

Career Development Series 2020

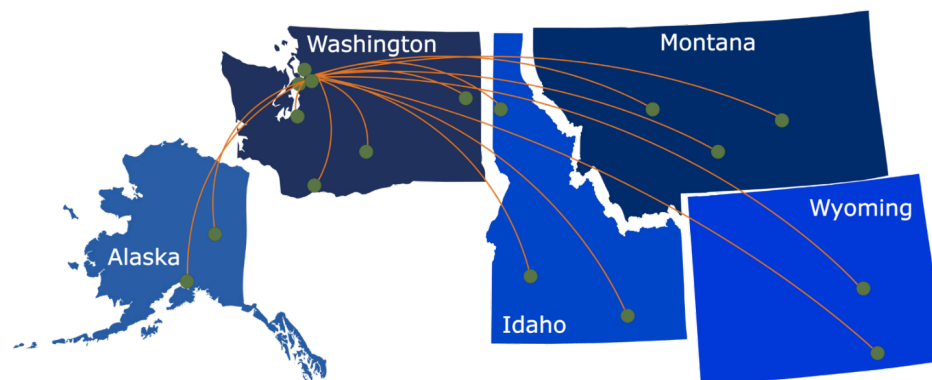
Entrepreneurship in Biomedicine: A Multi-faceted Approach

Presentation will begin at 12:00 PM (PT)



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What We Offer:

- 1 Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.
- 2 Community Engagement:** Members can connect with regional and community based practice networks
- 3 Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.
- 4 Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

Contact our Director of Research Development



- Project Consultation
- Strategic Direction
- Resources and Networking

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Feedback

At the end of the seminar, a link to the feedback survey
will be sent to the email address you used to register.

Career Development Series 2020

Entrepreneurship in Biomedicine: A Multi-faceted Approach

Presented by Robert H. Coker, PhD, FACSM, FTOS
Professor, Institute of Arctic Biology, University of Alaska Fairbanks



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Learning Objectives

- 1 Understand value proposition and customer segments
- 2 Describe the nine elements of a business model
- 3 How to “Get out of the building!” and why it is important
- 4 Recognize the value of the SBIR/STTR programs

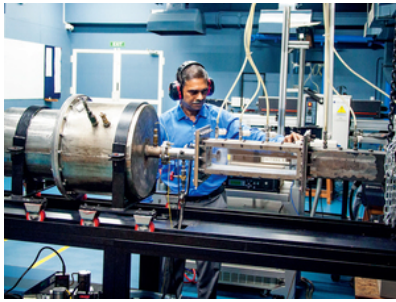
Entrepreneurship in Biomedicine

- Healthcare, Pharma and Life Sciences industry is changing with expiring business models – business plans are outdated
- Highly regulated, expensive and complex industry with constant challenges to effective care

We MUST minimize wasted time and eradicate ineffective models

Entrepreneurship in Biomedicine

Unique and especially difficult jobs require specific tools



Thermo acoustic burners
to improve jet fuel efficiency

OR



Robotics accelerating
medical device production

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Entrepreneurship in Biomedicine

What are the best tools for entrepreneurship?

Have you thought about it from a customer's perspective?

What is your commercialization plan; can you develop one?



Entrepreneurship in Biomedicine

Business Model Canvas developed by Alexander Osterwalder in 2004

- Integrates infrastructure, value, customers and finances
- Hands on tool that improves understanding, discussion, creativity and analysis



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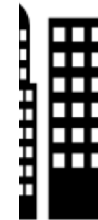
Business Model Canvas

**COGNITIVE
OVERLOAD**

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Customer Discovery



'There are no facts inside your building, so get the heck outside'

