



# ENCOURAGING INCLUSIVE ENTREPRENEURSHIP

NCI SMALL BUSINESS INNOVATION RESEARCH (SBIR) FUNDING

**Kory Hallett, PhD**  
**Christie A. Canaria, PhD**  
Program Director  
**NCI SBIR Development Center**

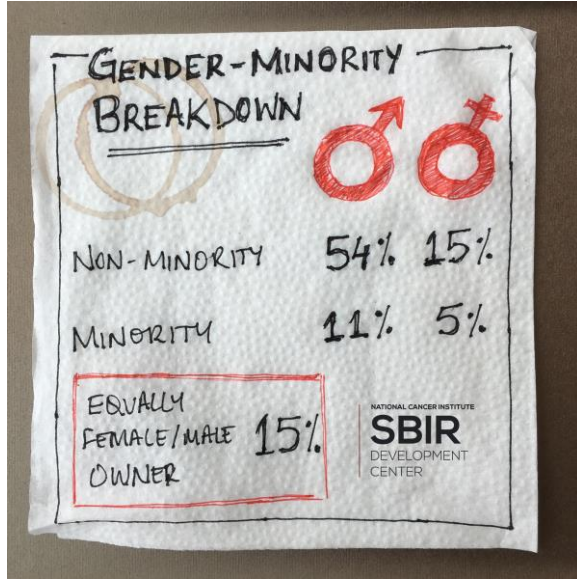
# SPEAKERS



Kory Hallett  
Program Director



Christie Canaria  
Program Director



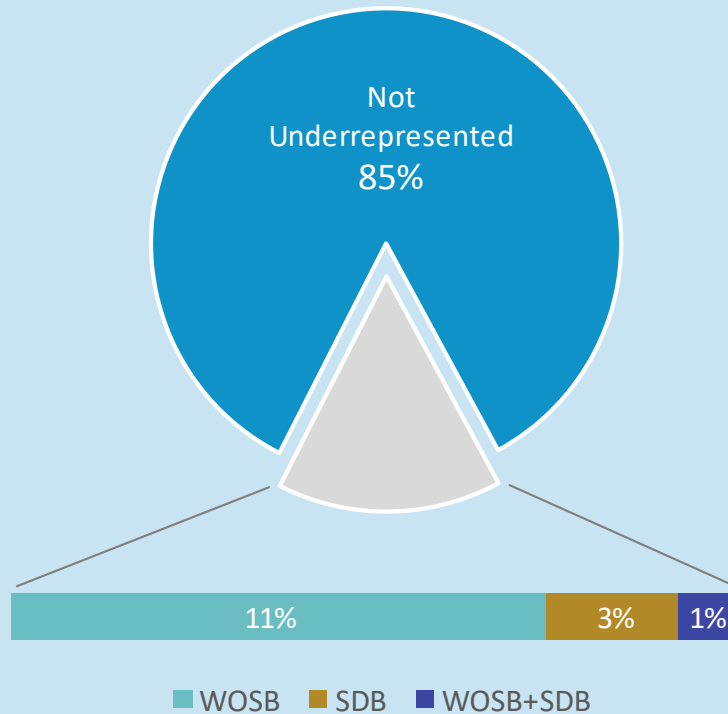
NATIONAL CANCER INSTITUTE  
**SBIR**  
 DEVELOPMENT  
 CENTER

**SBIR CAN HELP**

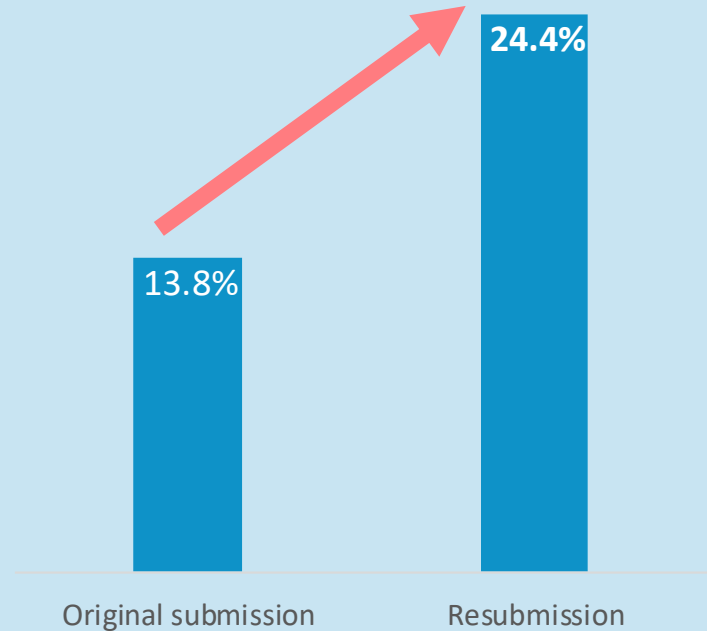
- ACCELERATE**  
 YOUR PATH TO COMMERCIALIZATION WITH NON-DILUTIVE FUNDING
- GAIN EXPOSURE**  
 TO ATTRACT INVESTORS AND BUILD MARKET INTEREST
- RECEIVE TRAINING**  
 TO AVOID COMMON SMALL BUSINESS PITFALLS

LEARN MORE AT:  
**SBIR.CANCER.GOV**

## NCI SBIR APPLICANT POOL



## SUCCESS RATES CHANGE



# Be Prepared to Resubmit!

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## Competitive Program:

- FY16 NIH SBIR Phase I Success Rate: 14%
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“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.”



