



I-Corps from the Trenches

Conversations with I-Corps Alum

December 8, 2016

COMING UP LATER TODAY



**NCI SBIR
TWITTER CHAT**

WITH PROGRAM MANAGER
CHRISTIE CANARIA

**THURSDAY, DECEMBER 8, 2016
2 - 3 PM EASTERN TIME
@NCISBIR #SBIRCHAT**

NATIONAL CANCER INSTITUTE
SBIR
DEVELOPMENT
CENTER



Q&A

sbir.cancer.gov/icorps

Submit your questions through the Q&A chat box

Please submit your questions via the chat box. We will be answering your questions throughout the webinar, with additional time dedicated at the end of the session.

Slides will be made available after the webinar event.



Michael Weingarten
NCI/NIH I-Corps



Christie Canaria
NCI/NIH I-Corps



David Charron
Lead Instructor



Brett Noel
Sr Scientist at Kinasense



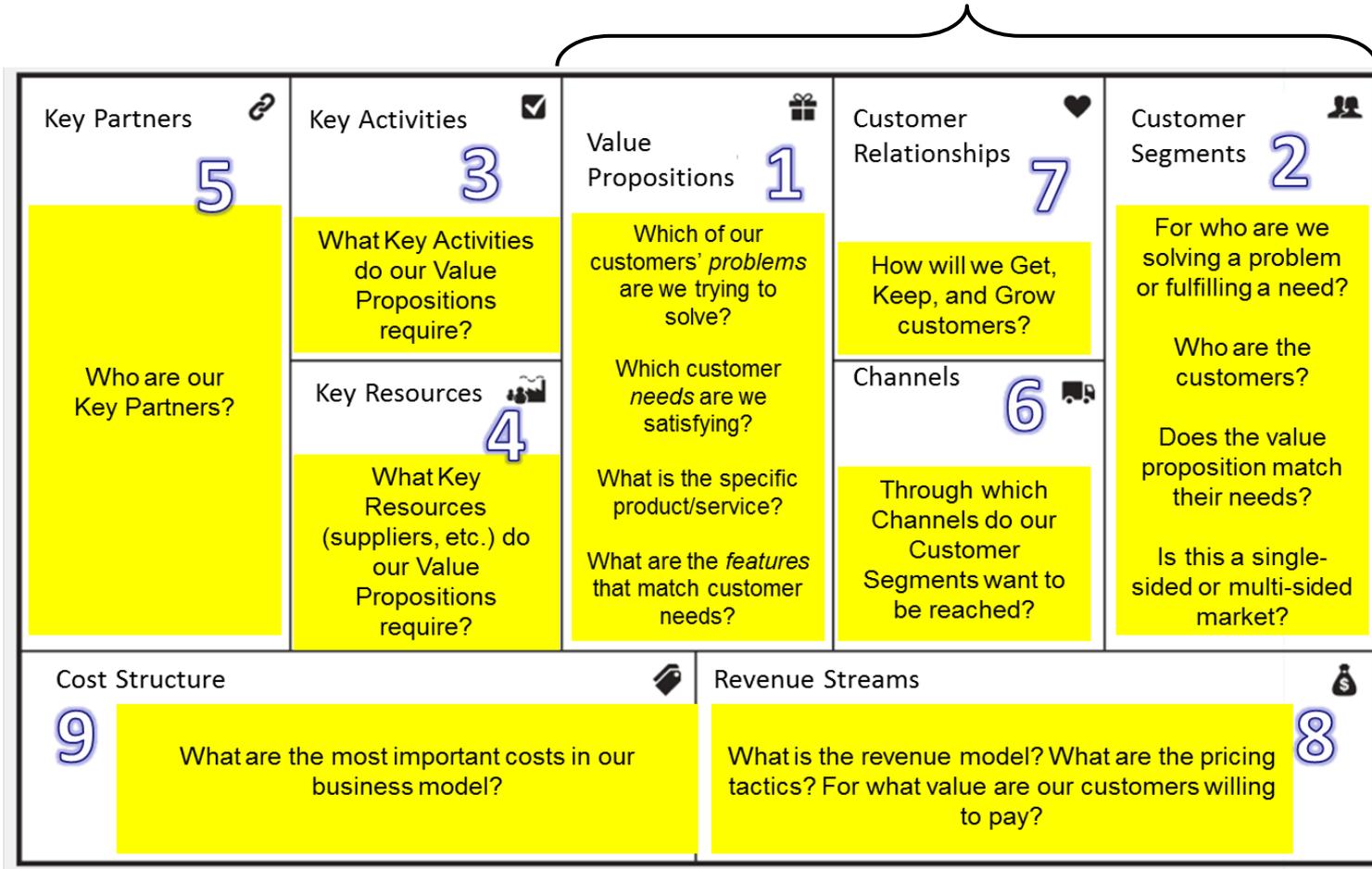
“We’re scaling up the National Science Foundation’s successful Innovation Corps program at six more federal agencies so we can help more of our scientists move their ideas out of the lab and into the marketplace.”

– President Obama (August 4, 2015)

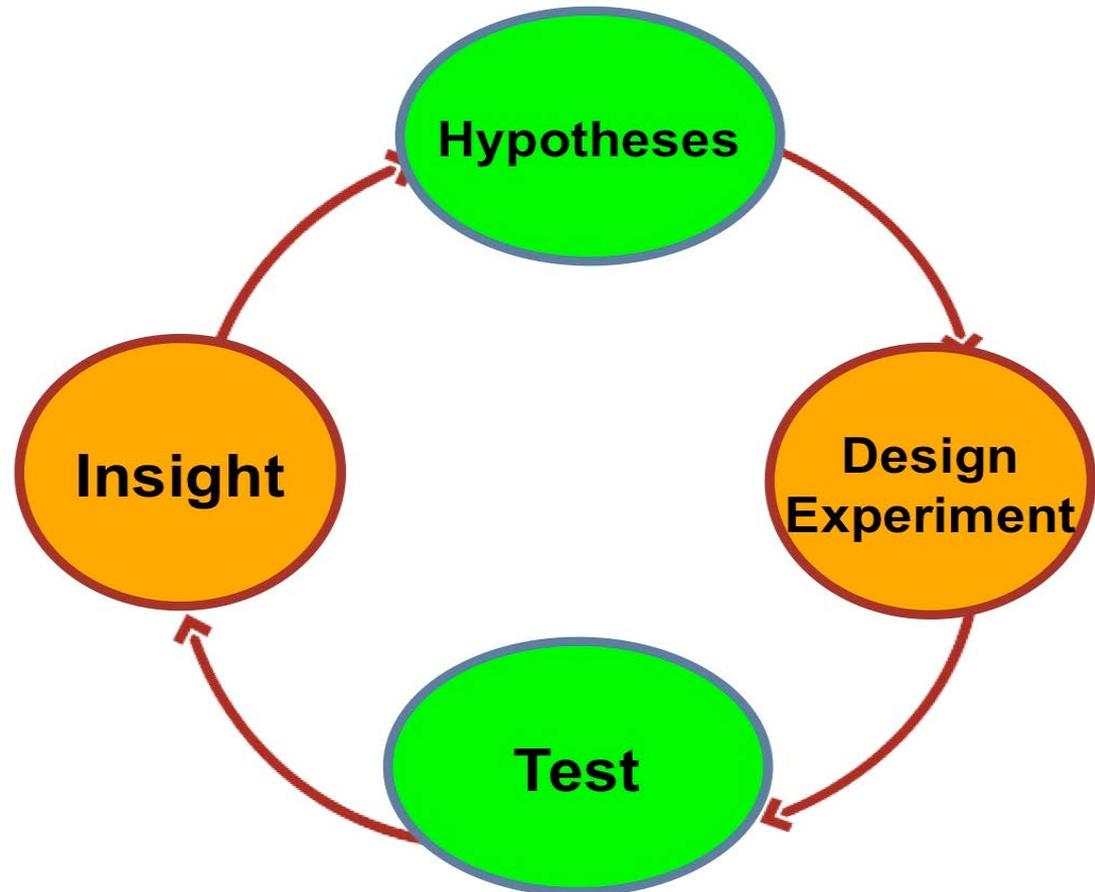
Program Description

- 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 8 weeks.
- Format is focused on ***Experiential Learning***.

“ Product-Market Fit ”



Hypotheses Testing and Insight...



SBIR/STTR Phase II grant applications have two components

1. The Research Strategy

2. The Commercialization Plan

- **Phase II applicants often focus on #1**
- **The strongest Phase II applications focus on both**

