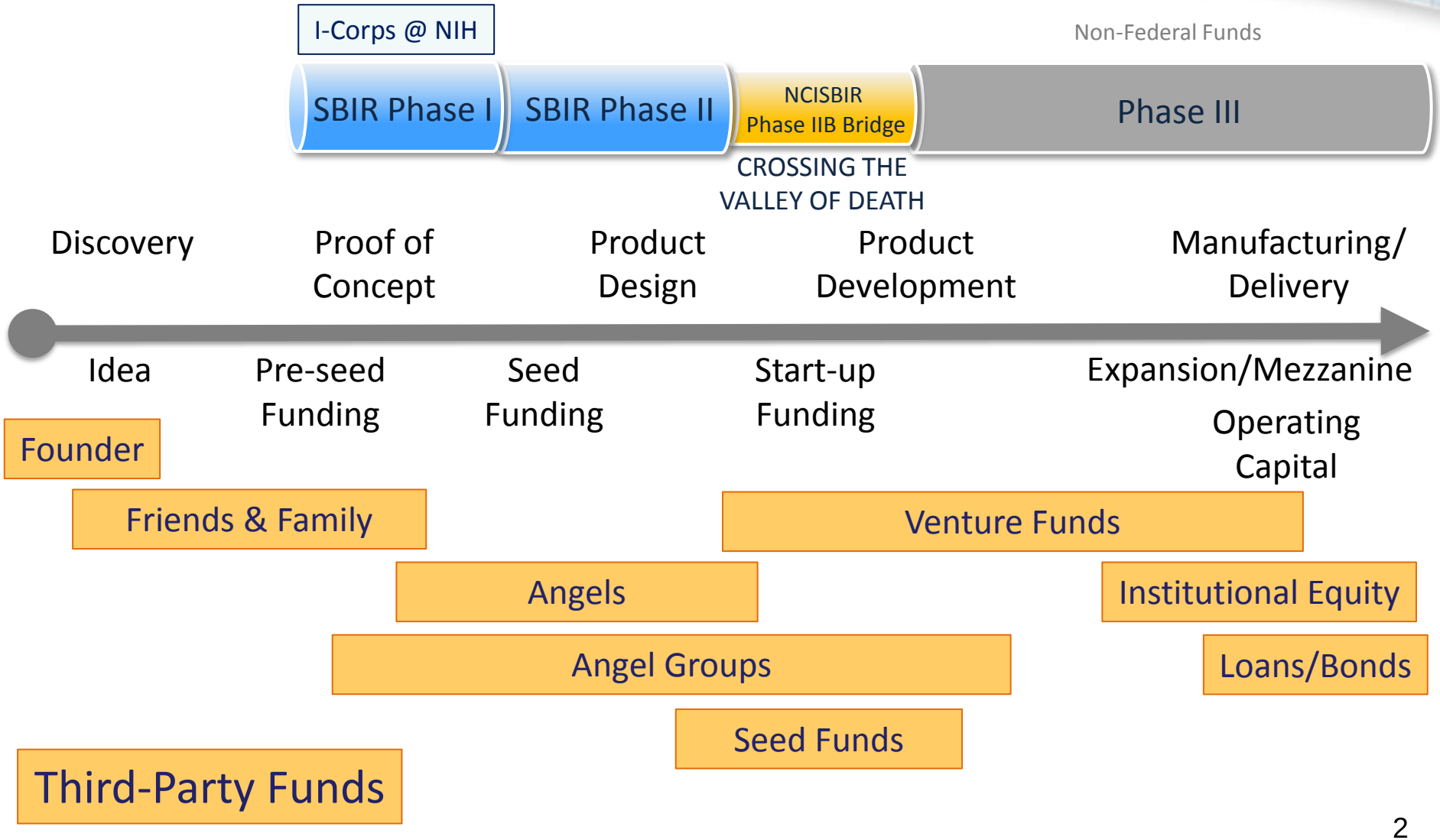
I-Corps™ at NIH

July 21, 2016

Michael Weingarten
Director
National Cancer Institute SBIR Development Center

NIH SBIR/STTR Resources



I-Corps™ at NIH

SBIR & STTR

Program for SBIR Phase I grantees to help:

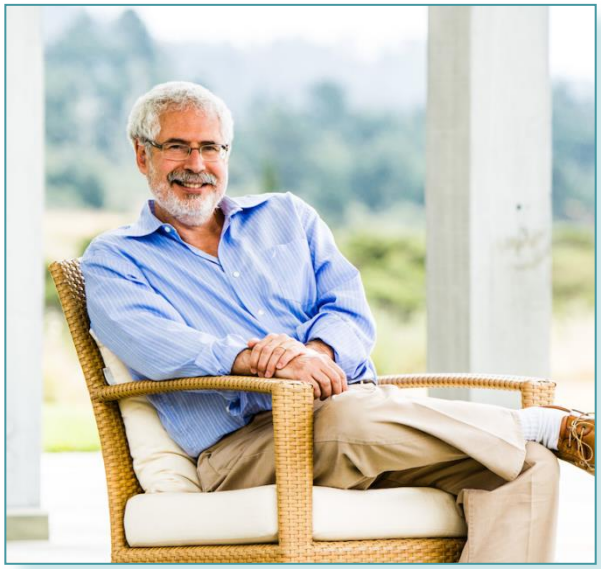
- Define the value proposition (e.g., clinical utility) **early** before spending millions – saves time AND money
- Assess IP and regulatory risk before design and build
- Better understand core customers and the **specific** steps required for downstream commercialization
  - Teams are required to conduct 100 interviews
- Gather information essential to customer partnerships/ collaborations/ purchases before doing the science
- Identify financing vehicles before they are needed (helping to avoid the “Valley of Death”)

Teaching Methodology

SBIR & STTR

I-Corps™ is based on a curriculum called Lean LaunchPad

- Developed by Steve Blank as a graduate course at Stanford
- Brings together customer development, agile development, business model generation, and pivots



Steve Blank

- Serial entrepreneur
- 21 years / 8 startups
- 13 years @ Berkeley, Columbia, Stanford, & UCSF

Lean LaunchPad

SBIR & STTR

Technology commercialization efforts have two components

1. **The science/technology**
2. **The business model**

- **Commercialization efforts often focus on #1**
- **Successful efforts require the team to do both**

Innovation Corps (I-Corps™) program is focused on developing the business model

NSF National Innovation Network

- 7 I-Corps™ Nodes
- > 50 I-Corps™ Sites
- I-Corps™ at NIH instructors come from nodes
  - Trained with I-Corps curriculum

Experienced Teaching Team

- Have taught an average of 12+ cohorts nationally
- Domain expertise in therapeutics, diagnostics, devices, digital health