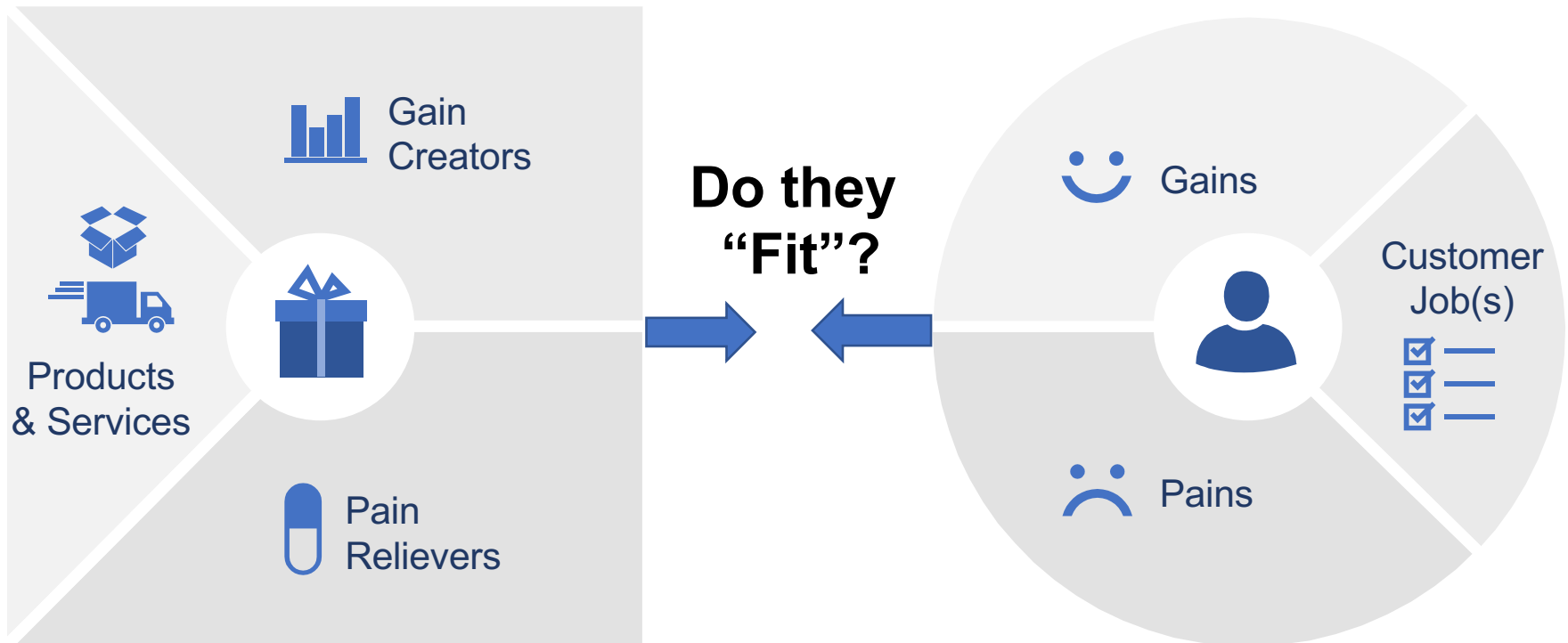
- Steve Blank

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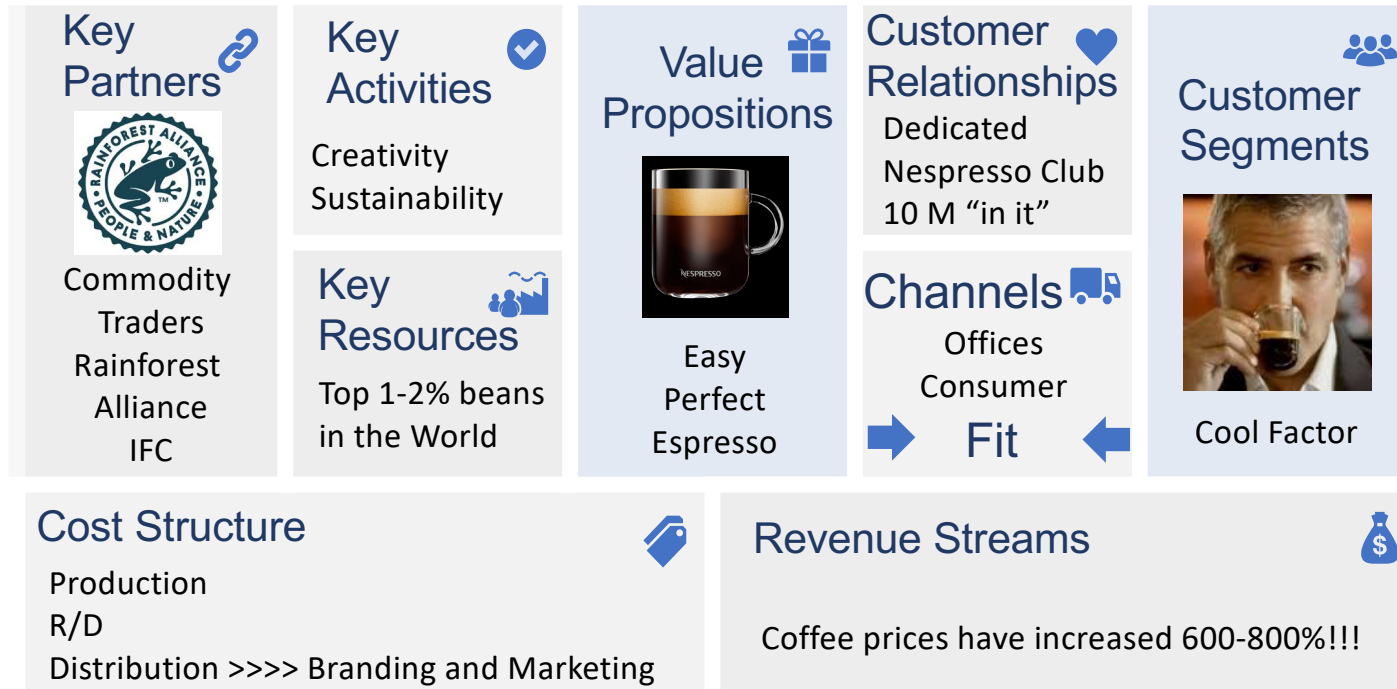
Value Proposition Canvas