**Mary Potasek, Ph.D.**

President and Co-founder  
Simphotek

# Development Center: 4 CORE ACTIVITIES

## FUNDING/OVERSIGHT

- Seed emerging technology areas by developing targeted funding opportunities either as grants or contracts
- Administer all 400+ SBIR/STTR awards at the NCI

## OUTREACH

- Attend conferences and workshops & visit state-based organizations and universities to raise awareness of the program

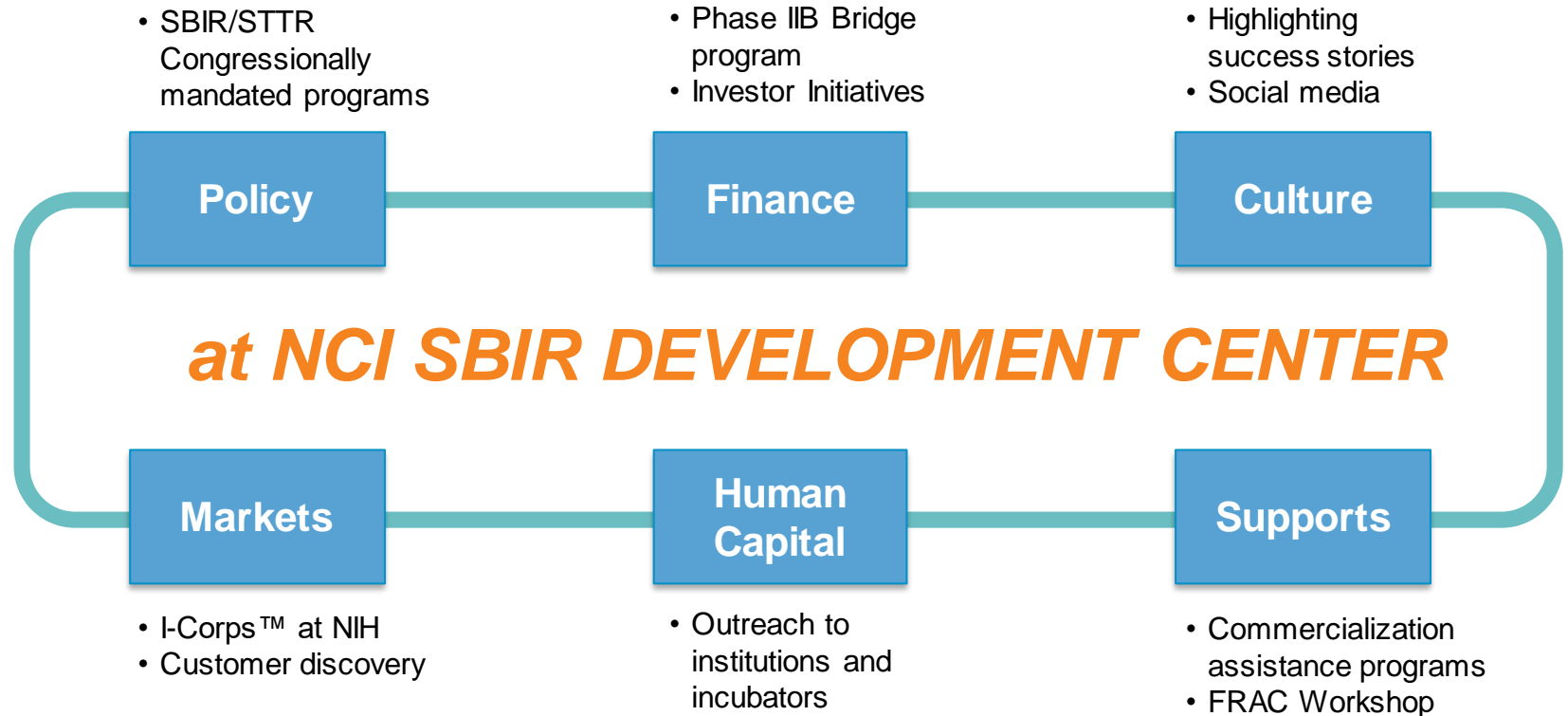
## GUIDANCE / MENTORSHIP

- Help applicants prepare for application, resubmission, and discuss funding options
- Other initiatives to assist our awardees – I-Corps, Translational Resources Workshops, Webinars