I-Corps™ at NIH

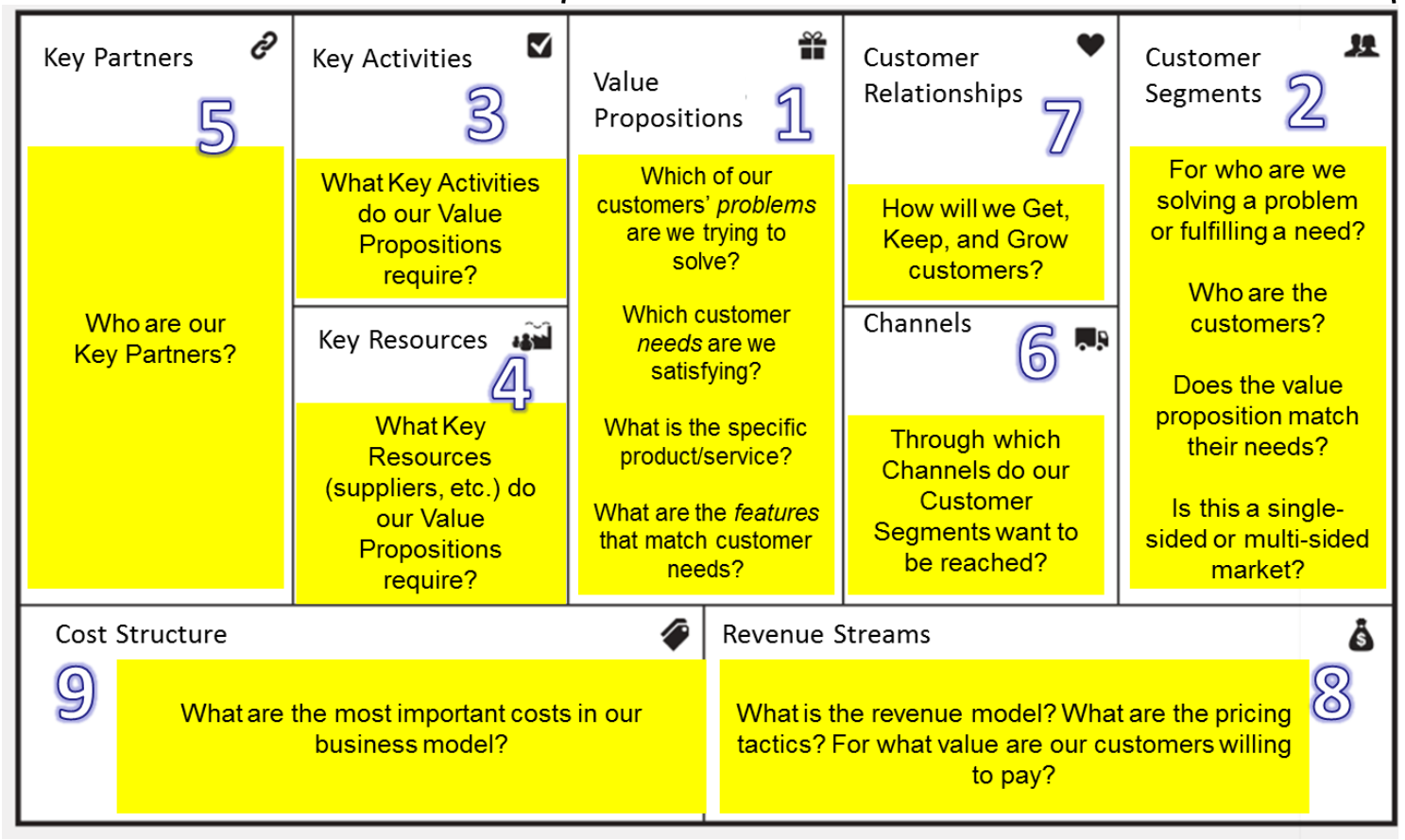
National Institutes of Health (NIH/OER)
National Cancer Institute (NCI)
National Heart, Lung, and Blood Institute (NHLBI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of General Medical Sciences (NIGMS)
National Institute of Mental Health (NIMH)
National Institute of Neurological Disorders and Stroke (NINDS)
National Center for Advancing Translational Sciences (NCATS)
National Center for Injury Prevention and Control (NCIPC/CDC)
National Institute for Occupational Safety and Health (NIOSH/CDC)

- NCI led
- 3 cohorts of NIH 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
- Planning for 2 more NIH Cohorts in Spring and Summer of 2017

Business Model Canvas

SBIR & STTR

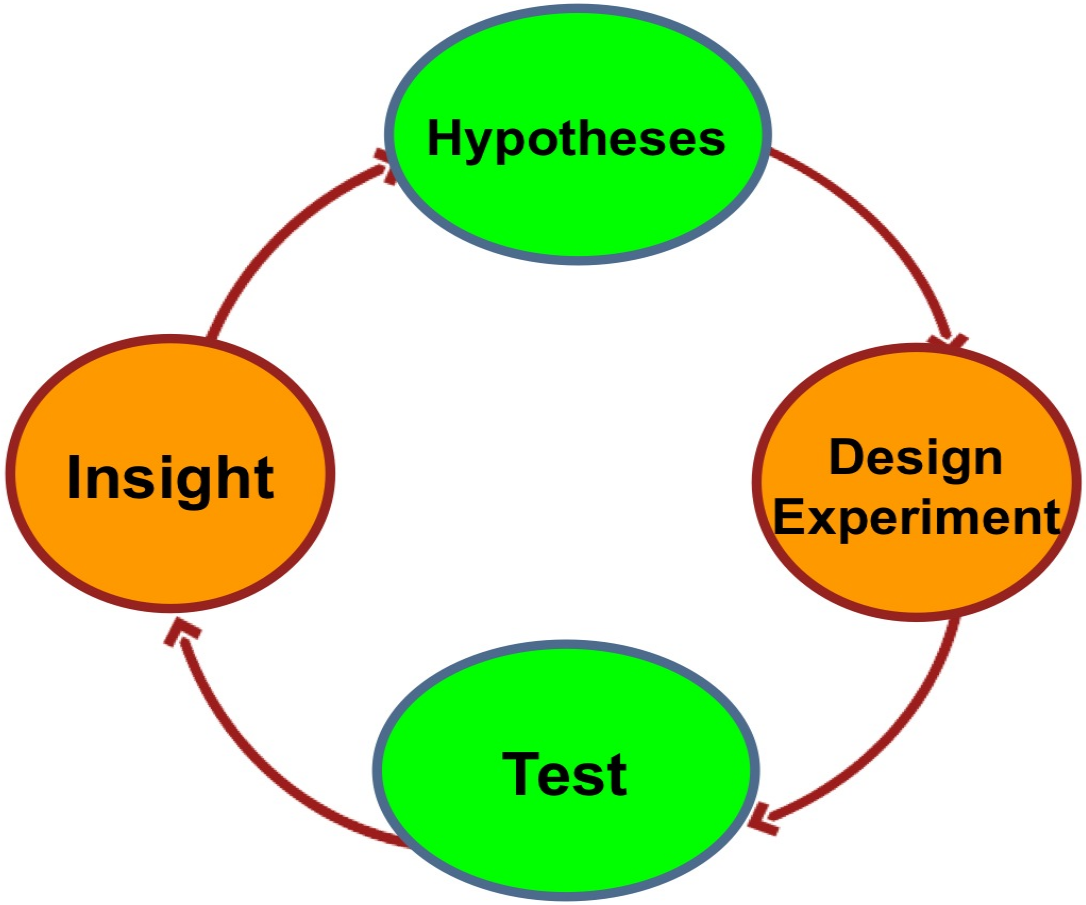
“ Product-Market Fit ”



Customer Development

SBIR & STTR

Hypotheses Testing and Insight…



Focus on Learning

Customer development is NOT sales!