Important goal of I-Corps™ at NIH is to inform the Commercialization Plan

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



3 cohorts to date

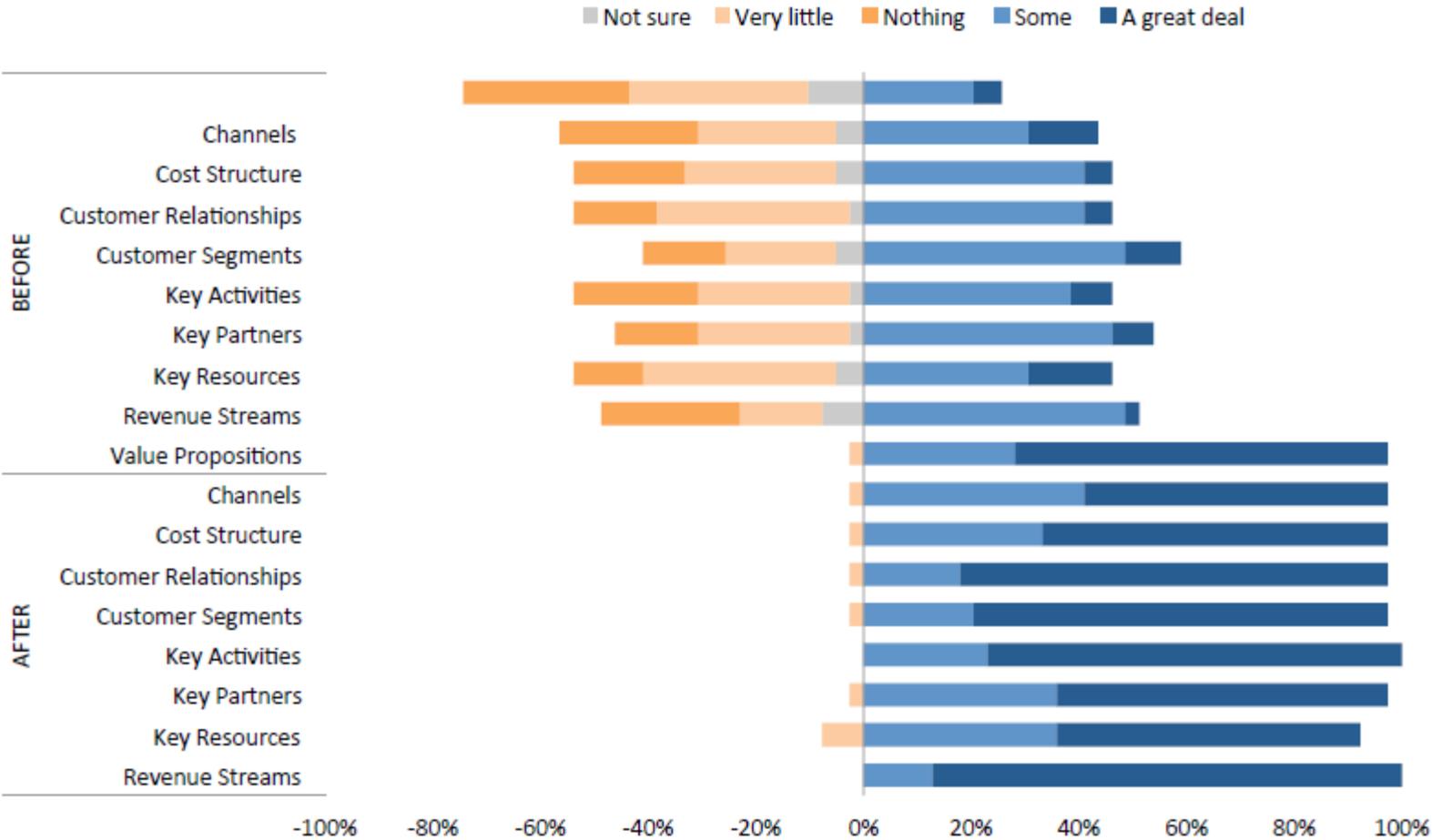
- 57 teams conducted 6,362 customer discovery interviews
- >90% found the program “very good” or “excellent”
- >90% would recommend I-Corps™ at NIH to other companies

“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.”

Business Model Canvas Knowledge

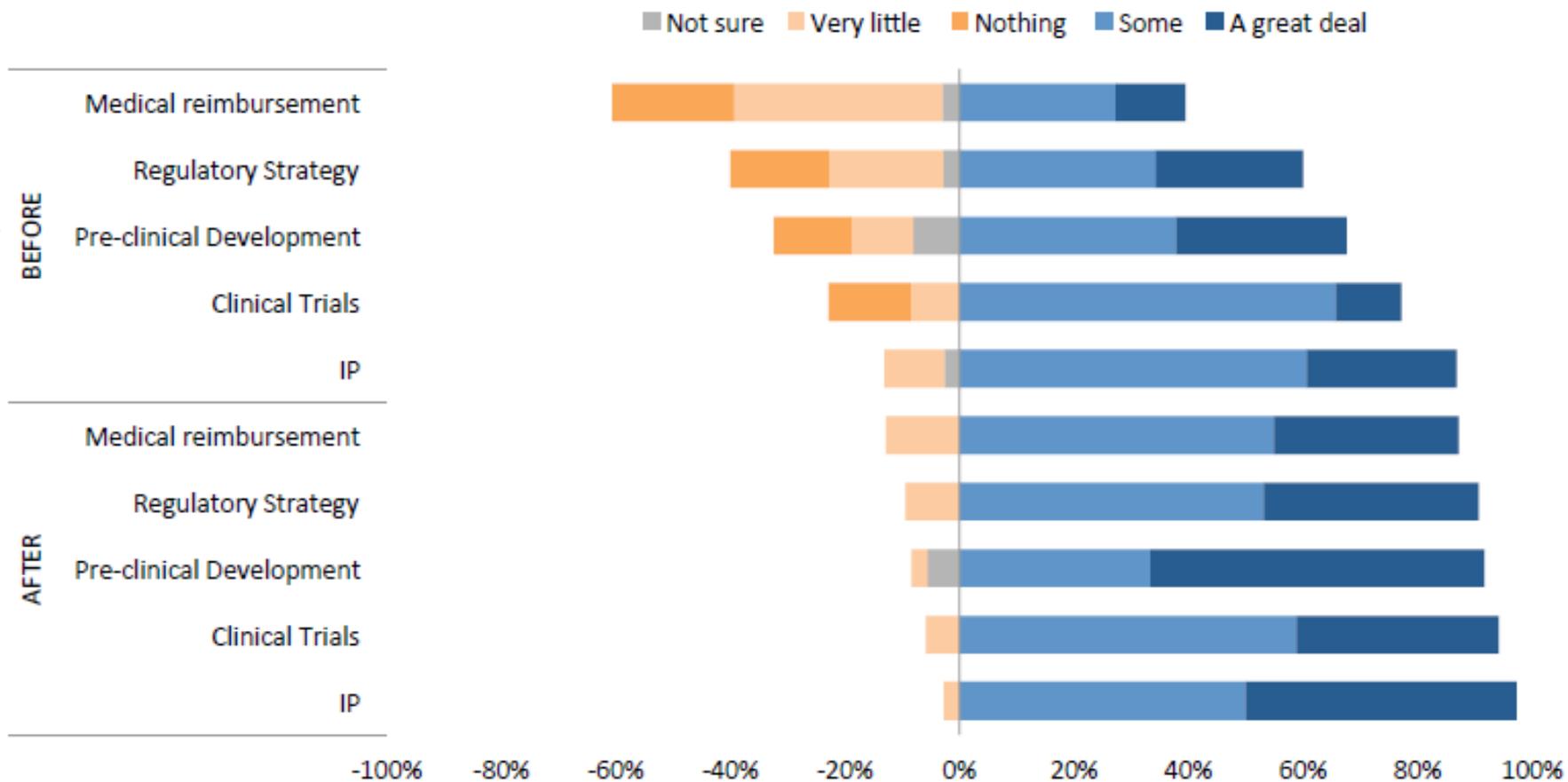
Spring 2016 Cohort



Life Science Commercialization Knowledge

Spring 2016 Cohort

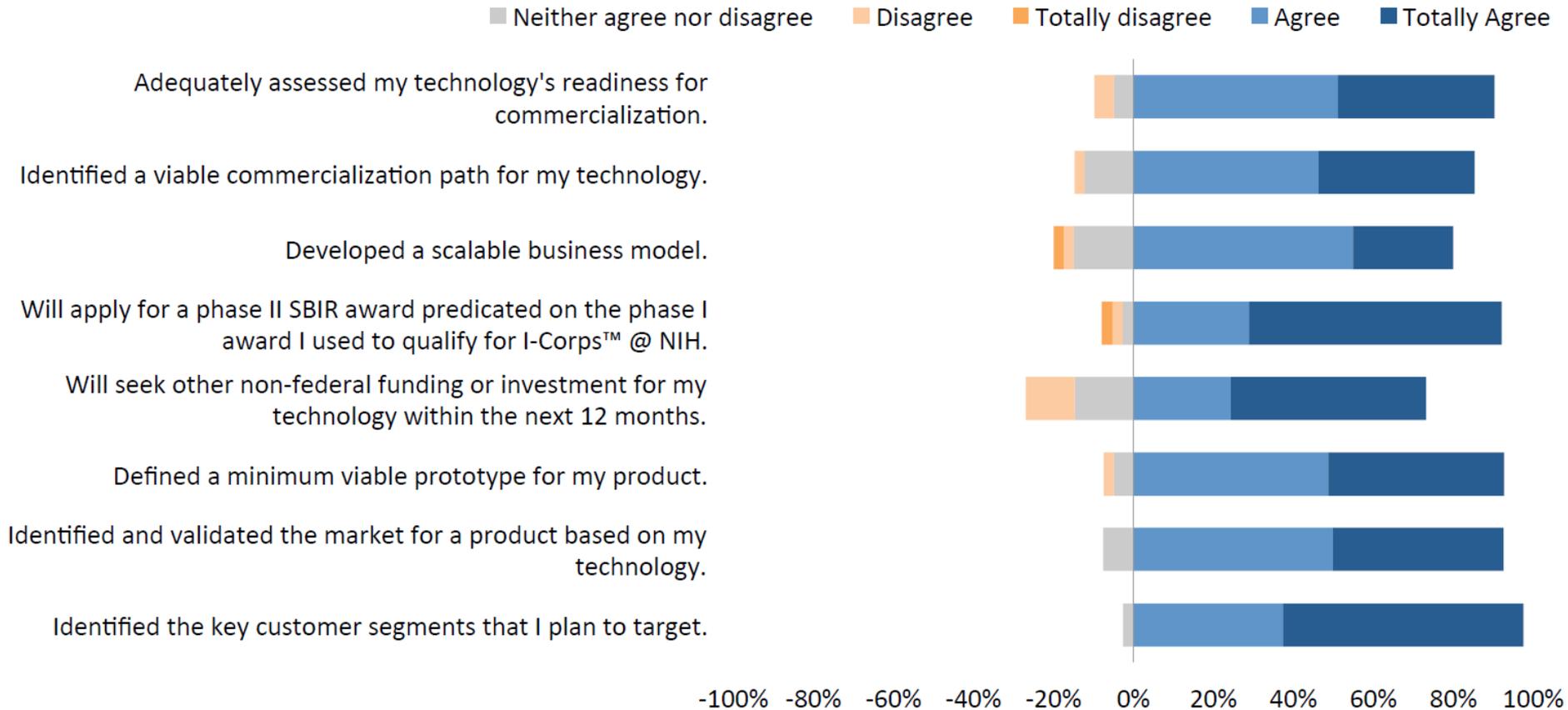
Knowledge of areas of Commercialization & Life Sciences



