I-Corps from the Trenches

Conversations with I-Corps Alum

September 28, 2016

Michael Weingarten
Director
National Cancer Institute SBIR Development Center
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.
White House Demo Day

“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)

https://www.whitehouse.gov/the-press-office/2015/08/04/remarks-president-white-house-demo-day
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 8 weeks.

• Format is focused on *Experiential Learning*
## Business Model Canvas

### “Product-Market Fit”

<table>
<thead>
<tr>
<th>Key Partners</th>
<th>Key Activities</th>
<th>Value Propositions</th>
<th>Customer Relationships</th>
<th>Customer Segments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who are our Key Partners?</td>
<td>What Key Activities do our Value Propositions require?</td>
<td>Which of our customers' problems are we trying to solve?</td>
<td>How will we Get, Keep, and Grow customers?</td>
<td>For who are we solving a problem or fulfilling a need?</td>
</tr>
<tr>
<td>Key Resources</td>
<td>What Key Resources (suppliers, etc.) do our Value Propositions require?</td>
<td>Which customer needs are we satisfying?</td>
<td>Channels</td>
<td>Who are the customers?</td>
</tr>
<tr>
<td></td>
<td>What is the specific product/service?</td>
<td>What are the features that match customer needs?</td>
<td>Through which Channels do our Customer Segments want to be reached?</td>
<td>Does the value proposition match their needs?</td>
</tr>
<tr>
<td></td>
<td>What are the most important costs in our business model?</td>
<td>Revenue Streams</td>
<td>What is the revenue model? What are the pricing tactics? For what value are our customers willing to pay?</td>
<td></td>
</tr>
</tbody>
</table>

For who are we solving a problem or fulfilling a need?
- For who are we solving a problem or fulfilling a need?
- Who are the customers?
- Does the value proposition match their needs?
- Is this a single-sided or multi-sided market?
Hypotheses Testing and Insight…
I-Corps™ at NIH

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
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
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

- Medical Reimbursement
- Regulatory Strategy
- Pre-clinical Development
- Clinical Trials
- IP

BEFORE

AFTER

Not sure  | Very little  | Nothing  | Some  | A great deal

Percentage of knowledge improvement in different areas.
Status of Technology and Future Plans

Spring 2016 Cohort

Company Status

- Adequately assessed my technology's readiness for commercialization.
- Identified a viable commercialization path for my technology.
- Developed a scalable business model.
- Will apply for a phase II SBIR award predicated on the phase I award I used to qualify for I-Corps™ @ NIH.
- Will seek other non-federal funding or investment for my technology within the next 12 months.
- Defined a minimum viable prototype for my product.
- Identified and validated the market for a product based on my technology.
- Identified the key customer segments that I plan to target.
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)*
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)
<table>
<thead>
<tr>
<th>Event</th>
<th>Start Date</th>
<th>End Date</th>
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<tr>
<td>Application Due Date</td>
<td>November 1, 2016</td>
<td>January 9, 2017</td>
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<tr>
<td>Phone Interview (estimated)</td>
<td>December 5-9, 2016</td>
<td>February 13-17, 2017</td>
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<tr>
<td>Notice of Award (estimated)</td>
<td>January 6, 2017</td>
<td>March 17, 2017</td>
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<tr>
<td>Kick-off/Close-out Venue</td>
<td>TBD</td>
<td>TBD</td>
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<tr>
<td>Course Kick-off</td>
<td>February 5-8, 2017</td>
<td>April 23-26, 2017</td>
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<tr>
<td>Web-Ex Courses (1-5PM ET)</td>
<td>February 14, 2017</td>
<td>May 2,</td>
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<td>February 21, 2017</td>
<td>May 9</td>
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<td>February 28, 2017</td>
<td>May 16</td>
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<td>March 7, 2017</td>
<td>May 23</td>
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<td></td>
<td>March 14, 2017</td>
<td>May 30</td>
</tr>
<tr>
<td></td>
<td>March 21, 2017</td>
<td>June 6</td>
</tr>
<tr>
<td>Course Close-out/Lessons Learned</td>
<td>March 27-28, 2017</td>
<td>June 12-13, 2017</td>
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<tr>
<td>Cohort Size</td>
<td>24 teams</td>
<td>24 teams</td>
</tr>
</tbody>
</table>

