

# Winning SBIR/STTR Funding: Raising Your Chances for Success

University of San Diego – the BRINK SBDC  
April 18, 2019

*Disrupting*  
*Old*  
*Habits*



Martin Kleckner III PhD MBA  
The Brink SBDC



**SBIR · STTR**  
America's Seed Fund



# **1st in a Four-Part Series**

**Winning SBIR & STTR Grants: The Basics (April 18, 2019)**

**SBIR & STTR – Phase II: Beyond the Basics (May 1, 2019)**

**Funding Your Innovation (May 23, 2019)**

**Roadmap to Commercialization: I-Corps (June 13, 2019)**

# SBIR “Deal Killer” (Avoidance) Program

1) **Registration** for SBIR/STTR Applications

2) Preparing a Fundable **Study Approach**

- Research Design/Protocol
- Writing Hypotheses and Aims

For Non-Academics

3) Writing Your Phase II **Commercialization Plan**

**Date: 6/3/2019 - 8/30/2019**  
**Time: 8:00 AM - 12:00 PM (PDT)**  
**Status: Open - 15 places remaining**  
**Registration Deadline: 7/15/2019 8:00 AM (PDT)**  
**Fee: \$350.00**

# **SBIR Writer's Work Group**

## **Program Format: Multi-session Course**

- 1) A facilitated peer learning work group – Target: the NIH September 5, deadline
- 2) In each session, instructors to guide the conversation toward a successful application
- 3) Not a guarantee that you will receive a SBIR; we will not write + submit an application for you

## ***Topics include***

- Understanding the requirements of an SBIR
- Preparing to apply for an SBIR (company formation, registration, identifying the best PI
- Assembling all the necessary parts of the application (letters of support, sub-contract quotes and letters, facilities to execute the grant, and research plan)
- Composing a competitive research plan
- Understanding and assembling a budget and justification
- Composing competitive innovation and significance sections as well as specific aims
- Searching for program announcements and finding opportunities
- Assembling and filing (completing the 424 correctly and filing on time)

# Industry Specific: (e. g. Life Sciences)

## Commercialization (Navigation Roadmap)

- Coding, Coverage; Joint FDA/CMS Parallel Review
- Analytical Validity, Clinical Validity; Clinical Utility
- Economics (Cost/Benefit Impact)
- Health Technology Assessment (HTA)
- FDA Regulatory Affairs
- Licensing Best Practices, Optimal Alliance/Partnership Structuring
- Enterprise Economic Value Management; Strategic Accounts

FDA, CMS, AMA, BS/BC (Evidence Street), Evicore, Hayes, ECRI, Aetna, Precision Medicine, New Ventures Funds, Quest, American Healthcare Research & Quality (AHRQ), U S. Preventive Services Task Force, Palmetto GBA; CLSA

# Future: BRINK I-Corps Site/Accelerator

## Fixed Term: 7 – 8 Weeks

- 1) Business Models & Customer Development
- 2) Value Proposition
- 3) Customer Segments
- 4) Distribution Channels
- 5) Customer Relationships
- 6) Revenue Streams
- 7) Partnerships/Alliances
- 8) Resources, Activities, & Costs

## Seed Fund/Equity Stake

- 1) Investor Presentations, Documents
- 2) Terms Sheets, Deal Terms, other Related Funding issues
- 3) Types of Funding Vehicles
- 4) Sales & Marketing Strategies
- 5) Management Policies/Procedures
- 6) Hiring & Staffing Issues -- Including cash and stock compensation for Other Team Members
- 7) Board of Directors Acquisition/Compensation
- 8) Advisory Board Creation, Utilization & Compensation
- 9) Board Governance Issues
- 10) Strategic & Tactical Planning

**Candidacy to National Cohort**

# Where I'm Coming From . . .

1) National Science Foundation I-Corps Adjunct Faculty; NIH I-Corps

2) Six Launches; Two Exits

- RegeneMed
- InSilicoMed
- SpyFinder (Sold)
- Sal-Flex (Sold)
- + RefluxMD



I-Corps™ at NIH

USC, Caltech, U C Irvine, Georgia Tech, Ohio State, U C Riverside, Cal State Fullerton