## NETWORKING / PARTNERSHIPS

- Collaborations with pharma, med-tech, and investor community
- Maintain a network of investors, and facilitate connections between NCI SBIR portfolio companies and potential investors/strategic partners

# ENTREPRENEURIAL ECOSYSTEM



# CONGRESSIONALLY MANDATED



NIST



## ❖ Small Business Innovation Research (SBIR)

Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization

*Federal agencies with an extramural R&D budget > \$100M*

## ❖ Small Business Technology Transfer (STTR)

Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization

*Federal agencies with an extramural R&D budget > \$1B*



## Set Aside

FY11	FY18
2.5%	3.2%
0.3%	0.45%

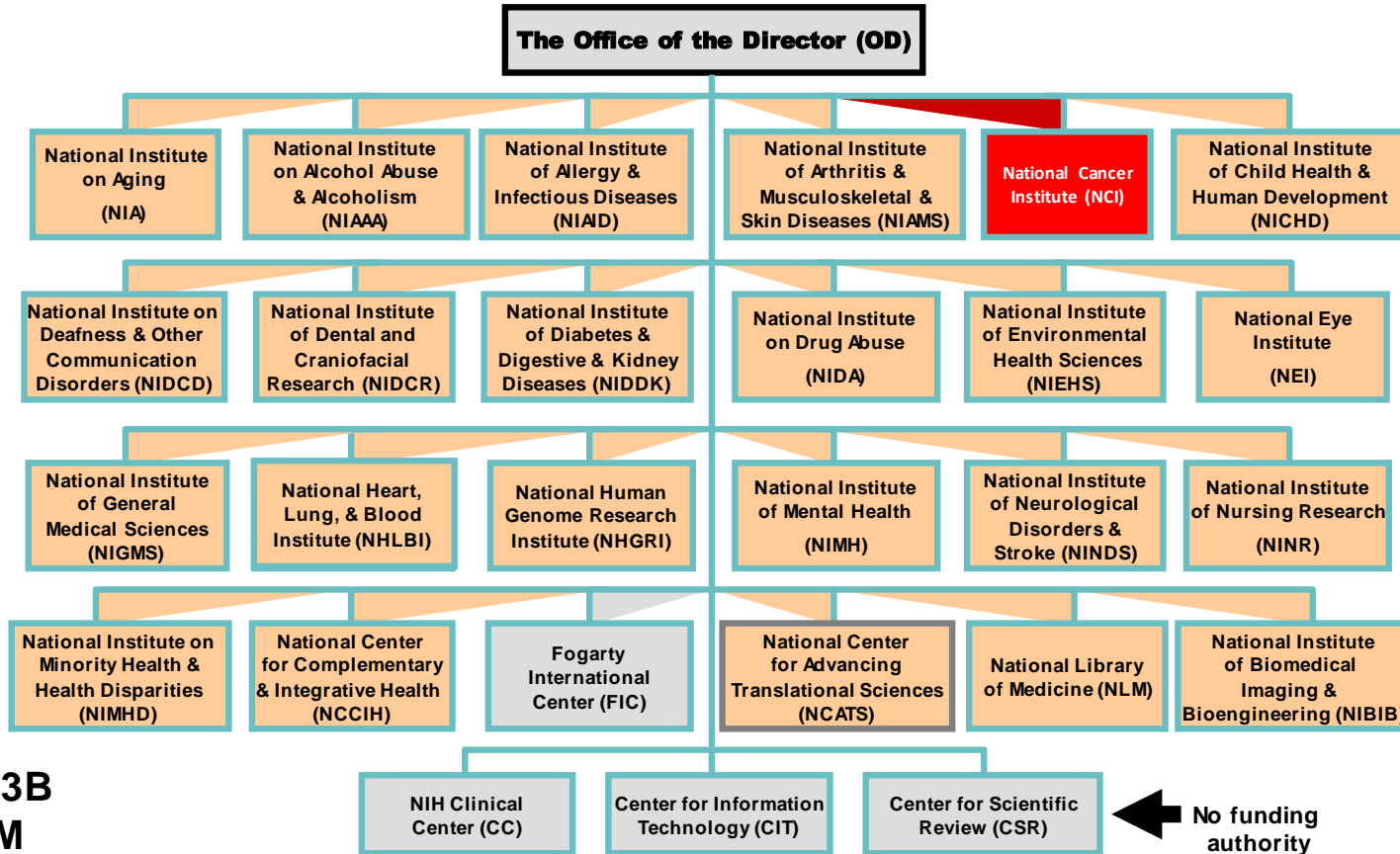
NIH: \$1.073B

NCI: \$167M



# NIH has 27 Institutes and Centers

## 23 “separate” SBIR/STTR Programs



# THREE-PHASE PROGRAM



- Proof-of-Concept
- **Up to \$400,000 over 6 to 12 months**

- Research & Development
- Commercialization plan required
- **Up to \$2M over 2 years**

