



NCI SBIR PROGRAM OVERVIEW

Jonathan Franca-Koh
Program Director
National Cancer Institute
SBIR Development Center

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Presentation Outline

- SBIR Overview
- Funding opportunities
 - SBIR IMAT
 - SBIR/STTR Omnibus
 - SBIR Contract Topics
- SBIR Development Center
 - Center Overview
 - I-CORPS Program
 - Other resources and activities

The NIH Medical Innovation Ecosystem

Over the past 30 years, the U.S. has become the world leader in biomedical research because of its unique innovation ecosystem. Read below to learn how funding for the National Institutes of Health strengthens our nation's health and economy from research laboratories to private industry to patients — the ultimate beneficiaries of medical research.

The Biotechnology and Pharmaceutical Industries

These industries build upon federally-funded scientific research to develop the next generation of drugs and devices to treat and cure disease.

The world market for the biopharmaceutical industry is greater than **\$140 billion**, with more than **1 million employees** in the U.S. alone.



Research Universities

Federally funded research conducted at these universities provides the foundation for private sector development of new drugs, technologies and treatments that aid our nation's health.

56% of basic scientific research in the U.S. takes place at research universities.



NIH:

The largest funder of biomedical research in the world, supporting the work of **135 Nobel Prize laureates**. The NIH community consists of more than 330,000 scientists and research personnel at over **2,500 research institutions** across all 50 states.

Research Tools and Technologies Sector

Providers of research tools and technologies develop critical equipment used for NIH-funded research, as well as private drug and diagnostic development.

The life sciences tools industry, with an **annual revenue of over \$42 billion**, employs hundreds of thousands of workers at facilities across the country, making everything from test tubes to gene sequencers.



Start-Ups and Spin-Offs

Universities often have offices of technology transfer that seek to turn research into **marketable applications and commercial ventures**.

These companies continue to advance discoveries in science while providing a growing sector of entrepreneurs interested in pursuing research.



Set-aside program for commercialization

❖ **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	FY17
2.5%	3.2%
0.3%	0.45%

~\$877M in FY16 at NIH
~\$136M in FY16 at NCI

Why SBIR/STTR?

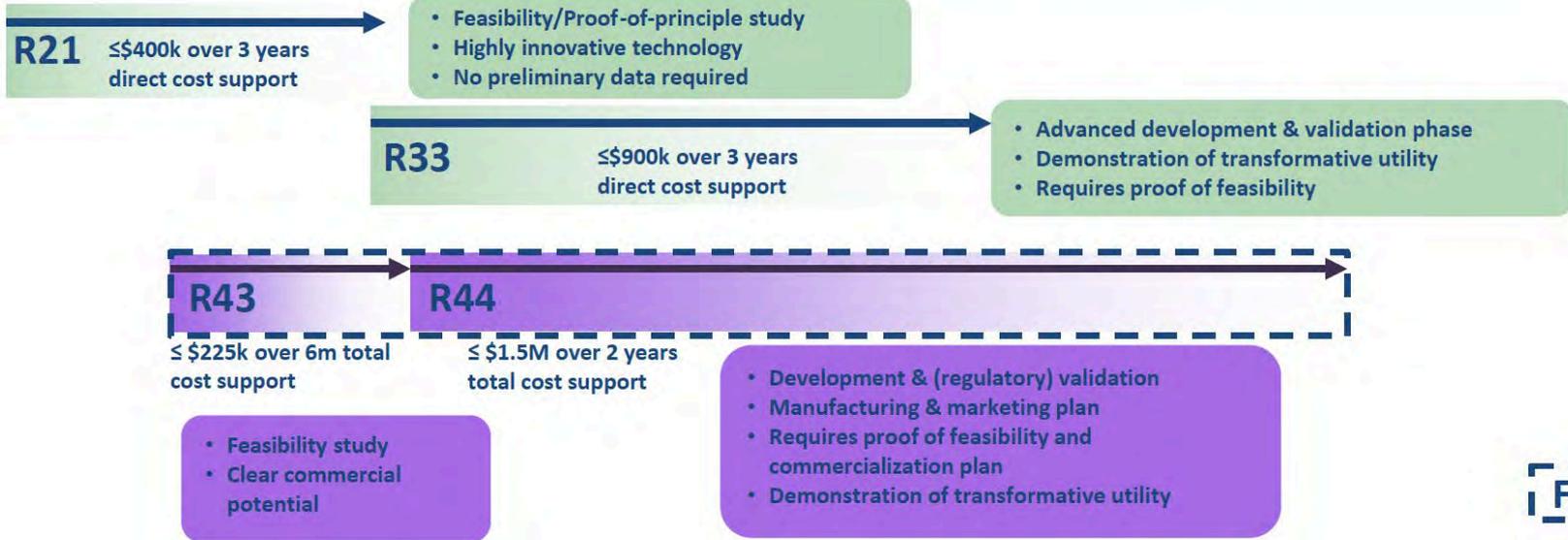
- Non-dilutive funding - not a loan/no repayment
- Allows small business to retain IP
- Provides validation, recognition, visibility
- Facilitates investments and partnerships