- Teams are not pitching their product or technology
- Teams are **listening** to potential customers and other stakeholders and **learning** about:
  - What customers want and need
  - Pain points in their customers' daily routines
  - Features of a technology that would provide value

Experiential Format

Online Curriculum

- During the program, online content is used to track the progress of the teams
- Each team's progress is shared with the entire cohort of teams to facilitate group learning

➢ Teaching Philosophy

- A key part of this class is seeing how various teams solve similar problems through listening to the instructors coach and critique
- The program provides a forum for participants to bounce ideas off their peers
- The success of the team is less about the original idea and more about the learning, discovery, and execution

Impactful Learning

- Clinical utility
- Customers / customer segments
- Data & data quality that is needed
- Aspects of the product that are (& are not) valuable
- Roles of partners

- **New insights can have a dramatic affect on the aims of a future Phase II SBIR grant**
- **Or new Phase I SBIR grants**

Novoron – an example

SBIR & STTR

novoron

A new drug to restore function after spinal cord injury (SCI)

Learnings & Pivot

No one was interested in early-stage SCI drugs
…but they are interested in **Multiple Sclerosis**

Timeline

- December 2014 - Novoron graduates from I-Corps at NIH
- August 2014 - Phase 1 NIH grants received to develop SCI and stroke therapeutics
- November 2012 - Dr. Travis Stiles' discovery published in *Journal of Cell Science*

Novoron Bioscience Awarded NIH Grant to Evaluate New Treatments for Multiple Sclerosis (Dec 2015)

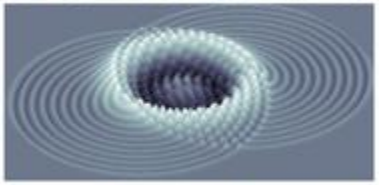
Negotiating **2** deals (including HubertBio in Korea)

Negotiating **2** strategic partnerships (with mutual NDAs)

Xconomy Recognizes Novoron as San Diego Life Science Startup to Watch in 2016 (Feb 2016)

Tomowave – an example

TomoWave



Imaging, Sensing & Monitoring

Laser Optoacoustic System for image-guided cryotherapy of prostate cancer

Sept 2015

PhotoSound Technologies, Inc.

PST

Modular tabletop small animal photoacoustic imaging system for researchers

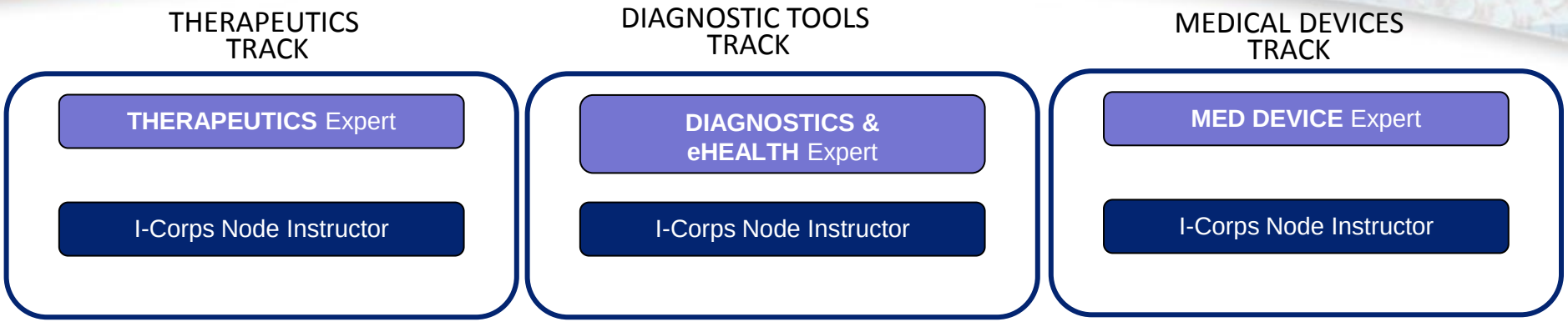
Hypothesis: Direct sales to physicians

Learnings:

- Doctors don't buy – Cryoablation Mfg & Providers (CMPs) purchase these systems.
- And they don't want to buy – they want to lease
- Instead of targeting urologists, pivot to provide services directly to CMPs

- Spin-off of company a direct result of I-Corps
- **1** active contract
- Negotiating **3** potential contracts w potential **$200K** revenue
- **2** investment plans in place
- **3** strategic partnerships

I-Corps™ at NIH - Program Format



COURSE FORMAT

- 3-Day Kick-off Event
- 6 Weekly web classes
- 2-Day Lessons Learned

LIFE SCIENCE TRACKS

- Therapeutics
- Diagnostics/eHealth
- Medical Devices

- Teams are distributed among track "rooms"