- Technology validation & clinical translation
- Follow-on funding for SBIR Phase II awardees from any federal agencies
- Expectation that applicants will secure substantial 3<sup>rd</sup> party investor funds
- **\$4M over 2-3 years**

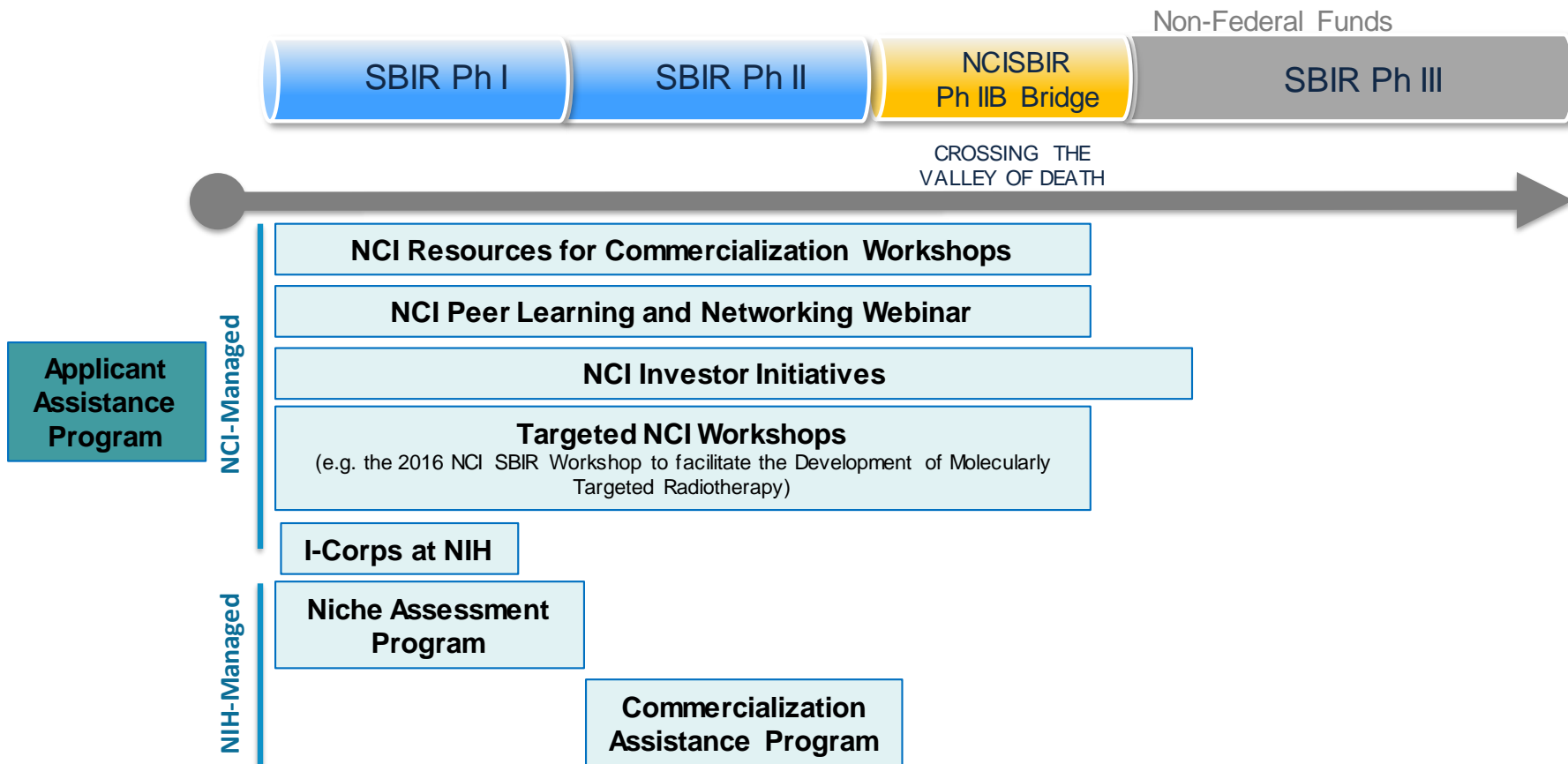
- Commercialization stage
- Use of non-SBIR/STTR funds

	Standard Award	Hard Cap	Waiver Cap (IC Specific)
Phase I	\$150K	\$252K	NCI: \$400K
Phase II	\$1.0M	\$1.68M	NCI: \$2.0M

