I-CORPS AT NIH INFORMATION SESSION

September 25, 2019

NATIONAL CANCER INSTITUTE
SBIR
DEVELOPMENT
CENTER

- If you have questions, **please type them in the chat box**. Questions will be answered after alumni presentations.
- Presentation **slides will be made available** a few days after the webinar.
- Please complete the post-event survey on **bit.ly/ncisbirfeedback**

For additional questions, contact **icorps@mail.nih.gov**

I-CORPS at NIH

Informational Session

Application deadline: Tuesday, October 22, 2019

More information: https://sbir.cancer.gov/icorps

Contact Email: icorps@mail.nih.gov

Today's Speakers

Christie Canaria
I-Corps at NIH Program Manager
NIH

Edmund Pendleton
I-Corps at NIH Lead Instructor
DC I-Corps

Michael Johnson
I-Corps at NIH Alum
CEO, Visikol

I-CORPS at NIH

Why I-Corps?

SBIR & STTR

I-Corps™ at NIH

I-Corps *Overview*

September 25, 2019

Invention

Innovation

What's the *difference?*

Invention

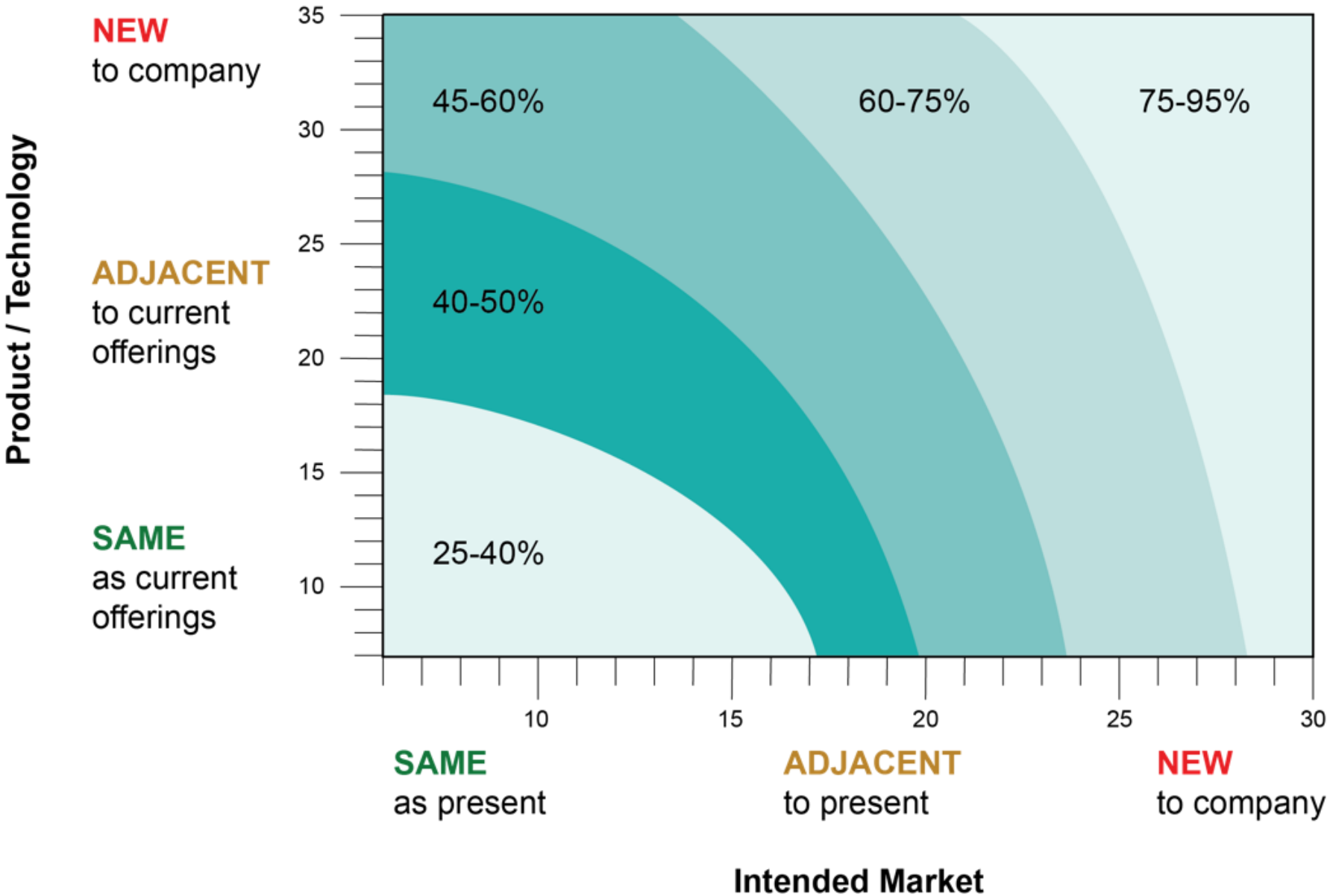
about creating "things"