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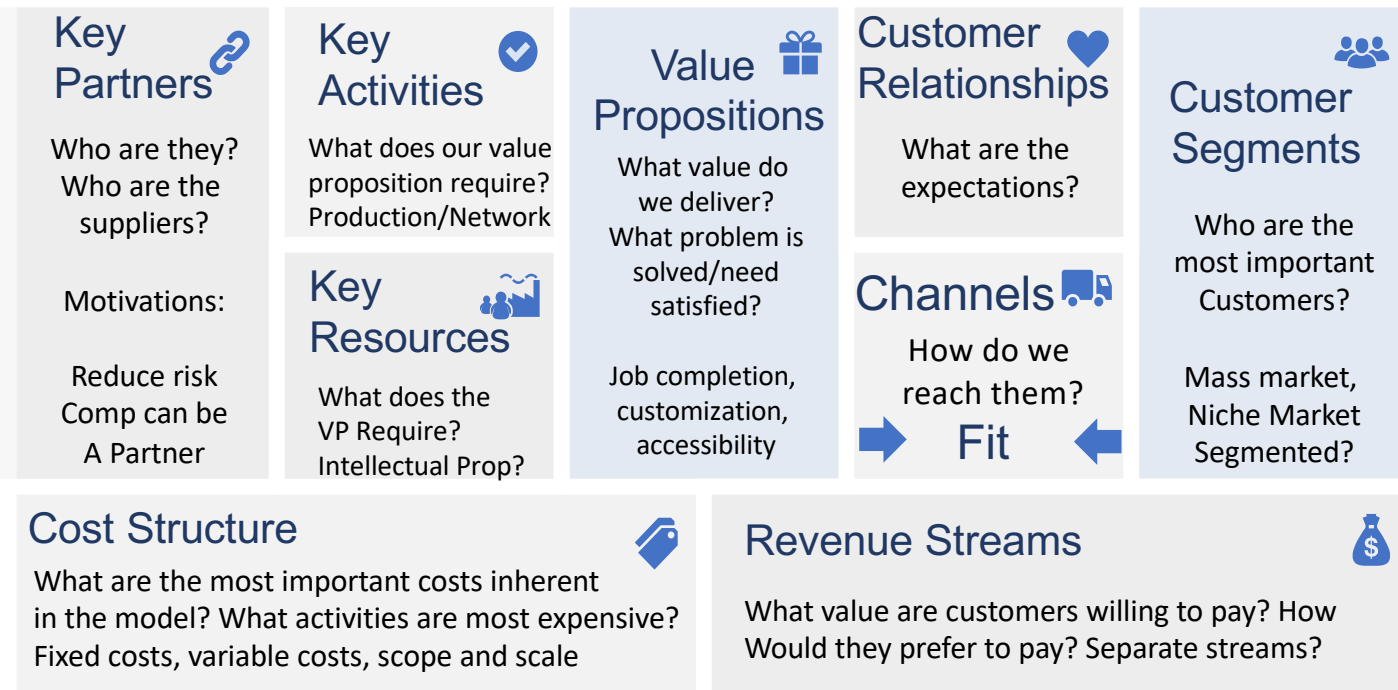
Business Model Canvas – Deep Dive Example