## Waiver topics:

[https://sbir.nih.gov/sites/default/files/NIH\\_Topics\\_for\\_Budget\\_Waivers.pdf](https://sbir.nih.gov/sites/default/files/NIH_Topics_for_Budget_Waivers.pdf)

# NIH and NCI Assistance: More than just \$\$\$



# ELIGIBILITY

- ✓ Applicant must be a Small Business Concern (SBC)
- ✓ Organized for-profit U.S. business
- ✓ 500 or fewer employees, including affiliates
- ✓ > 50% U.S.- owned by individuals and independently operated

**Award always  
made to  
small business**

**OR**

> 50% owned and controlled by another (one) business concern that is > 50% owned and controlled by one or more individuals

**OR (SBIR ONLY)**

> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

# SBIR – STTR : Critical Differences

SBIR	STTR
<b>Permits</b> research institution partners (e.g., universities)	<b>Requires</b> research institution partners (e.g., universities)
Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities	Minimum 40% of the work should be conducted by the small business concern (for profit), and minimum of 30% by a U.S. research institution (non-profit)
<b>ELIGIBILITY:</b> The PD/PI's primary employment (i.e., >50%) MUST be with the SBC for the duration of the project period	<b>ELIGIBILITY:</b> IP Agreement providing necessary IP rights to the SBC in order to carry out follow-on R&D and commercialization
	PI primary employment not stipulated (min. 10% effort to project)

# SCORED REVIEW CRITERIA

## Significance

Does the product address an important **problem**, and have commercial potential? Is there a market pull for the proposed product?

## Approach

Are **design and methods** well-developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?

## Innovation

How novel is the **technology/product** and the **approaches** proposed to test its feasibility?

## Investigator

Are the investigators, collaborators and consultants appropriately trained and **capable** of completing all project tasks?

## Environment

Does the **scientific environment** contribute to the probability of success? **Facilities**? Independence?

## Commercialization

Is the company's **business strategy** one that has a high potential for success?

# FOAs & Receipt Dates

TITLE	FOA		RECEIPT DATES
Omnibus Solicitation (expires April 7, 2020)	SBIR PA-19-272 (General) PA-19-273 (Clinical Trial)	STTR PA-19-270 (General) PA-19-271 (Clinical Trial)	September 5; January 5; April 5
SBIR Technology Transfer (technology transfer out of NIH intramural labs)	PA-18-705		
SBIR IMAT (Innovative Molecular Analysis Technology) Development	PAR-18-303 (SBIR only)		
Development of Highly Innovative Tools and Technology for Analysis of Single Cells	PA-17-147 (SBIR) PA-17-148 (STTR)		
Tools for Cell Line Identification	PA-16-186 (SBIR only)		
Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings	PAR-18-801 (SBIR)/PAR-18-802 (STTR)		
Phase IIB Bridge Award Open to federally-funded Phase II awardees	RFA-CA-19-047 (SBIR only)		August 9, 2019
Contract Solicitation	Program Solicitation PHS 2020 TBD		Historically October
Administrative Supplement to Support Ongoing Awards	PA-18-591		Throughout the project period
Administrative Supplement to Support Diversity	PA-18-837		Throughout the project period



**GET READY FOR  
SBIR/STTR**



# When is SBIR/STTR appropriate?



“My laboratory was working in drug development and it takes a long time to license a technology. It was hard to push forward with only R01 funding and we had neat technology, worth pursuing.”