NIH SBIR/STTR: 3-Phase Program



* NCI [waiver topics](#) allow caps of \$300k (Ph I) and \$2 mil (Ph II)

SBIR IMAT Program



SBIR IMAT FOA: PAR-18-303

Funding Opportunity Title

Innovative Molecular Analysis Technology Development for Cancer Research and Clinical Care (R43/R44 Clinical Trial Not Allowed)

Activity Code

R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track

Announcement Type

Reissue of [PAR-13-327](#)

Related Notices

- [NOT-OD-18-009](#) - Reminder: FORMS-E Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2018.

Funding Opportunity Announcement (FOA) Number

PAR-18-303

<https://sbir.cancer.gov/funding/opportunities/sbirimat>

Innovative Molecular Analysis Technology Development for Cancer Research (SBIR-IMAT; PAR-18-303)



Replaces previous SBIR-IMAT FOA PAR-13-327

- New receipt dates: Standard receipt dates
 - *April 5, September 5, January 5*
- Applications will be reviewed by Center for Scientific Review
 - *Reviewed as a group within standing study section*
 - *Additional review criteria and reviewer instructions*
 - *Additional application instructions*

Initial receipt date: April 5, 2018

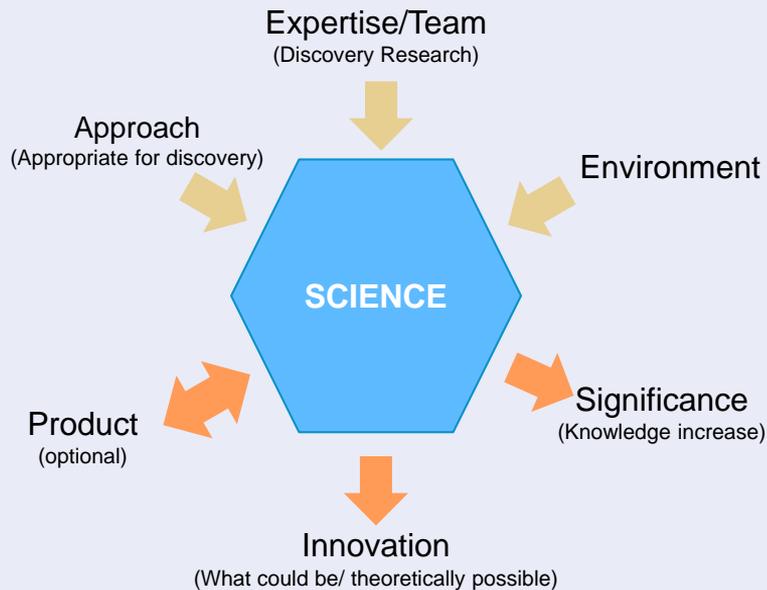
Applications will be accepted on standard due dates from April 2018 through Jan 2021