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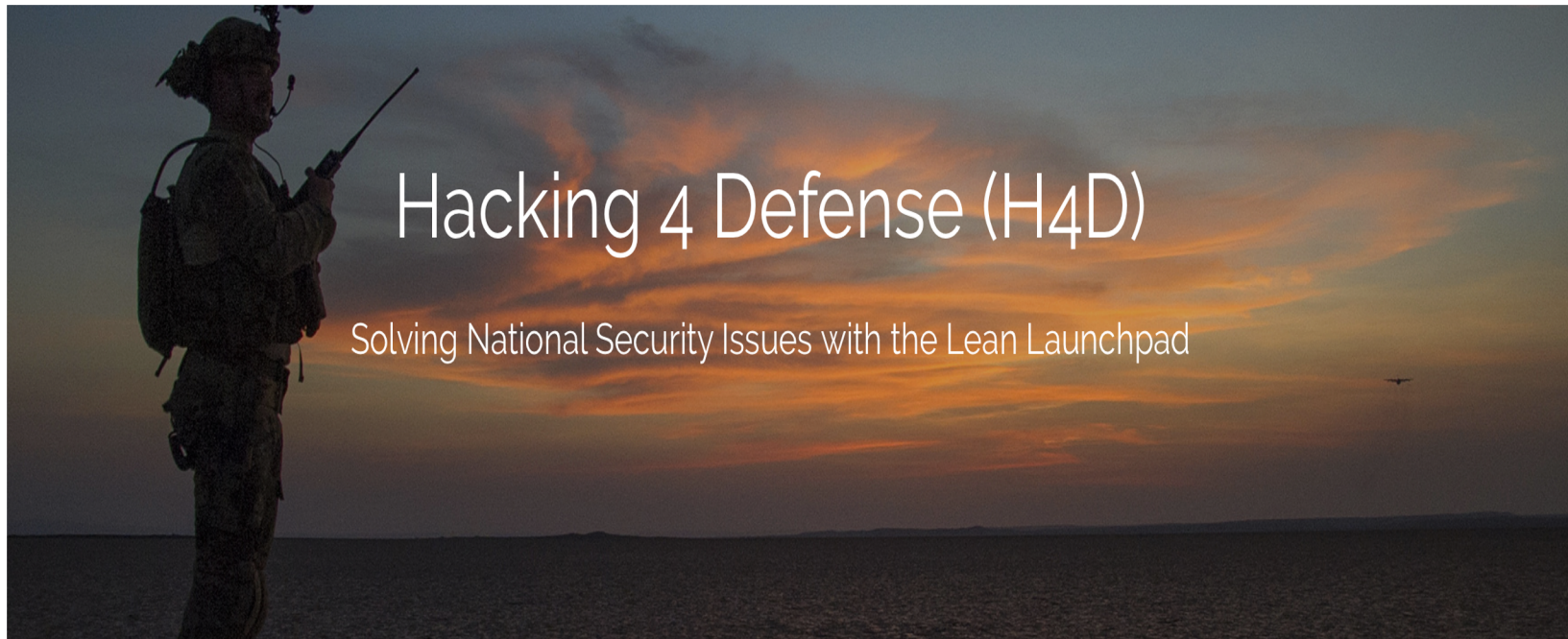
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Business Model Canvas – Questions to Ask