3) Also: **Not-For-Profit 501 (c) 3** – Venture Philanthropy

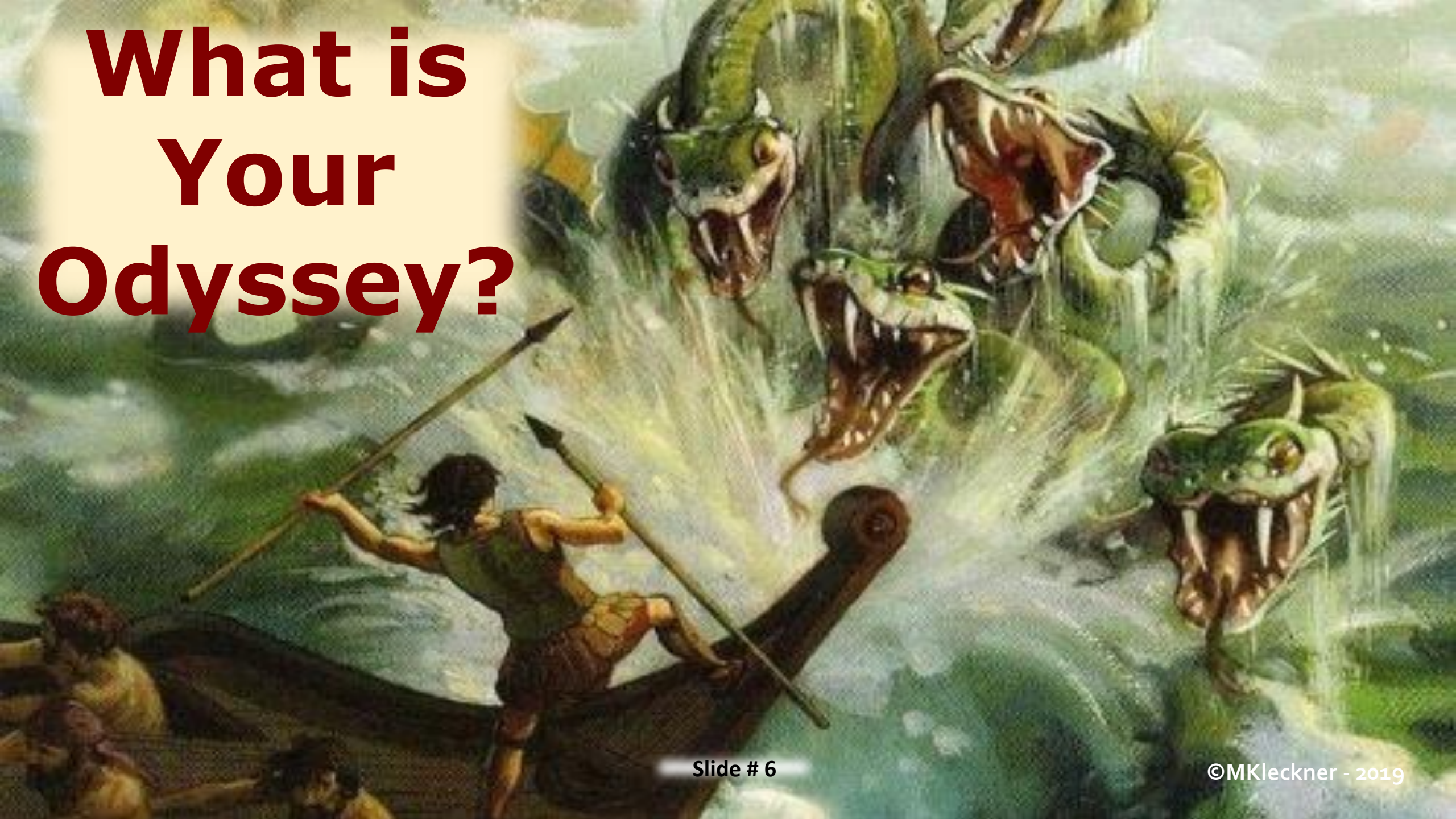
4) **SBIR/STTR**: NSF, NIH, DoD, DOE, DoEd, USDA, Coulter, Drexel; Univ of California

5) Times Mirror, American Healthcare Systems, General Electric, Roche Diagnostics, Toshiba America Medical Systems