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

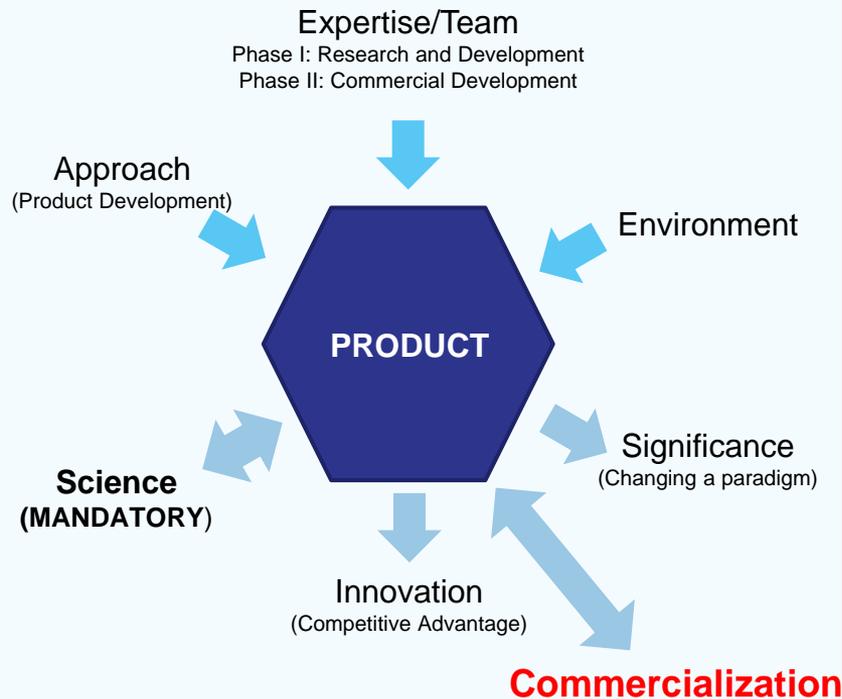
<https://sbir.cancer.gov/funding/opportunities/sbirimat>

Academic vs SBIR grant

ACADEMIC GRANT



SBIR/STTR GRANT



SBIR Technology Development Portfolio

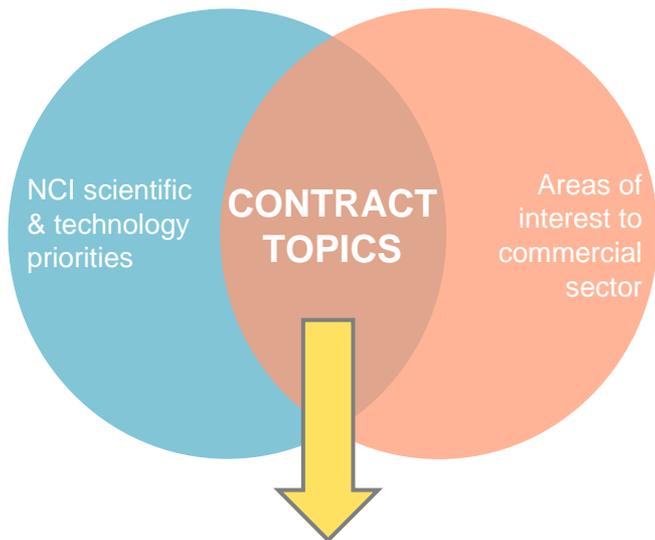


- 24 awards under PAR-13-327 (20 R43, 4 R44)
- 6/24 previously funded by IMAT R21/R33