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Mission Model Canvas



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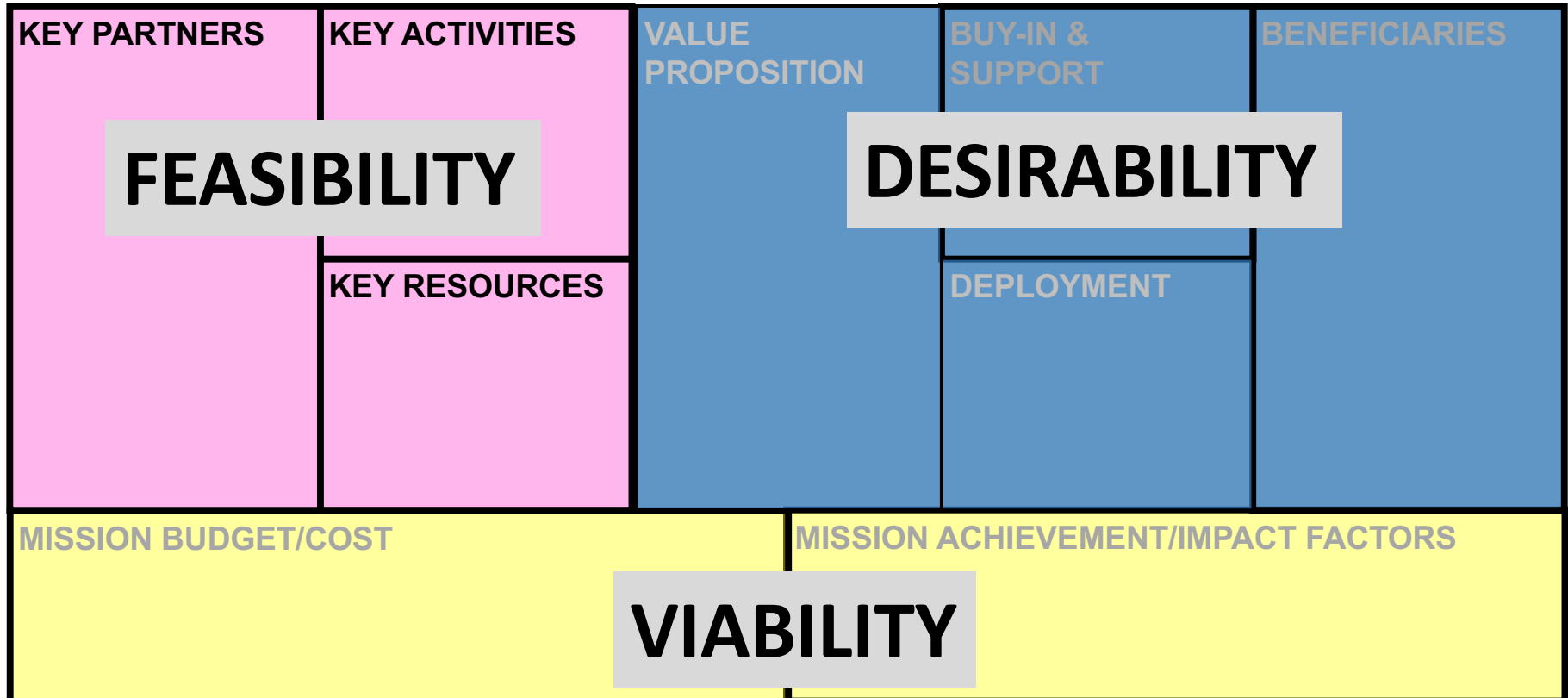
The Mission Model Canvas

Mission/Problem
Description:

Designed by:

Date:

Version:



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DESIGNED BY: Strategyzer AG & Steve Blank
The makers of Business Model Generation and Strategyzer

Strategyzer
strategyzer.com

Beneficiaries by Time



Operators



Medical Officer



Researcher



Time

Pivot or Proceed?

	Geolocation	Vitals Monitoring
Type of Need	This is the most immediate and active need the most often mentioned pain point.	This is a latent need that the divers are unaware of; and a passive need of the Medical Dive Officers; and an active need of Researchers
Beneficiary	Divers, Dive Officers	Researchers, Dive Officers, Divers, Dep of Navy, VA
Realistic Goal	A work around that will function within specific limitations	A working minimal viable product that ruggedization of off the shelf products and aggregation of sensors
Mission Achievement	Wholesale adoption within SDV, employment throughout broader NSW community; limited commercial opportunities for recreational divers	Adoption within SDV, application throughout NSW, DoD SOF elements, limited application within commercial dive sectors, athletes, etc
Aqualink		

Business Model and Mission Model

Key Points -

- must be relentlessly direct
- must utilize “innovation” throughout the canvas
- must continually utilize a high level of rigor
- must distinguish from standard business tools
- must recognize that all segments are vital
- must build product around customer; really listening.