Status of Technology and Future Plans

Spring 2016 Cohort

Company Status



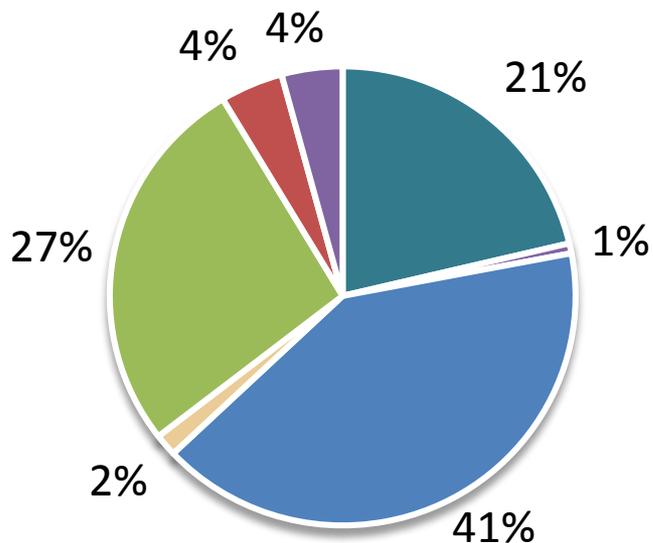


2011-2014 teams:

324 companies
\$93.8M raised
3 acquisitions

As of November 2016:

872 I-Corps™ Teams



Type of \$93.8M Raised, by Percentage:

- SBIR/STTR Phase 1
- Corporate
- SBIR/STTR Phase 2
- Debt
- VC Investment
- Angel Investment
- State Investment

NSF MPS-funded chemists developed imaging agents for biomedical applications

October 2011 – NSF I-Corps participants

June 2012 - NSF SBIR Phase I recipient

April 2014 - NSF SBIR Phase II recipient

State of Nebraska investment

Series A VC investment

June 2016 – Series B VC investment

PI - Stephen DiMagno - Professor at University of Nebraska-Lincoln

EL - Keil Neumann - current postdoc at UCSF

IM - Allan Green - CEO of Ground Fluor





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

Before I-Corps

- November 2012 - Dr. Travis Stiles' discovery published in *Journal of Cell Science*
- August 2014 - Phase I NIH grants awarded to develop drugs for SCI and stroke

Novoron at I-Corps

- December 2014 - Novoron completes I-Corps at NIH

I-Corps at NIH Learnings & Pivot

Low interest in early-stage SCI drugs ...but customer segments are interested in **Multiple Sclerosis**

After I-Corps

- December 2015 - **Novoron Awarded NIH Grant to Evaluate New Treatments for Multiple Sclerosis (MS)**
 - MS work led to increased interest in new indications
 - Entered **multiple** strategic partnerships with focus on negotiating **1** deal
- February 2016 - **Xconomy Recognizes Novoron as San Diego Life Science Startup to Watch in 2016**
- June 2016 - Patent issued



17 Participating ICs in 2017

- National Cancer Institute (NCI)
- National Center for Complementary and Integrative Health (NCCIH)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Human Genome Research Institute (NHGRI)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute of Allergy and Infectious Diseases (NIAID)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of Mental Health (NIMH)
- 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)



**PA-16-414 I-Corps at NIH Administrative Supplement
\$50,000 budget cap**

Application Due Date	January 9, 2017
Phone Interview (estimated)	February 13-17, 2017
Notice of Award (estimated)	March 17, 2017
Course Kick-off	April 23-26, 2017
Web-Ex Courses (1-5PM ET)	May 2 May 9 May 16 May 23 May 30 June 6
Course Close-out/ Lessons Learned	June 12-13, 2017
Cohort Size	24 teams

<http://grants.nih.gov/grants/guide/pa-files/PA-16-414.html>

Apply to I-Corps using ASSIST



PA-16-414: Innovation C... X

grants.nih.gov/grants/guide/pa-files/PA-16-414.html

with these instructions may be delayed or not accepted for review.

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional systems or system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. [Learn more.](#)

Apply Online Using ASSIST **Apply Using Downloadable Forms**

Problems accessing or using ASSIST should be directed to the [eRA Service Desk](#).
Problems downloading forms should be directed to [Grants.gov Customer Support](#).

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background

America's prosperity has originated in part from the ability to capitalize economically on ground-breaking discoveries from science and engineering research. Simultaneously, a knowledgeable, creative U.S. workforce has maintained the country's global leadership in critical areas of technology. These important discoveries and capable workforce result from substantial, sustained investment in science and engineering. A strong capacity for leveraging fundamental scientific discoveries into powerful engines of innovation is essential to maintain our competitive edge in the future.

DON'T FORGET TO JOIN US FOR...



NCI SBIR OFFICE HOUR ON TWITTER

*WITH PROGRAM MANAGER
CHRISTIE CANARIA*

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I-Corps @ NIH

David Charron

Welcome from the I-Corps Team



Albus Imaging: Week 1, Team 41



ALBUS IMAGING

ISFJ

The Defender



Specialty:
Bioinformatics &
Health Information

Ph.D., Vanderbilt
University

Yaorong Ge, PhD
Industry Expert

INTP

The Logician



Specialty:
Cardiovascular
monitoring

MBA, MIT

Holly Goodwin, MBA
Principle Investigator

ESFJ

The Consul



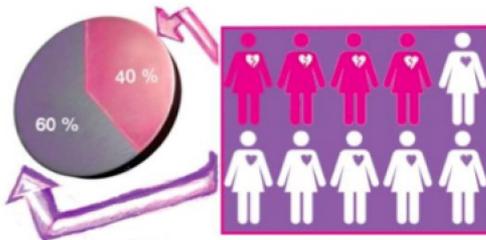
Specialty:
Cardiology & cardiac
imaging

MD, Medical College
of VA

Greg Hundley, MD
C-Level Executive

The Problem

**Today's cancer patient
becomes tomorrow's
heart failure patient**



- Heart failure is the leading cause of death of cancer survivors

The Solution (i.e. our product)

**A diagnostic tool that
identifies who is susceptible
to cardiotoxicity**

- Early detection of cardiotoxicity = earlier intervention = heart injury prevention

Who is the customer?

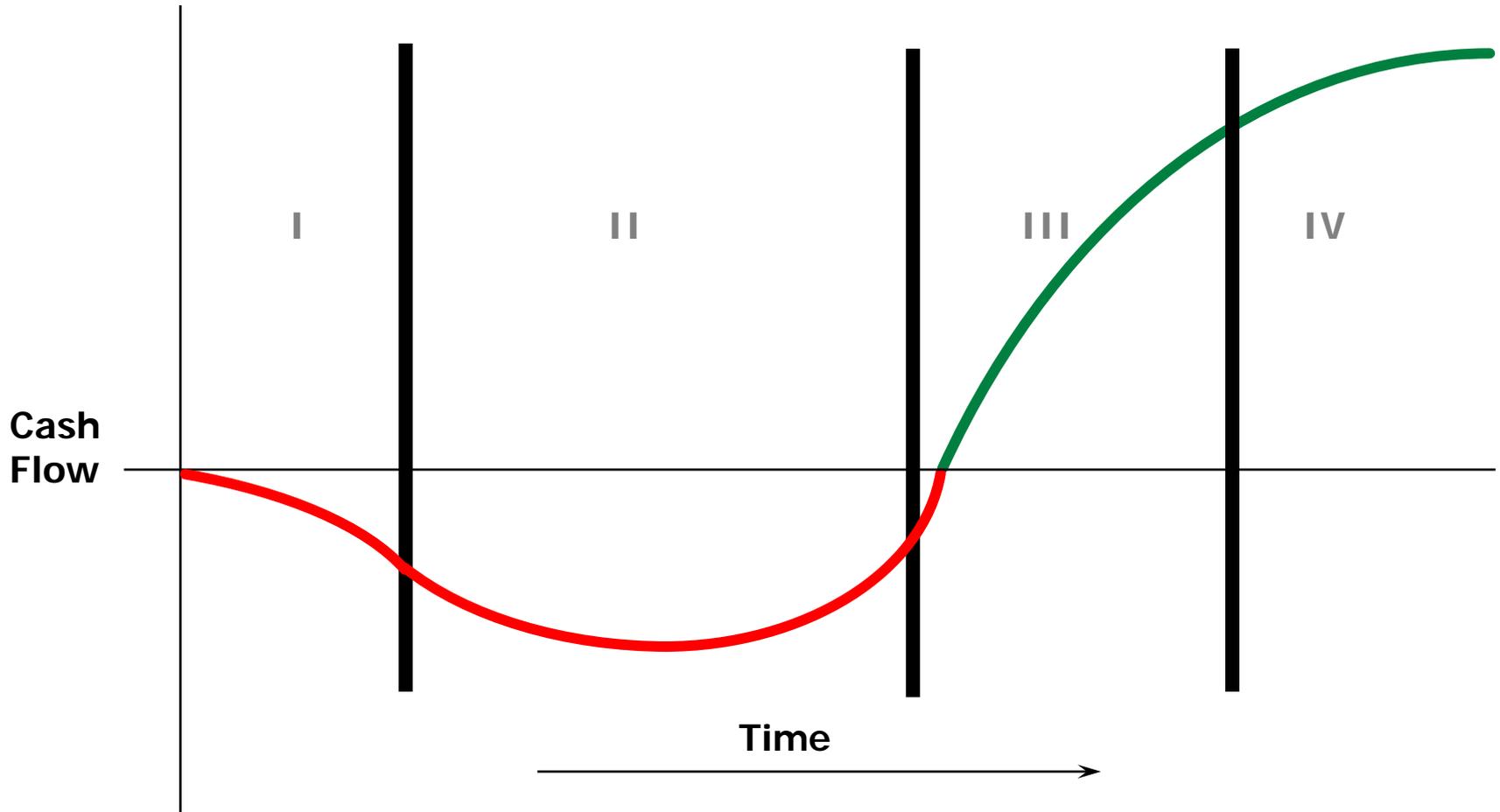
- Physicians
 - Oncologists
 - Cardiologists
 - Other Physicians: Radiologists
- Patients
- Payors (Health Insur Cos., Govt HC Admins, ACOs, Health Systems)
- FDA
- Pharma Companies

