ENCOURAGING INCLUSIVE ENTREPRENEURSHIP

NCI SMALL BUSINESS INNOVATION RESEARCH (SBIR) FUNDING

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

NATIONAL CANCER INSTITUTE SBIR DEVELOPMENT CENTER

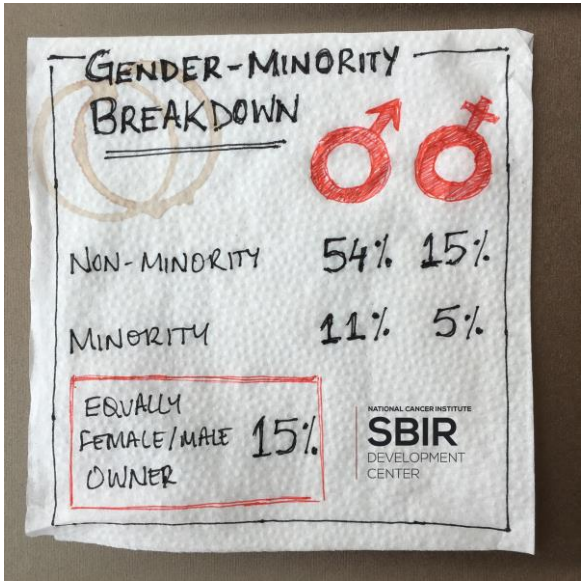
SPEAKERS

2019 NCI SBIR
APPLICANT
ASSISTANCE
PROGRAM

Kory Hallett
Program Director

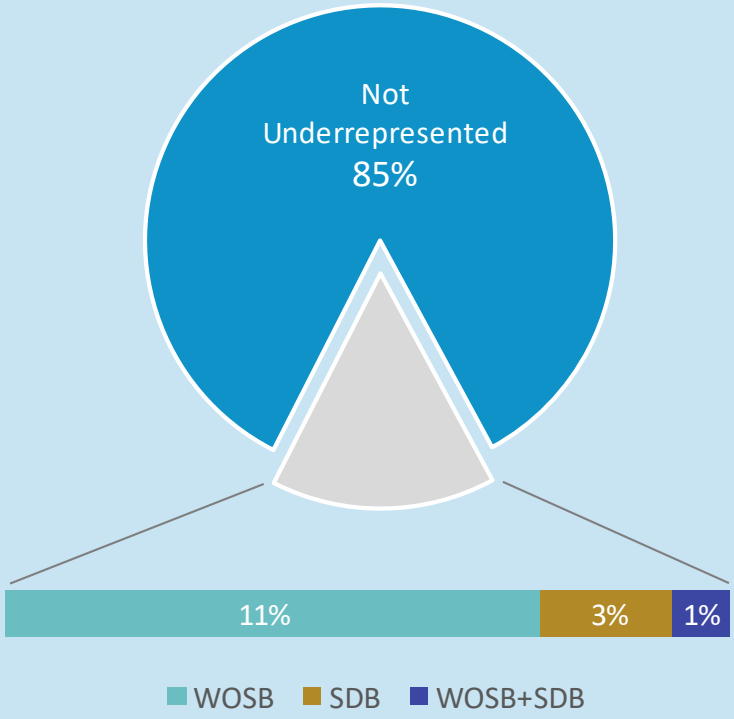
Christie Canaria
Program Director


GROWING OPPORTUNITIES
FOR WOMEN & MINORITY OWNED SMALL BUSINESSES.
2012 US CENSUS STATS FOR U.S. FIRMS W/ PAID EMPLOYEES.
314.1 MILLION.
POPULATION.
BUSINESS FIRMS
5.4 MILLION.
WOMAN OWNED BUSINESS
MINORITY OWNED BUSINESS
23.3 %
20%
115.2 M
EMPLOYEES.
$32.5 TRILLION.
SALES, RECIEPTS VALUE OF SHIPMENTS

