I-Corps from the Trenches

Conversations with I-Corps Alum

October 26, 2017

Christie Canaria
Program Director
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.
Christie Canaria
NCI/NIH I-Corps

Edmund Pendleton
Lead Instructor

Michael Schultz
CSO, Viewpoint Molecular Targeting
NSF National Innovation Network

- 8 I-Corps™ Nodes
- > 50 I-Corps™ Sites
- I-Corps™ at NIH instructors come from nodes
  - Trained with I-Corps curriculum
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></td>
<td>Key Resources</td>
<td>Which customer needs are we satisfying?</td>
<td>Channels</td>
<td>Who are the customers?</td>
</tr>
<tr>
<td></td>
<td>What Key Resources (suppliers, etc.) do our Value Propositions require?</td>
<td>What is the specific product/service?</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></td>
<td>What are the features that match customer needs?</td>
<td></td>
<td>Is this a single-sided or multi-sided market?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cost Structure</th>
<th>Revenue Streams</th>
</tr>
</thead>
<tbody>
<tr>
<td>What are the most important costs in our business model?</td>
<td>What is the revenue model? What are the pricing tactics? For what value are our customers willing to pay?</td>
</tr>
</tbody>
</table>
Hypotheses Testing and Insight…

“GET OUT OF THE BUILDING!”
“Talk to CUSTOMERS, PARTNERS, and VENDORS.”

There aren’t any facts in here!!
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
I-Corps™ at NIH - Program Format

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

TEAM STRUCTURE
- C-level executive (decision making authority)
- PD/PI (strong technical background)
- Industry Expert (rolodex & experience)

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
5 cohorts to date

- 100 teams conducted 10,000+ 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.”
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
Business Model Canvas Knowledge

Spring 2016 Cohort

- Channels
- Cost Structure
- Customer Relationships
  - Customer Segments
  - Key Activities
  - Key Partners
  - Key Resources
  - Revenue Streams
- Value Propositions

**BEFORE**

**AFTER**

Not sure  Very little  Nothing  Some  A great deal
Life Science Commercialization Knowledge

Spring 2016 Cohort

Knowledge of areas of Commercialization & Life Sciences

<table>
<thead>
<tr>
<th>BEFORE</th>
<th>AFTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Reimbursement</td>
<td>Medical Reimbursement</td>
</tr>
<tr>
<td>Regulatory Strategy</td>
<td>Regulatory Strategy</td>
</tr>
<tr>
<td>Pre-clinical Development</td>
<td>Pre-clinical Development</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>Clinical Trials</td>
</tr>
<tr>
<td>IP</td>
<td>IP</td>
</tr>
</tbody>
</table>

Legend:
- Not sure
- Very little
- Nothing
- Some
- A great deal
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.
16 Participating ICs in 2018

- National Cancer Institute (NCI)
- 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 on Deafness and Other Communication Disorders (NIDCD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Center for Advancing Translational Sciences (NCATS)
- National Center for Emerging Zoonotic and Infectious Diseases (NCEZID/CDC)
- National Institute for Occupational Safety and Health (NIOSH/CDC)
Apply to I-Corps using ASSIST
# PA-18-314 I-Corps at NIH Administrative Supplement

$50,000 budget cap

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


Next Application Deadline: December 18, 2017
Why *I-Corps*
More startups fail from a lack of customers than from product failure.
More startups fail from a lack of customers than from product failure.
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%)
#1 Building something nobody wants
Score: 300

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

#3 Lack of Focus
Score: 112
13% of Tot.
Our Goal
Improve Odds
Shift the Curve
ALSO
Innovation
Culture Change
Invention

Innovation
Invention about Technology
Innovation about Customer Needs
Solutions Based to Needs Based
Get out of the building!
TEST and VALIDATE assumptions
It’s not only about helping patients...
…or making the science work…
Your goal is to build a business.
What to expect from instructors?
Teaching Team
Practitioners... not Academics
Coaches... not Consultants
How to think...

not what to think.
Respectfully Direct
What make a good team?
Viewpoint’s ICORPS Story

Academic Entrepreneurship and True Grit

Michael K Schultz PhD
Chief Science Officer
Product: Targeted radiotherapy for metastatic melanoma.

Business Thesis: Initially, medical oncologists caring for metastatic melanoma patients who have failed current therapies will prescribe our product because it will improve survival by 6 months in greater than 20% of patients, with the potential to expand to front line therapy for all metastatic melanoma patients.