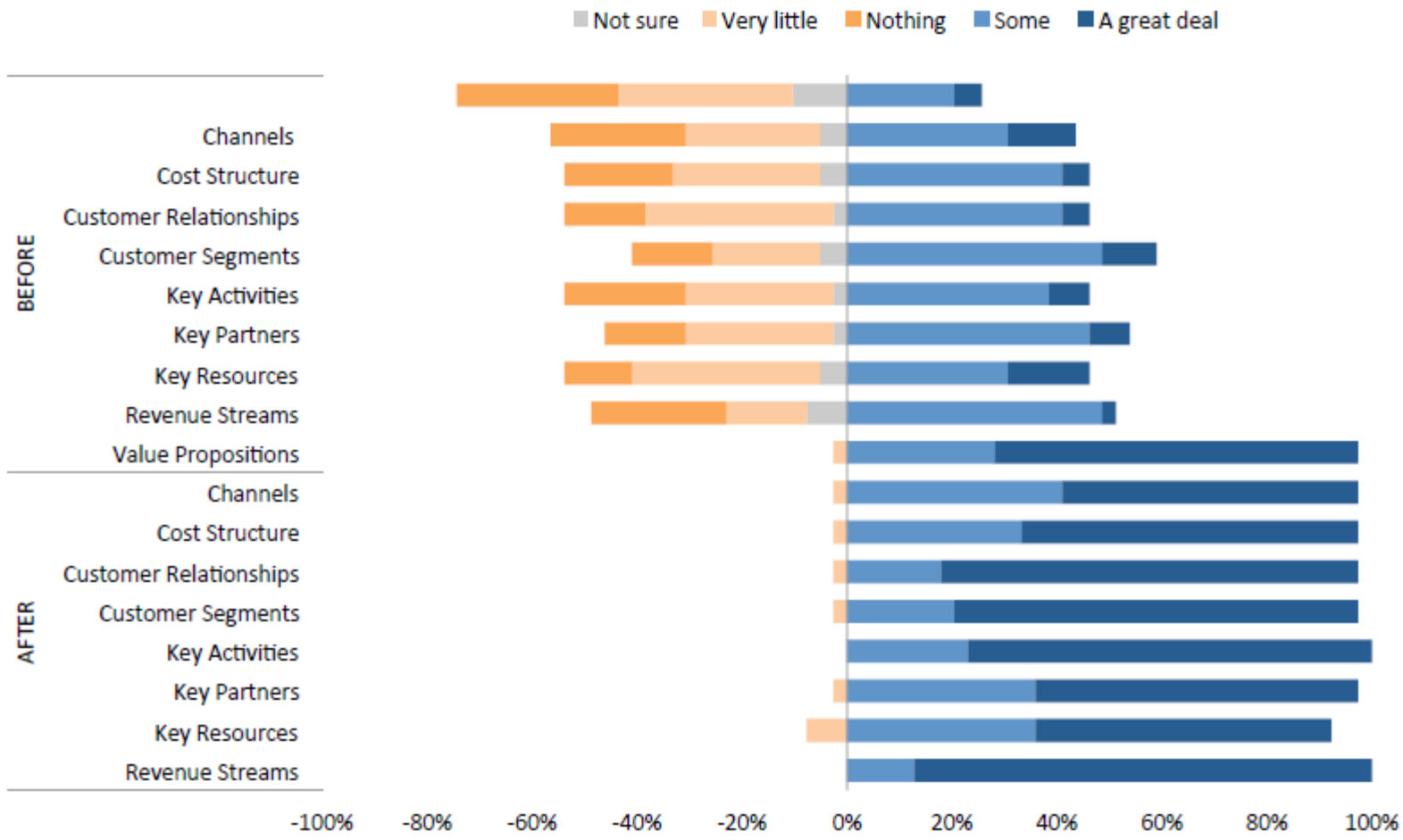
TEACHING TEAM

- I-Corps Node Instructors
- Industry Domain Experts

- Curriculum tailored to life sciences

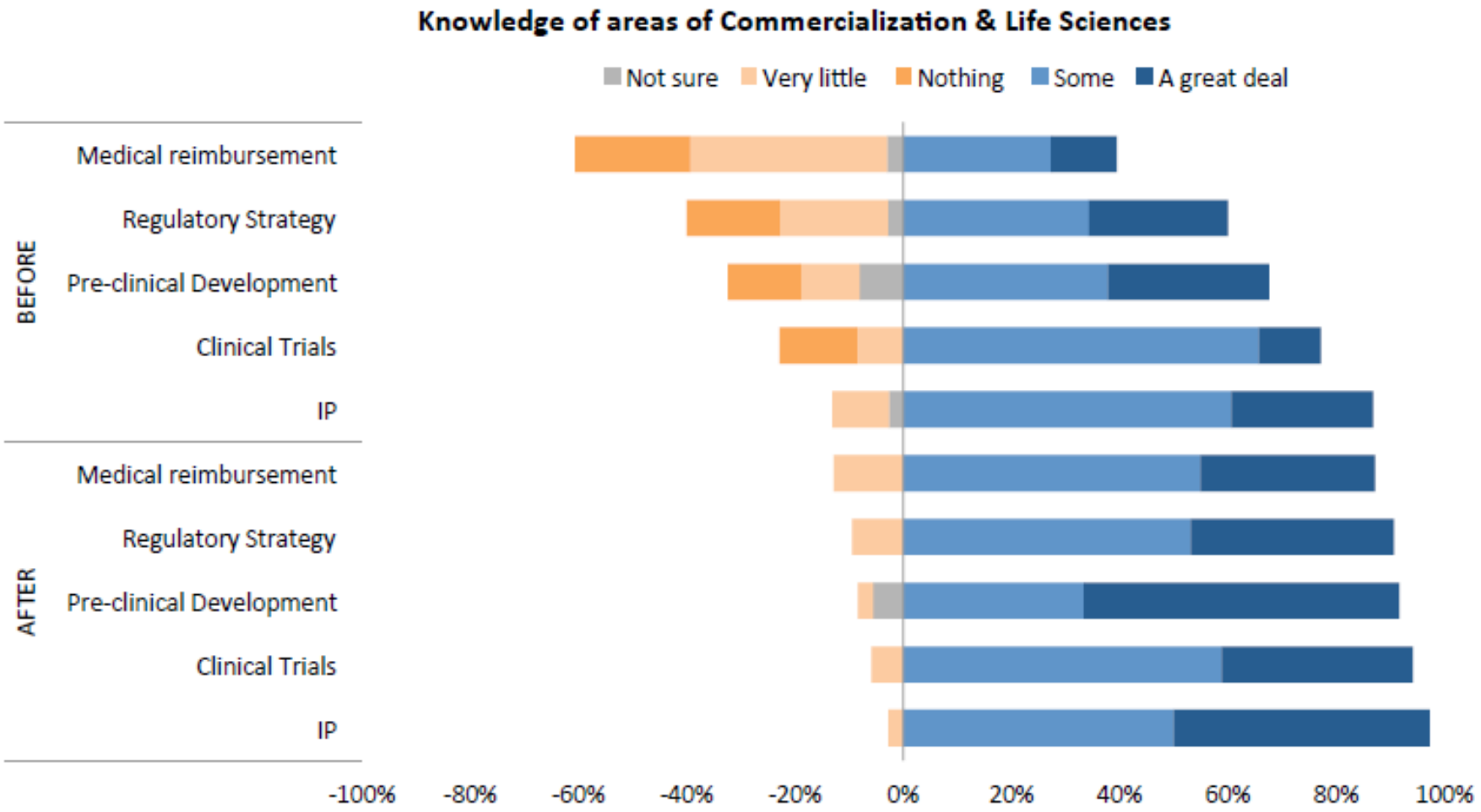
Business Model Canvas Knowledge

Spring 2016 Cohort



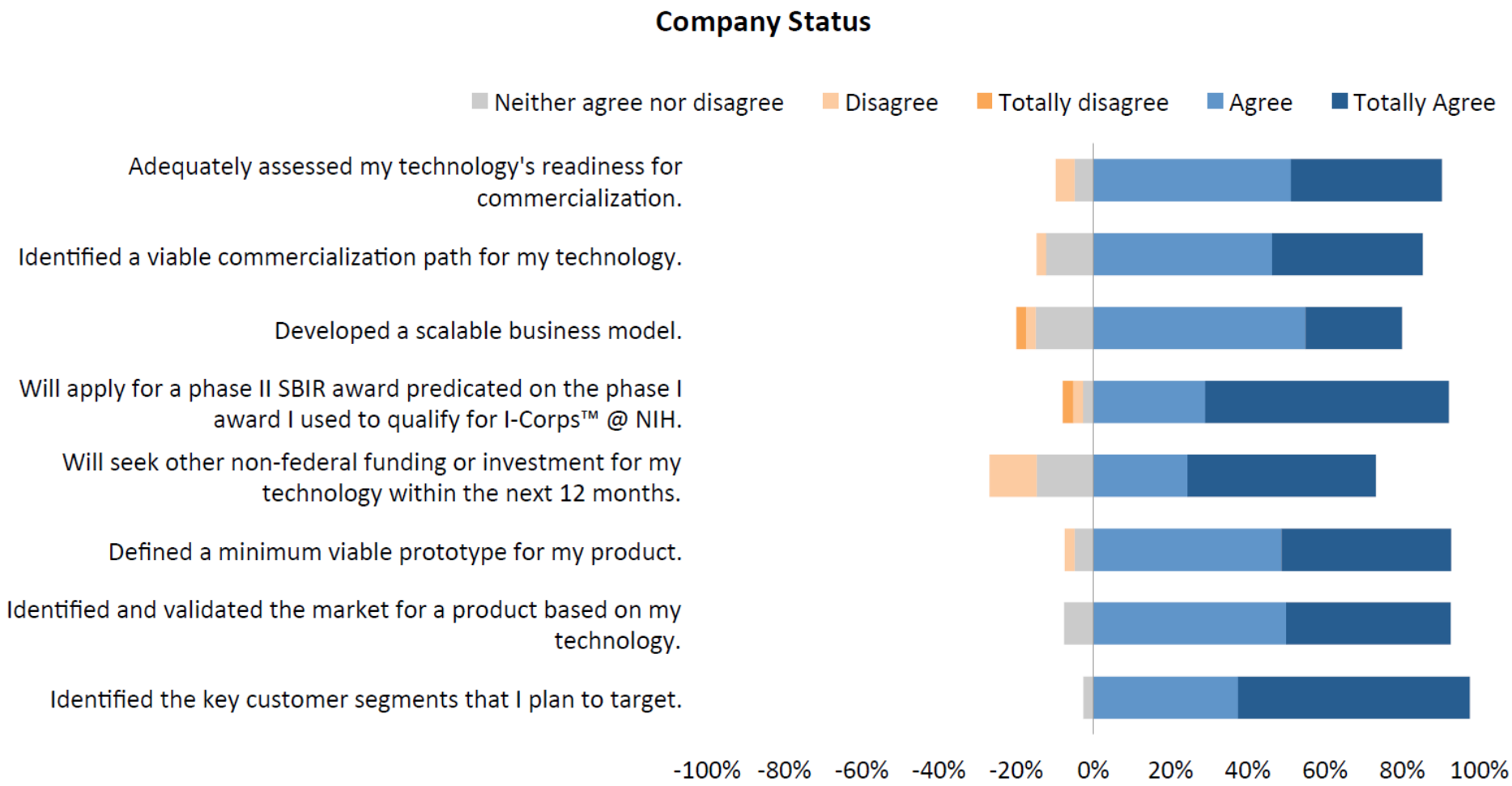
Life Science Commercialization Knowledge