**Lori Hazlehurst, Ph.D.**

Professor, Pharmaceutical Sciences  
West Virginia University

President and Co-founder, Modulation Therapeutics



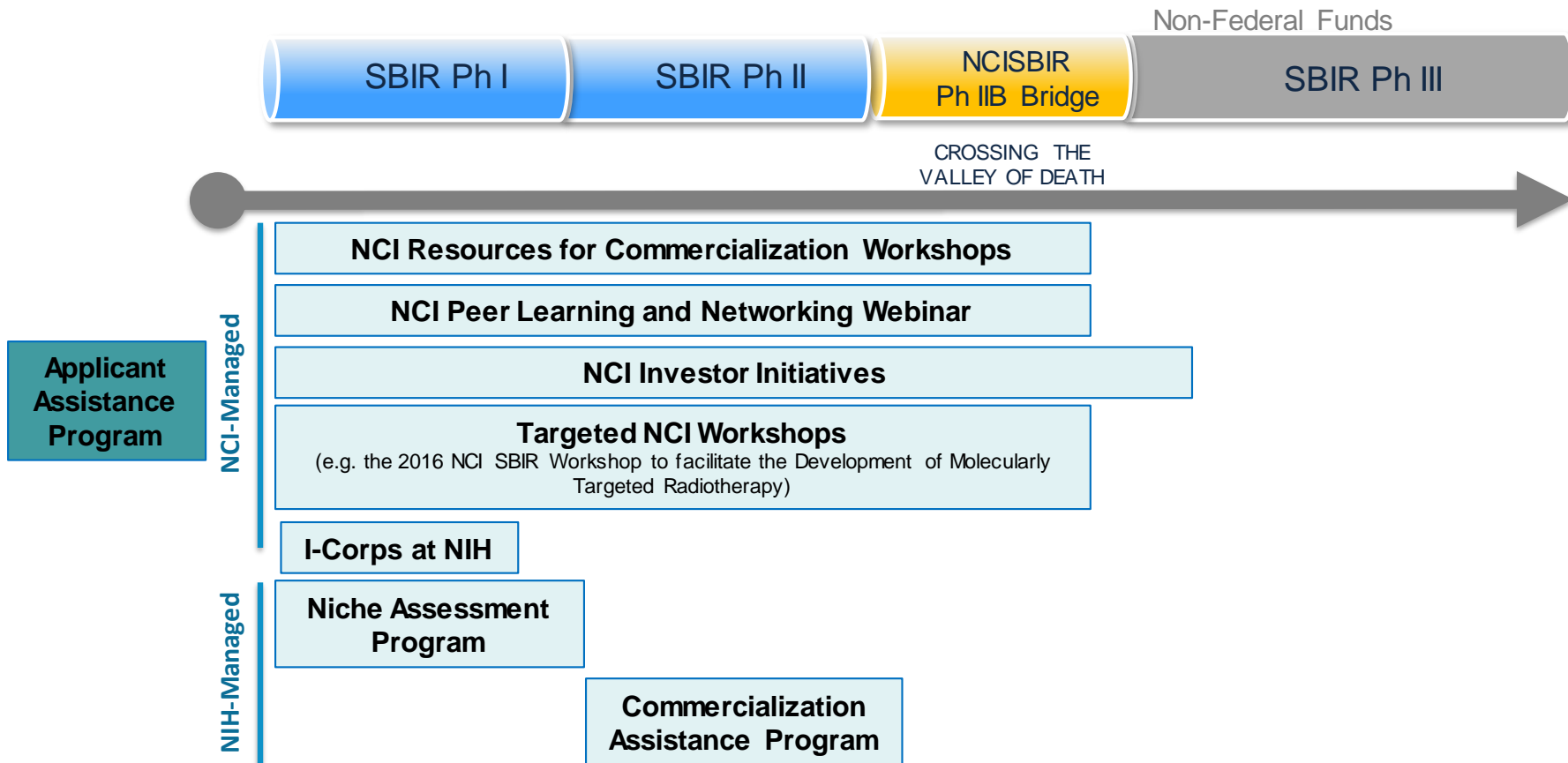
**Aruna Gambhir, MS, MBA**

CEO and Co-Founder, CellSight Technologies

“Investors want to see that a technology works. SBIR funding has been critical to our company to show that our technology works.”



# NIH and NCI Assistance: More than just \$\$\$



# NIH/NCI Applicant Assistance Program (AAP)

- **FREE!** Application preparation **ASSISTANCE**
- **2019: CANCER TECHNOLOGIES ONLY**

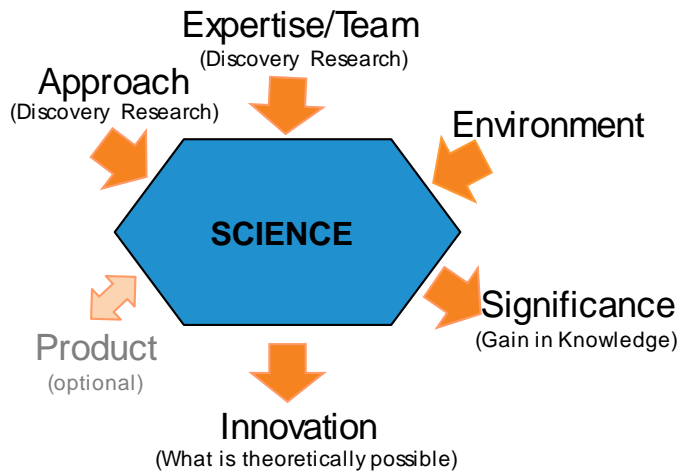
NIH AAP PROGRAM	NOT PROVIDED
Phase I Preparation Support and Review	Grant Writer
Specific Aims Page Review and Advice	Development of Research Plan
Submission Process Coaching	Register small business for you, apply to NIH for you