What *we* learned

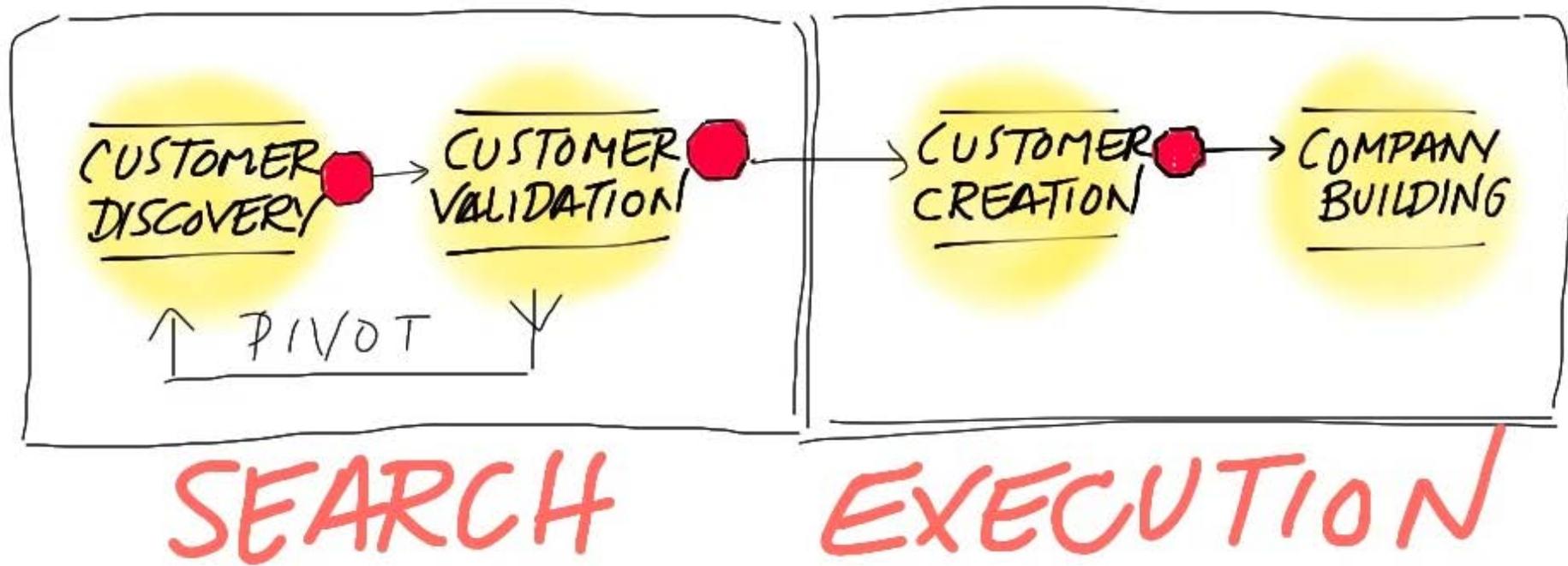
- SBIR
 - Phase I to II requires a “plan”
- Business outcomes
 - Founders “want” to go beyond SBIR
- Learning
 - Entrepreneurial skills are “required”