6) **\$55.8 MM** in Capital & Grants 2016 – Q4 2018



# What is Your Odyssey?



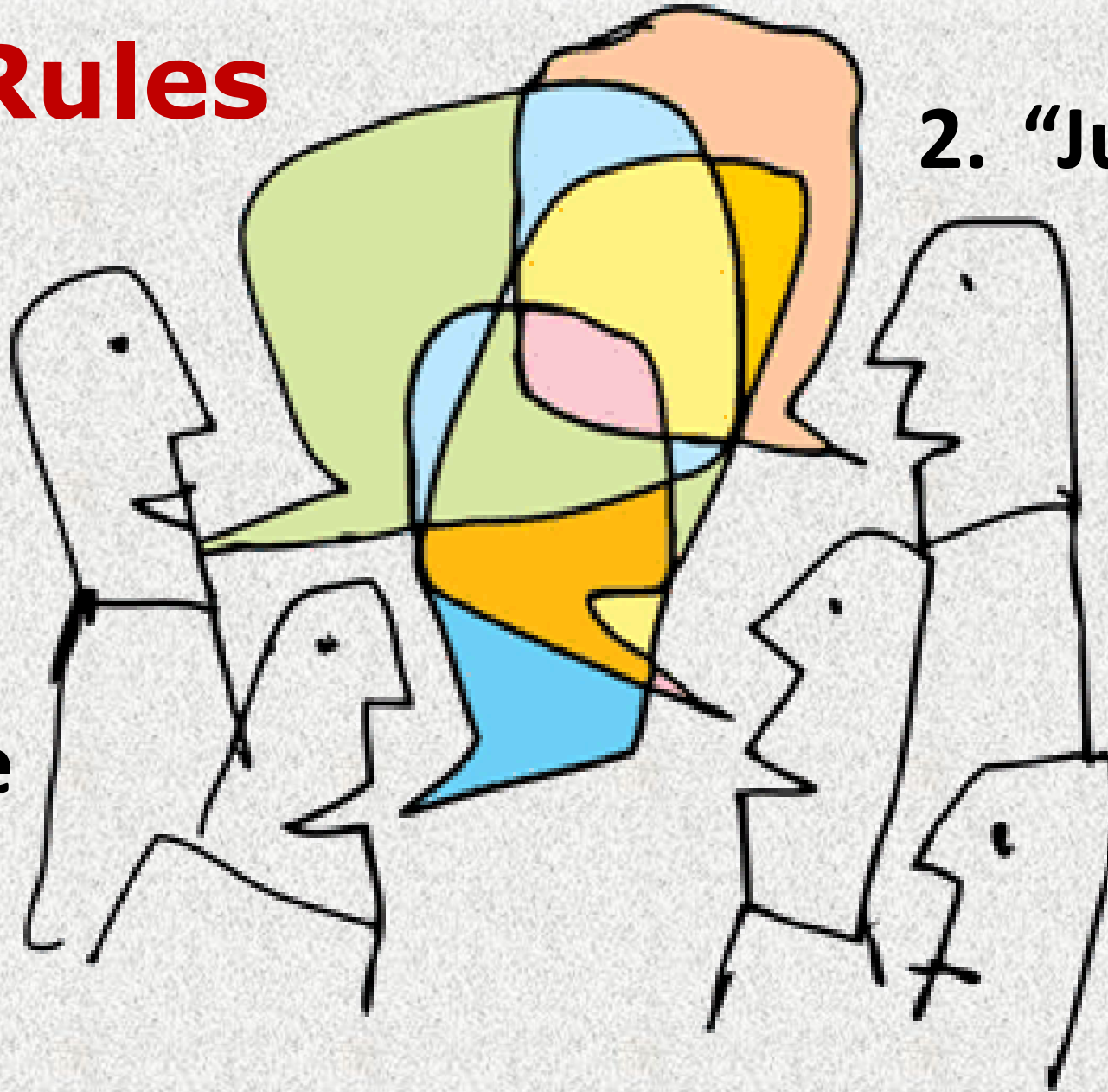


# Essential Rules

1. Ask  
Questions

2. "Jump In"

3. Participate





# **SBIR/STTR: The Basics**

- I. The PROGRAM BASICS (DOE, NIH, DoD, NSF, USDA et al.)**
  - **Legislative/Regulatory Affairs; Registration; Funding; Specifics**
- II. THE CONTENT –WHAT’S IMPORTANT: Understanding Criteria**
  - **Writing to the Reviewers: Understanding Their “Marching Orders”; Study Approach; Commercialization Plan**
  - **Key Criteria: Scoring, Ranking and Evaluation (“Go/No-Go”)**
- III. “Why Was I Rejected?”: COMMON PROBLEMS**
- IV. BRINGING YOUR INNOVATION TO MARKET**

# Part II: Beyond The Basics

- I. Designing and Defending a Fundable STUDY APPROACH**
  - a) Research Design, Protocol Essentials
- II. PHASE II Award Criteria**
  - a) Winning Phase II during Phase I
- III. Budgeting, Accounting & Government AUDITS**
  - a) “Firm Fixed Price Award” (FFP) to “Cost Plus Fixed Price” (CPFP)
  - b) “Pre-Award Accounting Audit”
- IV. COMMERCIALIZATION PLAN/Business Model Generation**
  - a) The Role of I-Corps, “Tech Assess” and Other Programs



# **PART I: THE BASICS/ORIENTATION**



# Introduction

- **SBIR – Small Business Innovation Research**
  - Small Business Development Act of 1982
  - Small Business Reauthorization Act of 2000 (through Sep 2022)
  - **3.2% Extramural Research** Agencies w/ Budget > \$100 MM
  - Mission: Stimulate Innovation; Economic Growth
- **STTR – Small Business Technology Transfer**
  - Small Business Technology Transfer Act of 1992
  - Reauthorized through September 2022
  - **0.45% of Agency Budget** (Budget > \$1B)
  - Collaboration Between Small Business and NFP Research

**SBIR: 6% by 2028 (S 2812)  
4.5% by 2022 (HR 4783)**

**STTR: 0.6% by 2022 in the House bill  
1% in the Senate bill**

**Latest Action:** **S. 2812 (Jeanne Shaheen S-NH; April 18, 2016):** Senate - 12/20/2016 By Senator Vitter from Committee on Small Business and Entrepreneurship filed written report under authority of the order of the Senate of 12/10/2016. Report No. 114-417 **(There are related bills introduced & pending.)**



~~SBIR: 6% by 2028 (S 2812)~~  
~~4.5% by 2022 (HR 4783)~~

~~STTR: 0.6% by 2022 in the House bill~~  
~~1% in the Senate bill~~

**SBIR & STTR reauthorized; SBIR stays at  
3.2%; STTR: 0.45%**

The government was initially funded through a series of five temporary [continuing resolutions](#). The final funding package was passed as an [omnibus spending bill](#), the [Consolidated Appropriations Act, 2018](#), enacted on 03/23/18.

**Base Program Remains . . .**

**. . . “pilot” programs  
expired, then rejuvenated**

# They're Back (through 2022):



National Institutes  
of Health

- **Direct to Phase II**
- **Phase 0 Proof of Concept Centers**  
(Commercialization Readiness Program: CRO Studies; IP Strategies; FDA Guidelines)
- **Expand Technical Assistance**
  - 1) Phase I \$6,500/year (up from \$5,000/year)
  - 2) Phase II \$50,000/project (up from \$5,000/year)
  - 3) SBC hire own vendor or use agency vendor



# Technical & Business Assistance

## Access to a Network of Scientists and Engineers

- Wide range of technologies
- Product sales
- IP protections
- Market Research & Validation
- Regulatory Plans
- Manufacturing Plans, or
- Access to Technical and Business Literature (on-line data bases)
  - Request in F. **Other Direct Costs** lines 8-10 on SBC budget
  - Label as **“Technical Assistance”**



# Proof-of-Concept Centers (Hubs)

GOAL: “De-risked technologies with well-designed business cases primed for licensing or startup company formation.