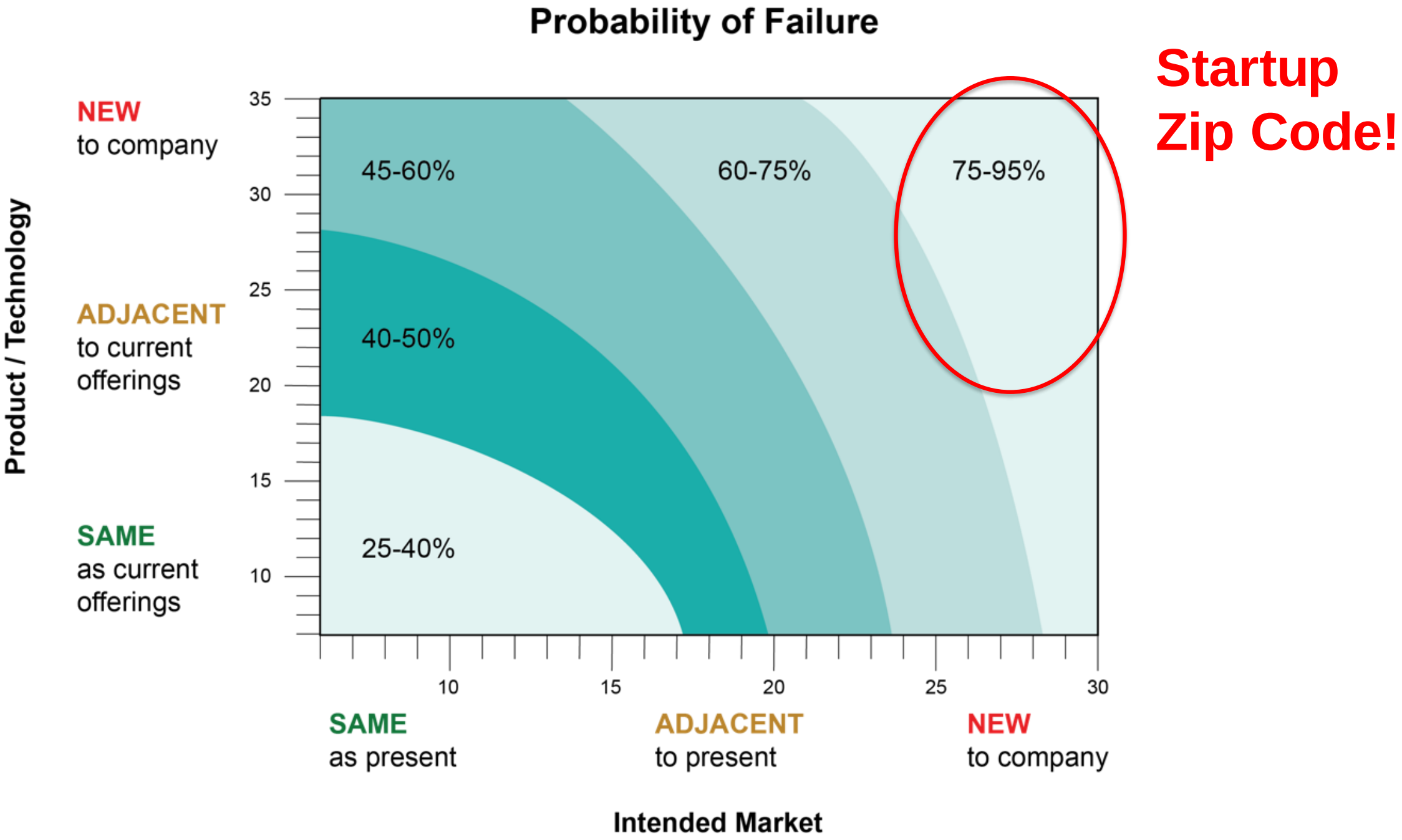
Innovation

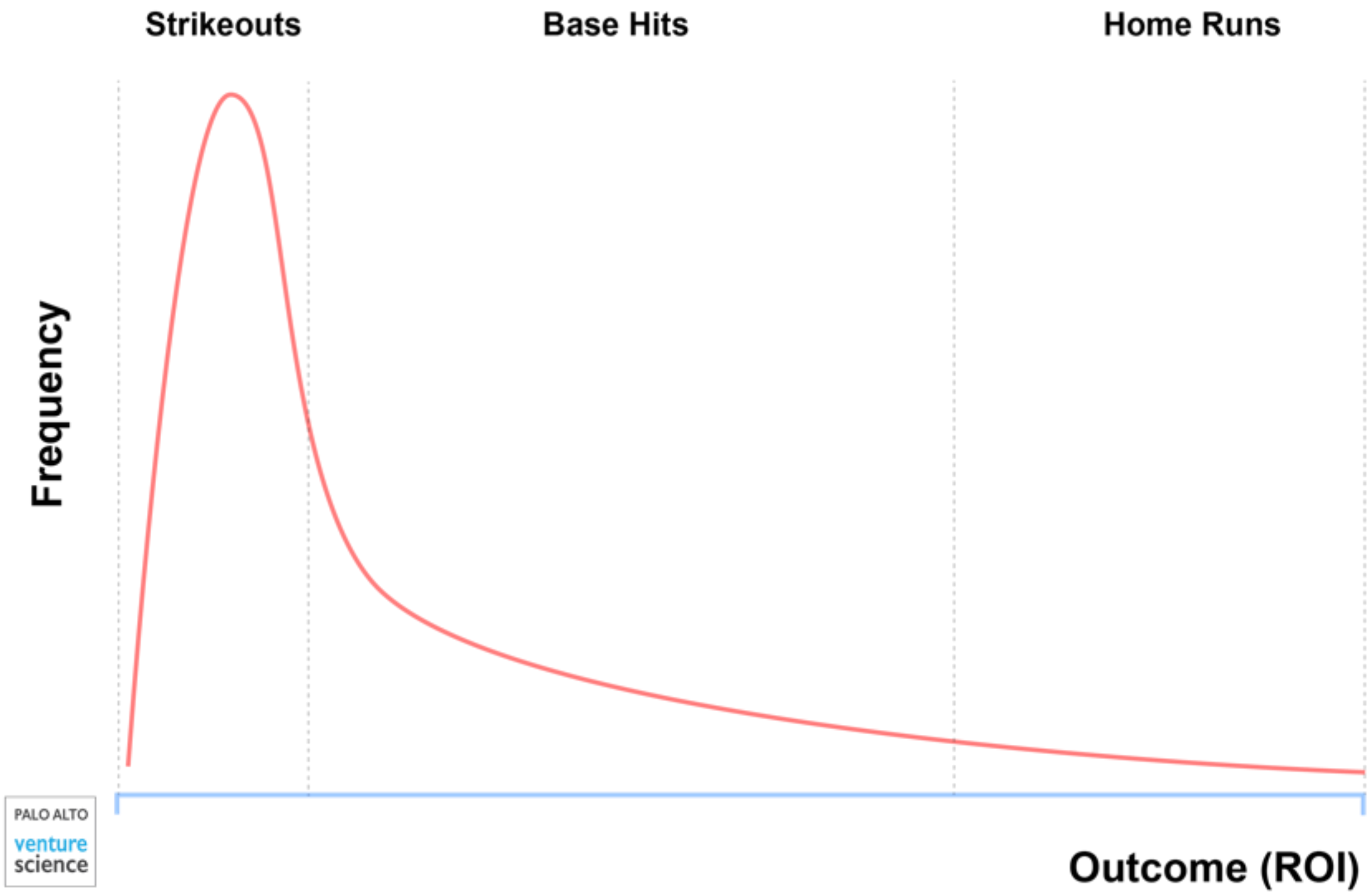
about finding solutions to unmet needs

The Innovation *Challenge*

Probability of Failure




Probability of Failure
Startup Zip Code!
NEW
to company
ADJACENT
to current offerings
SAME
as current offerings
Product / Technology
35
30
25
20
15
10
45-60%
60-75%
75-95%
40-50%
25-40%
10
15
20
25
30
SAME
as present
ADJACENT
to present
NEW
to company
Intended Market


Strikeouts
Base Hits
Home Runs
Frequency
PALO ALTO
venture
science
Outcome (ROI)