The Entrepreneurial Venture

FOUR PERIODS of DEVELOPMENT

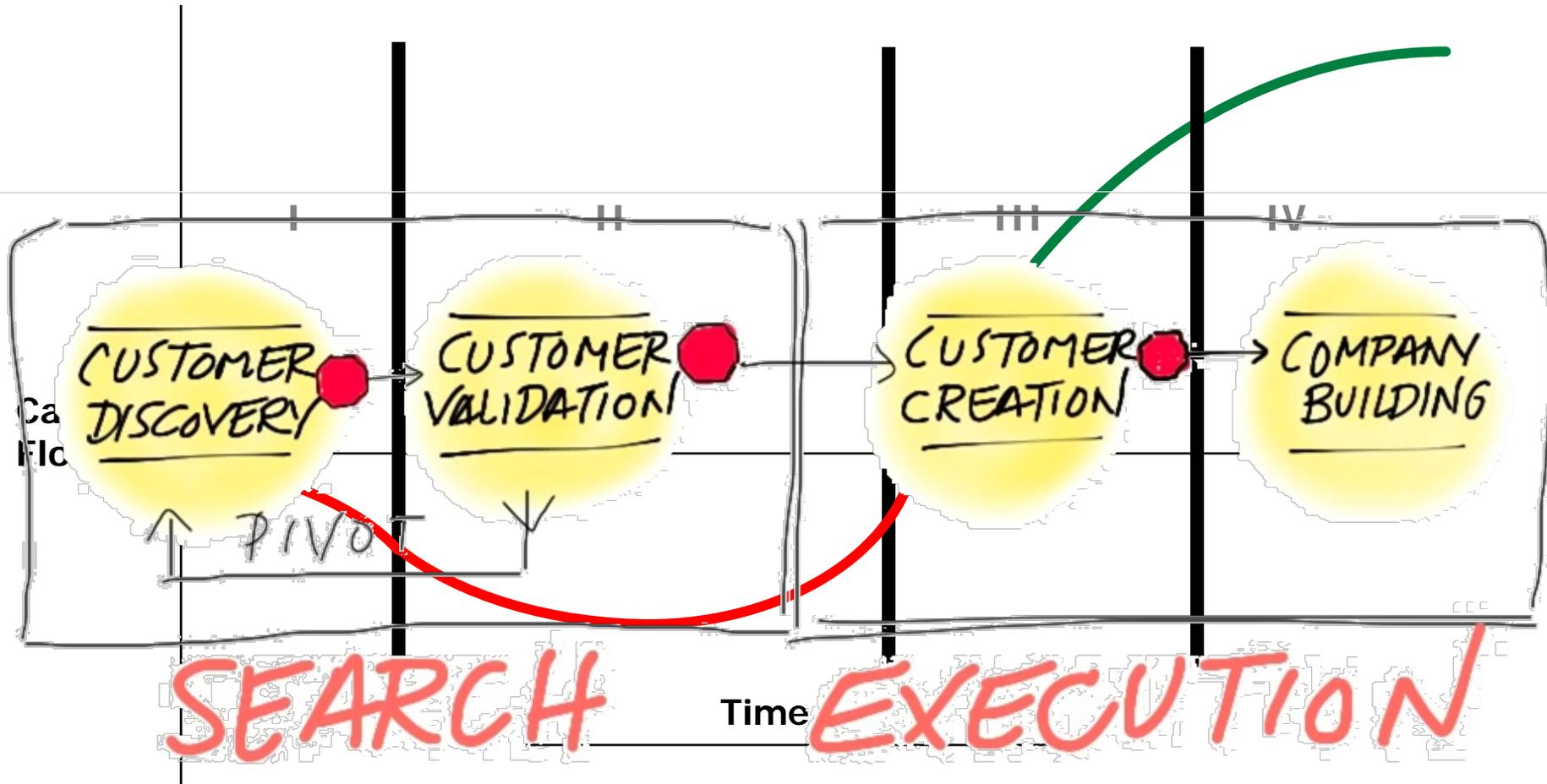


Customer Development is *how you search* for the model



The Entrepreneurial Venture

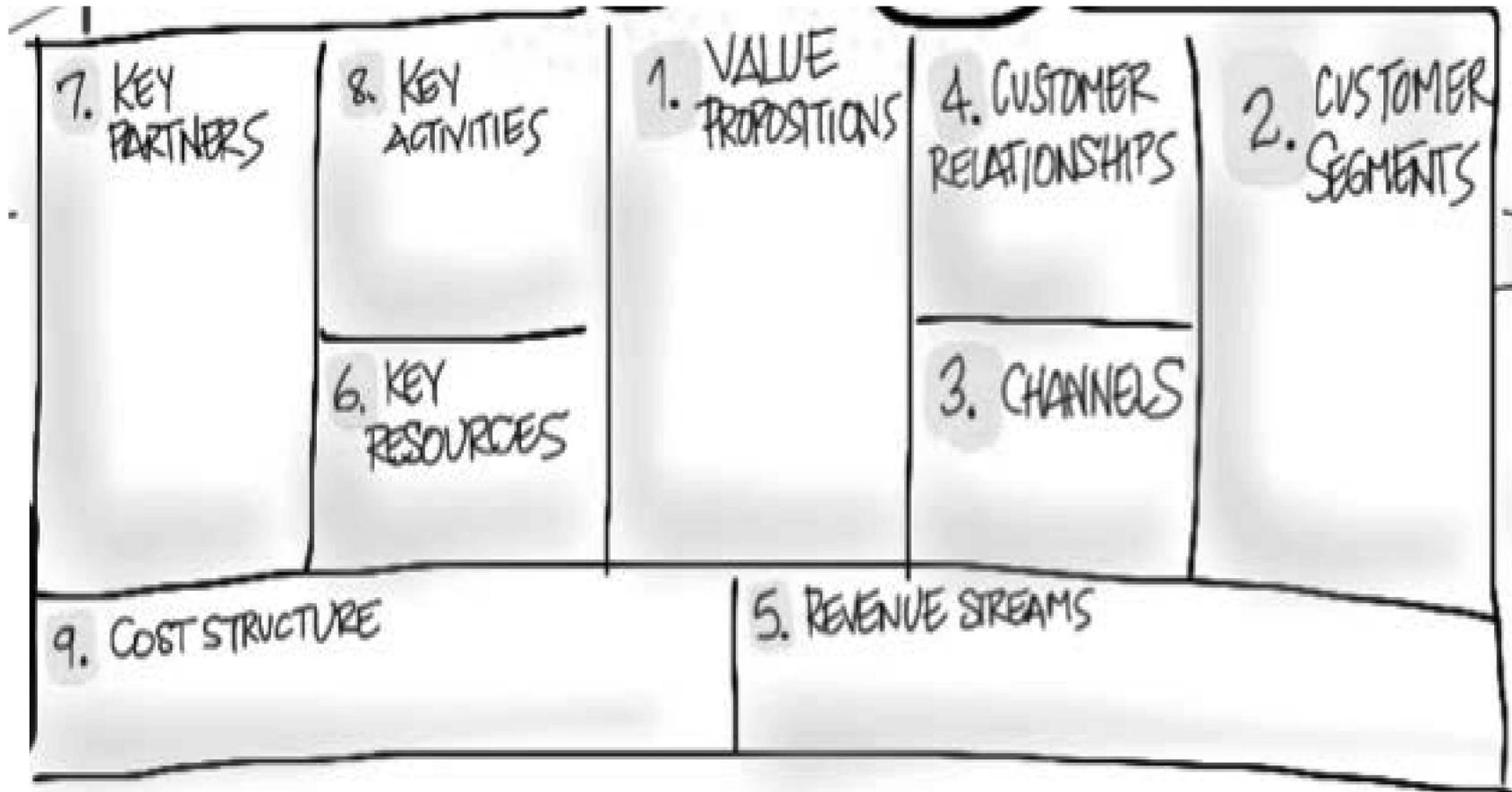
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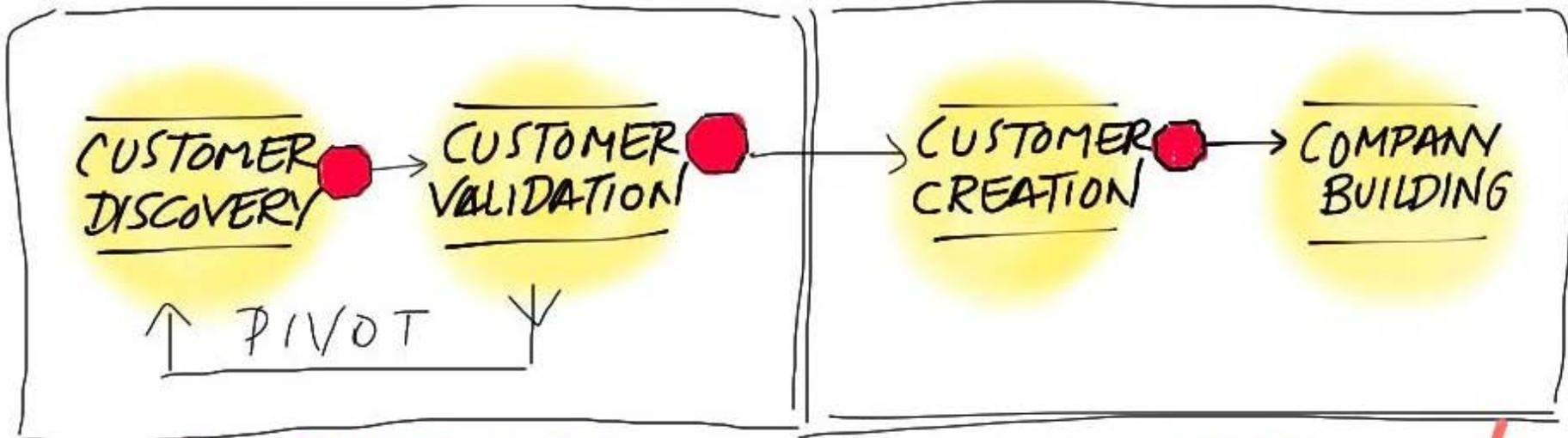
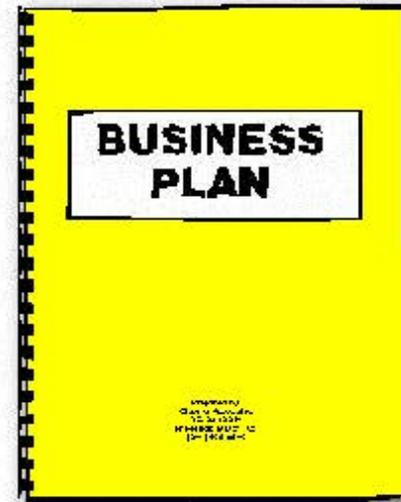
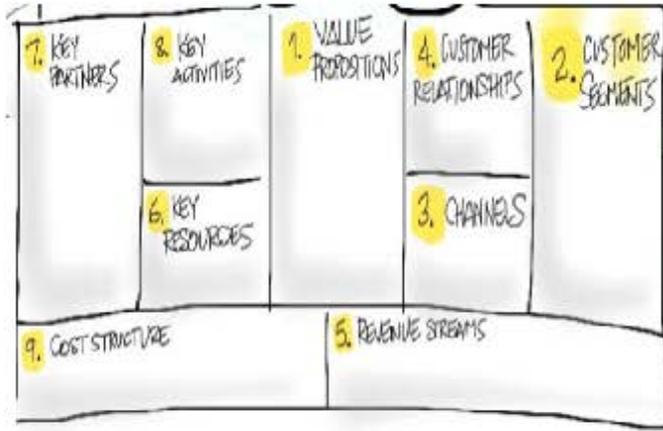


BUSINESS PLAN

Prepared by:
Olson & Associates
P.O. Box 2249
Frederick, MD 21705
(301) 695-2500

Business Models

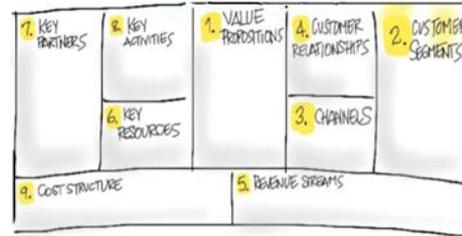




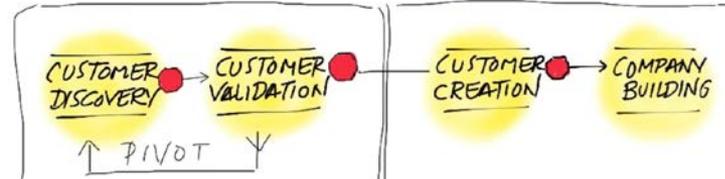
SEARCH

EXECUTION

Lean Startup



+



+



Agile Engineering

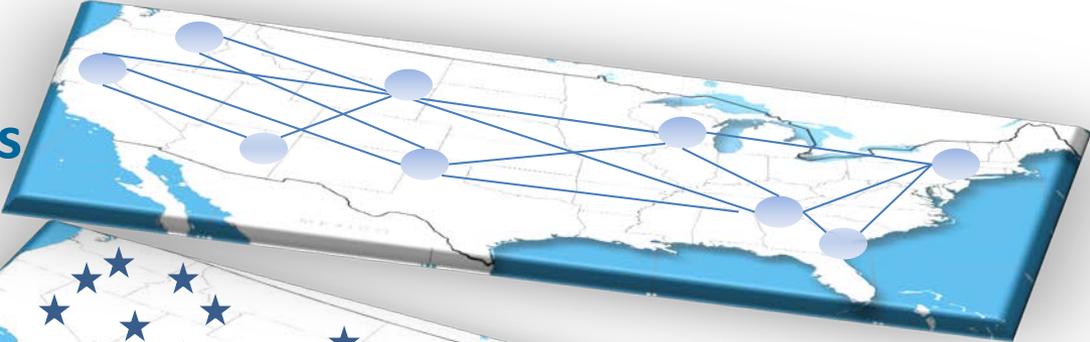
Part 1

Part 2

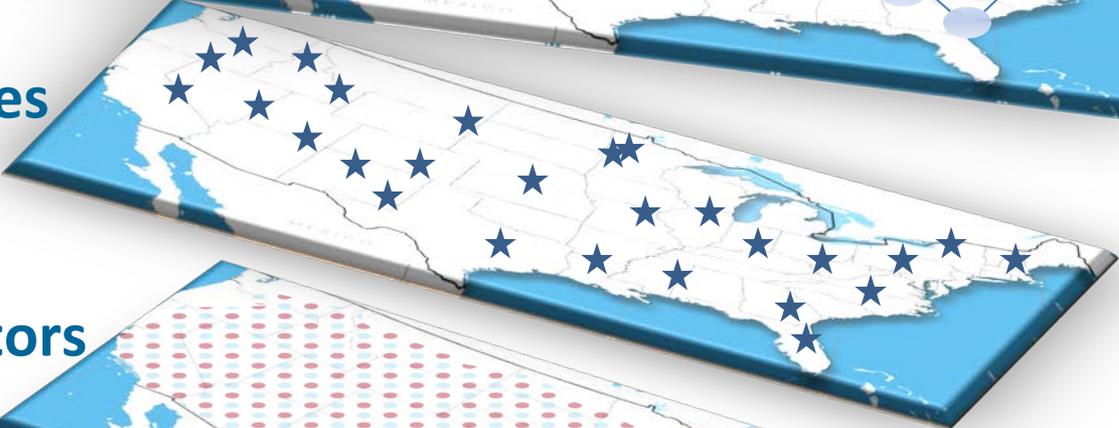
Part 3

Building the Nation's I-Corps™ “Innovation Fabric”