1

**Infrastructure**

2

**Feasibility; Prototype; POC**

3

**Access to Expertise**

4

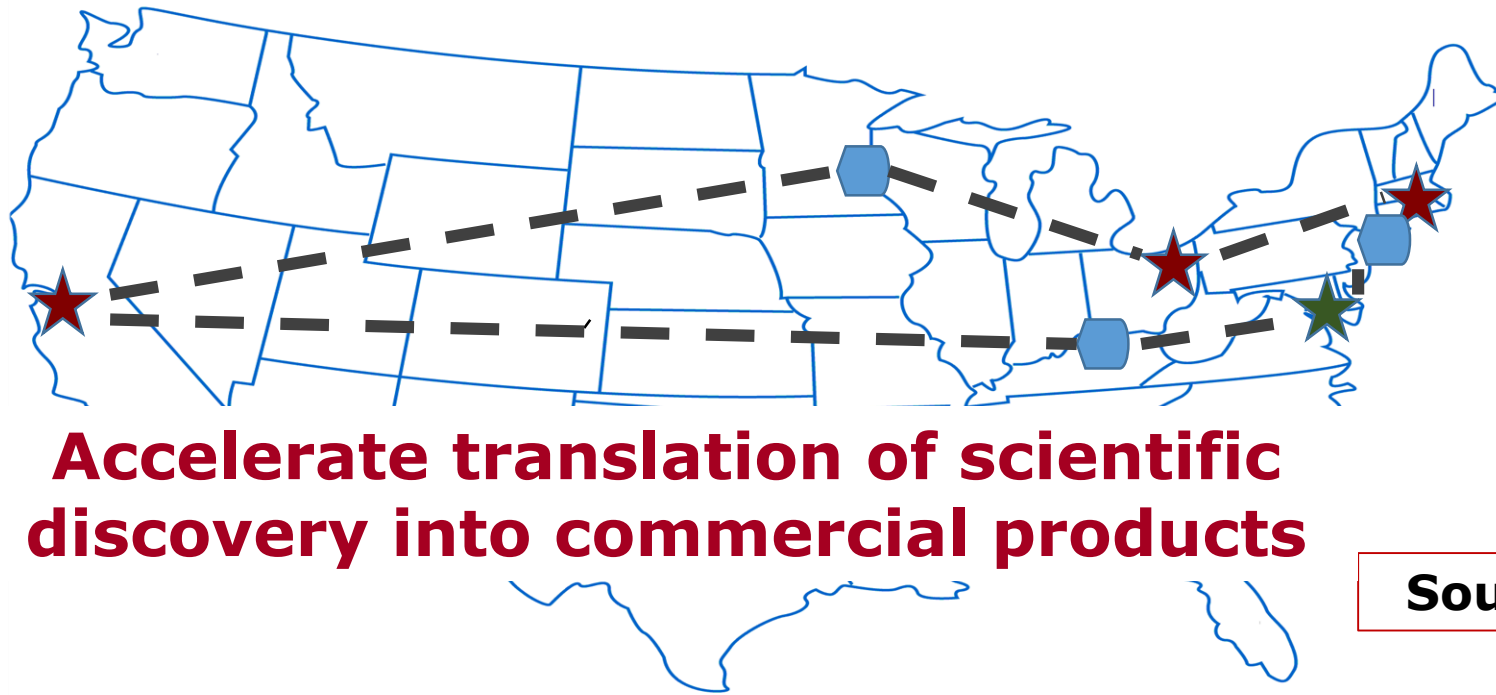
**Skills Development**



National Institutes  
of Health

Matthew Portnoy PhD  
Program Manager

Office of Extramural Research  
<https://ncai.nhlbi.nih.gov/ncai/aboutncai/mission>



National Institutes  
of Health

**Accelerate translation of scientific  
discovery into commercial products**

**Source: Matthew Portnoy PhD**

**NIH Centers for Accelerated Innovations (NCAI):** Boston Biomedical Innovation Center, Cleveland Clinic Innovation Center, UC BRAID Center for Accelerated Innovation

**Research Evaluation and Commercialization Hubs (REACH):** University of Minnesota, Long Island Biomedical Hub, University of Louisville

**National Institutes of Health + NSF, FDA, USPTO, CMS, Kaiser**

**DoD Commercialization  
Readiness Program  
(CRP) stays in force through  
SEP 30, 2022**



**DoD Rapid Innovation Fund (RIF):  
\$250 MM in Phase III funds (permanent)**



# Eleven Agencies

- Five (5) Have an STTR Program (✓)
- Early Stage, High Risk, High Payback
- Foster Socially/Economically Disadvantaged
- Transformative; Significant Societal Impact
- Strong Chance For Commercial Success
  - Credible Commercialization Plan
  - (I-Corps Programs “Linked to” SBIR)

- 1) Department of Commerce - [National Institute of Standards and Technology](#)
- 2) Department of Commerce - [National Oceanic and Atmospheric Administration](#)



# FY 2019 SBIR & STTR Budget (est.)

Agency	SBIR	STTR	Total	Chg
Defense (DoD)	\$1,535	\$215	\$1,750	+552
HHS/NIH	957	131	1,088	+184
Energy (DOE)	256	36	292	+58
NSF	178	24	202	-14
NASA	174	24	198	-27
USDA	27	-	27	+6
Homeland	21	-	21	+3
Commerce	14	-	14	+3
DOT	8.5	-	8.5	+0.5
Education	7.5	-	7.5	-7.5
EPA	4	-	4	-1
<b>TOTAL</b>	<b>\$3.2B</b>	<b>\$430M</b>	<b>\$3.6B</b>	<b>\$756</b>