<table>
<thead>
<tr>
<th>Interview Count</th>
<th>Medical Oncologists (16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL</td>
<td></td>
</tr>
<tr>
<td>105</td>
<td>Radiation Oncologists (5)</td>
</tr>
<tr>
<td>77</td>
<td>Nuclear Medicine/Radiologist Physicians (21)</td>
</tr>
<tr>
<td>2</td>
<td>Physician Assistants/Nurses (4)</td>
</tr>
<tr>
<td>26</td>
<td>Radio/Nuclear Pharmacist/Chemists (18)</td>
</tr>
<tr>
<td></td>
<td>Industry Experts/CRO (24)</td>
</tr>
<tr>
<td></td>
<td>Legal (3)</td>
</tr>
<tr>
<td></td>
<td>Regulatory (2)</td>
</tr>
<tr>
<td></td>
<td>Financial (12)</td>
</tr>
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</table>
Heyward Coleman MS, MBA – Co-Founder, CEO
- 40+ years’ experience as business executive and entrepreneur
- Founder of largest private radiochemistry company in U.S. (Environmental Physics, Inc. acquired by General Engineering Laboratories, LLC)
- Corporate spin-off experience at Maritrans GP, Inc.
- MS Nuclear Physics at Duke and MBA at Harvard

Michael Schultz PhD – Co-Founder, CSO
- 15+ years’ industry and research experience in radioactivity/nuclear medicine
- Associate Professor of Radiology and Nuclear Medicine at the University of Iowa
- Expert in targeted radiotherapies for cancer
- Business manager experience with Ametek Inc. (ORTEC brand)

Frances Johnson MD – Co-Founder, CMO
- 22 years’ experience as Clinical Trials PI
- Co-founded molecular diagnostic company (XDx, Inc. now CareDx, Inc.)
- Adjunct Associate Professor at University of Iowa
- MD University of Washington, Residency UC San Francisco, Faculty Stanford, University of Maryland, and University of Iowa

We didn’t know, what we didn’t know
2011 $25,000 Elevator pitch (University of Iowa)
2013 $150,000 Phase I SBIR
2015 $150,000 Phase I SBIR
  $300,000 Phase I SBIR (contract)
  $25,000 Iowa Innovation Corporation
  $100,000 State of Iowa Demo Funds
2016 $300,000 Phase I SBIR
  $100,000 Wellmark Funds
2017 $50,000 NCI ICORPS Program
  $2,000,000 Phase II SBIR (contract)
Goals

• What is ICORPS?
• Who are we?
• Where are we?
• Is ICORPS right for us?
• Are we right for ICORPS?
ICORPS

“eye” “core”

An intensive entrepreneurship program that emphasizes customer discovery as the means to energize your business.
ICORPS

"eye" "corpse"
Who are we? Why are we here?

- Great idea
- Start up company
- Next level
- ICORPS might help

“academic entrepreneur”
Academic Entrepreneurship?

academic; akəˈdemik/
adjective
1. relating to education and scholarship.
2. not of practical relevance; of only theoretical interest.
	noun

teacher or scholar in a college or institute of higher education.
Academic **Entrepreneurship**?

**entrepreneurship**

ˌäntrəprəˈnərˌSHip

*noun*

the activity of setting up a business or businesses, taking on **financial risks** in the hope of **profit**.
Technology Continuum & ROI

$\quad \star \quad $

Purely Academic
SBIR Phase I

Purely Commercial

Academic Discovery Grants/Papers R01/R21

Technology Transfer SBIR Phase II Equity

EDGE The R-Rated Superstar “ROI”
Why do most startups fail?

☐ The founders fight
☐ They can’t build their initial spec
☐ No one will fund their idea
☐ Too few people will buy/use the product

Steve Blank
Innovation Within
Why do most startups fail?

- The founders fight
- They can’t build their initial spec
- No one will fund their idea
- Too few people will buy/use the product
Who are we?
Where are we?

TRUE GRIT
Are we right for ICORPS?

- C-suite executives
- Time to participate
- Wants to contribute big
- Knowledge and skills
- Excited about it

TRUE GRIT
We didn’t know what we didn’t know...

### Business Model Canvas-1

#### Key Partners
- National Institutes of Health
- UI Research Foundation
- UI Ventures
- Economic Development Corporation
- Iowa Economic Development Authority
- Private Equity Investors
- Department of Energy
- Lantheus Medical Imaging
- Supply Chain Manufacturers
- Eckert Ziegler Eurotope
- National Cancer Institute
- Midwest Melanoma Partnership
- University of Iowa
- Mayo Clinic, Rochester

#### Key Activities
- Safety and efficacy in animals and human trials
- Regulatory approvals and compliance
- Development of manufacturing and distribution processes
- Develop customer support and technical personnel
- Assure supply of radioisotopes
- Reimbursement

#### Key Resources
- UI Laboratory/Schultz
- BioVentures Center Lab/Viewpoint
- SBIR Funding
- UIRF
- Patent Rights
- Clinical Expertise
- Technical Expertise
- Business Expertise

#### Value Propositions
- Safety and efficacy in animals and human trials
- Regulatory approvals and compliance
- Development of manufacturing and distribution processes
- Develop customer support and technical personnel
- Assure supply of radioisotopes

#### Customer Relationships
- Big Pharma
- Specialized Pharma - Cancer Therapy & Imaging
- Contract Research Organizations
- Patient Advocacy Groups
- Physicians and Patients
- Melanoma Clinics
- Healthcare Organizations
- Patient Advocacy Groups
- Sales and Distribution
- Clinical Site Support

#### Customer Segments
- Metastatic melanoma patients
- Physicians caring for metastatic melanoma patients
- Nuclear Medicine physicians and staff
- Healthcare organizations that care for metastatic melanoma patients
- Pharma companies expanding presence in melanoma market
- CMS and Reimbursement
- FDA Regulatory

#### Cost Structure
- Safety and efficacy in animals and human trials
- Regulatory approvals and compliance
- Development of manufacturing and distribution
- Customer support and technical personnel
- Radioisotopes

#### Revenue Streams
- Build value toward acquisition.

---

Viewpoint's radiopharmaceutical is a good prospect for acquisition for several specialized pharma. Our product uses a companion imaging scan to select patients that can benefit from our therapy and predict response. Melanoma develops resistance to all current approved drugs on the market today. Our product can be used as an adjuvant with any of approved therapy.
We didn’t know what we didn’t know...