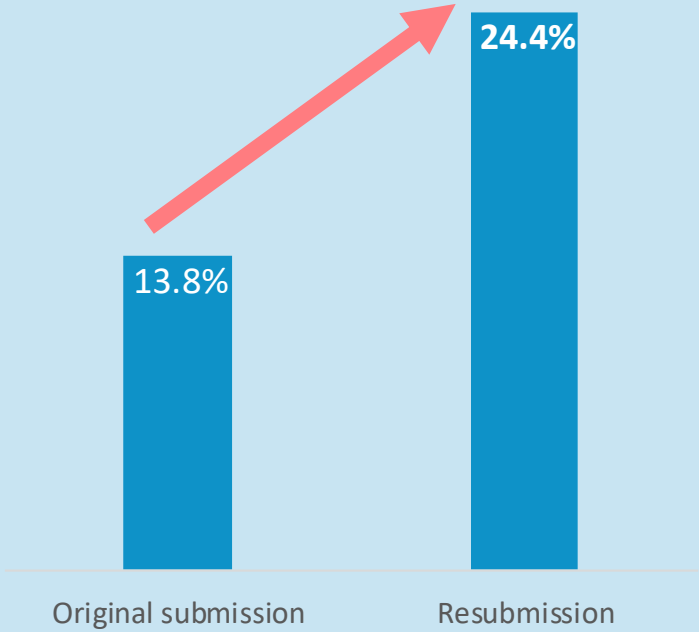

GENDER-MINORITY BREAKDOWN
NON-MINORITY 54% 15%
MINORITY 11% 5%
EQUALLY FEMALE/MALE OWNER 15%
NATIONAL CANCER INSTITUTE
SBIR
DEVELOPMENT CENTER


SBIR CAN HELP
NATIONAL CANCER INSTITUTE
SBIR
DEVELOPMENT CENTER
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!

Competitive Program:

- FY16 NIH SBIR Phase I Success Rate: 14%

simphotek
Light Interactions Matter

"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

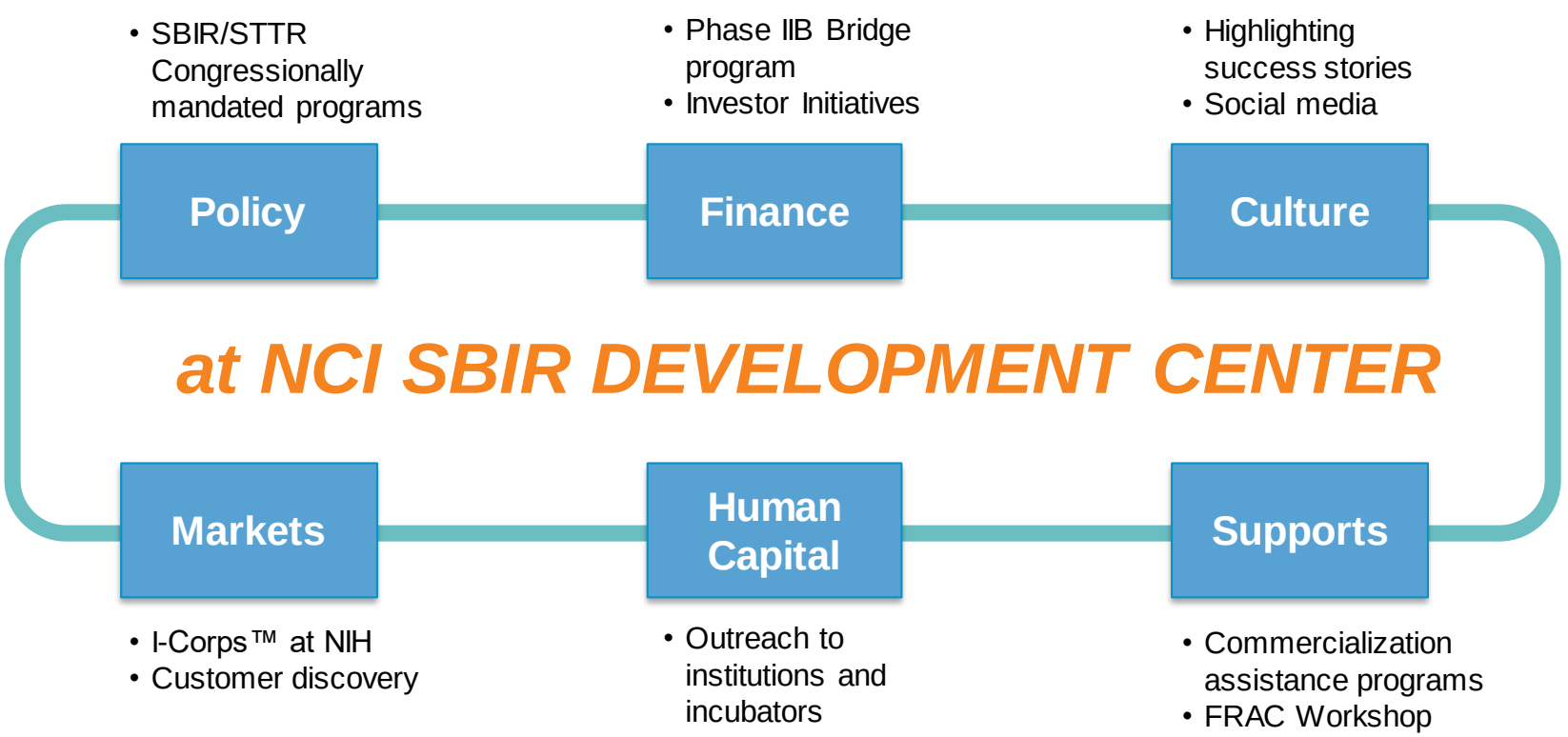
GUIDANCE / MENTORSHIP

- 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

NATIONAL CANCER INSTITUTE SBIR DEVELOPMENT CENTER

- **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

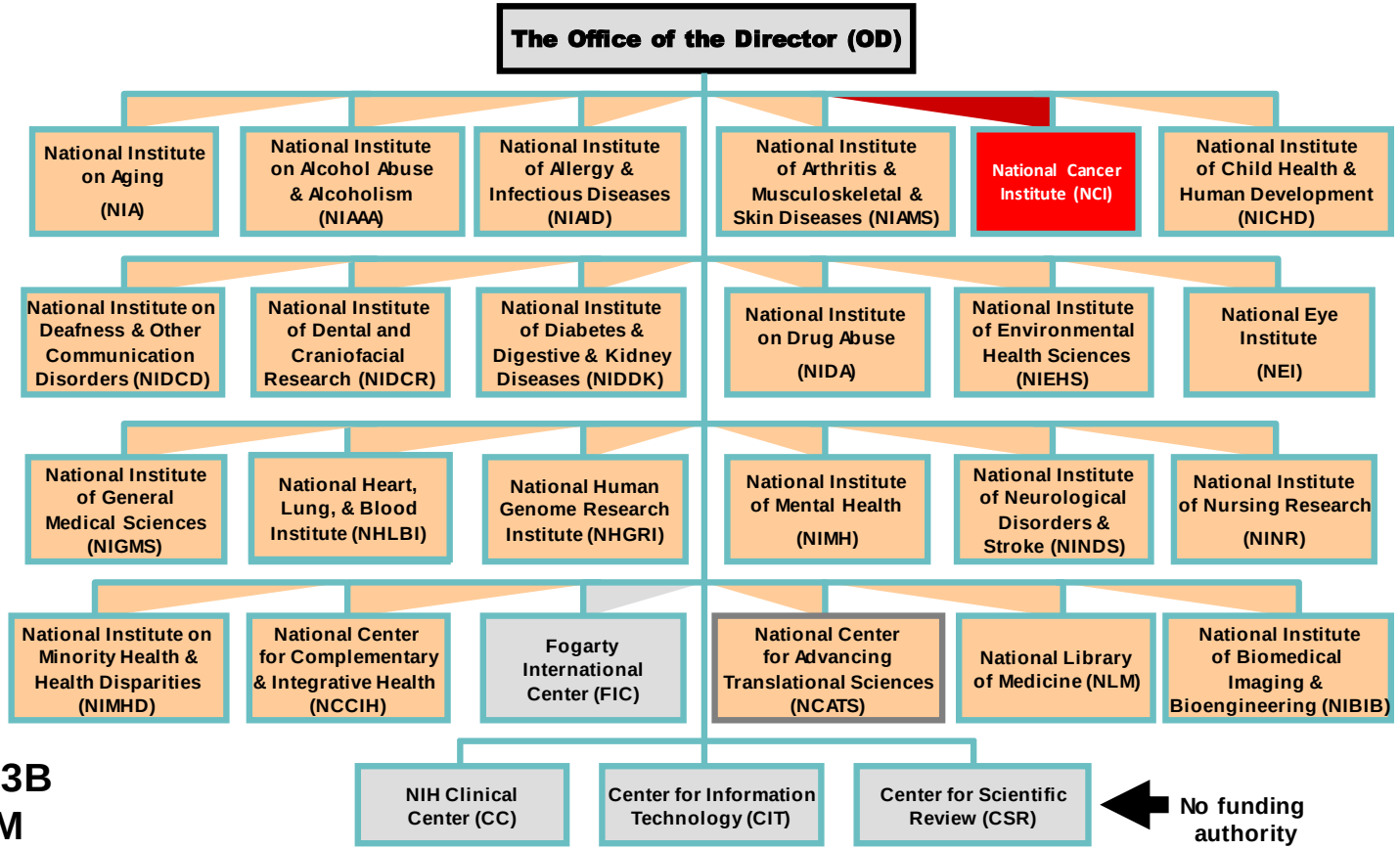
Set Aside

FY11	FY18
2.5%	3.2%
0.3%	0.45%

NIH: $1.073B
NCI: $167M