Solicitations and Due Dates

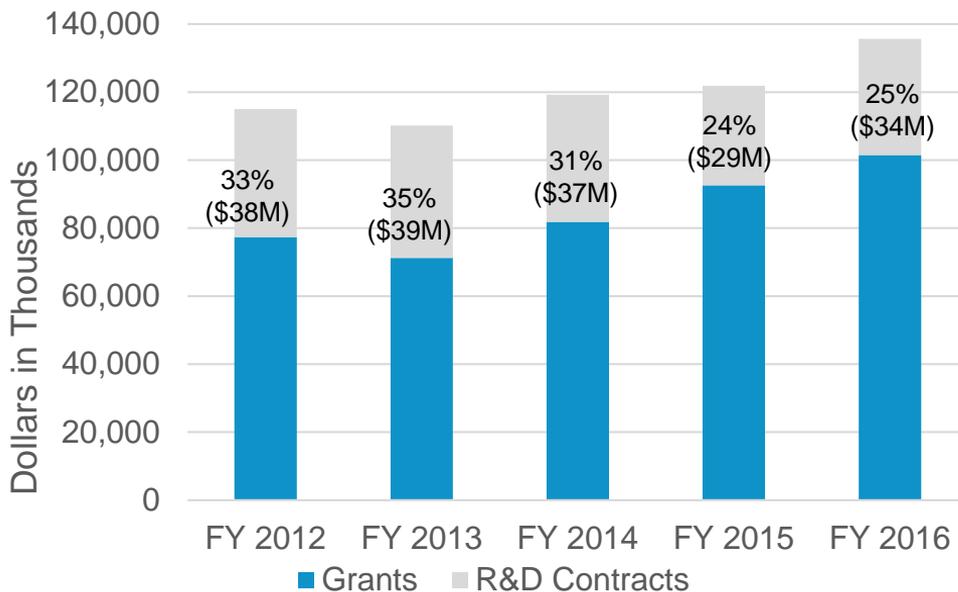
- **NIH, CDC, & FDA Omnibus SBIR/STTR Grant Solicitation**
[PA-17-302](#) (SBIR) and [PA-17-303](#) (STTR)
Standard Due Dates: January 5, April 5, September 5
- **SBIR Contract Solicitation (NIH, CDC) – Program Solicitation**
Release: *estimated July 2018*
<http://sbir.cancer.gov/funding/contracts/>
- **Targeted Funding Opportunities: e.g. SBIR IMAT**
- **NIH Guide for Grants and Contracts**
Release: Weekly Receipt dates specified in each FOA
<http://grants.nih.gov/grants/guide/index.html>

CONTRACT TOPICS



Topics are in NCI priority areas with strong potential for commercial success

Contracts in NCI SBIR Portfolio



NCI SBIR Development Center



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 Manager
Monoclonal Antibodies, Immunotherapy, Biologics, and Program Analysis

Let's discuss your project!
Send Specific Aims to 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



Todd Haim, PhD
Program Director
Small Molecules, Biologics, Immunotherapy, Theranostics, Investor Initiatives, FRAC Workshop



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

Development Center: 5 CORE ACTIVITIES

CENTRAL OVERSIGHT

- Administer all 400+ SBIR/STTR awards at the NCI

GUIDANCE

- Help applicants prepare for application, resubmission, and discuss funding options

OUTREACH

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

NETWORKING

- Maintain a network of investors, and facilitate connections between NCI SBIR portfolio companies and potential investors/strategic partners

FUNDING

- Seed emerging technology areas by developing targeted funding opportunities either as grants or contracts

FRAC WORKSHOP

Workshop on **F**ederal **R**esources to **A**ccelerate **C**ommercialization

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

<https://sbir.cancer.gov/programseducation/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
- **Brainstorm sessions** with other SBIR peers and NIH staff.



Investor Initiatives

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



If selected, companies...

- Receive coaching on presentation & pitching
- Get chances to present at top conferences (e.g. BIO, RESI, AdvaMed, & many more!)

Even if not selected, companies...

- Can receive expert review of call-for-investment language
- May develop connection with investors who are interested in the field

INVESTOR INITIATIVES – 2016

36

COMPANIES

7

**SHOWCASE
EVENTS**

300+

**MEETINGS WITH
INVESTORS &
STRATEGIC PARTNERS**

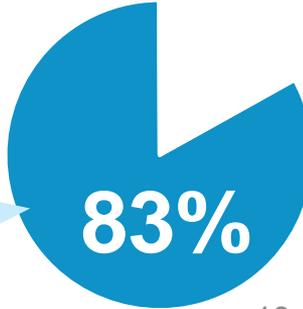


91%

“Investor
Initiatives helped
us progress
toward our
goals”