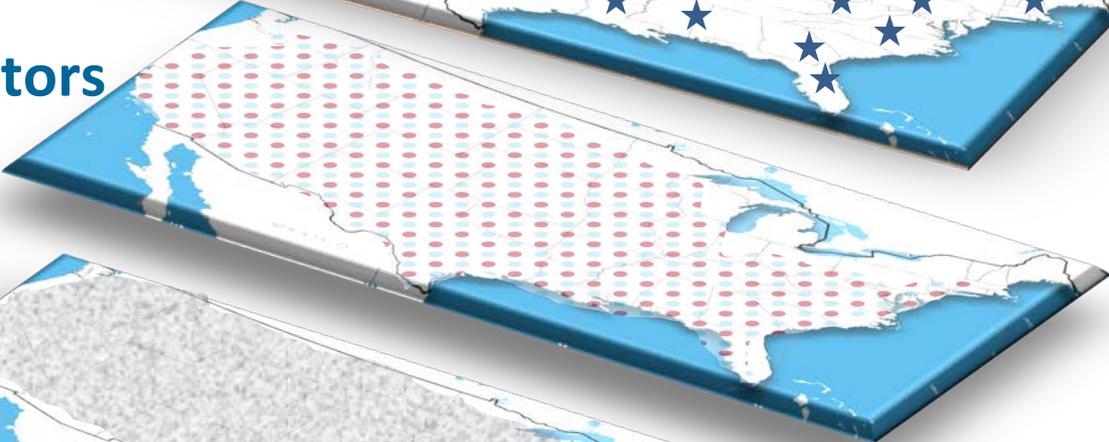
I-Corps™ Nodes



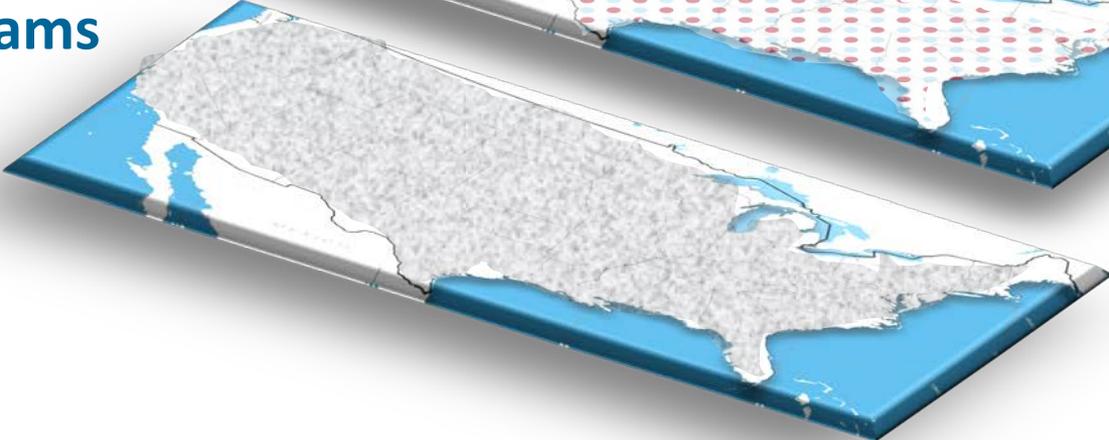
I-Corps™ Sites



I-Corps™ Mentors



I-Corps™ Teams



What you will get and produce

- Your team will
 - Be trained in lean startup methods
 - Develop answers to your business questions
- You will produce
 - A learning journey associated with customers and the business model canvas – in LPC
 - A final presentation and a final video

Evidence-based Entrepreneurship

Framing Hypotheses

Application by BMC, Initial Canvas, Updated Weekly Canvases

Customer Discovery

10-15 customer interviews/week, present results in front of peers

Product

Continual Revisions to MVP based on Customer Discovery

Mentorship

Mandatory Office Hours with Partners, a Mentor dedicated to team, uses LPC for review, Advisors as domain experts

Education / Community

Team presents weekly in front of cohort, formal curriculum, Optional: Office space, weekly dinners w/guest speakers

Lessons Learned

What we thought, what we did, what we found, what's next.

Mutual Expectations

- Relentless
 - Urgent and intense activity for 7 weeks
- Direct
 - Honest and clear communication
- Hypothesis driven
 - Hypothesis: Here's What We Thought
 - Experiments: So Here's What We Did
 - Results: So Here's What We Found
- Customer discovery
 - 100 interviews in 7 weeks

Expect us to be
RELENTLESS
and
DIRECT

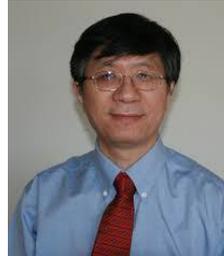
Albus Imaging: Team Members



ALBUS IMAGING

Goal: Collaborative and Productive Team

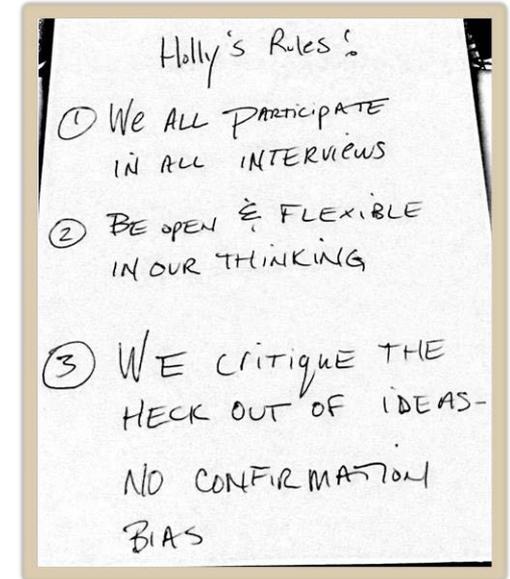
**Observe /
Active Bystander /
Adjudicator**



Yaorong Ge, PhD

Industry Expert

- Computer Scientist & Bioinformatics



Move

Greg Hundley, MD

C-Level Executive

- Cardiologist
- Cardiovascular Imaging Expert



Oppose



Holly Goodwin, MBA

Principle Investigator

- Translational research
- Commercialization of Cardiovascular monitoring technologies

Debating society



So here's what we did....



ALBUS IMAGING

We got out of the building!



- We interviewed:
 - 58 Cardiologists
 - 53 Oncologists
 - 31 Others ACOs, Payers, HCPs, RNs
- Weekly average = 20
 - 12 = Min
 - 31 = Max
 - 20 = Median
 - 15 = Mode

• Plus 10 places in Europe

We always asked who else the interviewee thought we should talk to <<-- this was very fruitful!

So Here's What We Are Going To Do for the next week!



Just kidding!

We have 10 interviews scheduled for Thursday & Friday.

Company 47



Brett Noel, Ph.D.
PI

Steve Ouellette, Ph.D.
C-level

Isaac Schumman, MBA
"Industry Expert"

Product: Preclinical assays to characterize new oncology therapies

Customers: Biopharma, academics, and preclinical CROs

Why: Save money and time on characterizing candidates in lead optimization

Academia	Number
Professor	11
Lab Director	7
Post-Doc	5
Grad Student	4
Administrator	1
Biotech/Pharma	
Scientist	24
Exec. Leadership	17
Bus. Dev.	7
CRO	
Scientist	3
Exec. Leadership	3
Bus. Dev.	1
Distributors	
Bus. Dev.	6
Sales	2
Consultants	
Drug Discovery	11

	Interview Count			
TOTAL	102	36	5	61

Team Profile



Steve Ouellette - Chief Technology Officer & Co-founder

- Ph.D. in Cancer Biology and Molecular Signaling (Purdue)
- Experience at preclinical CRO startup for *in vitro* toxicity
- Entrepreneurial training and developer of KS biz plan
- Coordinate overall effort of I-Corps team



Brett Noel – Senior Scientist

- Ph.D. in Cancer Biology and Molecular Signaling (Purdue)
- Expertise in core technology and development strategy
- I-Corps – Focus on technically oriented interviews



Isaac Schumann – Business Development Manager

- MBA from Krannert School of Management (Purdue)
- Experience at biochem CRO (Food, paper and biofuels)
- I-Corps – Focus on commercialization oriented interviews

Business Model Canvas – Day 1

Key Partners

- Biopharma
- Diagnostics
- Research oriented
- CROs
- Kit developers/manufacturers

Key Activities

- Product R&D
- Actively seek partnerships

Key Resources

- Laboratory and Staff
- Intellectual property
- Funding - grants,

Value Proposition

- Physiological relevance -
- Predictive biomarker
- Save \$\$\$ on ineffective

Customer Relationships

- technical publications
- conference presentations
- active outreach

Channels

- sales websites
- distribution and
- license agreements

Customer Segments

- Drug Discovery -
- Clinical - Biopharma,

Cost Structure

- Technology R&D
- Build partner relationships

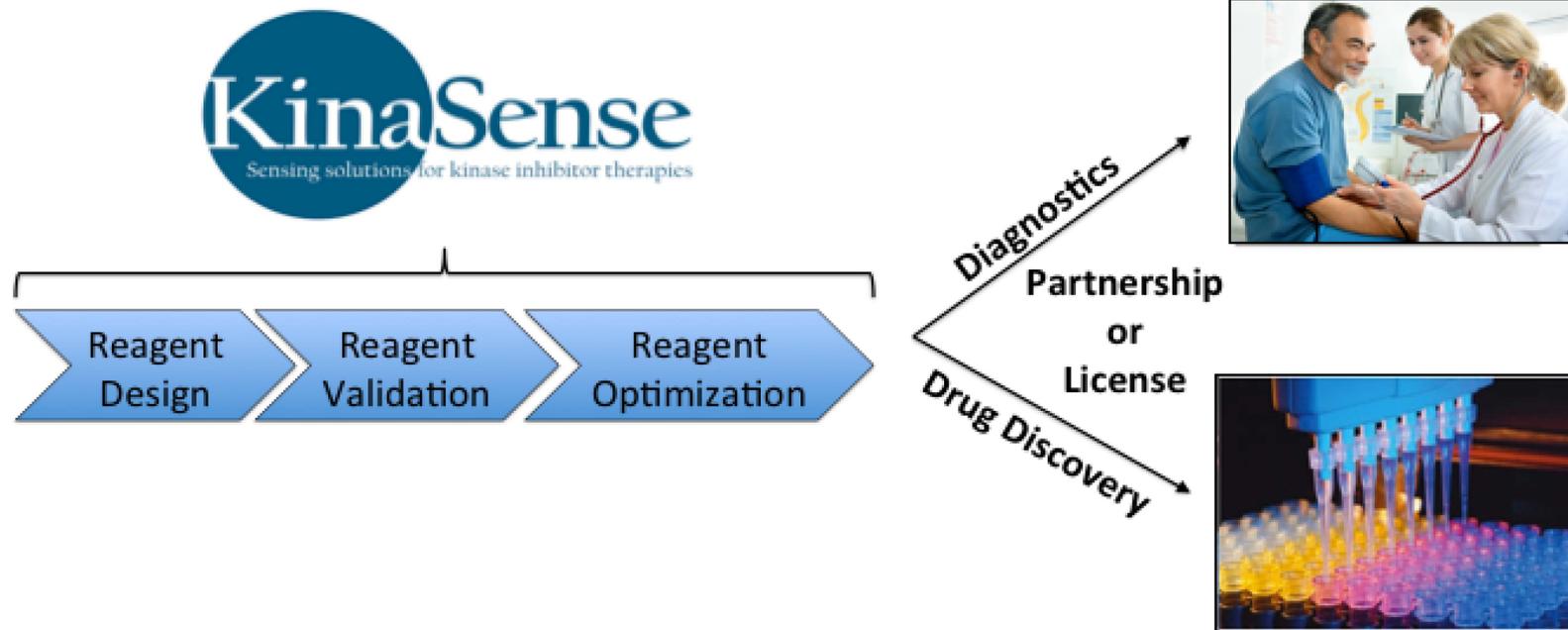
Revenue Streams

- Out-licensing results in revenue based on R&D milestones and royalties on

Original company hypothesis:

There is a market need for technologies to measure cell-based, endogenous tyrosine kinase activity in preclinical drug development and clinical diagnostic markets.