What drives *this failure rate?*

More startups fail from a

lack of customers

than from product / tech failure

More startups fail from a

lack of customers

than from product / tech failure

TOP 10 STARTUP MISTAKES

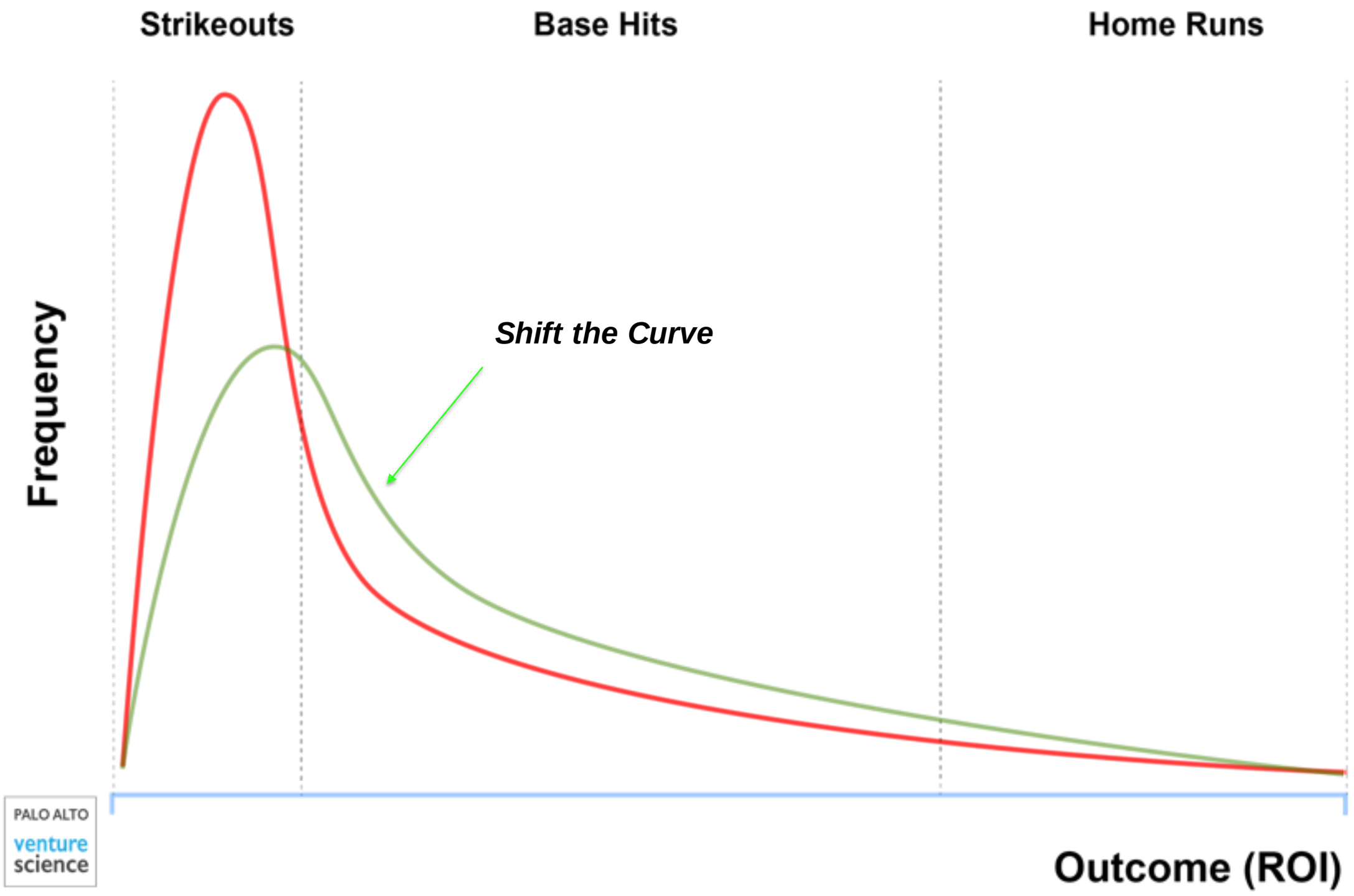
100 First Hits
www.100FirstHits.com

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*


Strikeouts
Base Hits
Home Runs
Frequency
Shift the Curve
PALO ALTO
venture
science
Outcome (ROI)

How will you
improve your odds?

Get *out* of the building!

Talk (listen)
to customers…

Essence of *Lean Approach*

Use a

systematic

approach…

...to identify
unmet needs.

Build, Show, and Hope!


Build,
Show, and
Hope!

Build,

Measure,

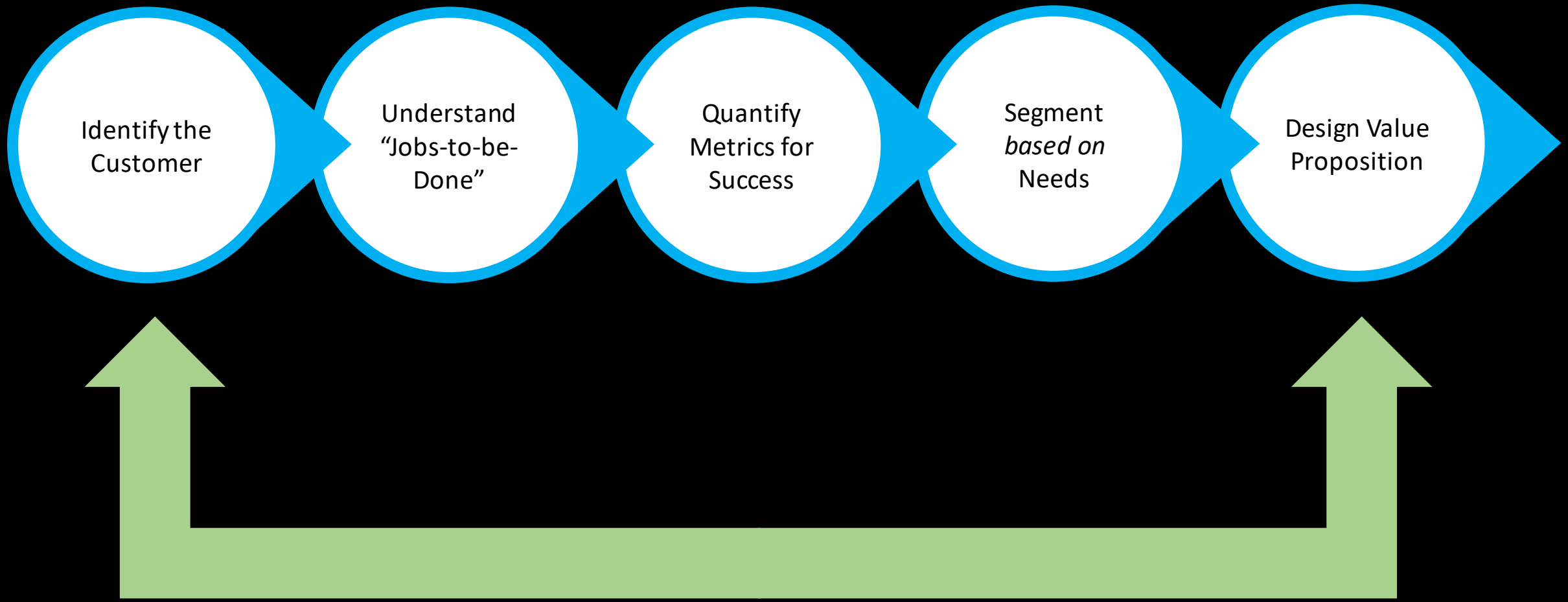
and Learn!