BIO
BIO Network
BIO Investor Forum
AdvaMed
RESI
Life Sciences Summit
PMWC

“NCI SBIR’s
assistance
was mostly to
extremely
valuable”



83%



*Entrepreneurship program
for SBIR awardees*

sbir.cancer.gov/icorps

COURSE FORMAT

- Curriculum tailored to life sciences
- 3-Day Kick-off Event
- 6 Weekly web classes
- 2-Day Lessons Learned

THERAPEUTICS TRACK

THERAPEUTICS
Expert

I-Corps Node
Instructor

DIAGNOSTIC TOOLS TRACK

DIAGNOSTICS &
eHEALTH Expert

I-Corps Node
Instructor

MEDICAL DEVICES TRACK

MEDICAL DEVICE
Expert

I-Corps Node
Instructor

I-CORPS AT NIH

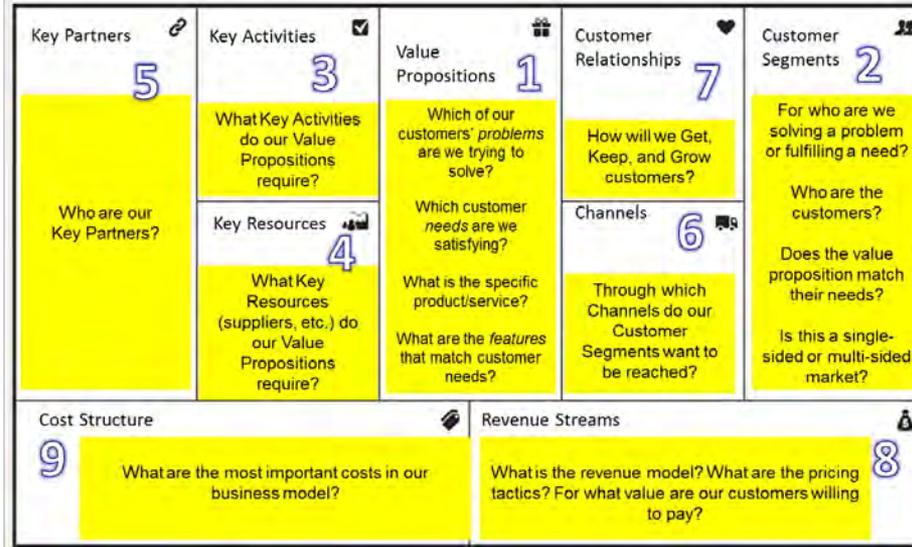
- Intensive ***Entrepreneurial Immersion*** course aimed at providing teams with skills and strategies to reduce commercialization risk
- Curriculum emphasizes ***Reaching out to Customers*** to test hypotheses about the market(s) for the technology
- Teams are expected to conduct over ***100 interviews*** in 8 weeks
- Format is focused on ***Experiential Learning***
- NCI SBIR designed, launched, and manages the program for NIH
- 17 Institutes at NIH and CDC participate



#ICorpsNIH 

Benefits to Translational Researchers

- Teaches the researcher how to build a business model around their technology
- Goal is to actively investigate where the technology can provide greatest impact and largest benefit in the life sciences ecosystem



CHALLENGES FACED BY INNOVATORS

Example: Investigator is developing an imaging sensor and tweaking to make it even better, but doesn't know if this is something to be used in diagnostic/screening/post therapy setting.