NIH has 27 Institutes and Centers

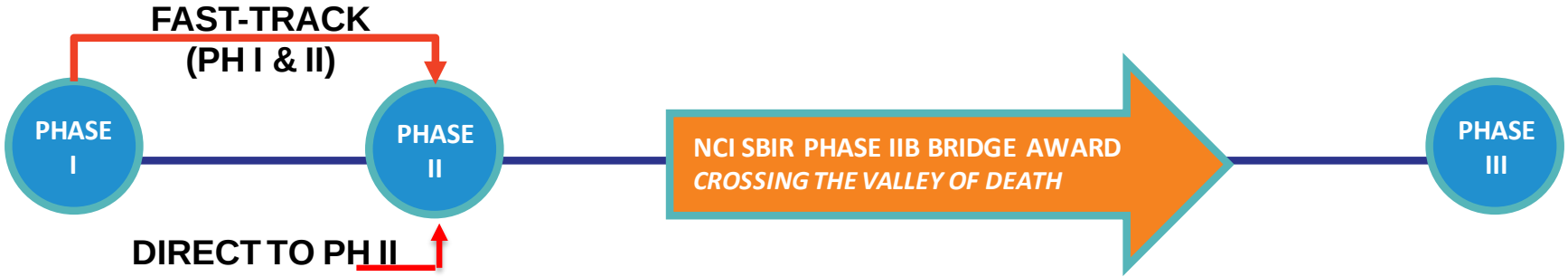
23 "separate" SBIR/STTR Programs



NIH: $1.073B

NCI: $167M

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**

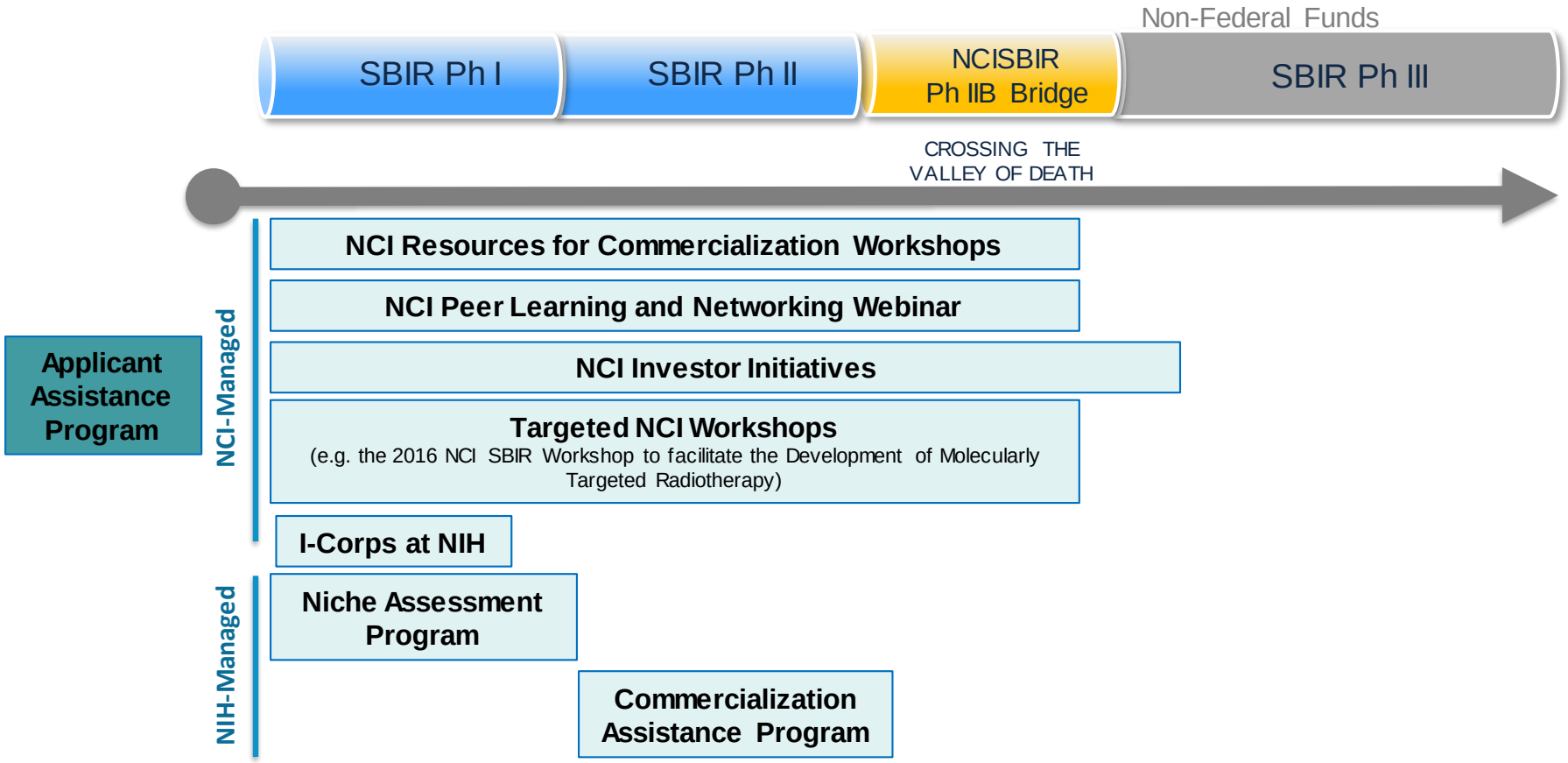
- Technology validation & clinical translation
- Follow-on funding for SBIR Phase II awardees from any federal agencies
- Expectation that applicants will secure substantial 3rd party investor funds
- **$4M over 2-3 years**

- 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

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
Permits research institution partners (e.g., universities)	**Requires** 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)
ELIGIBILITY: The PD/PI's primary employment (i.e., >50%) MUST be with the SBC for the duration of the project period	**ELIGIBILITY:** 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

NATIONAL CANCER INSTITUTE SBIR DEVELOPMENT CENTER

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?