### Business Model Canvas-1

<table>
<thead>
<tr>
<th>Key Partners</th>
<th>Value Propositions</th>
<th>Customer Segments</th>
</tr>
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<tbody>
<tr>
<td>• National Institutes of Health&lt;br&gt;• UI Research Foundation&lt;br&gt;• UI Ventures&lt;br&gt;• Economic Development Corporation&lt;br&gt;• Iowa Economic Development Authority&lt;br&gt;• Private Equity Investors&lt;br&gt;• Department of Energy&lt;br&gt;• Lantheus Medical Imaging&lt;br&gt;• Supply Chain Manufacturers&lt;br&gt;• Eckert Ziegler Eurotope&lt;br&gt;• Midwest Melanoma Partnership&lt;br&gt;• University of Iowa&lt;br&gt;• Mayo Clinic, Rochester</td>
<td>• Viewpoint has a radiopharmaceutical that will safely treat metastatic melanoma and save lives&lt;br&gt;• Viewpoint’s radiopharmaceutical is a good prospect for acquisition for several specialized pharma&lt;br&gt;• Our product uses a companion imaging scan to select patients that can benefit from our therapy and predict response.</td>
<td>• Metastatic melanoma patients&lt;br&gt;• Physicians caring for metastatic melanoma patients&lt;br&gt;• Pharma companies expanding presence in melanoma market&lt;br&gt;• CMS and Reimbursement&lt;br&gt;• FDA Regulatory</td>
</tr>
</tbody>
</table>
So, here’s what we did
Here’s what else we did

- Radiopharmaceutical Sciences Meeting
  Dresden, Germany

- Global Radiation Oncology Group
  China

- World Melanoma Research Congress
  Brisbane, Australia

Germany; China; Australia
And, here’s who we talked to

Memorial Sloan Kettering Cancer Center
Medical oncologists would prescribe our therapy with an expectation of 6 months increased survival and a 20% response rate \((n = 16; 34)\).

Dr. Mohammed Milhem (Founder Midwest Melanoma Partnership) “6 mo improved survival in 20% of patients is exciting…”
### Business Model Canvas - refined

#### Key Partners
- National Institutes of Health
- UI Research Foundation
- UI Ventures
- Economic Development Corporation
- Iowa Economic Development Authority
- Private Equity Investors
- Department of Energy
- Lantheus Medical Imaging
- Supply Chain Manufacturers
- Eckert Ziegler Eurotope
- National Cancer Institute
- Midwest Melanoma Partnership
- University of Iowa
- Mayo Clinic, Rochester

#### Key Activities
- Safety and efficacy in animals and human trials
- Regulatory approvals and compliance
- Development of manufacturing and distribution processes
- Customer support and technical personnel
- Radioisotopes

#### Value Proposition
- Medical oncologists will prescribe our product because it will provide an improvement in overall survival of at least 6 months with a response rate of 20% for patients for whom all current therapies have failed.

#### Customers
- Medical Oncologists caring for metastatic melanoma patients *(decision makers)*

#### Channels
- Melanoma Clinics
- Healthcare Organizations
- Patient Advocacy Groups
- Sales and Distribution
- Clinical Site Support

#### Revenue Streams
- Build value toward acquisition.

#### Business Model
- Value Proposition
- Customer Segments
- Customer Relationships
- Revenue Streams
- Costs
- Key Resources
- Key Activities
- Key Partnerships
- Value Proposition

---

**Refined understanding**
We thought we had two products; a therapeutic and a companion diagnostic, but finally after n = 40.

“Don’t do the diagnostic. It is going to hurt your therapeutic at best!”

George Segall MD; Director of Nuclear Medicine, Stanford University Palo Alto Veterans Administration Hospitalcal

We learned we have one!
Is ICORPS right for us?

The end of the beginning...

- TEAM CHEMISTRY
- OPEN MIND
- TIME TO DEVOTE
- START RIGHT NOW

“IPO
Late stage clinical trials
Early Exit

BEGIN...
...with the END in mind!

“Business is easy!”
Nancy Kamei PhD

“Business is NOT the easy part!”
ICORPS is right for us.

- START PLANNING INTERVIEWS NOW
- REVIEW YOUR PLAN/RESULTS EVERY WEEK
- CLEAR YOUR CALENDAR NOW
- BE PREPARED TO BE INTERRUPTED

- Interviews are not selling your product
- Interviews are not pitching your company
- Interviews are open ended conversations about your market space
THANK YOU!
Submit your questions through the Q&A chat box