# Characteristics

## PHASE I: Merit, Feasibility, Commercial Potential

- ALSO: Your Quality & Performance w/ a small amount of money
- Amounts Vary; 6 – 12 Months: \$163,952 +/- 50% (FY '18)
- There may be a **Hard Cap Waiver**

## PHASE II: Complete R & D; Efficacy, Potential, Merit

- Amounts Vary; 24 Months: \$1,093,015 MM + 50% (FY '18)
- Phase IIB (**NIH; DOE: Sequential**)
- **Special/Supplemental (e.g. DOE, NSF)**
- Commercial Potential: Past Record; Funding + “Commitments”

## PHASE III: Commercialization

- Unfunded; Non-Cash; In-Kind Support



# To Be Eligible (SBIR) . . .

1. SBC<sup>1</sup> Organized **For-Profit**; based in the U. S.
2. No more than 500 **employees** (incl. Affiliates, PT & Temp.)
3.  $\geq 50.1\%$  directly-owned or controlled by 1 or more **permanent citizens or resident aliens** ('Green Card' & 'Substantial Presence')<sup>2</sup>
4. A Joint Venture wherein each entity meets the above
5.  $1/3$  of Funded Work May Be Sub-Contracted
6. **Principal Investigator Must Be > 50% "Employed" By You**

1) Proprietorship, Partnership, LLC, Corporation, Joint Venture, Association, Cooperative

2) Thirty-one (31) days in current year; 183 days past three years – including current

# Eligibility (STTR) . . .

1. Organized **For-Profit**; based in the U. S.;  $\leq$  **500 employees**
2.  $\geq$  **51%** directly-owned or controlled by **1 + permanent citizens or resident aliens**; Other small businesses meeting the above criteria
3. **Research Institution Partner:**
  - Located in the US; Nonprofit college or university; Domestic Nonprofit Research Organization; Federally Funded R&D Center (FFRDC)
4. **Must Have an IP Agreement:** Allocation, Research, Commercialization
5. **Company Performs 40% - 70%**; NFP Partner Does 30% - 60%
6. **Principal Investigator Does Not Need To Be SBC Employed**

# And Other News . . .

- **Cross Program Awards**
  - Agency Discretion: Can Allow STTR Phase I Awardee to receive SBIR Phase II Award/Other Way as Well
- **Cross Agency Awards**
  - Phase I Awardee May Receive Phase II Award From Another Agency
- **All Phase I Awardees** Must be Allowed To Apply For Phase II
- **Second Sequential Phase II (NIH, DOE) May Be Awarded**



# Performance Benchmark . . .

## . . . Transition Rate Requirement

- Applies to SBIR & STTR Phase I Applicants Having Received **More Than 20 Phase I Awards** Over The Past 5 Years
- There must be a **Minimum Number of Phase II Awards** Received For A Given Number of Phase I Awards (In Order To Remain Eligible For Phase I)
- **Minimum Transition Rate = 0.25 (25%)**



# Commercialization Benchmark

- 1) Applies if you have received more than **15 (16 or more) Phase II awards** over the past **10 fiscal years**, excluding last two years.
- 2) You must have received, to date, an average of At Least **\$100,000 of sales and/or investments** per Phase II award received
- 3) . . . OR have received a **Number of Patents** resulting from SBIR work equal to or greater than **15%** of the number of Phase II awards received during the period.



# Consequence . . .

## . . . of Failure to Meet Benchmarks



- SBA identifies on June 1 each year those who fail to meet either benchmark.
- They will be **not be eligible to receive a Phase I award** for a period of one year from that date.



# VC, Hedge Fund, Private Equity

1) Can a VC (HF, PEF) owned company apply for a SBIR grant?

- VC, HF, PEF can hold minority shares
- Affiliation Rule: majority VC-owned companies (Total  $\leq$  500 employees)

2) Can a Single VCOC (HF, PEF) hold a majority share ( $> 50\%$ )?

- **NO.** They can hold a **Minority Share + Not Have Control**. No single VC, hedge fund or private equity firm may own more than 50%
- **EXCEPT:** VCs owned/controlled by 1 + US Citizens, permanent resident aliens

3) NDAA authorizes NIH, CDC, & DOE (Advanced Research Projects Agency – “ARPA-E”) to award SBIR Funds to VC Majority-owned

- **BUT ONLY IF** no one VC/HF/PEF owns more than 50%



# VC, Hedge Fund, Private Equity

- 1) **What about STTR?** Companies that are more than 50% owned by multiple VCs, hedge funds, or private equity firms or any combination are **NOT eligible to apply**
- 2) **Joint Venture?** Still 'No' (& each party must meet ownership requirements)
- 3) Each VC must have a **U.S. place of business** AND **be created or organized in the U. S.;** operate under **U. S. laws**