Edmund Pendleton

Lead Instructor, NIH & NSF I-Corps
Asst. Faculty Director, NSF I-Corps
Why *I-Corps*
I WANT YOU FOR NSF Innovation Corps NEAREST RECRUITING STATION
$7 Billion
“How can we increase the economic impact of the research dollars invested every year?”
Developed by Entrepreneurs
Taught by

Entrepreneurs
Lean Startup
Why the Lean Start-Up Changes Everything

by Steve Blank

“Lean” is changing everything you know about starting a new venture. In the past, entrepreneurs were taught that the key to success was to create a minimum viable product (MVP) and then quickly pivot their strategy based on customer feedback. However, the lean start-up methodology has changed this approach.

Written by Harvard Business School’s Shikhar Ghosh, the article highlights that over 75% of start-ups fail. But recently, a new methodology has emerged. The “lean start-up” focuses on experimentation over elaborate planning. This approach places greater importance on customer feedback and iterative design over traditional “big design up front” development. Although the methodology is still relatively new, its concepts—such as minimum viable product (MVP) and pivot—are already widely adopted.

The delivery of the product is now the first test to see if the idea the entrepreneur thought they had can survive the market. There is a huge advantage to this approach, and the market is learning this the hard way. As frameworks and terms are thrown around, the majority of entrepreneurs are learning the hard way what the “big boys” have known all along.

This new lean methodology is not just changing the way entrepreneurs work but is also changing the way business schools are teaching business. In fact, it’s only a matter of time before the correct curriculum begins to appear in the right places, and the notion of minimalism and flexibility starts to become the norm for startups.

The notion of “minimum viable product” and “pivoting” have quickly taken root in the startup world, and business schools have already begun adapting their curricula to teach them.

The lean start-up movement hasn’t gone totally mainstream, however, and we have yet to feel its full impact. In many ways it is roughly where the big data movement was five years ago—consisting mainly of buzzwords that aren’t yet widely understood, whose applications companies are just beginning to grasp. As its practices spread, they’re turning the conventional wisdom about entrepreneurship on its head. New ventures of all kinds are attempting to improve their chances of success by following its principles of failing fast and continually learning. And despite the methodology’s name, in the long term some of its biggest payoffs may be gained by the large companies that embrace it.

In this article, I’ll offer a brief overview of lean start-up techniques and how they’ve evolved. Most important, I’ll explain how, in combination with other business trends, they could ignite a new entrepreneurial economy.
A Cambrian moment
You Promised Me Mars Colonies. Instead, I Got Facebook.

We’ve stopped solving big problems. Meet the technologists who refuse to give up. p.26
You Promised Me Mars Colonies. Instead, I Got Facebook.
I-Corps first program to apply lean startup principles to complex engineering, technology, and science based startups
Life Sciences?
$7 Billion
“How can we increase the economic impact of the research dollars invested every year?”
Just like NSF grantees,
Just like NSF grantees, we believe there is a better way to build life sciences startups.
Reinventing Life Science Startups – Evidence-based Entrepreneurship

Posted on August 21, 2013 by steveblank

What if we could increase productivity and stave the capital flight by helping Life Sciences startups build their companies more efficiently?

We’re going to test this hypothesis by teaching a Lean LaunchPad class for Life Sciences and Health Care (therapeutics, diagnostics, devices and digital health) this October at UCSF with a team of veteran venture capitalists.

Part 1 of this post described the issues in the drug discovery. Part 2 covered medical devices and digital health. This post describes what we’re going to do about it. And why you ought to take this class.

——

When I wrote Four Steps to the Epiphany and the Startup Owners Manual, I believed that Life Sciences startups didn’t need Customer Discovery. Heck how hard could it be? You invent a cure for cancer and then figure out where to put the bags of money. (In fact, for oncology, with a successful clinical trial, this is the case.)
In most cases, it’s not just about the execution of science.
You need to reduce technology, regulatory, and market/customer risk...
...by using an approach *driven by customer* needs.
Why are we here?
Our Goal
Improve *Odds*
Pick Winners
Pick Winners
Startup Statistics
Create More Winners
Shift the Curve
How do we build a startup?
We use **Customer Development** to build Business Models
Search for...

Problem-Solution Fit
“Can you identify and validate a problem or need in the market that enough people care about?”
Search for...