Customer *Discovery*

What are you *trying to discover?*

Customer Discovery

Process Steps


Identify the Customer
Understand "Jobs-to-be-Done"
Quantify Metrics for Success
Segment *based on* Needs
Design Value Proposition

Key Partners

Key Activities

Key Resources

Value Propositions

Customer Relationships

Channels

Customer Segments

Cost Structure

Revenue Streams

Key Partners

?

Key Activities

?

Key Resources

?

Value Propositions

Customer Relationships

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Channels

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Customer Segments

Cost Structure

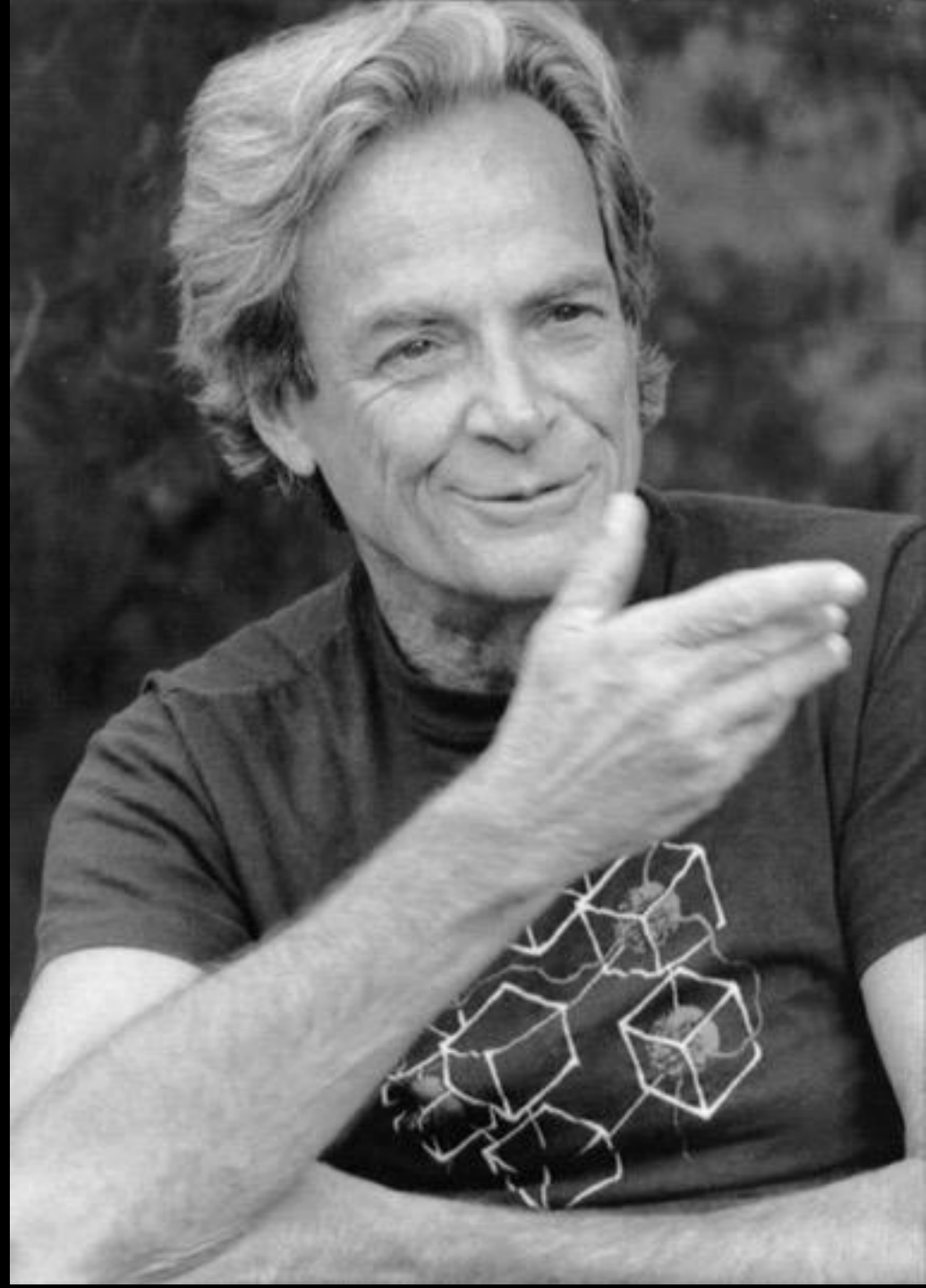
?

Revenue Streams

?

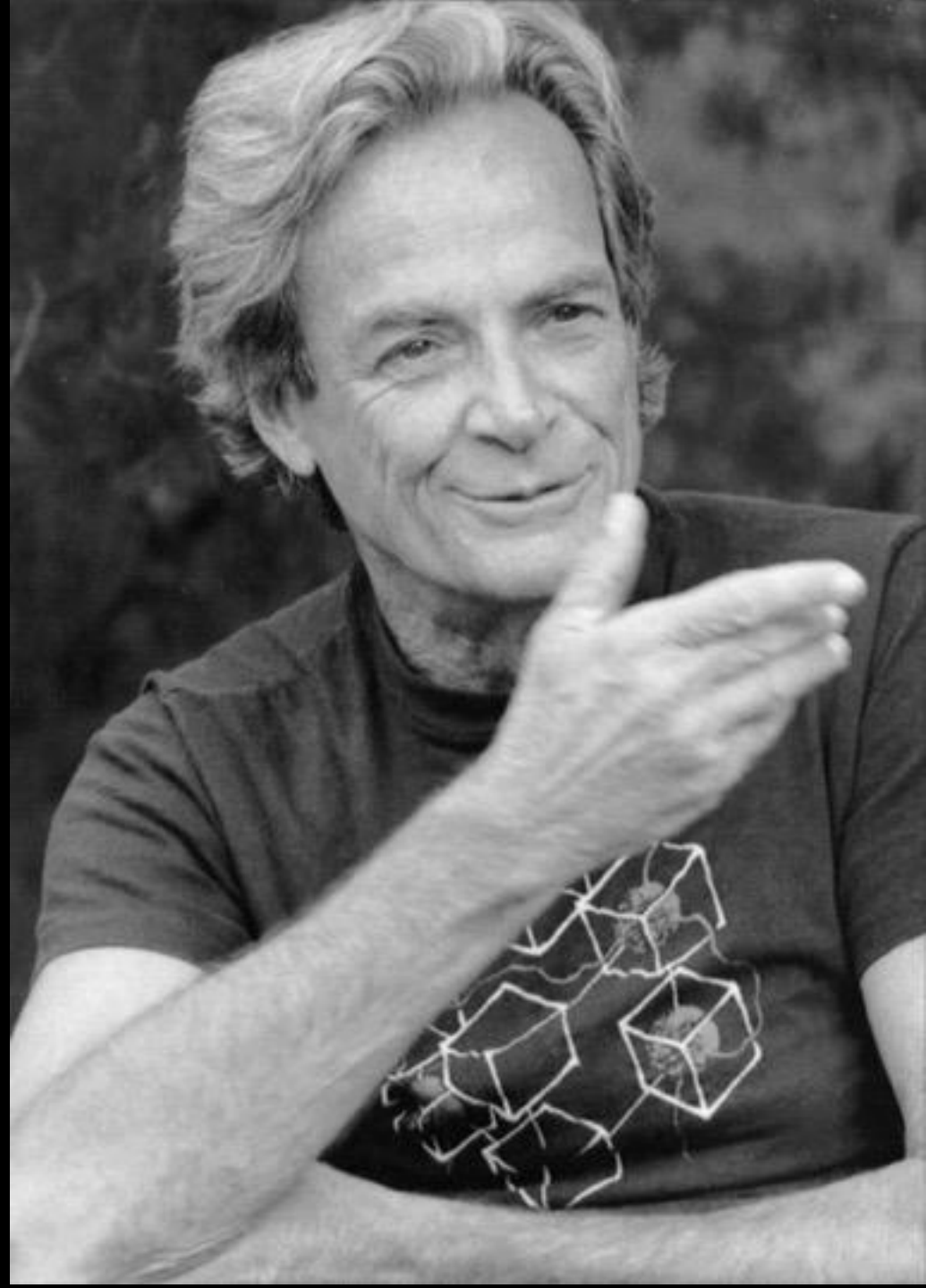
"I have approximate answers and possible beliefs and different degrees of certainty about different things