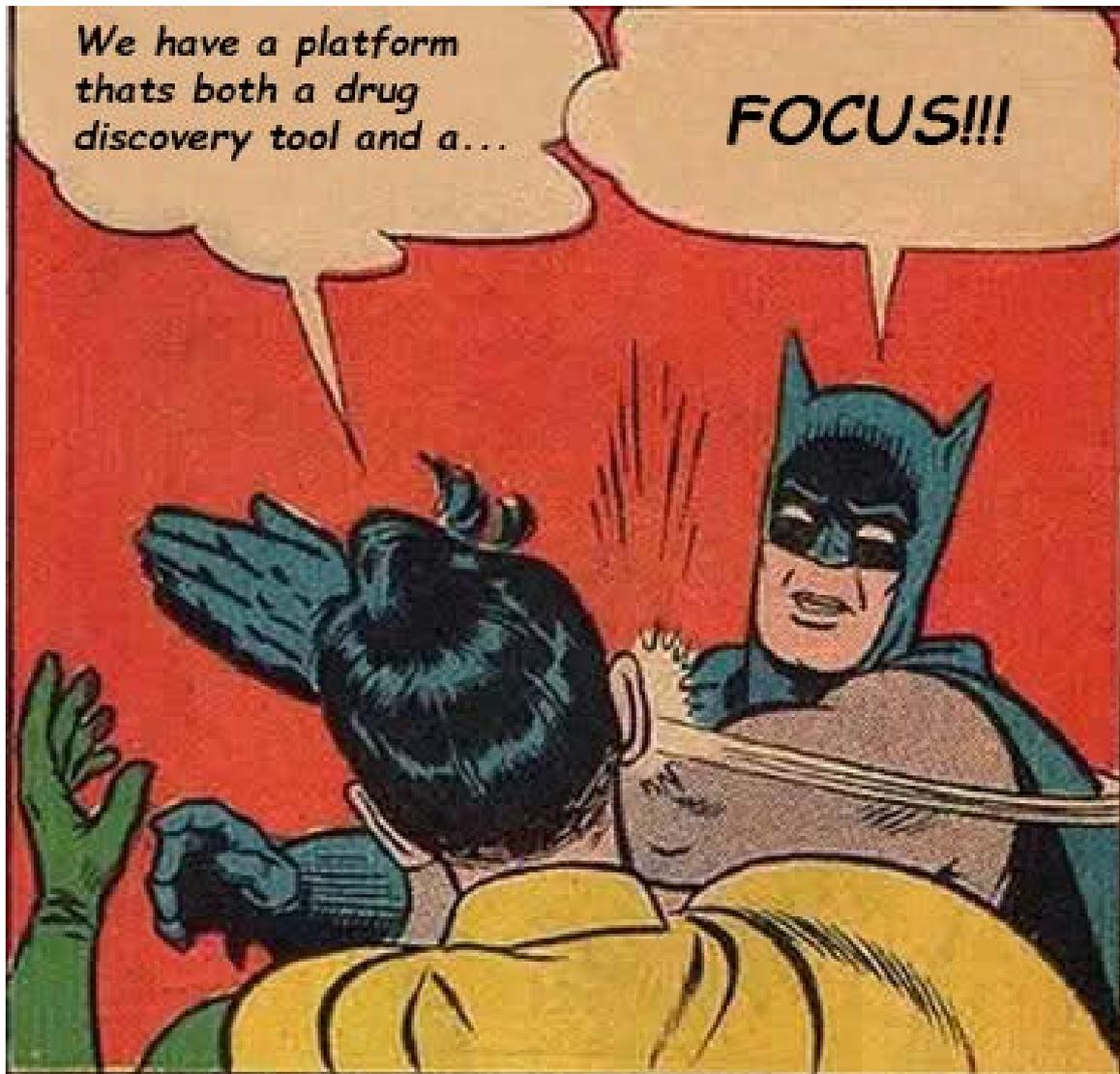
Business Model



- **Diagnostics Partners**
 - Clinical trials
 - FDA regulatory hurdles
 - Reimbursement

- **Drug Discovery Partners**
 - Pre-clinical services and products
 - Early Revenue

Our first lesson...



Nancy



Scott Patterson



Changes in Strategy and Philosophy on Business Models

Drop the clinical applications...for now

Customer Segments



Drug Discovery



Re-segment

Customer Segments



Changes in Strategy and Philosophy on Business Models

Drop the clinical applications...for now

Customer Segments



Drug Discovery



Re-segment

Customer Segments



Many business models



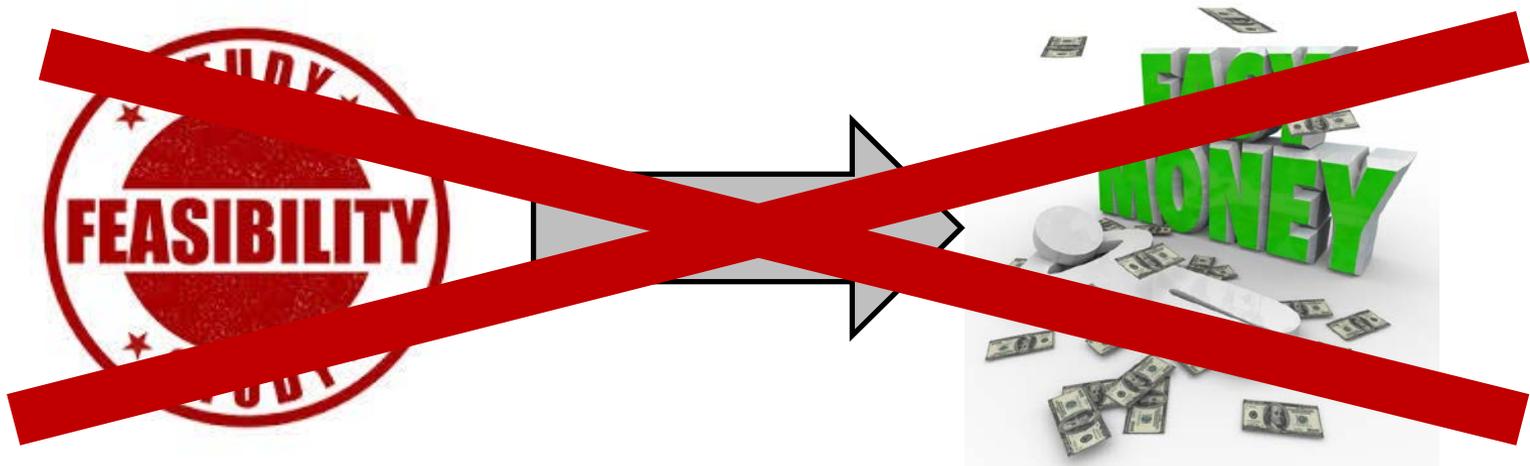
The Big Pivot: Revenue Model



Bob Lowery
CEO, Bellbrook Labs



Brian Murphy
Director, Axiogenesis



Revenue Model: What We Learned

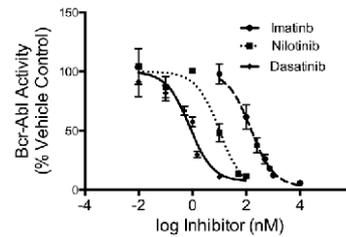
We had to build...