Product-Market Fit
“Can you build and deliver a product / service that satisfies the customer problem or need?”
Search for...

Business Model Fit
“Can you build and validate a repeatable and scalable (profitable) business model?”
Search for Business Model
Get out of the building!
Validated facts versus untested guesses...
Evidence comes from
Evidence comes from Customer Discovery Interviews
This is what we call...
This is what we call...

Evidence Based

Entrepreneurship
What will you do?
Jump In
8 Weeks
100 Interviews
Gut Feeling
But why?
“The first principle is that you must not fool yourself.

– Richard Feynman
“The first principle is that you must not fool yourself, and you are the easiest person to fool.”

– Richard Feynman
Everyone has a plan...
...until he gets punched in the face.”
TOP 10 STARTUP MISTAKES

1. Building something nobody wants: Score: 300 (36% of Tot.)
2. Hiring Poorly: Score: 153 (18% of Tot.)
3. Lack of Focus: Score: 112 (13% of Tot.)
4. Fail to execute Sales & Marketing: Score: 98 (12% of Tot.)
5. Not Having The Right Co-Founders: 66 (7.9%)
6. Chasing Investors, Not Customers: 45 (5.4%)
7. Not Making Sure You Have Enough Money: 28 (3.3%)
8. Spending Too Much Money: 18 (2.1%)
9. Failing To Ask For Help: 12 (1.4%)
10. Ignoring Social Media: 6 (0.7%)
Top Three

1. Building something nobody wants
   - Score: 300
   - 36% of Tot.

2. Hiring Poorly
   - Score: 153
   - 18% of Tot.

3. Lack of Focus
   - Score: 112
   - 13% of Tot.

Other mistakes:
- Not Having The Right Co-Founders
  - 36% of Tot.
- Chasing Investors, Not Customers
  - 18% of Tot.
- Not Making Sure You Have Enough Money
  - 13% of Tot.
- Spending Too Much Money
  - 12% of Tot.
- Failing To Ask For Help
  - 12% of Tot.
- Ignoring Social Media
  - 6% of Tot.

www.100FirstHits.com

Top Three
Why is I-Corps especially valuable for Life Sciences?
There is A LOT to learn in these markets.
Markets are often complex with many stakeholders.
Pathways to market are often *lengthy, costly, and complex.*
Startup risks are generally very high.
NIH I-Corps
Our Dx determines the exact number of HIV virus particles in patients where virus is dormant. With this tool, researchers can develop better drugs, AND doctors can decide when to stop therapy.
Ms. Jennifer A. Nichols, President & Co-Founder
- 10 years biotech startup experience
- Commercialization, Licensing
- Regulatory compliance, Patents

Dr. Janet L. Huie, PhD, CSO & Co-Founder
- PI for NIH, DoD, NOAA Grants & Contracts
- IRB Chair
- FDA validation

Mr. Dennis Brown, Industry Expert
- Software, Finance, Logistics
- CEO/President with $47M in sales
- Launch stage for latest venture
MS. KNOW-IT-ALL
Here’s what we thought:

**Design:** Testing bulk RNA

**Price:** Lowest price

**Partner:** Big Pharma
Here’s what we learned:

- Testing bulk RNA: ✖️

- New HIV RNA target site: 👍

- Single cell analysis/cell separation (FACS): 👍
Here’s what we learned:

**Price:** Lowest price

**Value pricing**
The Client expects to test 6 times a year, though 3 times a year is covered by insurance. Perhaps 3% of 1.2 million could receive 3 tests in year one, and you would expect $2,397,600 in revenues (3% x 4.44 x10^5 x $60/test x 3 tests per year). Market access increments are 3% 6%, 10%, 25% and 40%.