## **AAP GOAL:**

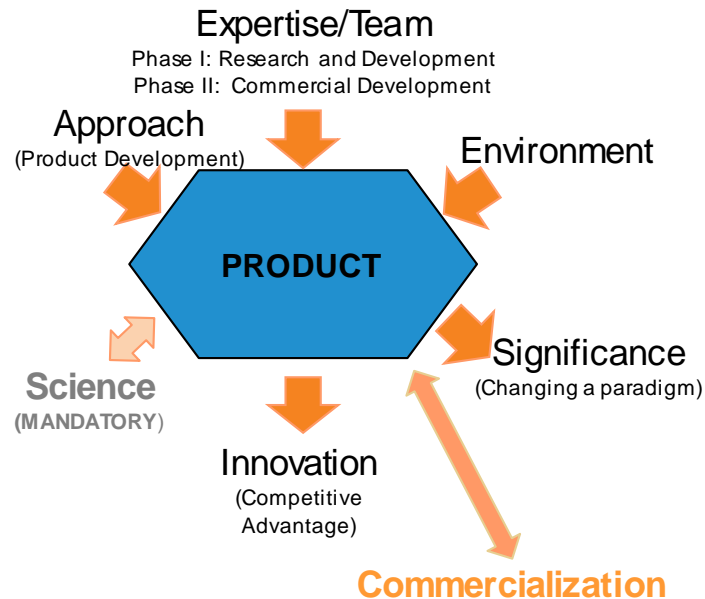
**Provide a mentor for applicants with great technology, but little NIH experience and limited NIH experience in their network.**

# Application

## ACADEMIC GRANT



## SBIR/STTR GRANT

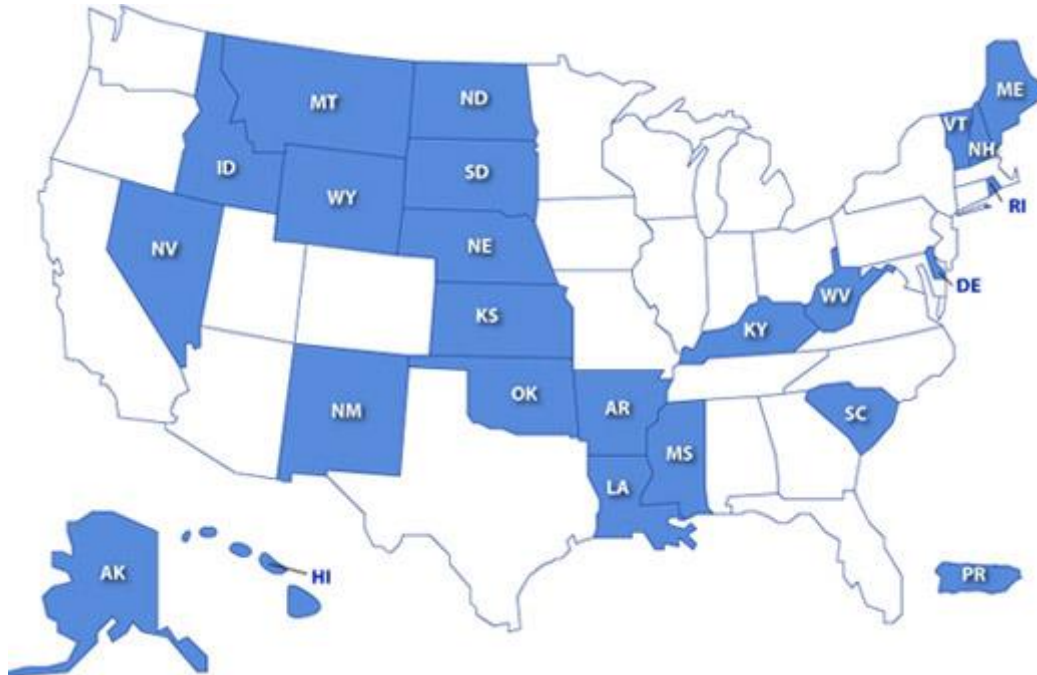


- **Simple eligibility criteria:**
  - **Not previously funded through NIH SBIR/STTR\***
- **Particularly interested in applicants by individuals currently underrepresented in the biosciences** (not a requirement for program)
  - **Women-owned / Run businesses**
  - **Minority-owned / Run businesses**
  - **Small Businesses operating in an underrepresented (IDeA) state**

\* Applicants who received NIH SBIR/STTR funding prior to 2009 *may* still be eligible

# Recognizing IDeA States

Institutional Development Award (IDeA)



