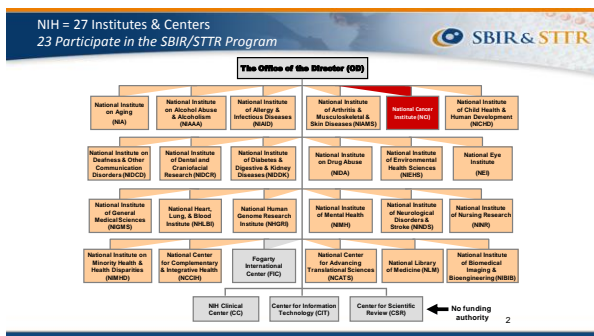


NCI SBIR & STTR

Funding, mentoring & networking assistance for next-generation cancer technologies

August 2, 2016

Deepa Narayanan
Program Director
National Cancer Institute SBIR Development Center



Congressionally-Mandated Programs

➤ **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 (FY17*)

3.2%

0.45%

~\$877M annually at NIH
~\$136M annually at NCI

* FY2017 Level is Estimated 27% increase over FY2011

Reasons to Seek SBIR/STTR Funding 

- Provides seed funding for innovative technology development
- Provides recognition, verification and visibility
- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)
- **Not a loan** : No repayment is needed, non dilutive



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."

SBIR Eligibility 

- Applicant must be a Small Business Concern (SBC)
- Organized for-profit U.S. business
- 500 or fewer employees, including affiliates
- PD/PI's primary employment (i.e., > 50%) must be with SBC at the time of award and for duration of the project period
- > 50% U.S.- owned by individuals and independently operated

OR

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

OR

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

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STTR Eligibility 

- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
 - Minimum 40% by small business concern
 - Minimum 30% by U.S. research institution
- U.S. Research Institution: College or University; Non-profit research organization; Federally-Funded R&D Center (FFRDC)
- Intellectual Property Agreement
 - Should provide the necessary IP rights (to the SBC) in order to carry out follow-on R&D and commercialization
- Principal Investigator's primary employment may be with either the Small Business Concern or the research institution

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SBIR and STTR Programs (Critical Differences)



SBIR

- **Permits** research institution partners (e.g., universities)
- Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities

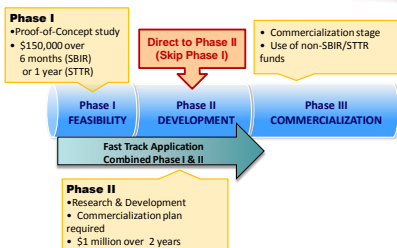
STTR

- **Requires** research institution partners (e.g., universities)
- 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)

Award always made to small business

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SBIR & STTR: Three-Phase Program



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NCI Waiver Topics



APPENDIX A: PHS 2015-2 SBIR/STTR PROGRAM DESCRIPTIONS

- 1. Therapeutics**
 - e.g. Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies
- 2. In Vitro and In Vivo Diagnostics**
 - e.g. Companion Diagnostics and Prognostic Technologies
- 3. Imaging Technologies**
 - e.g. Agents, Devices, and Image-Guided Interventions
- 4. Devices for Cancer Therapy**
 - e.g. Interventional Devices, Surgical, Radiation and Ablative Therapies
- 5. Agents for Cancer Prevention**
 - but not "Technologies for Cancer Prevention"
- 6. Development of Low Cost Technologies for Global Health**
- 7. Development of Companion Diagnostics**
- 8. Vaccine Development for Cancer Prevention**
- 9. Novel Technologies to Address "Undruggable" Drug Targets**

THREE AWARD "CAPS"

	PHASE I	PHASE II
Standard	\$150k	\$1M
Hard Cap	\$225k	\$1.5M
Waiver Cap	\$300k	\$2M