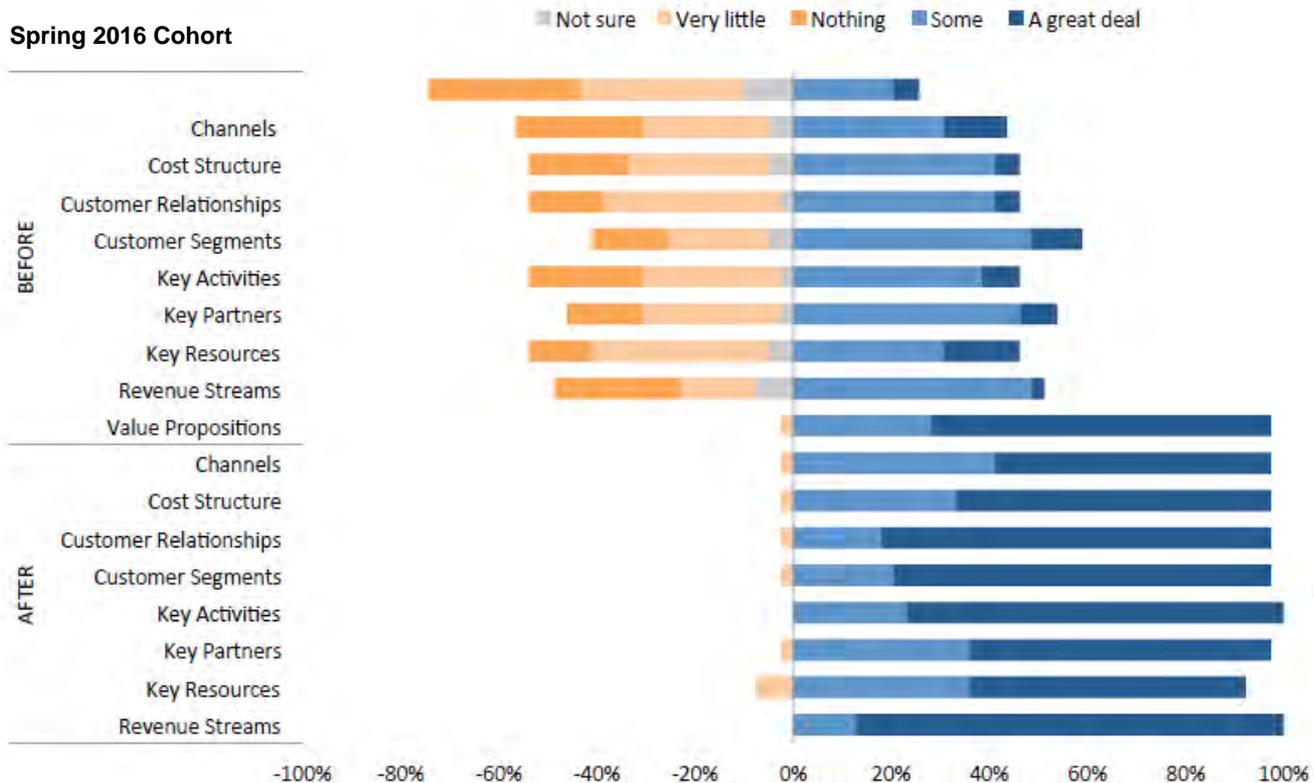
In each case, the customer segments, value propositions, and regulatory and reimbursement challenges are different. The translation of this technology to the clinic will require that inventors understand landscape and where their technology can have the greatest impact.