– Richard Feynman



"I have approximate answers and possible beliefs and different degrees of certainty about different things ***but I'm not absolutely sure about anything."***

– Richard Feynman



We are ALL *stakeholders…*

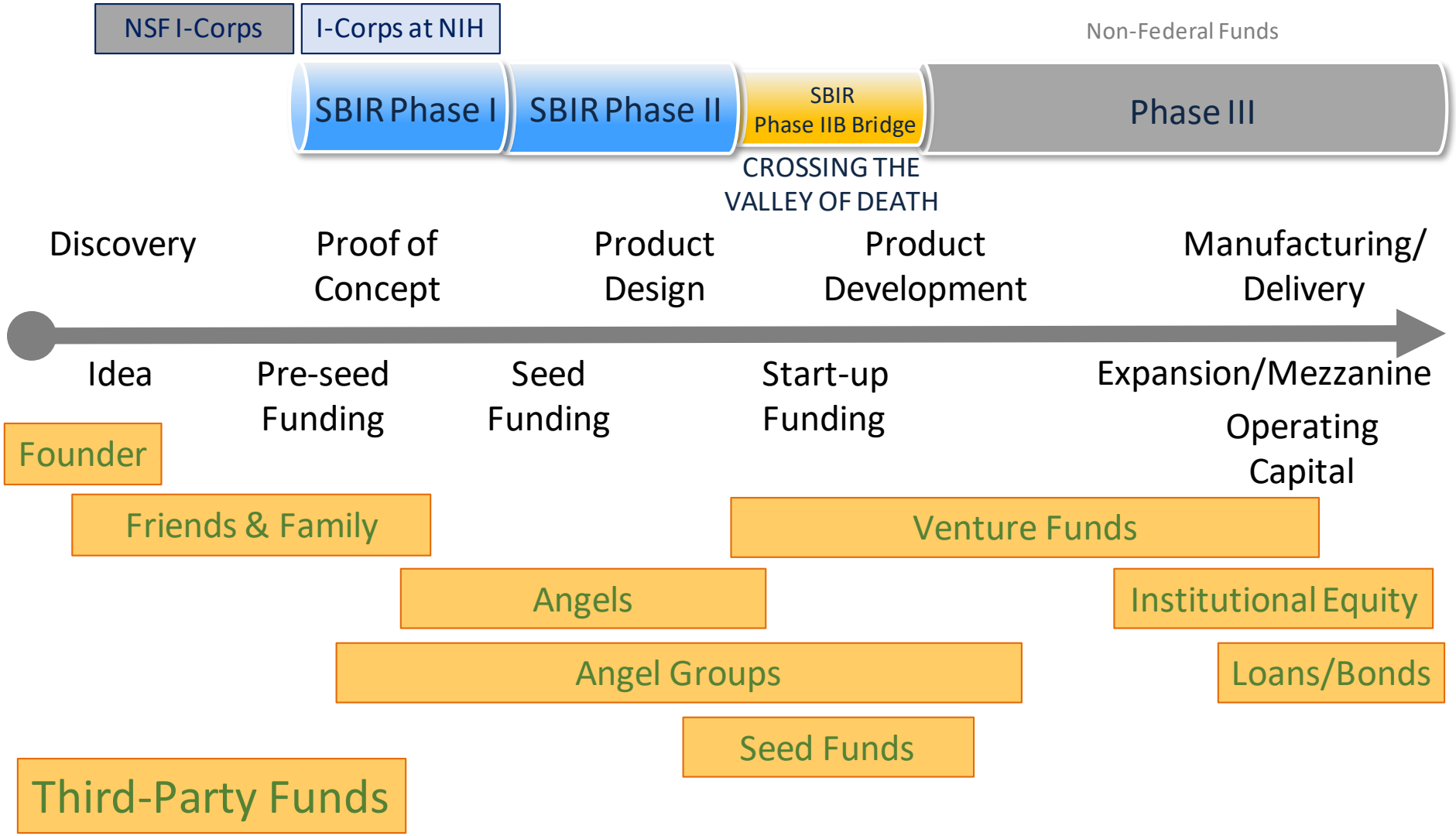
...and want to

improve your odds.