Year 1: 2.4 million dollars based on 40,000 units sold

Year 2: 4.8 million dollars based on 80,000 units sold

Year 3: 8.0 million dollars based on 133,200 units sold

Year 4: 20 million dollars based on 333,000 units sold

Year 5: 32 million dollars based on 532,800 units sold
CURRENT INVESTOR ROI

*$3M to get to RUO (need preclinical data)
*$125M to get to Clinical Dx

For a return on a $50M investment we must exceed $500 mil in sales within 5-7yrs assuming the company is valued at 5-10x sales (assuming they own 50% equity):

1.2M x 37% (HIV+ on ART) = 444,000 patients treated that need testing
3 tests per year = 1.32M tests/yr
x $1,000/test = $1.3B total market

Yr 1: 3% $40M
Yr 2: 6% $80M
Yr 3: 10% $130M
Yr 4: 25% $325M
Yr 5: 40% $520M
Here’s what we learned:

- **Gilead**: Crossed out
- **University of Rochester Medical Center**: Thumb up
- **UCSF University of California San Francisco**: Thumb up
**LESSONS LEARNED**

**Design:**
- Then: Testing bulk RNA
- NOW: Single cell analysis (FACS) + new Target

**Price:**
- Then: Lowest price
- NOW: Value pricing

**Partner:**
- Then: Big Pharma
- NOW: UCSF and University of Rochester
DAY 1 BMC DAY 1
OUR ORIGINAL IDEA - WHAT WE THOUGHT

Key Partners
- University of Rochester
- Southern Research
- UCSF
- Cornell University
- UCSF Hospital Clinicians
- Gilead Sciences, Inc.
- Monogram Biosciences, Inc.
- Johnson & Johnson

Key Activities
- We need to become
  - Clinical validation

Value Proposition
- Improve specificity
- Provide accurate quantification of the latent

Customer Relation
- By engaging in
  - Offering an assay that

Customer Segments
- Pharmaceutical Companies
- Diagnostic Companies
- Clinicians monitor
- FDA sponsored

Key Resources
- Regulatory consultant
- Clinical trials consultant
- Chemist for synthesis

Channels
- For sale via web
- For sale via cold mail and
  - Non-commercial
  - Corporate seller

Cost Structure
- Pre-clinical trials
- Probe synthesis
- Synthesis of dye components

Revenue Streams
- Provide a sample assay to researchers to try in their labs
- Provide an assay at a cost/experiment/kit for researchers to
- Licensing the technology to pharmaceutical companies
As a result of the I-Corps process:

**Within the next 3 months**
- Write an NIH/SBIR phase II
- Expand our current IP
- Enter into pre-clinical testing
- File for new IP

**Partnerships**
- U. Rochester (pre-clin samples)
- Southern Research (NHP Study, validation against QVOA)
- UCSF (RNA, proteomics study)
- Partner for rebound study

**NON-NIH funding**
- Maybe VC
- Maybe Angel
### BUSINESS MODEL CANVAS #2

#### LaunchPad Central

<table>
<thead>
<tr>
<th>Key Partners</th>
<th>Key Activities</th>
<th>Value Proposition</th>
<th>Customer Relation</th>
<th>Customer Segm</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Rochester</td>
<td>We need to become</td>
<td>Improve specificity and quantify latent</td>
<td>By engaging in</td>
<td>Pharmaceutical Companies engaged in</td>
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<td>Monogram Biosciences/Lab.com</td>
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</table>

#### Key Resources

- Regulatory consultant
- Clinical trials consultant
- Chemist for synthesis

#### Channels

- For sale via web
- For sale via cold call
- Non-commercial
- Corporate seller

#### Cost Structure

- Pre-clinical trials
- Probe synthesis
- Synthesis of dye components

#### Revenue Streams

- Provide a sample assay to researchers to try in their labs.
- Provide the assay at a cost/experiment/kit for researchers to use.
- Licensing the technology to pharmaceutical companies.
Value Propositions

1. Improve specificity and sensitivity
2. Direct detection of RNA
3. Offer accurate testing on tissue
4. Detection of blood samples

Customer Segments

1. Pharmaceutical companies ...
2. Diagnostic companies ...
3. Clinicians who monitor latent HIV
4. Govt. sponsored programs ...
5. Non-profit organization's ...

BIOTECH
**Current Business Model Canvas #4**

**Key Partners**
- UCSF
- UR CFAR
- Southern Research Institute
- ACTG
- Cornell University
- UCSF Hospital Clinicians
- Gilead Sciences, Inc.