SBIR STTR Programs

- Incredible source of non-dilutive funding
- \$982 million across 27 Institutes of the NIH in 2016]
- Foster commercialization of new biomedical technologies
- Pre-clinical and clinical stages of development
- Includes all Federal agencies with budgets over \$100 million



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Eligibility

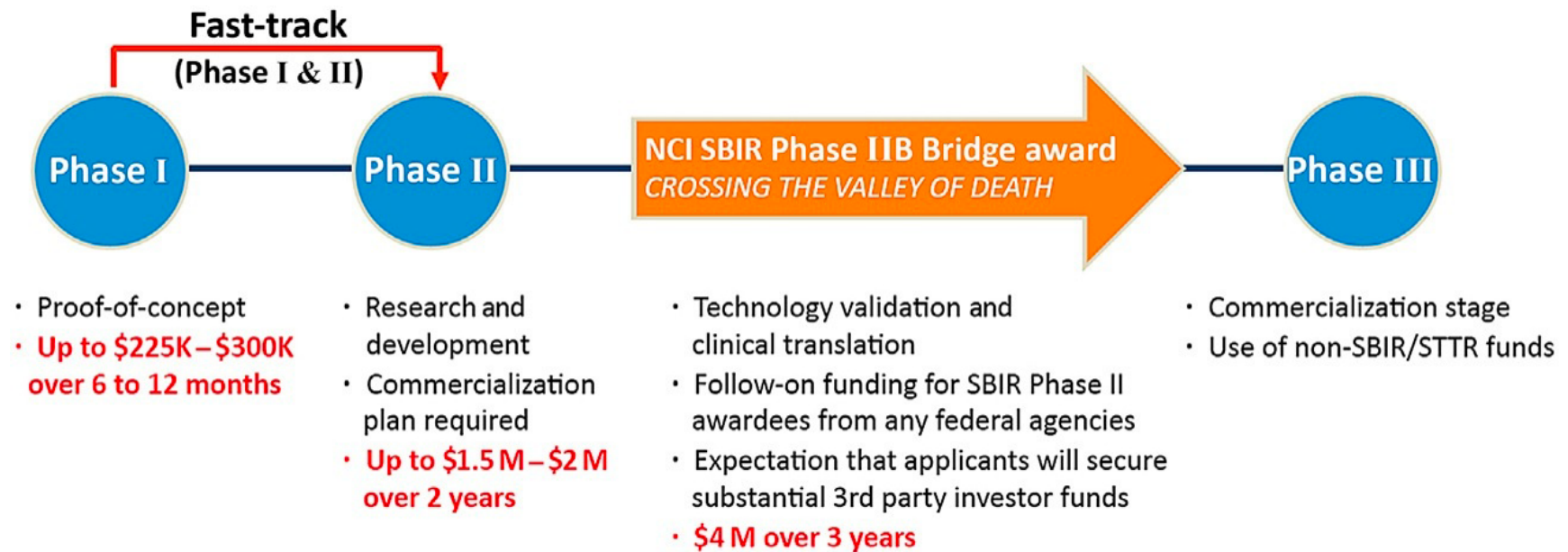
Company

- must be a small business
- must be for profit based and operating in the US
- must have 500 or fewer employees
- Is 50% owned by US individuals and independently operated

Differences between SBIR and STTR

- STTR requires academic partner; SBIR does not
- Funding allocation for SBIR is about 8 times higher than STTR
- PI of SBIR must be primarily employed by small business
- STTR allows PI to stay primarily employed by academia
- SBIR can outsource 33% of Phase I and 50% of Phase II
- Primary awards for SBIR STTR go to small business

Phase I, II, Fast Track, Straight to Phase II, IIB, Phase III



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Narayanan and Weingarten, Med Innov, 2018.