I-CORPS at NIH

How to Apply

Assorted Resources for Small Business



PA-19-029 Administrative Supplement

I-CORPS at NIH

$55,000 budget cap – New Dates https://grants.nih.gov/grants/guide/notice-files/NOT-CA-19-067.html

Application Due Date	***October 22, 2019***	***January 21, 2020***
Phone Interview	***December 19-20, 2019 (estimated)***	***March 2-6 (estimated)***
Kick-off/Close-out Venue	***TBD***	***TBD***
Course Kick-off	***February 24-27, 2020 (Monday - Thursday)***	***May 4-7, 2020 (Monday - Thursday)***
Web-Ex Courses	***Wednesdays, 1-5PM ET*** ***March 4*** ***March 11*** ***March 18*** ***March 25*** ***April 1*** ***April 8***	***Wednesdays, 1-5PM ET*** ***May 13*** ***May 20*** ***May 27*** ***June 3*** ***June 10*** ***June 17***
Course Close-out/ Lessons-Learned	***April 14-15, 2020 (Tuesday-Wednesday)***	***June 22-23, 2020 (Monday-Tuesday)***

https://grants.nih.gov/grants/guide/pa-files/PA-19-029.html

Next Application Deadline: October 22, 2019

23 Participating ICs in 2019-20

I-CORPS at NIH

- National Cancer Institute (NCI)
- National Eye Institute (NEI)
- 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)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- 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 General Medical Sciences (NIGMS)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Center for Complementary and Integrative Health (NCCIH)
- National Center for Advancing Translational Sciences (NCATS)
- National Heart, Lung, and Blood Institute (NHLBI)
- Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)
- National Center for Emerging and Zoonotic Infectious Diseases (NCEZID/CDC)
- National Institute for Occupational Safety and Health (NIOSH/CDC)
- *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
- National Institute on Minority Health and Health Disparities (NIMHD)

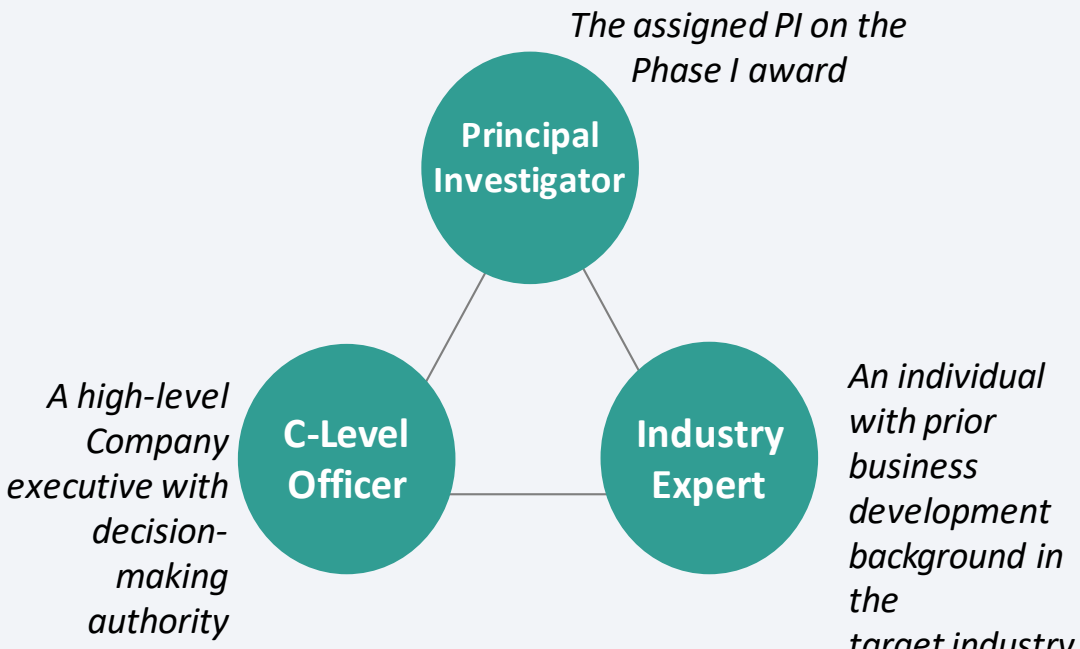
Program basics

I-CORPS at NIH

REQUIREMENT

Eligible SBIR/STTR grantees are required to assemble **3-member teams** that will work collaboratively to complete the activities and assignments required by the I-Corps curriculum.

THE I-CORPS TEAM



INSTRUCTORS

- Experienced, business-savvy instructors work closely with project teams to help them explore potential markets for their Federally funded innovations
- Instructors possess specific domain expertise in the major product areas that comprise the biomedical industry

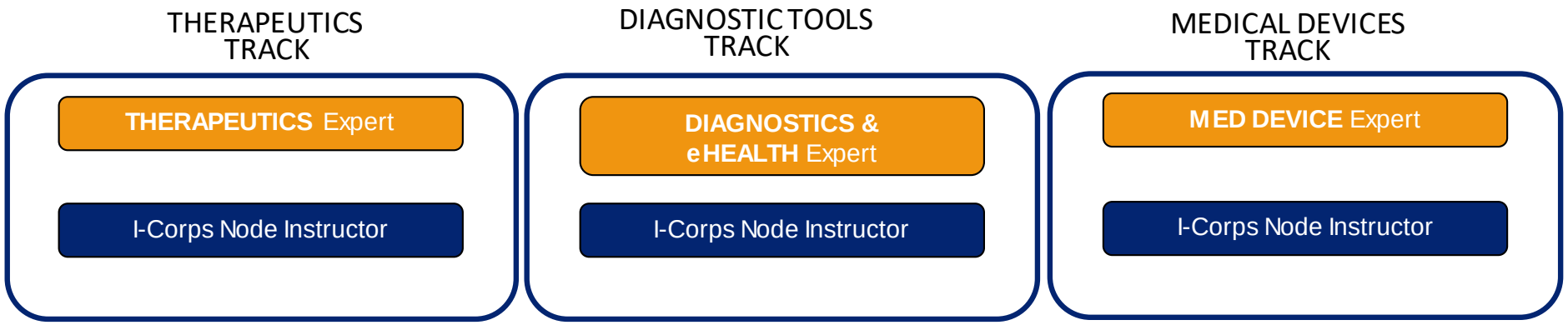
AWARD

- The selected project teams receive grant supplement funding ($55,000) to support entrepreneurial training, mentorship, and collaboration opportunities for translating their research ideas into viable products.

ELIGIBILITY

- To be eligible, a company must have an ACTIVE Phase I SBIR or STTR grant from one of the 21 participating NIH and CDC Institutes and Centers
  The predicate Phase I grant **must** have project and budget timelines that are active from application date through end of I-Corps course syllabus.