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

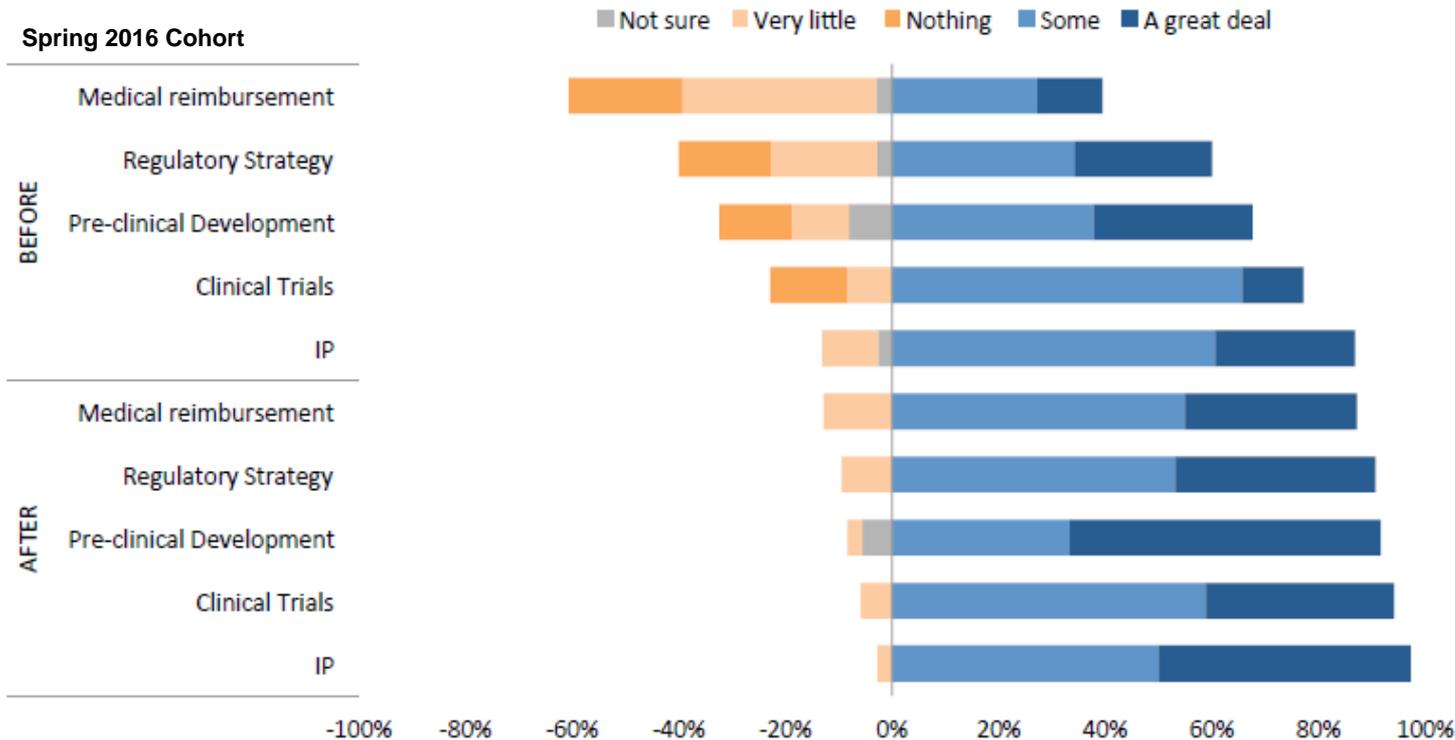
BUSINESS MODEL CANVAS KNOWLEDGE

Spring 2016 Cohort



LIFE SCIENCE COMMERCIALIZATION KNOWLEDGE

Knowledge of areas of Commercialization & Life Sciences



I-CORPS CASE STUDY

 GigaGen



David Johnson

GIGAGEN

ENDPOINTS NEWS

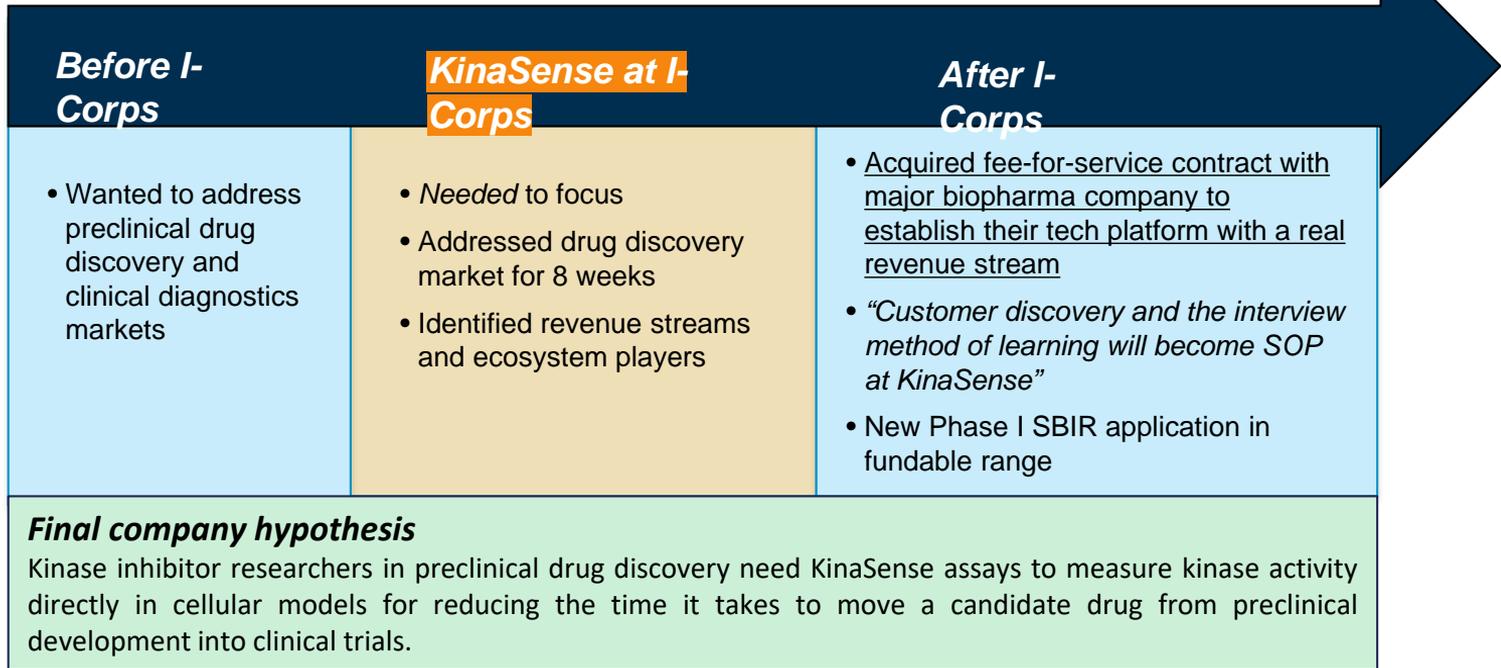
Leveraging the learnings from I-Corps at NIH, GigaGen from I-Corps at NIH pilot cohort recently:

- Raised **\$50 million** investment
- Secured licensing partnership
- Launched a fee-for-service product

I-CORPS CASE STUDY



Developing preclinical assays to characterize new oncology therapies





 NATIONAL CANCER INSTITUTE

I-Corps at NIH Entrepreneurship Program

8 Weeks with I-Corps at NIH
by SBIR-funded NERx BioSciences

PA-18-314 I-Corps at NIH Administrative Supplement \$50,000 budget cap

Application Due Date	December 18, 2017
Phone Interview (estimated)	January 29, 2018
Notice of Award (estimated)	February 2018
Kick-off/Close-out Venue	TBD
Course Kick-off	April 9-12, 2018 (Monday-Thursday)