Spring 2016 Cohort



Status of Technology and Future Plans

Spring 2016 Cohort



Additional Metrics for Longitudinal Studies

For longitudinal assessment of I-Corps participants, we anticipate collecting data around:

- **Business operational status**
- **Licensing & IP activity**
- **Job creation**
- **Funding activity (government or non-government)**
- **Sales/Generated revenue**
- **New Partnerships, ventures**

Q&A

NCI SBIR & STTR

Funding, mentoring & networking assistance for next-generation life science technologies

July 21, 2016

Christie Canaria, PhD
Program Manager
National Cancer Institute SBIR Development Center

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Cancer Biology, Biologics, Small Molecules, Cell Based Therapies

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NCI SBIR Development Center: 5 Core Activities

- Play active role in seeding emerging technology areas
- Coach applicants in preparation of funding applications
- Provide central oversight of all 400+ NCI-funded SBIR and STTR projects (Program Director role)
- 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

Congressionally-Mandated Programs

SBIR & STTR

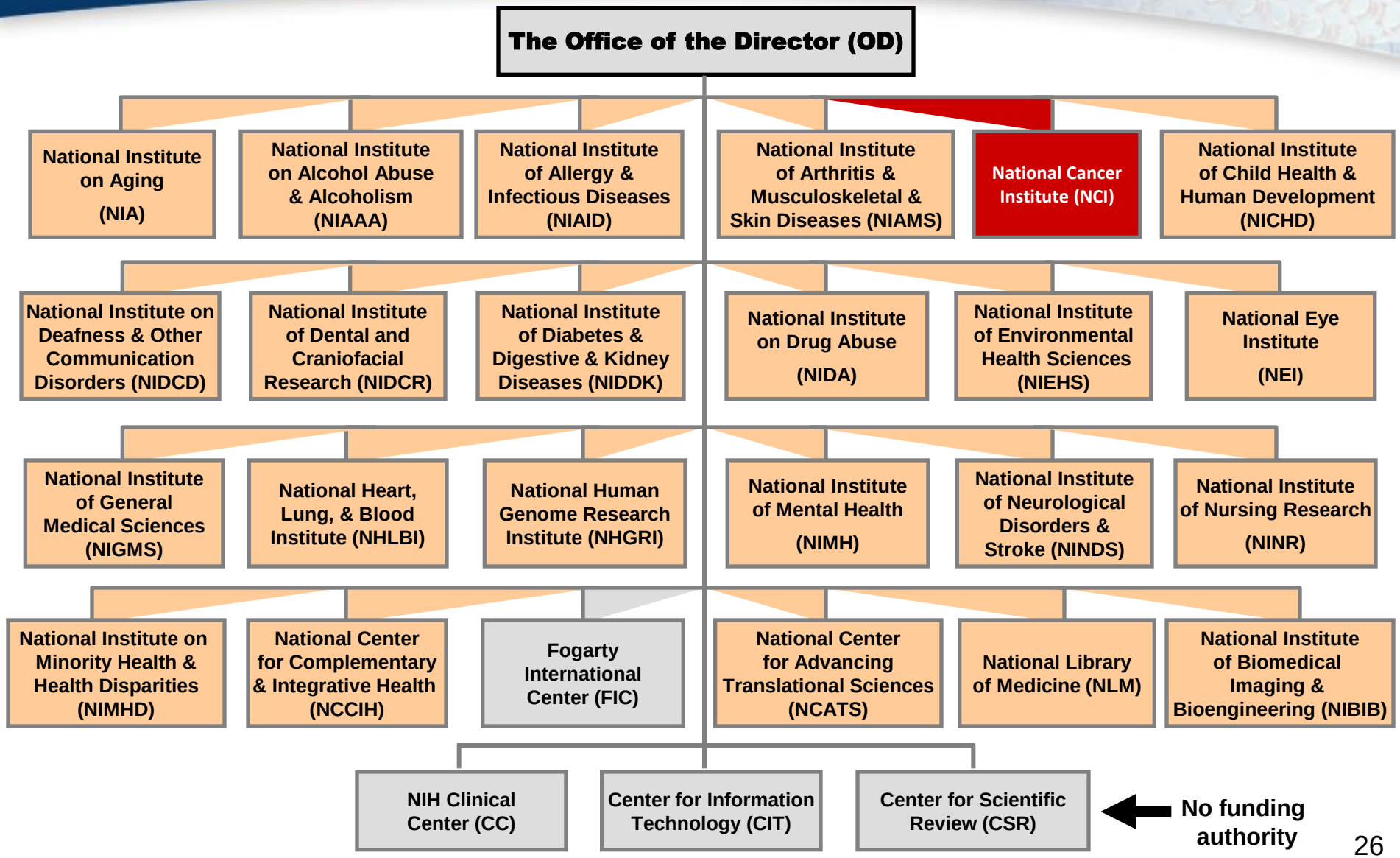
	Set Aside (FY16)	Set Aside (FY17)
Small Business Innovation Research (SBIR) Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization *Federal agencies with an extramural R&D budget > $100M*	3.0%	3.2%
Small Business Technology Transfer (STTR) Set-aside 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*	0.45%	0.45%

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

NIH = 27 Institutes & Centers

23 Participate in the SBIR/STTR Program

SBIR & STTR



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

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**

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)