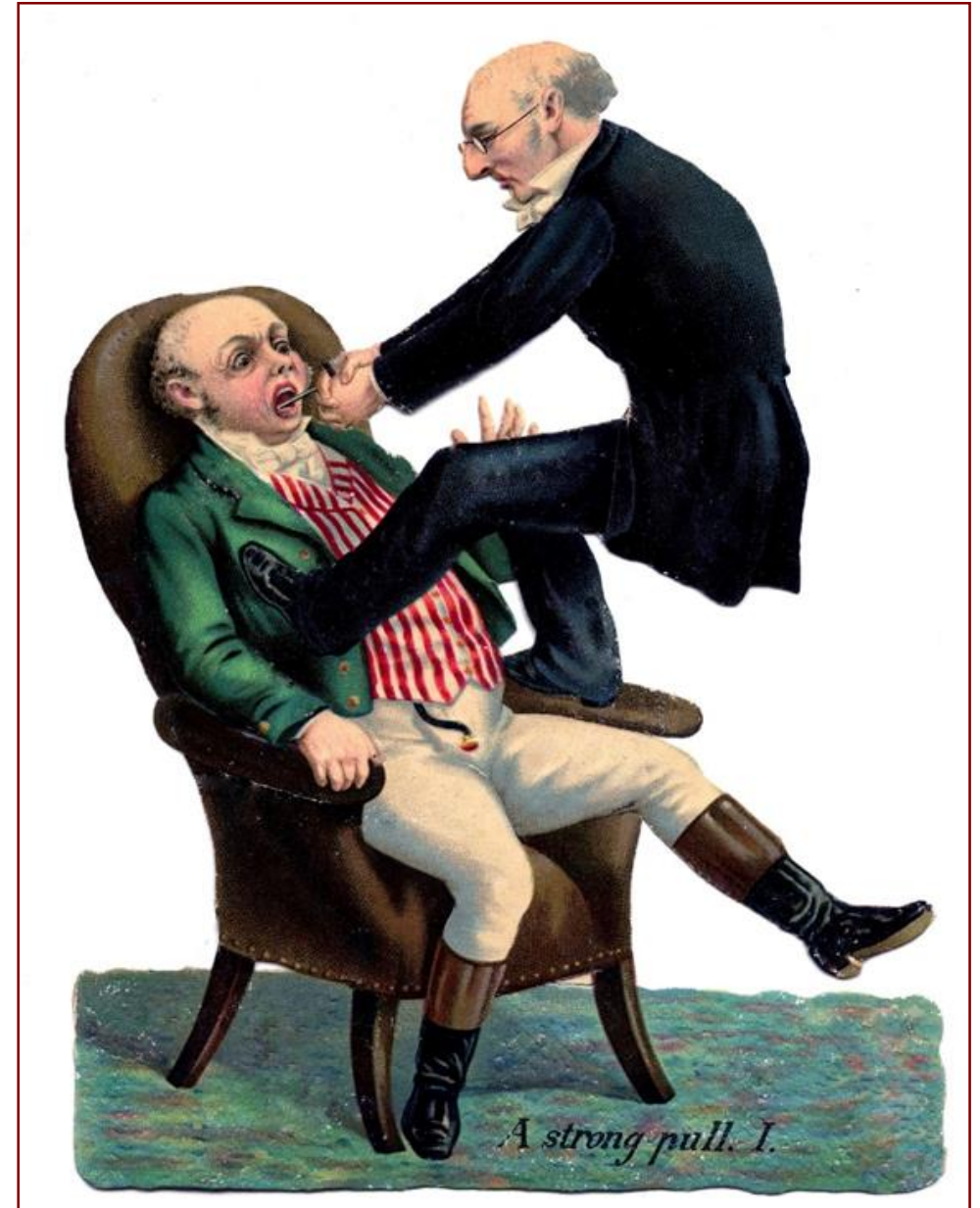


# **Part II: Getting Started**

# Registration

1. DUNS
2. System for Awards Management (SAM)
3. Grants.gov
4. SBA
  - eRA Commons (National Institutes of Health)
  - Also: National Science Foundation (NSF):  
research.gov
  - Also: Department of Defense (DoD): Separate  
Registration
  - Department of Energy Portfolio Analysis and  
Management System (PAMS)

**Can take 6 – 8 weeks**





# Sequential

1. Dun and Bradstreet Universal Numbering System (DUNS) number. (See <http://www.sba.gov/content/getting-d-u-n-s-number>)
  - **To get an EIN:** <https://www.irs.gov/businesses/small-businesses-self-employed/how-long-will-it-take-to-get-an-ein>
2. After DUNS: **System for Award Management (SAM)** and (for NIH) **eRA Commons** registrations.
3. The **SBA (SBIR)** registration is the most recent requirement for a **SBC (Small Business Concern) Control ID**

# To get a DUNS number online,

go to this link:

<http://fedgov.dnb.com/webform/displayHomePage.do;jsessionid=81407B1F03F2BDB123DD47D19158B75F>. You will be guided through the request protocol beginning on <https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm>:

**“Find DUNS or Request New DUNS”**

Memo: You can use your home address as your business address for a startup.

**You will need 2 documents** to complete this process. The documents must reflect the Correct Legal Business Name at the Current Physical Address. (See examples of accepted documentation below).

## Example of **Accepted Documents for New DUNS**

- Secretary of State Articles of Incorporation
- Taxpayer Identification Number (TIN) Confirmation Letter
- Employer Identification Number (EIN) Confirmation Letter
- DBA / Assumed Name Certificate Filing
- Lease Agreement
- Utility Bill

**Memo: for NIH applicants**, use this link (it provides a “simple” step-by-step way to get through this.) :  
<https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/registration/org-representative-registration.htm>



# System for Award Management (sam.gov)

- 1) Provide your company's "DUNS number" and bank account information.
- 2) Submit a notarized letter stating that you are the authorized Entity Administrator before your registration will be activated.