Product / Kit



Service / Data

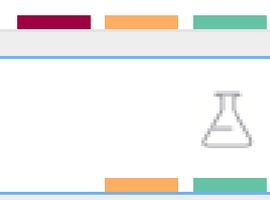


Revenue Streams

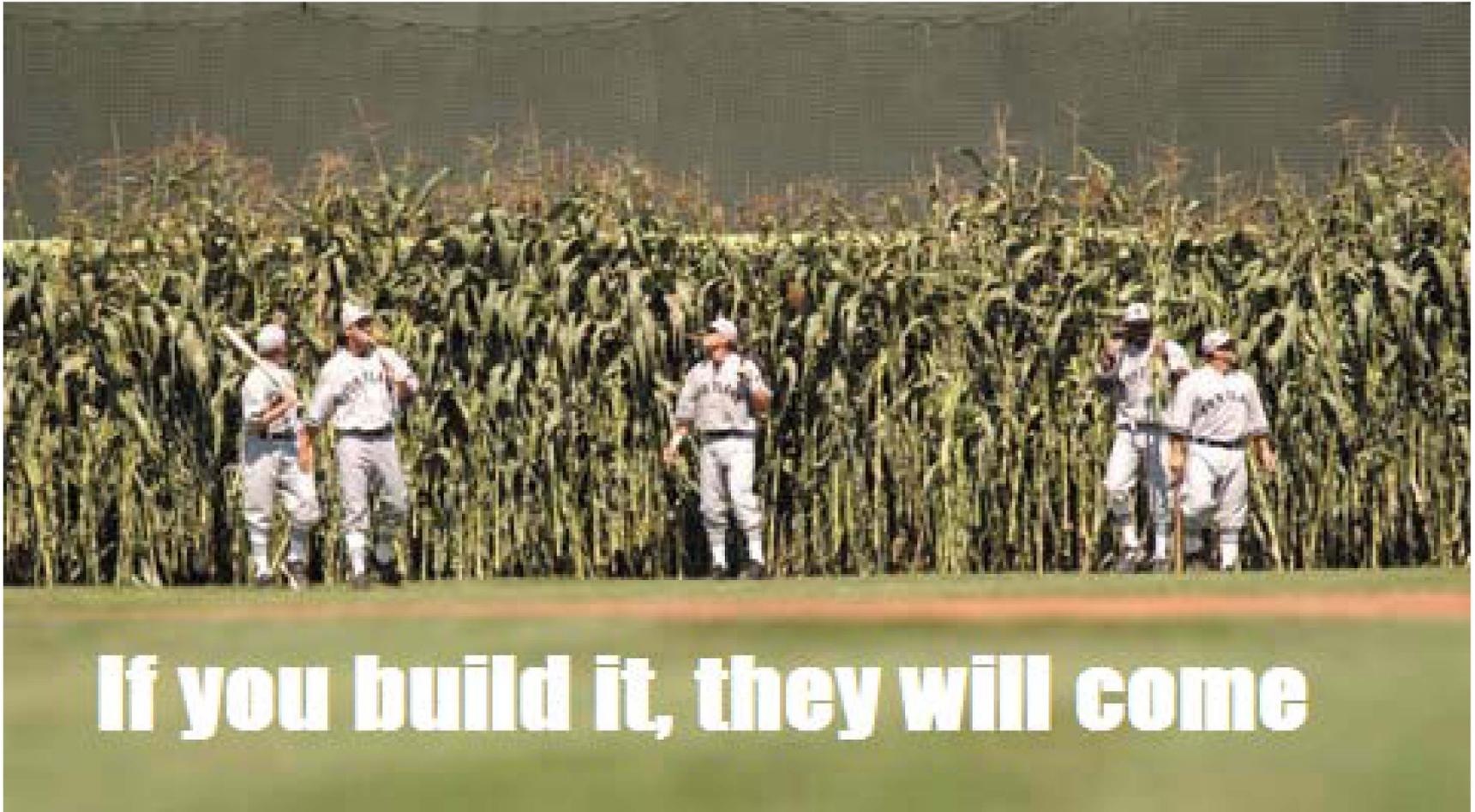
Direct sales to customers



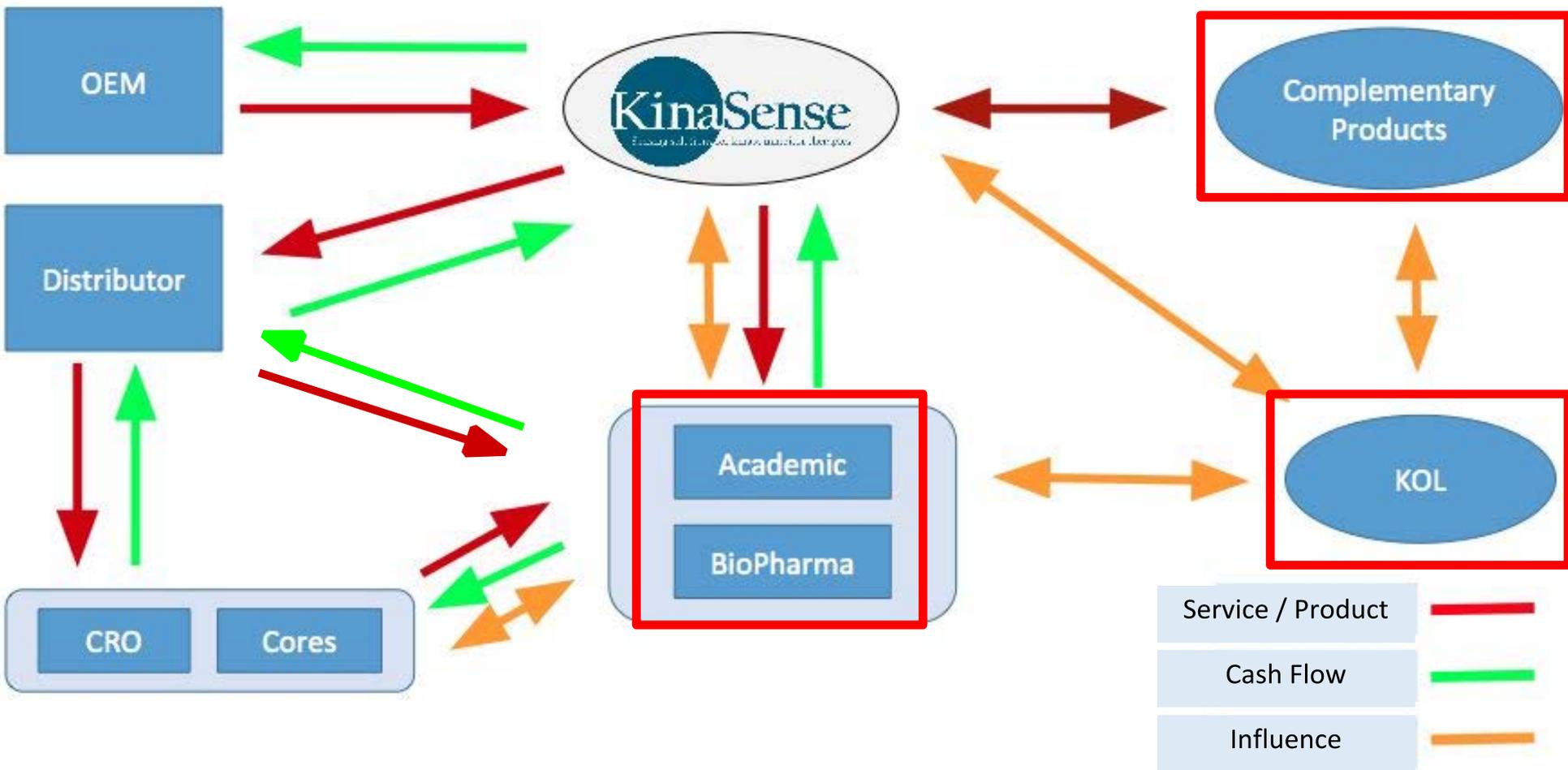
Providing assay services



How to Reach the Paying Customers?



Promoting Adoption in the Ecosystem



There is a Community Effort Involved in Driving Adoption

Partners

KOLs



David Drewry Bill Zuercher Jon Elkins

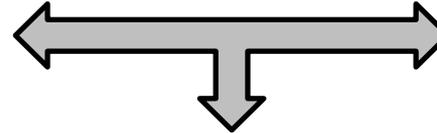
Complementary Products



Pilot Studies with Potential Customers



Assay Companies



- Publish
- Co-develop
- Endorse
- Present

In Summary We Learned...

Focus



Pivot

Product / Kit



Community

Partners

KOLs



David Drewry



Bill Zuercher

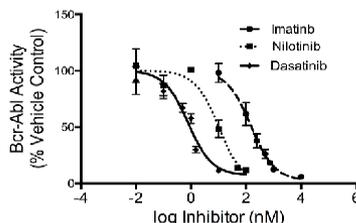


Jon Elkins

P



Service / Data



Complementary Products



Pilot Studies with Potential Customers



Final company hypothesis: Kinase inhibitor researchers in preclinical drug discovery need KinaSense assays to measure kinase activity directly in cellular models for reducing the time it takes to move a candidate drug from preclinical development into clinical trials.

Future Plans

- Continue building the platform as a research tool
- Establish KOL relationships and collaborations
- Customer discovery and the interview method of learning will become SOP at KinaSense
- Explore larger market opportunities of the technology

Activities	
Phase II Submission	Phase II submission expected second half of 2017
Phase I Submission	At least 2 additional Phase I applications based on I-Corps learning
Next 3 months	Partnerships with KOLs License IP to strengthen Phase I application
3 rd party funding	No plans to pursue before Phase II submission



Acknowledgements

Teaching Team

David Charron
Aileen Huang-Saad
Edmund Pendleton
Nancy Kamei
Todd Morrill
Bob Storey

TA

Lauren Sheridan

Cohort Teams

NIH

Michael Weingarten
Christie Canaria

VentureWell

Future Plans- 4 month Follow up

- Continue building the platform as a research tool
- Establish KOL relationships and collaborations
- Customer discovery and the interview method of learning will become SOP at KinaSense
- Explore larger market opportunities of the technology

Activities	
Phase II Submission	Phase II submission expected second half of 2017 <u>On Track</u>
Phase I Submission	At least 2 additional Phase I applications based on I-Corps learning <u>On Track (One scored well after I-Corps insights)</u>
Next 3 months	Partnerships with KOLs License IP to strengthen Phase I application <u>Finalizing Deals</u>
3 rd party funding	No plans to pursue before Phase II submission <u>Have had offers for outside funding</u>

Future Plans- 4 month Follow up

- Continue building the platform as a research tool
- Establish KOL relationships and collaborations
 - **Finalizing a contract with major pharmaceutical company**
 - **Will fund company for at least 1 year**
- Customer discovery and the interview method of learning will become SOP at KinaSense
- Explore larger market opportunities of the technology

Activities	
Phase II Submission	Phase II submission expected second half of 2017 <u>On Track</u>
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Future Plans- 4 month Follow up

- Continue building the platform as a research tool
- Establish KOL relationships and collaborations
 - **Finalizing a contract with major pharmaceutical company**
 - **Will fund company for at least 1 year**
- Customer discovery and the interview method of learning will become SOP at KinaSense
 - **Currently in contact with at least 1 other major pharmaceutical company**
- Explore larger market opportunities of the technology

Activities	
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I-Corps Lessons

- I-Corps is time-consuming
 - 40 hours/week
 - Research will slow down
 - Can you afford to participate in I-Corps?

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 - Can you afford to participate in I-Corps?
- Customer discovery is a skill that needs development
 - Academic articles can be **very** misleading
 - Interviews with customers and key opinion leaders are most important data points
 - Networking leads to an understanding of your **market ecosystem**

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- Customer discovery is a skill that needs development
 - Academic articles can be **very** misleading
 - Interviews with customers and key opinion leaders are most important data points
 - Networking leads to an understanding of your **market ecosystem**
- Teaching team and industry mentors are valuable resources
 - Experienced entrepreneurs and are invested in your success

I-Corps Lessons

- I-Corps is time-consuming
 - 40 hours/week
 - Research will slow down
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I-Corps Lessons

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Can you afford NOT to participate in I-Corps?



Q&A

sbir.cancer.gov/icorps

Submit your questions through the Q&A chat box

Please submit your questions via the chat box. We will be answering your questions throughout the webinar, with additional time dedicated at the end of the session.

Slides will be made available after the webinar event.