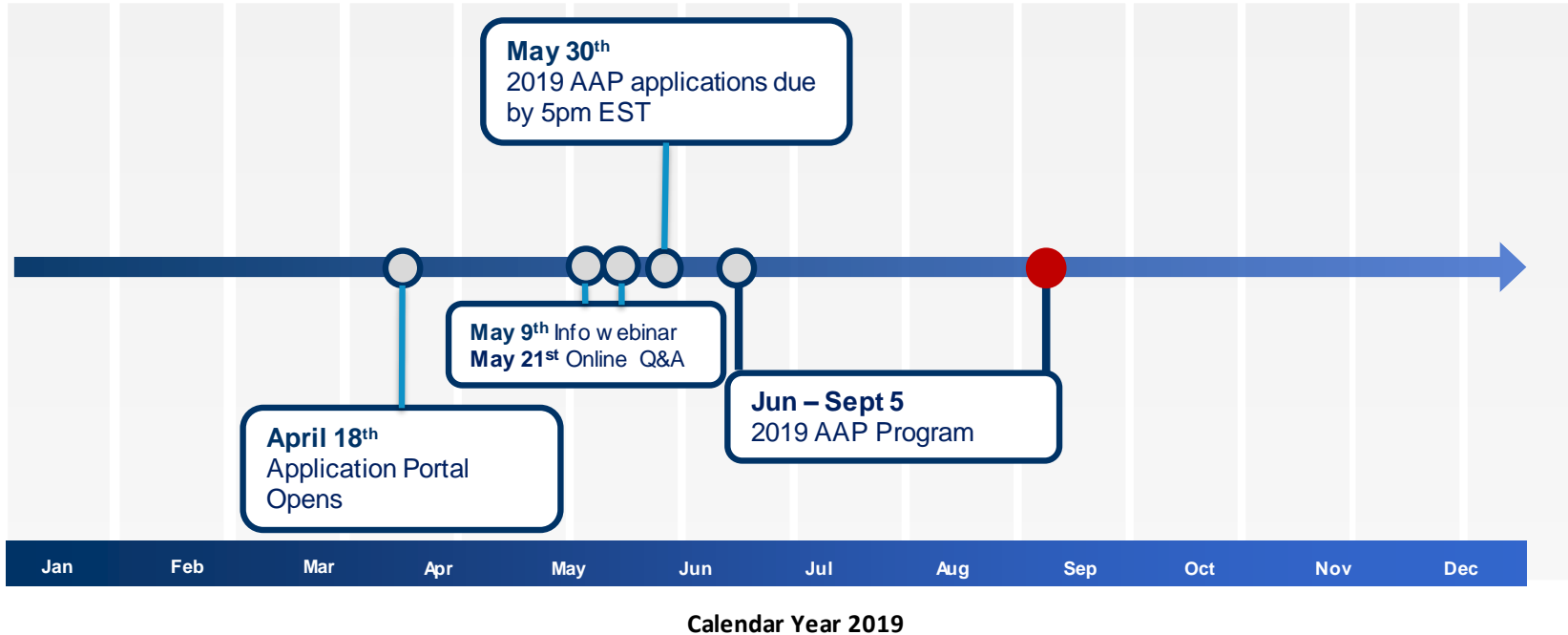
# AAP Application

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- **Simple**
- **Designated AAP application portal**
  1. **Answer a series of structured questions**
  2. **Upload supporting documents, e.g. abstract**
  3. **Submit**

## 1 Cohort in 2019

For applicants applying to the September 5<sup>th</sup> 2019 NCI SBIR/STTR receipt date





# NCI SBIR Program Staff



**Michael Weingarten, MA**  
*Director*  
NCI SBIR Development Center



**Greg Evans, PhD**  
*Lead Program Director*  
Cancer Biology, E-Health, Epidemiology, Research Tools



**Patricia Weber, DrPH**  
*Program Director*  
Digital Health, Therapeutics, Biologics, FRAC Workshop



**Deepa Narayanan, MS**  
*Program Director*  
Imaging, Clinical Trials, Radiation Therapy, Investor Initiatives, FRAC Workshop



**Ming Zhao, PhD**  
*Program Director*  
Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells



**Christie Canaria, PhD**  
*Program Director*  
Cancer/Biological Imaging, Research Tools, Devices, I-Corps at NIH, Scientific Communications



**Kory Hallett, PhD**  
*Program Director*  
Monoclonal Antibodies, Immunotherapy, Biologics, and Program Analysis

**Let's discuss your project!**  
**Send Specific Aims to [ncisbir@mail.nih.gov](mailto:ncisbir@mail.nih.gov)**



**Andrew J. Kurtz, PhD**  
*Lead Program Director*  
Biologics, Small Molecules, Nanotherapeutics, Molecular Diagnostics, Bridge Award



**Jian Lou, PhD**  
*Program Director*  
In-Vitro Diagnostics, Theranostics, early-stage drug development, Bioinformatics, Investor Initiatives



**Amir Rahbar, PhD, MBA**  
*Program Director*  
In-Vitro Diagnostics, Biologics, Therapeutics, Proteomics



**Jonathan Franca-Koh, PhD, MBA**  
*Program Director*  
Cancer Biology, Biologics, Small Molecules, Cell Based Therapies



**Ashim Subedee, PhD**  
*Program Director*  
Cancer Therapeutics and Diagnostics, Imaging, Cancer Prevention and Control, Digital Health, Investor Initiatives



# THANK YOU

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