Modulation Therapeutics, Inc

"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

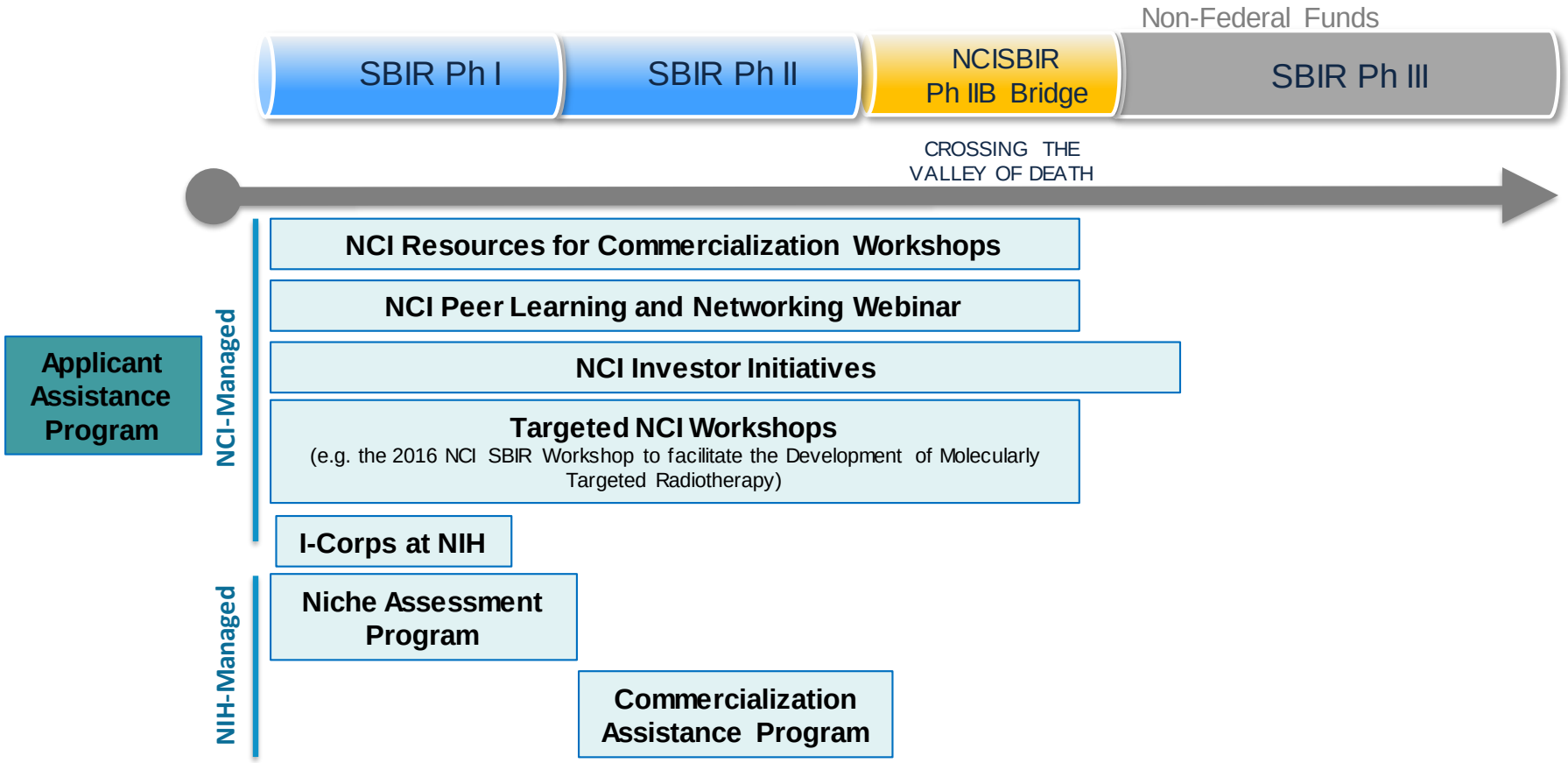
Aruna Gambhir, MS, MBA

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."