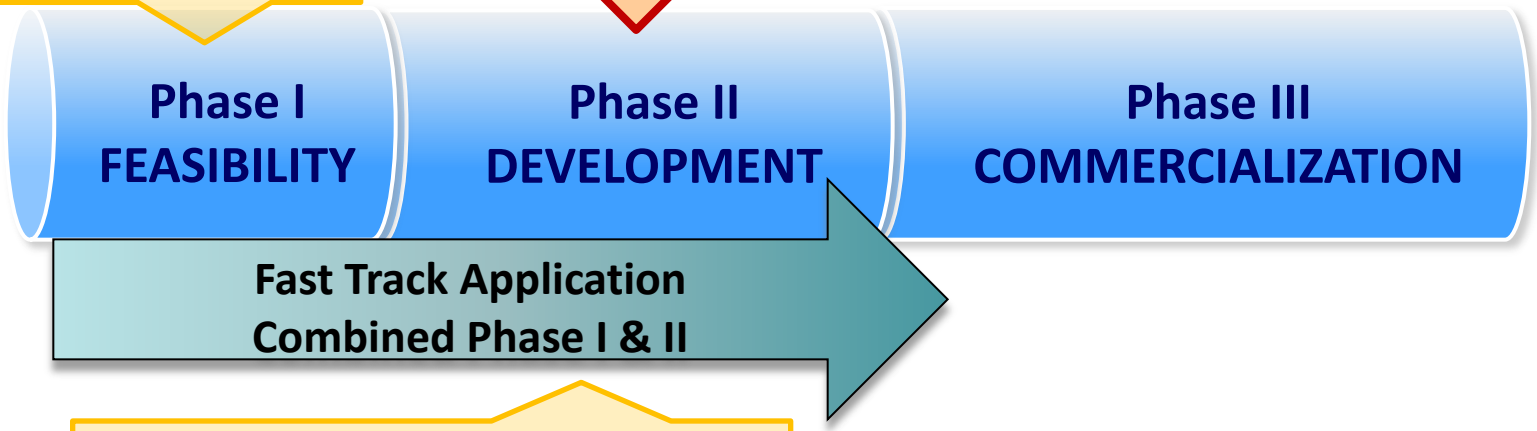
Award always made to small business

NIH SBIR & STTR: Three-Phase Program

Phase I
- Proof-of-Concept study
- $225,000 over 6 months (SBIR) or 1 year (STTR)

Direct to Phase II (Skip Phase I)

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



Phase II
- Research & Development
- Commercialization plan required
- $1.5 million over 2 years

Investigator-Initiated Grants

SBIR & STTR

- **Omnibus Solicitations (Phase I, Phase II, FastTrack)**
  - PA-16-302 (SBIR) and PA-16-303 (STTR)
- **Direct to Phase II Solicitation**
  - PAR-14-088 (SBIR only)

We encourage applications for any topic within the NIH mission

Due **September 5**, January 5, April 5

NIH National Institutes of Health
Turning Discovery Into Health

SBIR Technology Transfer (PA-15-354)

Goal: To encourage SBIR grant applications that transfer technology out of NIH intramural research labs and into the private sector.

- Royalty-free, non-exclusive patent license agreement for internal research use will be granted to the SBC upon award
- Collaborate with NIH intramural researchers (no SBIR funds may go back to intramural investigators)
- For a searchable listing of NCI inventions: http://www.ott.nih.gov/ic/nci

Standard due dates apply. Expires September 6, 2018.

Contact Dr. Christie Canaria: christie.canaria@nih.gov and

John D. Hewes, NCI Tech Transfer Center: john.hewes@nih.gov

http://grants.nih.gov/grants/guide/pa-files/PA-15-354.html

Early Stage Development of Technologies in Biomedical Computing, Informatics, and Big Data Science

SBIR & STTR

Goal: To support small businesses that propose development of a broad base of innovative technologies in biomedical computing, informatics, and Big Data Science that will support rapid progress in areas of scientific opportunity in biomedical research.

- SBIR FOA: PA-14-154
- STTR FOA: PA-14-157
- Direct-to-Phase II FOA: PA-15-288

Standard due dates apply. Expires April 6, 2017.

Contact Dr. Jonathan Franca-Koh: jonathan.franca-koh@nih.gov

Application Timeline: Its Getting Faster!

SBIR & STTR

OLD TIMELINE: 8 -16 months from application to award

Due Date	Scientific Review	Council Review	Award Date (earliest)
April 5	July	October	December
August 5	October	January	April
December 5	March	May	July

NEW TIMELINE GOAL: Funding of > 50% of applications within 6 months

Standard Due Date	Scientific Review	Council Review	Award Date (earliest)
September 5	December	January	March
January 5	March	May	June
April 5	June	September	September

NIH National Institutes of Health
Turning Discovery Into Health

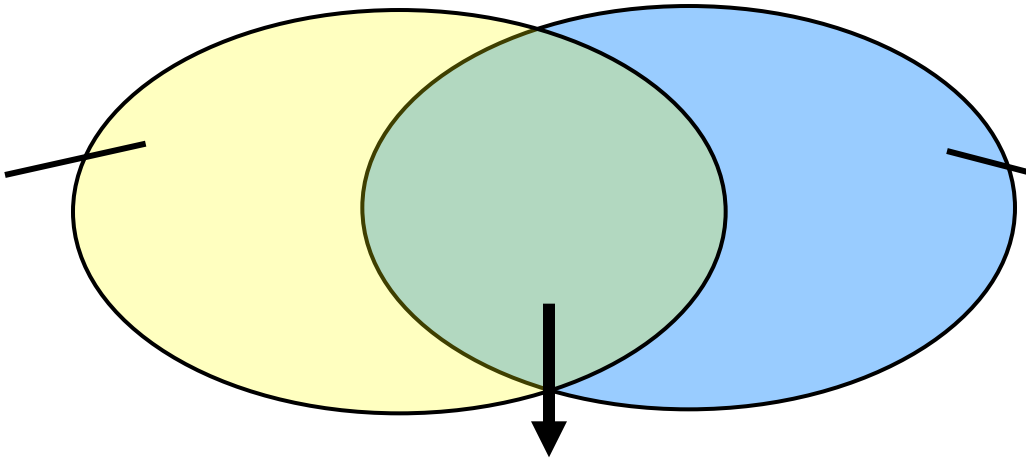
SBIR & STTR

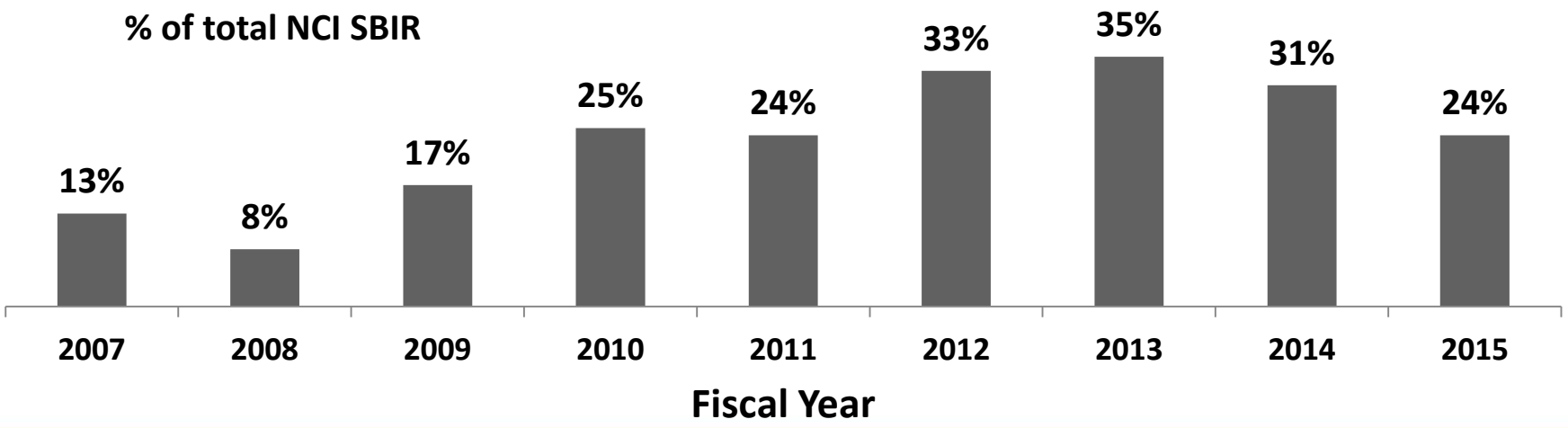
NATIONAL CANCER INSTITUTE

NCI SBIR
Contract Funding Opportunities

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

Annual Solicitation for NCI SBIR Contract Topics





SBIR Contracts vs. Grants

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

Funding Opportunity Summary

- **PHS-2017-1: A SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) CONTRACT PROPOSALS**