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

Program for SBIR/STTR Phase I awardees 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")

I-CORPS at NIH

Stories from the Trenches

Erin Edwards PhD
Industry Expert

Graeme Gardner PhD
PI

Michael Johnson PhD
CEO

Team 167: Visikol

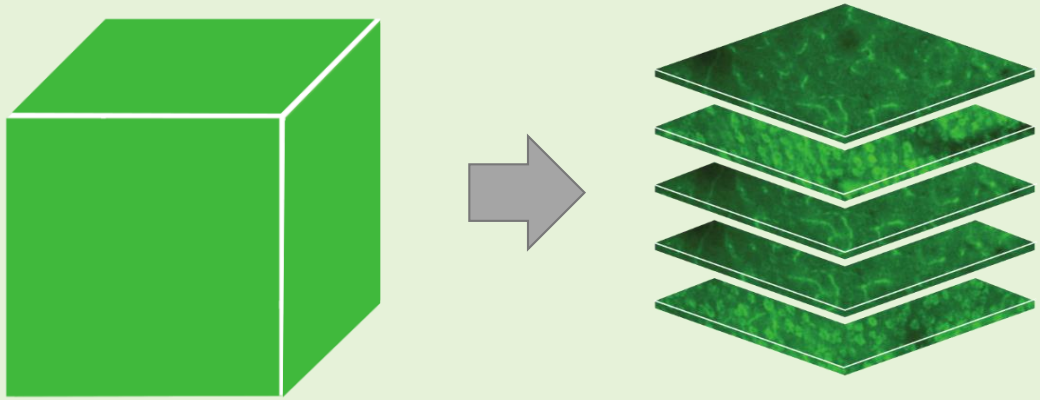
Where We Started

- As a company we have developed a suite of reagents and kits for 3D tissue imaging that have been used by over 500 research labs from around the world
- We signed OEM relationships with Thermo Fisher, Millipore and Abcam to sell these products
- Currently we operate as a CRO focused on drug discovery and count the following companies as Clients
- Our long term goal is to use our technologies in a clinical context to improve patient outcomes

Where We Started

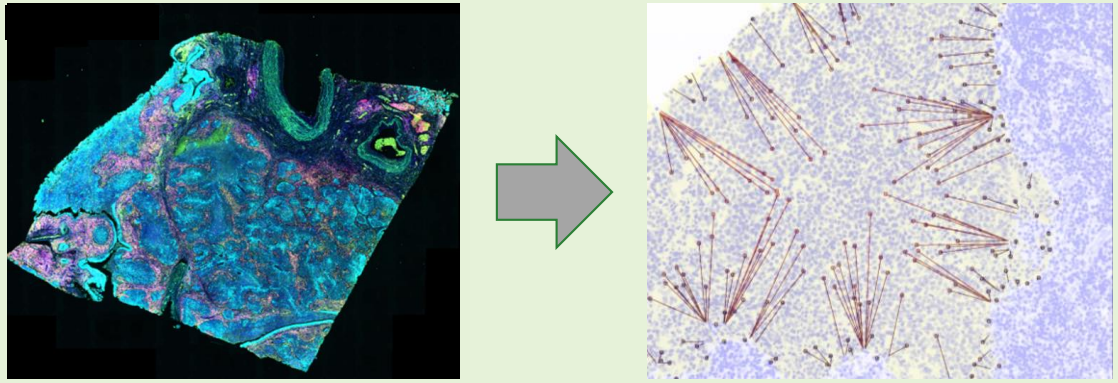
- We have tools for imaging tissues in 3D as well as proprietary image analysis software
- We focused our Phase I project on leveraging these tools to develop an automated tissue processing approach for transforming clinical breast cancer FFPE tissues into quantitative three-dimensional histology data sets

3D Tissue Imaging



3D Data

AI Image Analysis



3Screen™

VISIKOL™

The Problem

Coming into I-Corps we had a very cool technology and hit our Phase I objectives but had a major problem – ***we had a solution looking for a problem***…..

1. We had no idea what clinical value our technology would have for patients
2. We did not understand if our test was possible with the current pathology workflow
3. We had no understanding of how much a test like ours could even cost
4. We did not have a reliable source of tissues and data

Our main I-Corps goal was to identify how our tool could improve patient outcomes and if it could do so in a financially viable manner

Early Feedback

We thought our tool might be helpful for improving breast cancer diagnosis.

"You need to find a specific clinical problem that your tool can address such as deciding which treatment will be most effective for a patient, reducing false negatives or determining if a patient should or should not get chemotherapy and then work backwards from there."

Ciaran Mannion M.D. Hackensack University Medical Center

- This is where our idea to focus on the sentinel lymph node came from.
- The sentinel lymph node is removed in breast cancer patients to determine if the cancer has metastasized and traveled throughout the body. Currently a large tissue is sectioned into a few slices and cancer cells can easily be missed resulting in false negatives.

Feedback

We thought our tool would better inform how to treat breast cancer patients

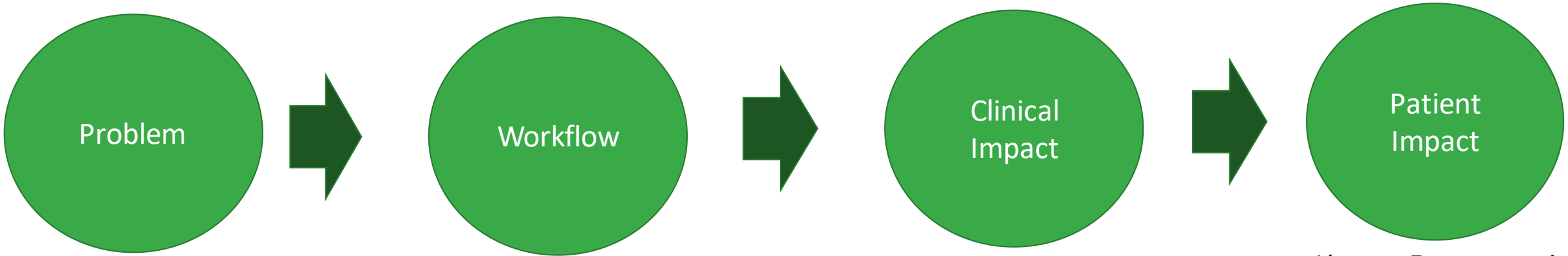
"Reducing false negative sentinel lymph node results for breast cancer will have zero impact on the patient as only huge >2mm metastases will change the clinical treatment practice and these are easily detected today."

Bonnie Balzer M.D., PhD – Cedars Sinai

"Detecting a single cell in a melanoma sentinel node will change the clinical treatment approach dramatically and reducing false negatives will improve patient outcomes in a meaningful way."

