due to strong programmatic outreach
  - New pool of new small businesses were engaged who are new to NCI SBIR funding
  - Early but promising indicators of follow-on funding (project de-risking)
- White paper review is a key program feature
  - Triaging technologies to select the most innovative projects for full proposal review
  - Timeline evaluation metrics met and all awards made in 6 months

## White Paper Process



70 NIH White Paper reviewers each year across NCI, NCATS, NIBIB, NIGMS, and NINDS.

# External Evaluation Recommendations

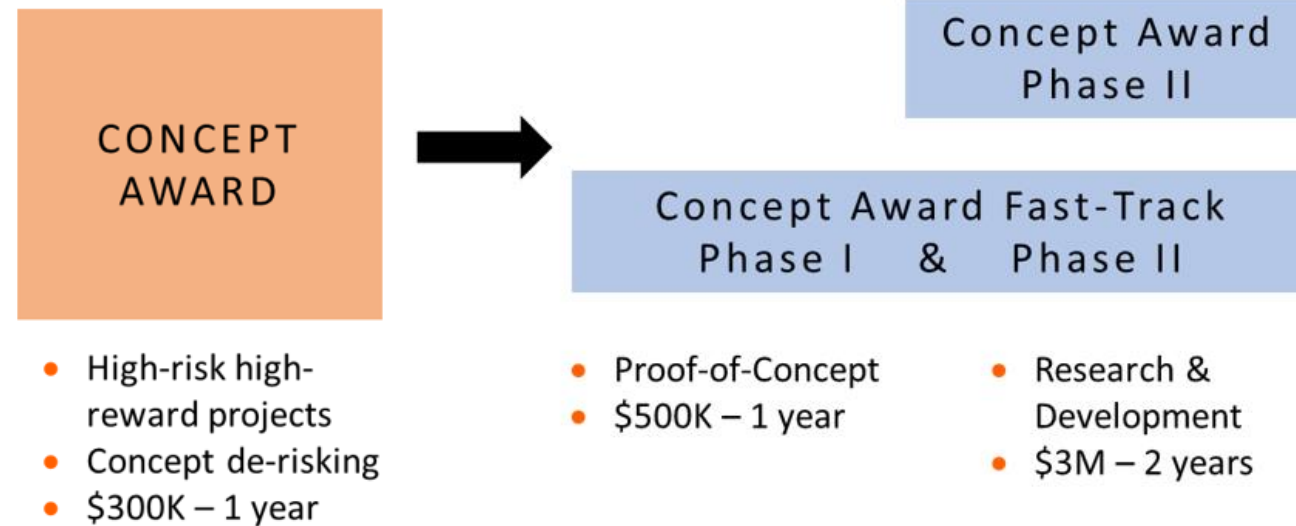
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- The Evaluation Committee unanimously recommends that the Concept Award program continue
- Additional federal funding to further support de-risked technologies
- Pitch day event (investors, disease foundations, etc.)

# Proposed RFP Reissuance Requests & Budget Recommendations

- 5-year approval
- Maintain Phase I Concept Award size at \$300K
  - Set-aside of \$3M per year
- Add follow-on Phase II NOFOs
  - Phase II & Fast-Track applications
  - **ARPA-H 50% co-fund (co-funded \$5.7M in SBIR projects in FY23)**
  - NCI set aside of \$3.5M per year



# RFP Justification

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- Special review criteria and panel
  - 50% weight scoring on innovation
  - Reviewers with expertise in evaluation of early-stage technologies
- Short and streamlined proposals
  - White paper triage
  - Fillable full proposal template
  - Awards within 6 months



# THANK YOU

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## CONTACT INFO

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