- **ONE application receipt date per year:**
  - Published July 12, 2016

Receipt Date: to be announced

- **Pre-Solicitation Notice can be found at:**
  - https://www.fbo.gov/spg/HHS/NIH/NIAID/PHS-2017-1/listing.html
- **More info about NCI's topic areas:**
  - http://sbir.cancer.gov/funding/contracts/

NCI Topics of Interest

SBIR & STTR

View more at http://sbir.cancer.gov/funding/contracts

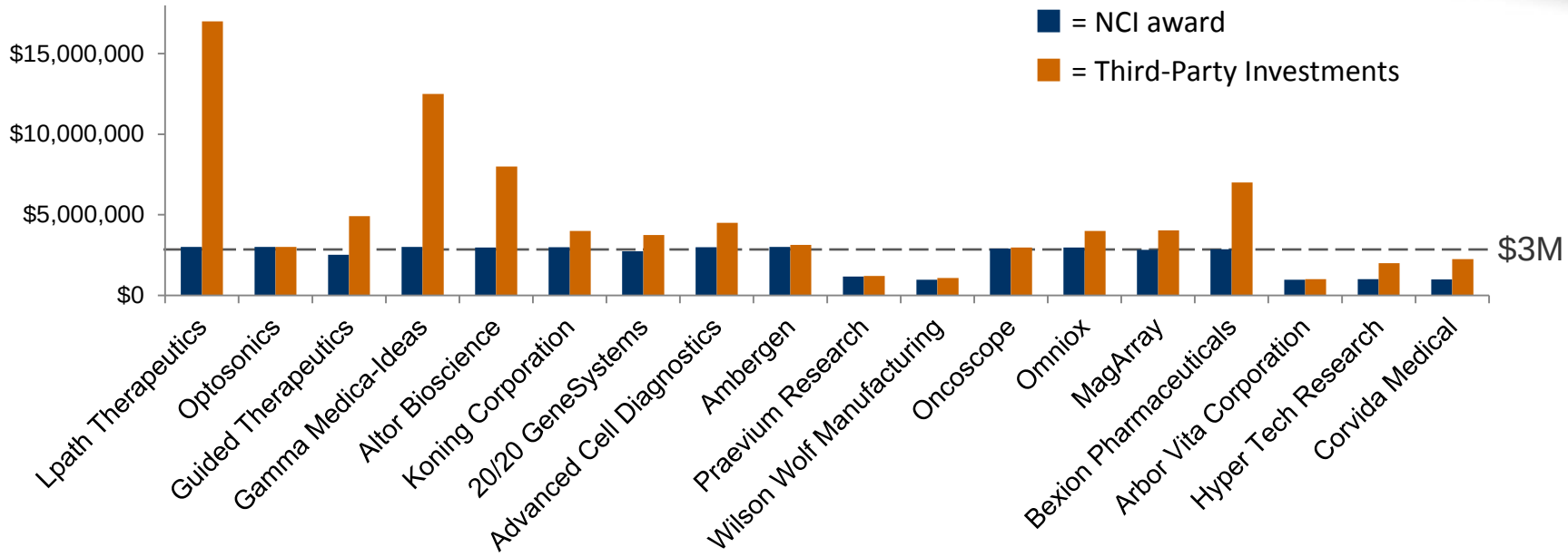
1. Cell and Animal-Based Models to Advance Cancer Health Disparity Research
2. Tools and Technologies for Monitoring RNA Modifications
3. Innovative Tools for Interrogating Tumor Microenvironment Dynamics
4. Modulating the Microbiome to Improve Therapeutic Efficacy of Cancer Therapeutics
5. Technologies for Differential Isolation of Exosomes and Oncosomes
6. Manufacturing Innovation for the Production of Cell-Based Cancer Immunotherapies
7. Highly Innovative Tools for Quantifying Redox Effector Dynamics in Cancer
8. Informatics Tools to Measure Cancer Care Coordination
9. Connecting Cancer Caregivers to Care Teams: Digital Platforms to Support Informal Cancer Caregiving
10. Methods and Software for Integration of Cancer Metabolomic Data with Other Omic and Imaging Data
11. Imaging Informatics Tools and Resources for Clinical Cancer Research
12. Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators
13. Predictive Biomarkers to Improve Radiation Treatment
14. Molecularly Targeted Radiation Therapy for Cancer Treatment
15. Development of Pediatric Cancer Drug Delivery Devices

NCI SBIR Phase IIB Bridge Award, Launched 2008

- 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., ≥ 1:1 match)

18 Bridge Awards

FY2009 – FY2014



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

SBIR & STTR

LEAP OF FAITH® TECHNOLOGIES

MagArray

Omniox
Targeted oxygen delivery

Venrock

SOFINNOVAVENTURES

Genentech
A Member of the Roche Group

NCI SBIR Investor Forum

Exclusive opportunity for some of the most promising NCI-funded companies to showcase their technologies

http://sbir.cancer.gov/newsevents/events/2014-sbir-investor-forum

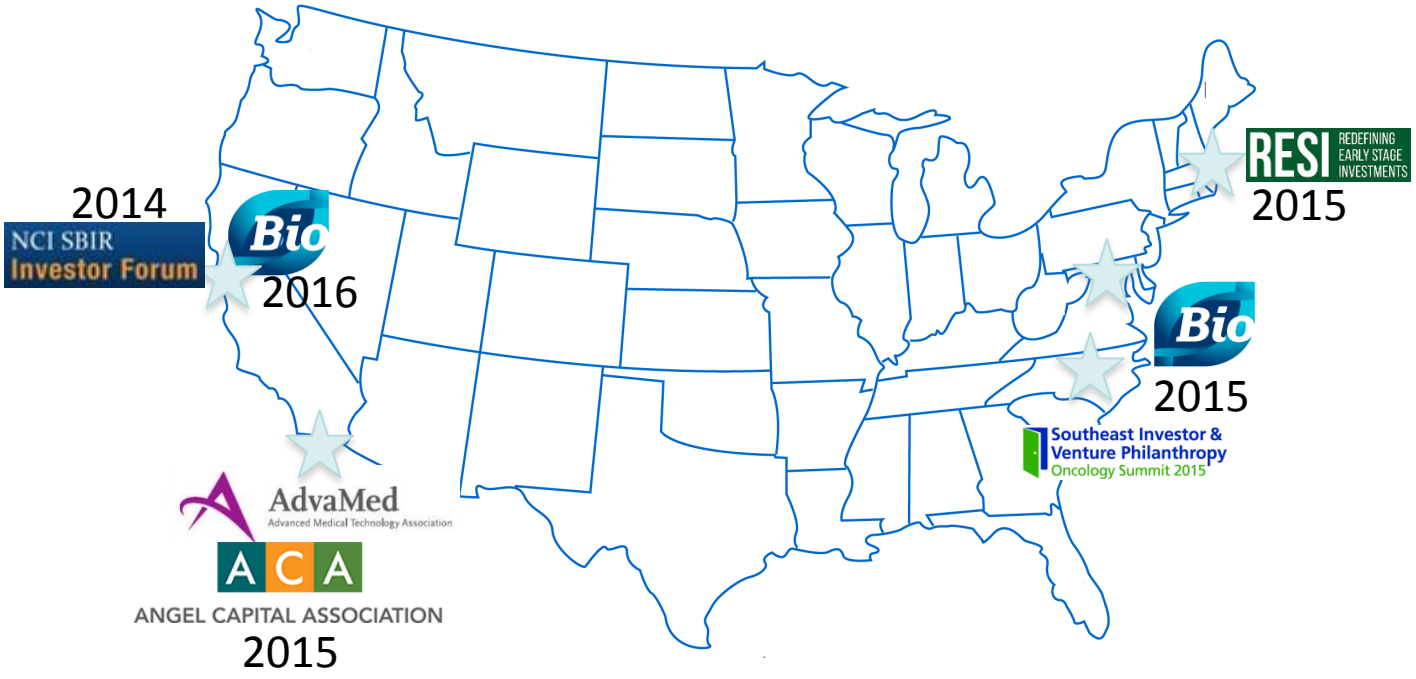
An exclusive event designed to connect the strongest and most promising NCI SBIR-funded companies with life science investors and strategic partners.