Jing Zhai M.D. – Cedars Sinai

Summary



5-19% false negative in sentinel lymph node procedure

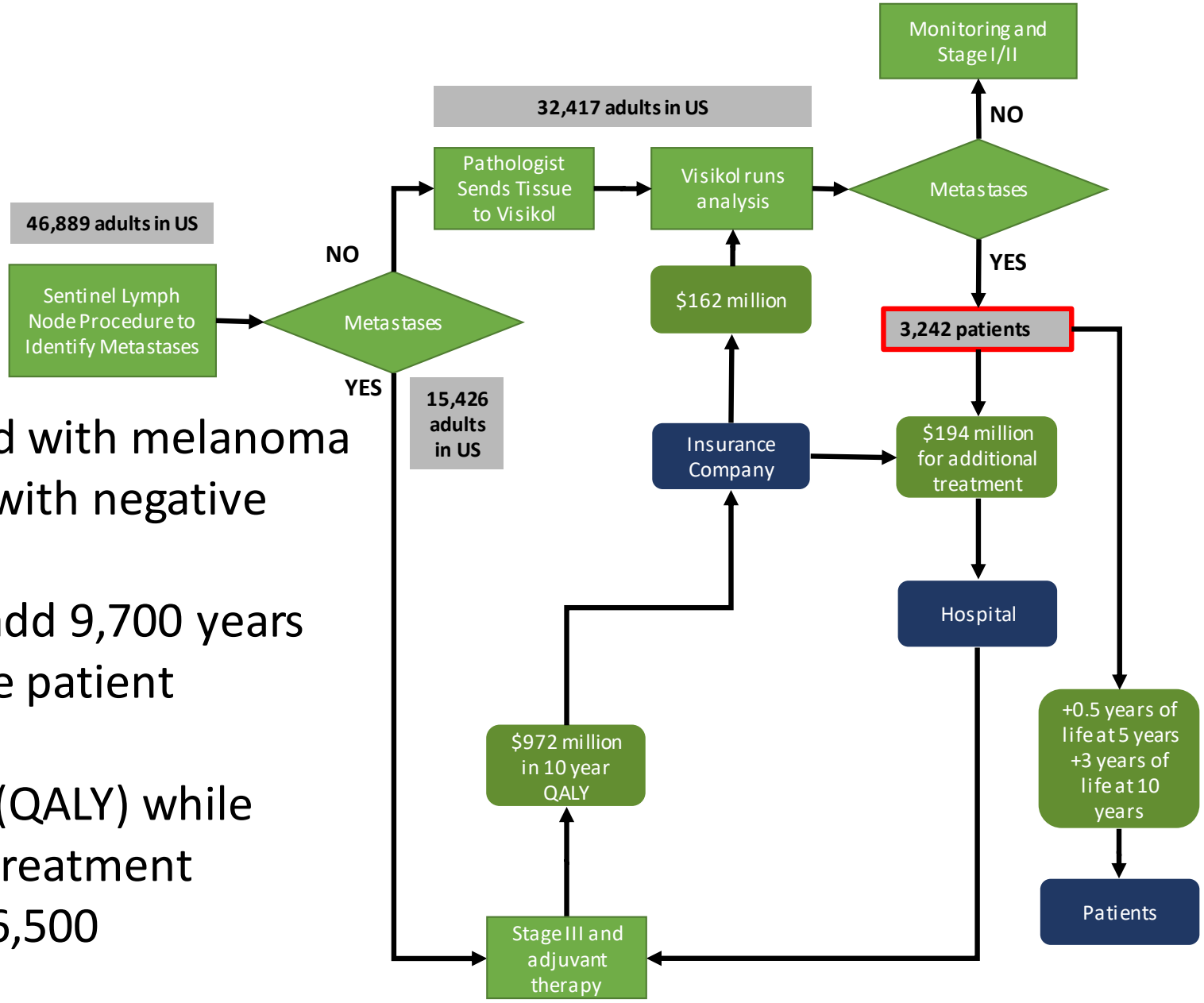
Pathologists will send tissues from patients for follow up analysis to 3rd party labs

Patients do not receive chemotherapy and other more aggressive treatments as their cancer is thought to not be metastatic

+½ year, 5-year survival
+3 year, 10-year survival

Healthcare Economics

- 95,500 patients per year diagnosed with melanoma
- Our target market are all patients with negative SLNB
- If our test is 100% accurate it will add 9,700 years of life over a ten-year period to the patient population
- This will add $972 million in value (QALY) while costing $194 million in additional treatment
- Max price of our test would be $16,500
- Initially will be a second line test



Healthcare Economics

Our interviews gave us several important aspects on pricing:

- Every patient will pay out of pocket at $1,000 per test → $32M market
- Insurance companies would reimburse $2-4,000 for the test → $64M to $128M market

We can then actually use these numbers to determine the quantitative endpoints for accuracy and false negative detection within our Phase II project

End Points For Phase II Study

We know based upon this data what our specific endpoints are for our Phase II study for accuracy and false negatives and also generally what our overhead cost per test can be

NEGATIVE SLNB QALY VALUE

ACCURACY	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
100	$0	$3,000	$6,000	$9,000	$12,000	$15,000	$18,000	$21,000	$24,000	$27,000	$30,000	$33,000	$36,000	$39,000	$42,000	$45,000
90	$0	$2,700	$5,400	$8,100	$10,800	$13,500	$16,200	$18,900	$21,600	$24,300	$27,000	$29,700	$32,400	$35,100	$37,800	$40,500
80	$0	$2,400	$4,800	$7,200	$9,600	$12,000	$14,400	$16,800	$19,200	$21,600	$24,000	$26,400	$28,800	$31,200	$33,600	$36,000
70	$0	$2,100	$4,200	$6,300	$8,400	$10,500	$12,600	$14,700	$16,800	$18,900	$21,000	$23,100	$25,200	$27,300	$29,400	$31,500
60	$0	$1,800	$3,600	$5,400	$7,200	$9,000	$10,800	$12,600	$14,400	$16,200	$18,000	$19,800	$21,600	$23,400	$25,200	$27,000
50	$0	$1,500	$3,000	$4,500	$6,000	$7,500	$9,000	$10,500	$12,000	$13,500	$15,000	$16,500	$18,000	$19,500	$21,000	$22,500
40	$0	$1,200	$2,400	$3,600	$4,800	$6,000	$7,200	$8,400	$9,600	$10,800	$12,000	$13,200	$14,400	$15,600	$16,800	$18,000
30	$0	$900	$1,800	$2,700	$3,600	$4,500	$5,400	$6,300	$7,200	$8,100	$9,000	$9,900	$10,800	$11,700	$12,600	$13,500
20	$0	$600	$1,200	$1,800	$2,400	$3,000	$3,600	$4,200	$4,800	$5,400	$6,000	$6,600	$7,200	$7,800	$8,400	$9,000
10	$0	$300	$600	$900	$1,200	$1,500	$1,800	$2,100	$2,400	$2,700	$3,000	$3,300	$3,600	$3,900	$4,200	$4,500
0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0

FALSE NEGATIVE

Data Access and Customer

- Through our Phase II study we identified that Cedars-Sinai, Baylor and UConn have the tissues and data that we need for our study
- We have subsequently parterned with Cedars-Sinai on our Phase II project
- We identified that our customer is actually not the Pathologist but instead the Clinical Oncologist

Next Steps

Immediate next steps

- Quantitatively determine the number of images and tissue volume to image to identify a false negative SLNB
- Purchase a new confocal microscope with improved imaging depth
- File provisional patent applications on tissue processing approach, image analysis approach and general approach to assay
- We are going to fund these initial efforts through our current business profits

We submitted a Phase II grant in September 2019

- Conduct retrospective study on 170 negative sentinel lymph node melanoma biopsies

Thanks!

Michael Johnson PhD

I-CORPS at NIH

Q&A

Type your questions in the chat box.