Awards above waiver topic cap
EXTREMELY uncommon

**NCI SBIR Development Center
Program Staff**


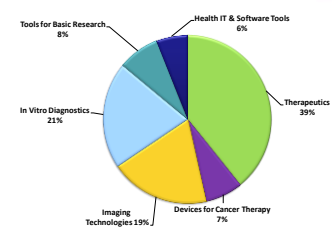


Michael Weingarten, MA
Director
NCI SBIR Development Center

 Oleg Evens, PhD Lead Program Director Cancer Biology, E-Health, Epidemiology, Research Tools	 Patricia Weber, DVM Program Director Digital Health, Therapeutics, Biology, SBIR Investor Forum, FRAC Workshop	 Deepa Narayanan, MS Program Director Medical Devices, Cancer Tools, Radiation Therapy, SBIR Investor Forum, FRAC Workshop	 Ming Zhao, PhD Program Director Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells	 Christie Casarillo, PhD Program Director Cancer/Biological Imaging, Research Tools, Devices, Scientific Communications, and i-Coops @ NIH	 Kory Hillert, PhD Program Director Monoclonal Antibodies, Immunotherapy, Biologics and Program Analysis	 Andrew J. Kurtz, PhD Lead Program Director Biology, Small Molecules, Nanotherapeutics, Molecular Diagnostics, Bridge Award	 Jan Lee, PhD Program Director In-Vitro Diagnostics, Therapeutics, early-stage drug development, Bioinformatics, FRAC Workshop	 Todd Hahn, PhD Program Director Small Molecules, Biology, Immunotherapeutics, Therapeutics, SBIR Investor Forum, FRAC Workshop	 Amit Rajbhar, PhD, MEd Program Director In-Vitro Diagnostics, Biology, Therapeutics, Proteomics, SBIR Investor Forum	 Jonathan Franco-Koh, MD, MEd Program Director Cancer Biology, Biology, Small Molecules, Cell Based Therapies
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ncisbir@mail.nih.gov
sbir.cancer.gov @NCIsbir


NCI's SBIR/STTR Portfolio

Category	Percentage
Therapeutics	39%
In Vitro Diagnostics	21%
Imaging Technologies	19%
Tools for Basic Research	8%
Health IT & Software Tools	6%
Devices for Cancer Therapy	7%

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NCI SBIR Development Center: 5 Core Activities



- Provide central oversight of all 400+ NCI-funded SBIR and STTR projects (Program Director role)
- Coach applicants in preparation of funding applications
- Conduct regular outreach events all over the U.S. (with state-based, BIO-like organizations)
- Maintain a network of investors, and broker personal connections between NCI SBIR companies and potential third-party investors/strategic partners
- Play active role in seeding emerging technology areas

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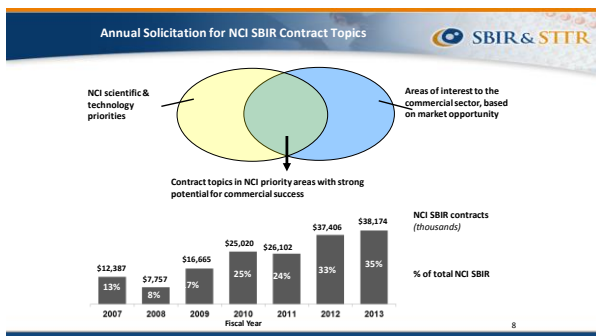
The image shows a screenshot of the sbir.cancer.gov website. At the top, there is a blue header with the text "sbir.cancer.gov" on the left and the "SBIR & STTR" logo on the right. Below the header is a navigation menu with tabs for "HOME", "ABOUT", "FUNDING", "ROSETTES", "RESOURCES & EDUCATION", "RESOURCES", and "NEWS & EVENTS". The main content area features a large image of two people in a laboratory setting, one holding a petri dish. Below this image is a section titled "What are the SBIR & STTR Programs?" followed by a "Learn More About the Programs" link. To the right, there is a section for "Learn About Us" with various icons representing different aspects of the program.

This slide is titled "Investigator-Initiated Grants" and features the "SBIR & STTR" logo in the top right corner. It contains a bulleted list of solicitation types:

- Omnibus Solicitations (Phase I, Phase II, FastTrack)
 - [PA-15-269](#) (SBIR) and [PA-15-270](#) (STTR)
- Direct to Phase II Solicitation
 - [PAR-15-288](#) (SBIR only)

 A red-bordered box in the center contains the text: "We encourage applications for any topic within the NIH mission". Below this box, it states "Due September 5, January 5, April 5". At the bottom left, the number "14" is visible. At the bottom right, there is the NIH logo and the text "National Institutes of Health Turning Discovery Into Health".

This slide is titled "NCI SBIR Contract Funding Opportunities" and features the "SBIR & STTR" logo in the top left and the "NATIONAL CANCER INSTITUTE" logo in the top right. The background is a photograph of a laboratory setting with two people working. A yellow box contains the URL <http://sbir.cancer.gov/funding/contracts>. The slide is set against a white background with a blue footer.