CELLSIGHT TECHNOLOGIES

NIH and NCI Assistance: More than just $$$



NIH/NCI Applicant Assistance Program (AAP)

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

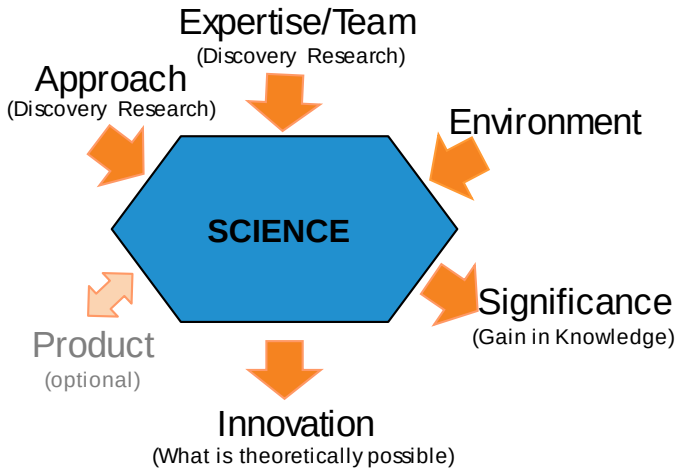
NIH AAP PROGRAM	NOT PROVIDED
Phase I Preparation Support and Review	Grant Writer
Specific Aims Page Review and Advice	Development of Research Plan
Submission Process Coaching	Register small business for you, apply to NIH for you

AAP GOAL:

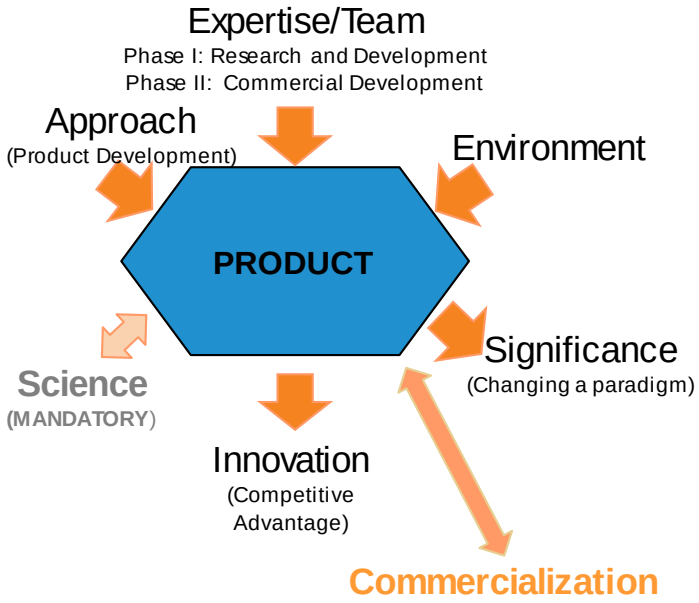
Provide a mentor for applicants with great technology, but little NIH experience and limited NIH experience in their network.