See: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/sam-update>

# How to Submit a Notarized Letter Formally Appointing an Entity Administrator

[https://fsd.gov/fsd-gov/answer.do?sysparm\\_kbid=d2e67885dbod5foob3257d321f96194b&sysparm\\_search=kboo13183](https://fsd.gov/fsd-gov/answer.do?sysparm_kbid=d2e67885dbod5foob3257d321f96194b&sysparm_search=kboo13183)

***Step 1:*** Find template at the above site

***Step 2:*** Complete the template and print on your entity's letterhead\*

***Step 3:*** Sign the completed letter in the presence of the notary

***Step 4:*** Mail the completed, signed, notarized letter to:

**FEDERAL SERVICE DESK**

**ATTN: SAM.GOV REGISTRATION PROCESSING**

**460 INDUSTRIAL BLVD**

**LONDON, KY 40741-7285**

**UNITED STATES OF AMERICA**

**\* Or enter your SBC legal business name & physical address at the top of the letter.**

# Register With The SBA

Company registration is meant for small businesses to register and gain access to the SBIR.gov system.

Completed registrations will receive a **unique SBC Control ID to be used for submissions** at any of the participating agencies in the SBIR or STTR programs.

<https://www.sbir.gov/registration>

## **Grants.gov, registration** See the “Get Registered” tab ([http://grants.gov/applicants/get\\_registered.jsp](http://grants.gov/applicants/get_registered.jsp)).

- While Grants.gov registration is a one-time only registration process, **it involves several steps & will take some time.**
- To complete this process **start early** allowing at least six (6) weeks to complete all the steps before actually submitting an application through Grants.gov.



# NIH Applicants

**Register with the Electronic Research Administration (eRA Commons)** via the below link:

<https://era.nih.gov/erahelp/commons/default.htm#cshid=1026>

**To Register with the NSF** for proposal submission, access [https://www.research.gov/research-portal/appmanager/base/desktop?\\_nfpb=true&\\_pageLabel=research\\_home\\_page](https://www.research.gov/research-portal/appmanager/base/desktop?_nfpb=true&_pageLabel=research_home_page)

- 'click' on "Register" on the upper right side of the page to go to <https://www.research.gov/accountmgmt/#/registration>

**The Department of Defense** requires separate registration - even though you have already registered in SAM.gov and at SBA.gov.

<https://sbir.defensebusiness.org/user/register>

See the DoD Web Portal “Frequently Asked Questions” for guidance  
<https://sbir.defensebusiness.org/FAQS>.

**Department of Energy** applicants will need to register with the **DOE Portfolio Analysis and Management System (PAMS)** to create an account:

<https://pamspublic.science.energy.gov/WebPAMSExternal/Interface/Registration/CreateAccount.aspx>



# PART III



National Institutes  
of Health



# WHAT'S IMPORTANT



The ensuing discussion generally applies to the other agencies also.





# DOE External Peer Review: CRITERIA

- At least 3 technical reviewers
- 1 Reviewer for the Phase II commercialization plan
- **Review Criteria (equally weighted)**
  - 1) Strength of the Scientific/Technical Approach
  - 2) Ability to Carry Out Project Cost Effectively
  - 3) Impact



## Panel

### Composition/Affiliation:

- 1) National Laboratory (49%)
- 2) University (32%)
- 3) Government (10%)
- 4) Private Sector (9%)



Handwritten text in a cursive script, likely Indonesian or Malay, on aged paper. The text is partially obscured by a circular graphic overlay on the right side of the image.