SBIR Contracts vs. Grants

	SBIR Grants	SBIR Contracts
<i>Scope of the proposal</i>	Investigator-defined within the mission of NIH	Defined (narrowly) by the NIH
<i>Questions during solicitation period?</i>	May speak with any Program Officer	MUST contact the contracting officer (eshanahan@mail.nih.gov)
<i>Receipt Dates</i>	3 times/year for Omnibus	Only ONCE per year
<i>Peer Review Locus</i>	NIH Center for Scientific Review (CSR)	NCI DEA (target 50% business reviewers)
<i>Basis for Award</i>	Peer review score/ Program assessment	Peer review score/negotiation of technical deliverables, budget
<i>Reporting</i>	One final report (Phase I); Annual reports (Phase II)	Kickoff presentation, quarterly progress reports, final report, commercialization plan
<i>Set-aside funds for particular areas?</i>	No	Yes
<i>Program Staff Involvement</i>	Low	High

- ### Funding Opportunity Summary
- PHS-2017-1 "HHS Small Business Innovation Research (SBIR) Program Contract Solicitation"
 - ONE application receipt date per year:
 - Published August 1, 2016
 - Receipt Date: October 21, 2016, 5:00 PM ET**
 - RFP can be found at:
 - <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-123.html>
 - More info about NCI's topic areas:
 - <https://sbir.cancer.gov/funding/contracts/currentcontracts>

NCI Contract Topics (Due October 21, 2016)

- **NIH/NCI 355:** Cell and Animal-Based Models to Advance Cancer Health Disparity Research
- **NIH/NCI 356:** Tools and Technologies for Monitoring RNA
- **NIH/NCI 357:** Innovative Tools for Interrogating Tumor Microenvironment Dynamics
- **NIH/NCI 358:** Modulating the Microbiome to Improve Therapeutic Efficacy of Cancer Therapeutics
- **NIH/NCI 359:** Technologies for Differential Isolation of Exosomes and Oncosomes
- **NIH/NCI 360:** Manufacturing Innovation for the Production of Cell-Based Cancer Immunotherapies
- **NIH/NCI 361:** Highly Innovative Tools for Quantifying Redox Effector Dynamics in Cancer
- **NIH/NCI 362:** Informatics Tools to Measure Cancer Care Coordination
- **NIH/NCI 363:** Connecting Cancer Caregivers to Care Teams: Digital Platforms to Support Informal Cancer Caregiving
- **NIH/NCI 364:** Methods and Software for Integration of Cancer Metabonomic Data with Other –Omic and Imaging Data
- **NIH/NCI 365:** Imaging Informatics Tools and Resources for Clinical Cancer Research
- **NIH/NCI 366:** Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators
- **NIH/NCI 367:** Predictive Biomarkers to Improve Radiation Treatment
- **NIH/NCI 368:** Molecularly Targeted Radiation Therapy for Cancer Treatment
- **NIH/NCI 369:** Development of Pediatric Cancer Drug Delivery Devices

<http://sbir.cancer.gov/funding/contracts>

NCI SBIR Phase IIB Bridge Award, Launched 2008

Phase I FEASIBILITY Phase II DEVELOPMENT NCI SBIR Phase IIB Bridge Award CROSSING THE VALLEY OF DEATH Phase III COMMERCIALIZATION

- Provides up to \$1M per year for up to 3 years
- Open to any NIH-funded Phase II awardees with projects relevant to NCI mission
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners *earlier in the development process*
- Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., \geq 1:1 match)

18 Bridge Awards
FY2009 – FY2014

Project	NCI Award	Third-Party Investments
Leap Therapeutics	~\$1.5M	~\$1.5M
Chondrex	~\$1.5M	~\$12M
Galectin Therapeutics	~\$1.5M	~\$12M
Galectin Medicines	~\$1.5M	~\$12M
Abio Horizons	~\$1.5M	~\$12M
Kronos Corpn.	~\$1.5M	~\$12M
2025 Genetic Systems	~\$1.5M	~\$12M
Advanced Cell Technologies	~\$1.5M	~\$12M
EnteroGen	~\$1.5M	~\$12M
TransAct Research	~\$1.5M	~\$12M
Ultracell Manufacturing	~\$1.5M	~\$12M
Corvix	~\$1.5M	~\$12M
Corvix	~\$1.5M	~\$12M
Beigee Pharmaceuticals	~\$1.5M	~\$12M
Ando USA Corporation	~\$1.5M	~\$12M
Wipac Tech Research	~\$1.5M	~\$12M
Concavo Medical	~\$1.5M	~\$12M

NCI Total	\$42.8 M
Third-Party Investments	\$86.3 M
Leverage	> 2 to 1

~40% Venture Capital
~35% Strategic Partners
~25% Angels & Individuals

4 Cancer-Focused NCI SBIR Investor Forums- 2009, 2010, 2012, and 2014

MagArray

Omniox

Genentech

Workshop on Federal Resources to Accelerate Commercialization

Bringing together NCI SBIR/STTR awardees to move funded technologies from bench to bedside

<http://sbir.cancer.gov/programeducation/fracworkshop>

- Speakers from FDA, CMS, USPTO, and across NIH
- Panels on other sources of federal funding, resources & collaborative programs at NIH, and unique life science investment organizations
- Over 300 One-on-one meetings with program directors and speakers
- Brain storm sessions with other SBIR peers and NIH staff.