- Showcases top SBIR-funded companies presented
- Convenes 200 life science investors & leaders
- Facilitates 150+ one-on-one meetings
- **Previous forums closed deals collectively valued at more than $300M**

Innovation Showcase Partnerships

SBIR & STTR

Leveraging existing investor and partnering events



NIH National Institutes of Health
Turning Discovery Into Health

Workshop on Federal Resources to Accelerate Commercialization

SBIR & STTR

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

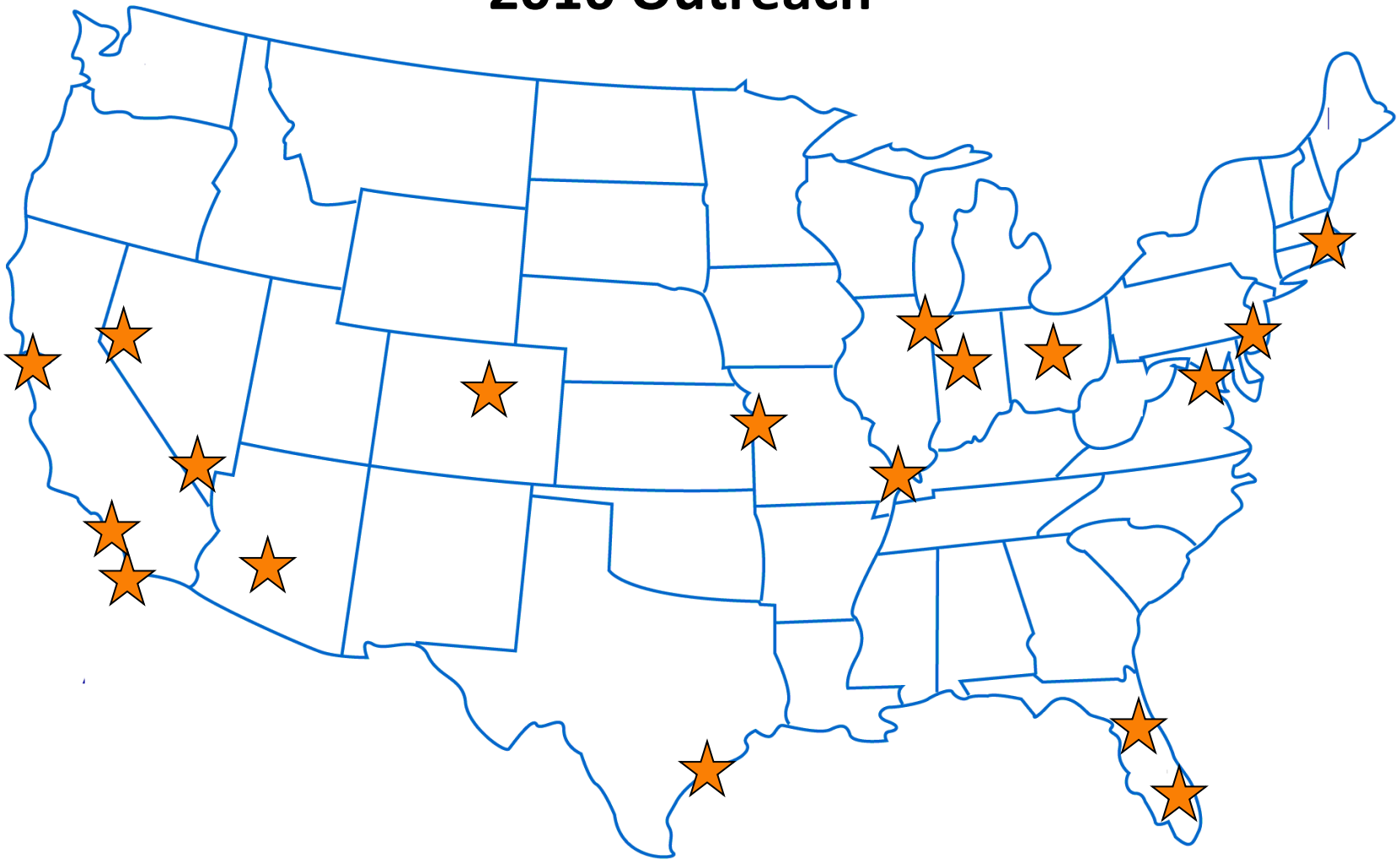
http://sbir.cancer.gov/programseducation/fracworkshop

- **May 24-25, 2016 at NCI Shady Grove**
- **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**
- **One-on-one meetings with program directors and speakers**

NCI SBIR Outreach Across the Country

SBIR & STTR

2016 Outreach



Additional NIH Resources

Therapeutics for Rare and Neglected Diseases (TRND) Program

- **Model**: Comprehensive drug development collaboration between DPI and academic and small business labs with disease-area/target expertise

- **Projects:**
  - May enter at various stages of preclinical development
  - Disease must meet FDA orphan or WHO neglected tropical disease criteria
  - Milestone driven

- **Eligible applicants:**
  - Academic, non-profit, government lab, biotech/pharma
  - Ex-U.S. applicants accepted

Bridging Interventional Development Gaps (BrIDGs) Program

- **Model:** In-kind, government contract-based services provided to overcome obstacles in later-stage preclinical development

- **Projects:**
  - » May address any disease or disorder, regardless of prevalence or incidence
  - » May require only one or two key development steps

- **Eligible Applicants:**
  - » Academic, Nonprofit, NIH Intramural, or *SBIR Eligible* Small Business
  - » Ex-U.S. applicants accepted, but businesses must satisfy SBIR criteria

Comparison of BrIDGs and TRND

BrIDGs	TRND
PI must have identified lead agent	PI may start with lead optimized
No clinical trial support provided	Some clinical trial support provided
Universal disease scope	Rare and neglected diseases only
Investigator prepares IND	Regulatory affairs assistance provided

Applications to both programs are accepted on a rolling basis. Please check out our websites for BrIDGs https://ncats.nih.gov/bridgs and for TRND https://ncats.nih.gov/trnd for more information.

Additional Resources

SBIR & STTR

- Life Science Contacts (by state)

https://sbir.nih.gov/resources/lifescience-state-contacts

- Small Biz Hangouts

NHLBI YouTube Channel

- SBIR/STTR State Contacts

https://www.sbir.gov/state_services?state=105809

- NIH Technical Assistance Programs – Niche and CAP

https://sbir.nih.gov/tap

- NIH, CDC, FDA, and ACF Program Descriptions & Contacts

https://sbir.nih.gov/sites/default/files/2015-2_SBIR-STTR-topics.pdf

SBIR & STTR

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