Web-Ex Courses (1-5PM ET)	Wednesdays Apr 18 Apr 25 May 2 May 9 May 16 May 23
Course Close-out/Lessons Learned	May 31 – Jun 1, 2018
Cohort Size	24 teams

**Next Application Deadline:
December 18, 2017**

<https://grants.nih.gov/grants/guide/pa-files/PA-18-314.html>

Discussion Group

Discussion Group Topic: **Small Business Innovation Research (SBIR) Opportunities and Strategies**

Organizer: Jonathan Franca-Koh (NCI SBIR Development Center)

Room: 6E030

Contact Info: jonathan.franca-koh@nih.gov; 240.276.7622

Details: The NCI Small Business Innovation Research Development Center ([SBIR DC](#)) hosts a broad diversity of research contract and grant opportunities (including the SBIR-IMAT grant opportunity) and a diversity of other initiatives (e.g. the Innovation Corps, or [I-Corps™](#)). Dr. Franca-Koh will hold a broad Q&A session during the first hour and offer times to meet individually during the second hour.



THANK YOU

ncisbir@mail.nih.gov
@NCIsbir

PLEASE PROVIDE FEEDBACK:

bitly.com/NCIsbirFeedback

NATIONAL CANCER INSTITUTE

SBIR

DEVELOPMENT
CENTER