@NCISbtr 23

I-Corps™ Training Program

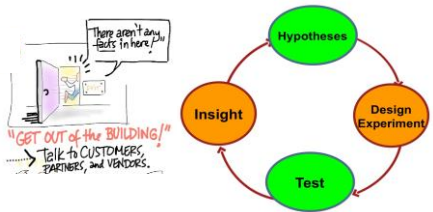
Program Description

- Intensive **Entrepreneurial Immersion** course aimed at providing teams with skills and strategies to reduce commercialization risk
- Curriculum emphasizes **Reaching out to Customers** to test hypotheses about the need and market for the technology being developed.
 - Each team is expected to conduct over 100 interviews over 10 weeks.
- Format is focused on **Experiential Learning**

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Customer Development 

Hypotheses Testing and Insight...



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 I-Corps™ at NIH 

-  National Institutes of Health Office of Extramural Research
 -  National Center for HIV/AIDS, Dermatology and STDs
 -  National Heart, Lung, and Blood Institute
 -  National Institute of Neurological Disorders and Stroke
 -  National Cancer Institute
 -  National Center for Human Genome Research
 -  National Institute of Diabetes and Digestive and Kidney Diseases
 -  National Institute of Mental Health
 -  National Institute of Environmental Health Sciences
- 3 cohorts offered NIH and NSF SBIR/STTR Phase I grantees
 - Oct – Dec 2014, Mar – May 2016, Jun – Aug 2016
 - 38 teams conducted 4,264 customer discovery interviews
 - 86% (on avg) found the program "very good" or "excellent"
 - 86% (on avg) would recommend I-Corps™ at NIH to other companies

"We clarified the value propositions, who our target customers would be, revenue streams, customer relationships..."

"After going through I-Corps we understand we have to focus on a small subset [of customers] and prioritize segments based on their value propositions."

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NIH Technical Assistance Programs 
(open to all eligible NIH SBIR/STTR Awardees)

-  **Niche Assessment Program**
Foresight S&T
(Phase I awardees)
 - Identifies other uses of technology
 - Determines competitive advantages
 - Develops market entry strategy
-  **Commercialization Accelerator Program Larta, Inc.**
(Phase II awardees)
 - "Menu" of technical assistance/training programs in:
 - Strategic/business planning
 - FDA requirements
 - Technology valuation
 - Manufacturing issues
 - Patent and licensing issues
 - Helps build strategic alliances
 - Facilitates investor partnerships
 - Individualized mentoring/consulting

@NCISBIR



What Does It Take to Get Funded? *Tips on Applying*

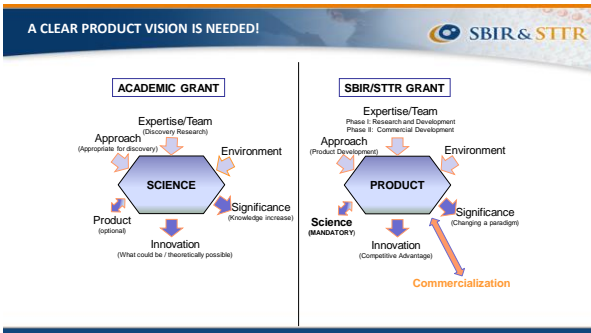




- NIH receives many strong SBIR/STTR proposals
- SBIR/STTR awards are highly competitive
 - Funding success rate around 15%
 - Resubmissions are very common
- You **must** prepare a strong application!



- 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?



- Before You Write an Application**
- Consider your company's strengths and how to exploit them
 - Consider your company's weaknesses and how to address them
 - Contact an appropriate NIH Program Director in advance (at least 1 month before due date!), to discuss your specific aims and receive feedback
 - Review similar, currently-funded NIH projects
 - NIH Project RePORTER

Search Previous Awards

<http://projectreporter.nih.gov>

What if you are not funded?



- **Rejection is painful, BUT...**
- **Feedback provides a roadmap for next steps**
 - Carefully review the Summary Statement (written critiques)
 - Use reviewer comments to improve your application
 - [Discuss Summary Statement with your NIH Program Director](#)
- **Revise and resubmit the application**
 - Introduction Page: Response to reviewer critiques
 - [Be constructive not defensive](#)
- **Learn more about SBIR/STTR grants**
 - Talk to successful applicants
 - Understand review process and dynamics - <http://csr.nih.gov>



THANK YOU!

NCI SBIR Development Center
NCIsbir@mail.nih.gov
 Phone: 240.276.5300
<http://sbir.cancer.gov>
 Sign up for updates!

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<http://www.linkedin.com/company/nci-sbir-development-center>