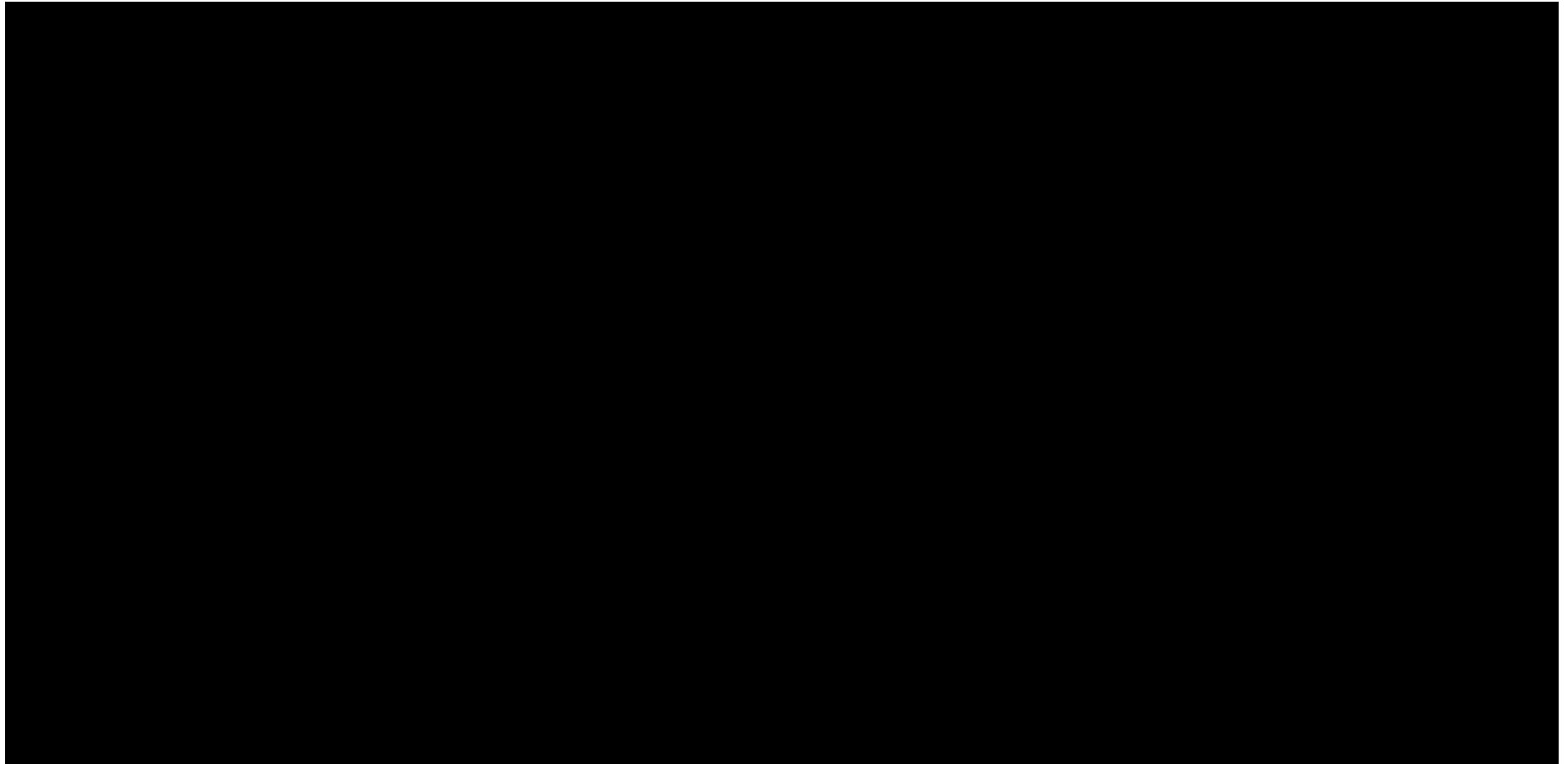
NIH I-Corps Program

Purpose - help you develop your own business model

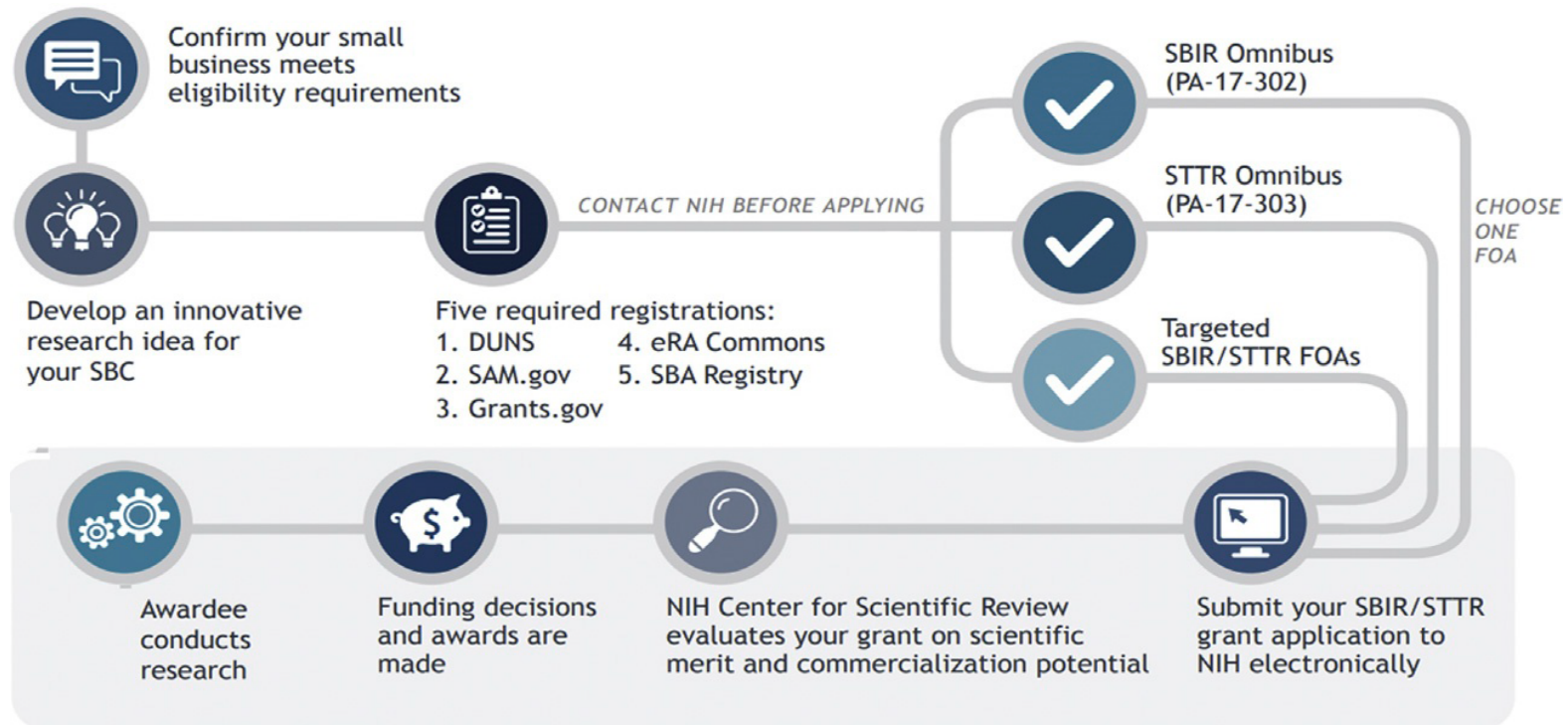
You (PI, Industry Expert and C-level exec) will learn how to quickly

- Delineate clinical utility before wasting \$\$\$\$\$
- Understand your core and tertiary customers
- Evaluate intellectual property and regulatory risk
- Examine value of future partnerships
- Determine sources of financing prior to the need for them.

NIH I-Corps Program – Example BCN Biosciences



START EARLY!!!!



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Narayanan and Weingarten, Med Innov, 2018.

Scored Review Criteria

Significance

- Does the product address an important problem?
- Does the product have commercial potential?

Approach

- Are the design and methods well-developed and appropriate?
- Are potential pitfalls and alternative approaches discussed?

Innovation

- How novel is the technology?
- Are the approaches to test the product novel?

Investigator

- How novel is the technology?
- Are the approaches to test the product novel?

Environment

- Does the scientific environment contribute success probability?
- What about facilities and independence? Institutional support?

Commercialization

- Is the company's business strategy one that high potential for success? Can you make this convincing and how will do it?



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Useful Tools for SBIR/STTR Applicants

NIH reporting and tracking tool	https://projectreporter.nih.gov	NIH Reporter provides access to reports data and analysis for previously funded NIH grants and could be useful for potential applicants to understand competitive landscape and find collaborators
CSR receipt, referral, and review process	https://public.csr.nih.gov/ApplicantResources/ReceiptReferral/Pages/Submission-and-Assignment-Process.aspx	Center for Scientific Review (CSR) process for receipt, referral, and assignment of applications
SF424 guide	https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/sbir-forms-d.pdf	SF424 SBIR/STTR Application Guide for NIH and other PHS Agencies
Application Guide	https://grants.nih.gov/grants/how-to-apply-application-guide.html	Application guide to submit grant applications to NIH and other Public Health Service Agencies



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Conclusions

- Application of the scientific method gives us an advantage
- Customer/beneficiary pains and gains drive innovation
- Business model and mission model canvas allows true testing
- Funding streams are available through the SBIR STTR programs
- NIH and NSF I-Corps programs can be excellent resources

Questions?



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Thank You!



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Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.