**Key Activities**
- We need to become experts at knowing what the clinical validation

**Value Propositions**
- Detection of blood samples
  - FACS separation of latent reservoir blood cells
  - Sensitivity to 1-5 copies of RNA per $10^6$ cells
  - Specificity - no false positives, no false negatives

**Customer Relationships**
- Use with FACS for LR blood cell collection
- Company/Univ vaccine/drug/etc ...
- Faster to result
- Detection of LR virus

**Channels**
- For sale via web
- For sale via cold call and sampling
- Non-commercial distribution to researchers

**Customer Segments**
- HIV latent reservoir (LR) researchers
- Pharmaceutical companies developing ...
- Diagnostic companies distributing diagnostics ...
- Clinicians who monitor latent HIV reservoir in ...
- Govt. sponsored programs supporting HIV cure ...

**Cost Structure**
- Pre-clinical trials
- Probe synthesis
- Synthesis of dye components

**Revenue Streams**
- Provide a sample assay to researchers to try in their labs.
- Provide the assay at a cost/experiment/sell for researchers to use in validating their experiments and include us on manuscripts
- Licensing the technology to pharmaceutical companies

CURRENT BUSINESS MODEL CANVAS #6

Value Propositions:
- Detection in blood
- FACS separation of latent reservoir blood cells
- Sensitivity to 1-5 copies of RNA per 10^6 cells
- Specificity - no false positives, no false negatives
- Detection in tissue
- Faster time to result

Customer Segments:
- HIV Cure researchers who believe a blood assay...
- Researchers at HIV diagnostic companies
- Clinicians who monitor latent HIV reservoir in ...
- Govt-sponsored programs supporting HIV cure ...
- Non-profit organizations engaged in HIV cure ...

Customer Relations:
- Get - Conferences
- Keep - Product updates
- Grow - Products related to assay
- Sales Force
- IP licensing
- Revenue Streams
  - Direct sales
  - email/phone/web
  - IP licensing royalties

Customer Relations - more one-to-one connections with Customer Segments
**Value Propositions**
- Detection in blood
- Detection in tissue
- FACS separation of latent reservoir blood cells

Sensitivity to 1-5 copies of RNA per 10^6 cells
Specificity - no false positives, no false negatives
Faster time to result

**Customer Relationships**
- Get - Conferences
- Keep - Product updates
- Grow - Products related to assay

**Channels**
- Sales Force
- IP licensing
- Distributors

**Customer Segments**
- Researchers at pharmaceutical companies
- Researchers in Academia
- Physicians/Clinicians monitoring patients on antiretroviral therapy

**Revenue Streams**
- Kit and reagent sales
- Licensing
### Key Partners
- Suppliers: PNABIO, Lean Chemical co.
- Strategic alliance: URoch, UCSF, SRI, Rush
- Joint Bus. Dev.: Gilead Merck
- Contract lab: LabCorp, Quest
- NGO: WHO, Gates, amfAR
- Cornell University

### Key Activities
- Preclinical testing
- Clinical validation
- R&D for FACS latent blood cell separation

### Value Propositions
- Detection in blood
- Detection in tissue
- FACS separation of latent reservoir blood cells
- Sensitivity to 1-5 copies of RNA per 10^6 cells
- Specificity - no false positives, no false...

### Customer Relations...
- Get - published peer reviewed journals/R&D
- Keep - Product updates, customer service
- Grow - Increase number of products related to...

### Customer Segments
- Researchers at pharmaceutical...
- Researchers in Academia
- Physicians/Clinicians monitoring patients on...

### Key Resources
- FDA Approval
- Clinical trials consultant
- Regulatory consultant

### Channels
- Sales Force
- IP licensing

### Cost Structure
- R&D costs
- SG&A costs
- Manufacturer costs

### Revenue Streams
- IP licensing
- Direct sales
Current Business Model Canvas #9

**LaunchPad Central**

### Key Partners
- Suppliers: ex. PNABio, Lean Chemical co.
- Strategic Alliances: U of R, U.Pitt, UCSF, Southern Research
- Joint Bus.: Gilead, Merk
- Contract Lab: LabCorp, Quest
- NGO: Gates Foundation, amfAR, WHO

### Key Activities
- Grant writing
- KOL
- Preclinical testing
- Clinical validation
- FDA approval

### Key Resources
- Clinical trials consultant
- Regulatory consultant
- IP
- Suppliers: ex. PNABio, Lean Chemical co.
- Advisory Board
Q&A

sbir.cancer.gov/icorps
Submit your questions through the Q&A chat box