Application

ACADEMIC GRANT



SBIR/STTR GRANT



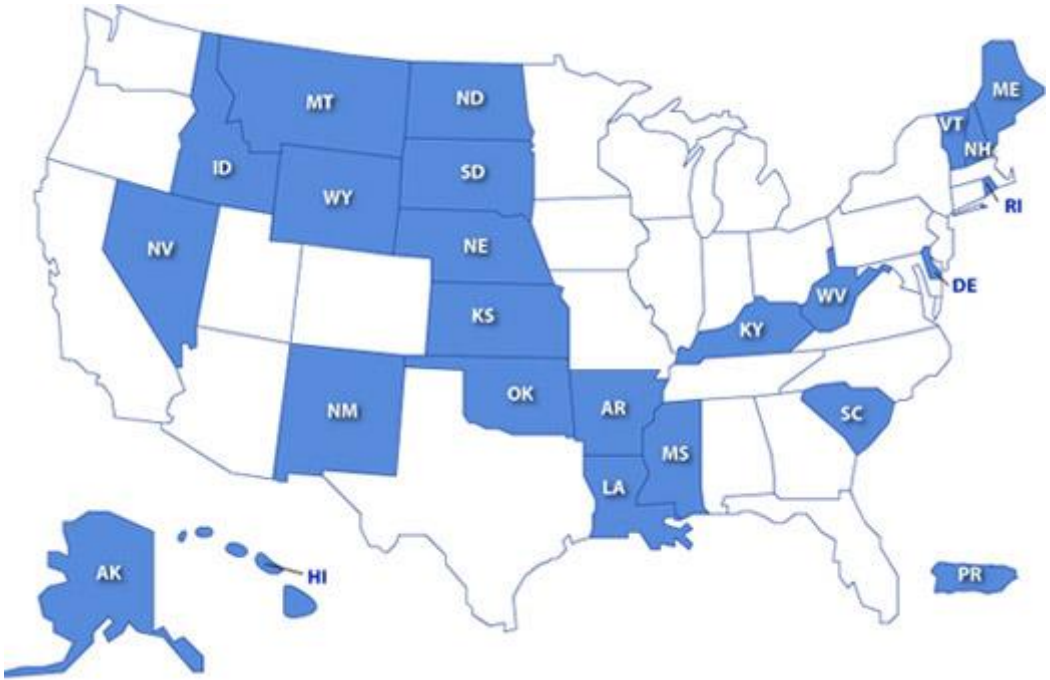
AAP Eligibility

- **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)



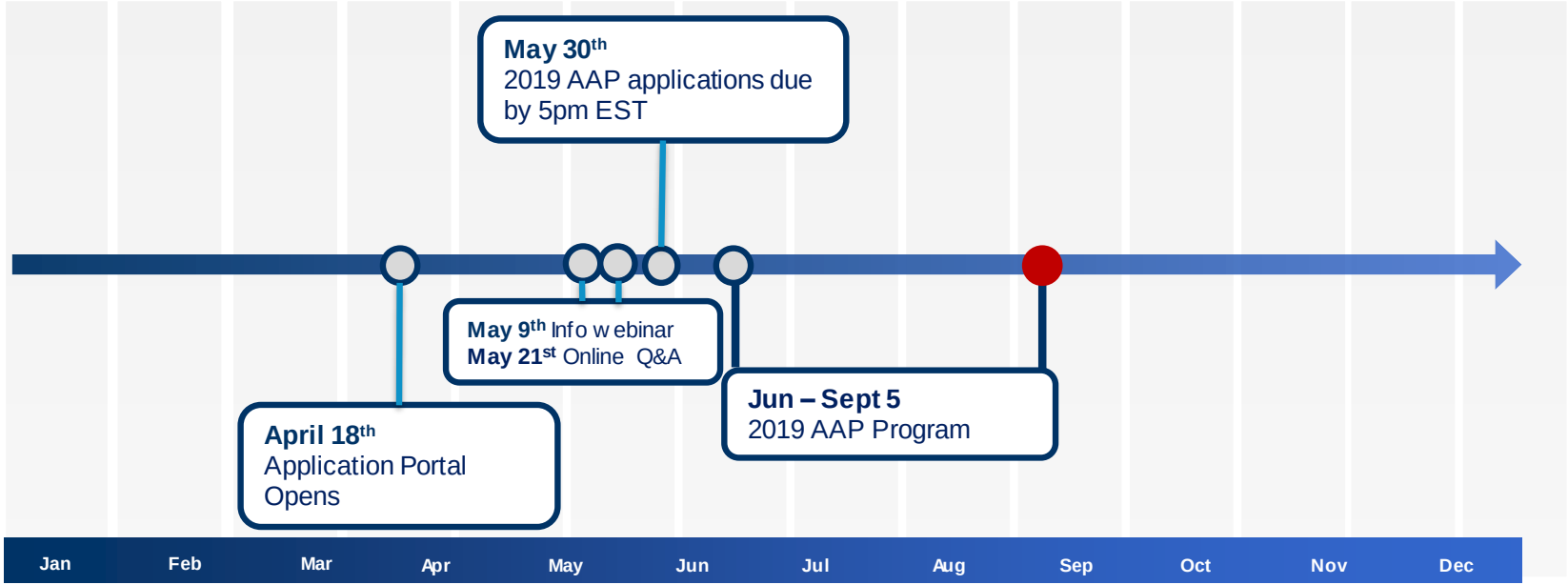
AAP Application

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

AAP Timeline

1 Cohort in 2019

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



Calendar Year 2019

NCI SBIR Program Staff

Michael Weingarten, MA
Director
NCI SBIR Development Center

Let's discuss your project!
***Send Specific Aims to* ncisbir@mail.nih.gov**

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

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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