22. Aug 1929

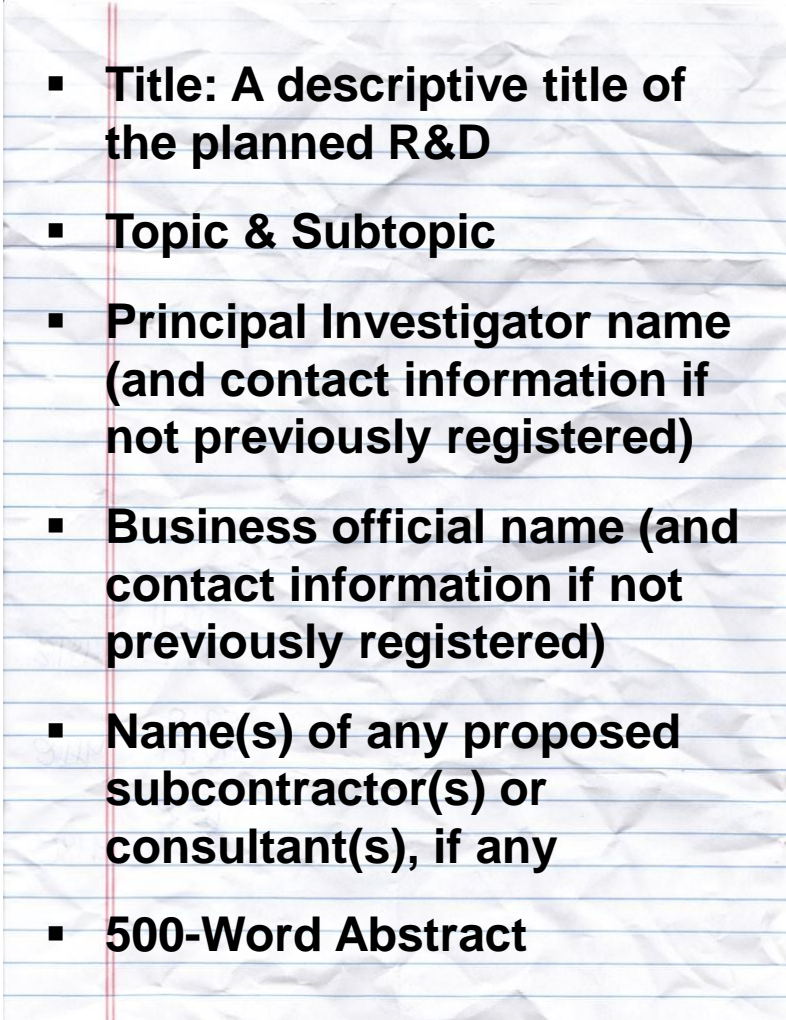
**Not Required  
(except for the DOE)**

**Letter of  
Intent/Inquiry**

# Letters of Intent (DOE)

**LOI required by a specified due date** to be eligible to submit an application (Due 3 weeks after FOA issued)

- Why: to begin reviewer assignments/reduce award cycle time
- **You will not receive a response unless your proposed R & D is non-responsive to selected topic**
- Up to 10 LOIs and 10 applications per FOA
- Submit electronically through the DOE Office of Science Portfolio Analysis and Management System (PAMS) website <https://pamspublic.science.energy.gov/>.

- 
- **Title:** A descriptive title of the planned R&D
  - **Topic & Subtopic**
  - **Principal Investigator name** (and contact information if not previously registered)
  - **Business official name** (and contact information if not previously registered)
  - **Name(s) of any proposed subcontractor(s) or consultant(s), if any**
  - **500-Word Abstract**

# Submit LOI online

directly to the DOE Portfolio Analysis & Management System (PAMS) website:

<https://pamspublic.science.energy.gov/>

- Select “Create New PAMS Account” (if you do not have an account)
- Submit your LOI as a PDF file
- Utilize the [LOI instructions](#) available at the DOE website to ensure that you submit all the required information
- For additional details on the LOI submission process, see the Funding Opportunity Announcement

The screenshot shows the DOE Office of Science Portfolio Analysis and Management System (PAMS) login page. The page header includes the DOE logo and the text "Office of Science Portfolio Analysis And Management System". The page is titled "Existing User" and shows a date of "Tuesday 28<sup>th</sup> November 2014 02:22:17 P.M. ET". A notification banner at the top states: "Mac users who have recently upgraded to Safari 6.2, 7.1, or 8.0 will experience issues using PAMS due to a widespread issue with the new browsers. Additionally, Mac users using more recent versions of Firefox are also experiencing issues. If you are on a Mac and using any of these browser versions, we recommend using Google Chrome until these issues can be resolved." The main content area is titled "Existing User Login" and contains a "Username" field, a "Password" field, and a "Login" button. To the right, there is a "New User Registration" section with links for "Search Solicitations" and "Create New PAMS Account". Below that, there is an "Other Links" section with links for "Award Search", "Recommended Settings", "Contact Us", and "PAMS External User Guide". At the bottom, there is a "System Use Notification" section with a disclaimer: "You are accessing a US Government Information System, which includes servers, network devices, and storage media. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following: • You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system. • Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose."

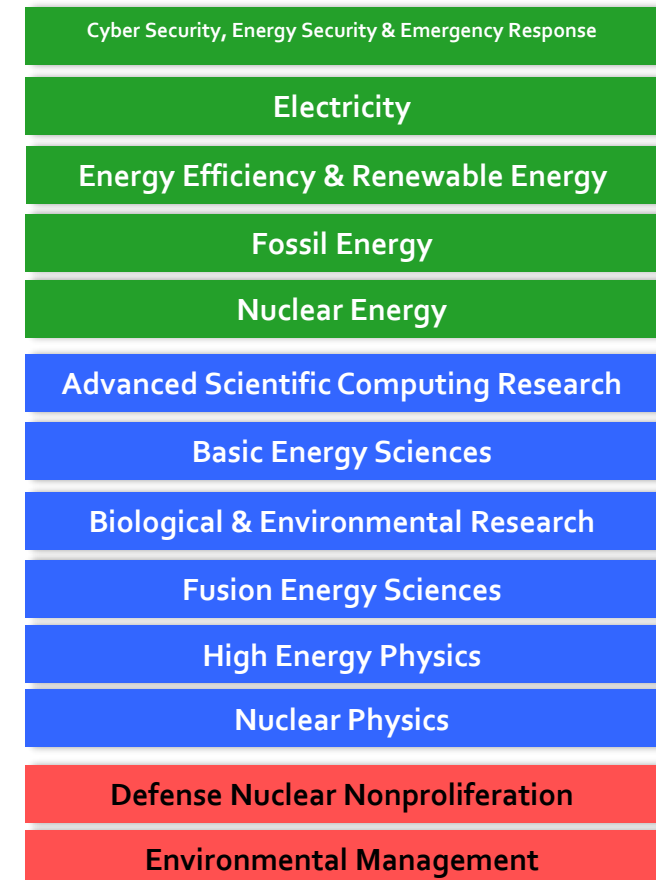


# U.S. Department of Energy Interests

- **Goal 1:** Catalyze the timely, material, and efficient transformation of the nation's energy system and secure **U.S. leadership in energy technologies**.
- **Goal 2:** Maintain a **vibrant U.S. effort in science and engineering** as a cornerstone of our economic prosperity, with clear leadership in strategic areas.
- **Goal 3:** Enhance **nuclear security** through defense, nonproliferation, and environmental efforts.

Source: Chris O'Gwin, DOE SBIR/STTR Programs Office; SBIR/STTR Con 19, UC Riverside, March 12, 2019

## Program Offices Participating in DOE SBIR/STTR Programs





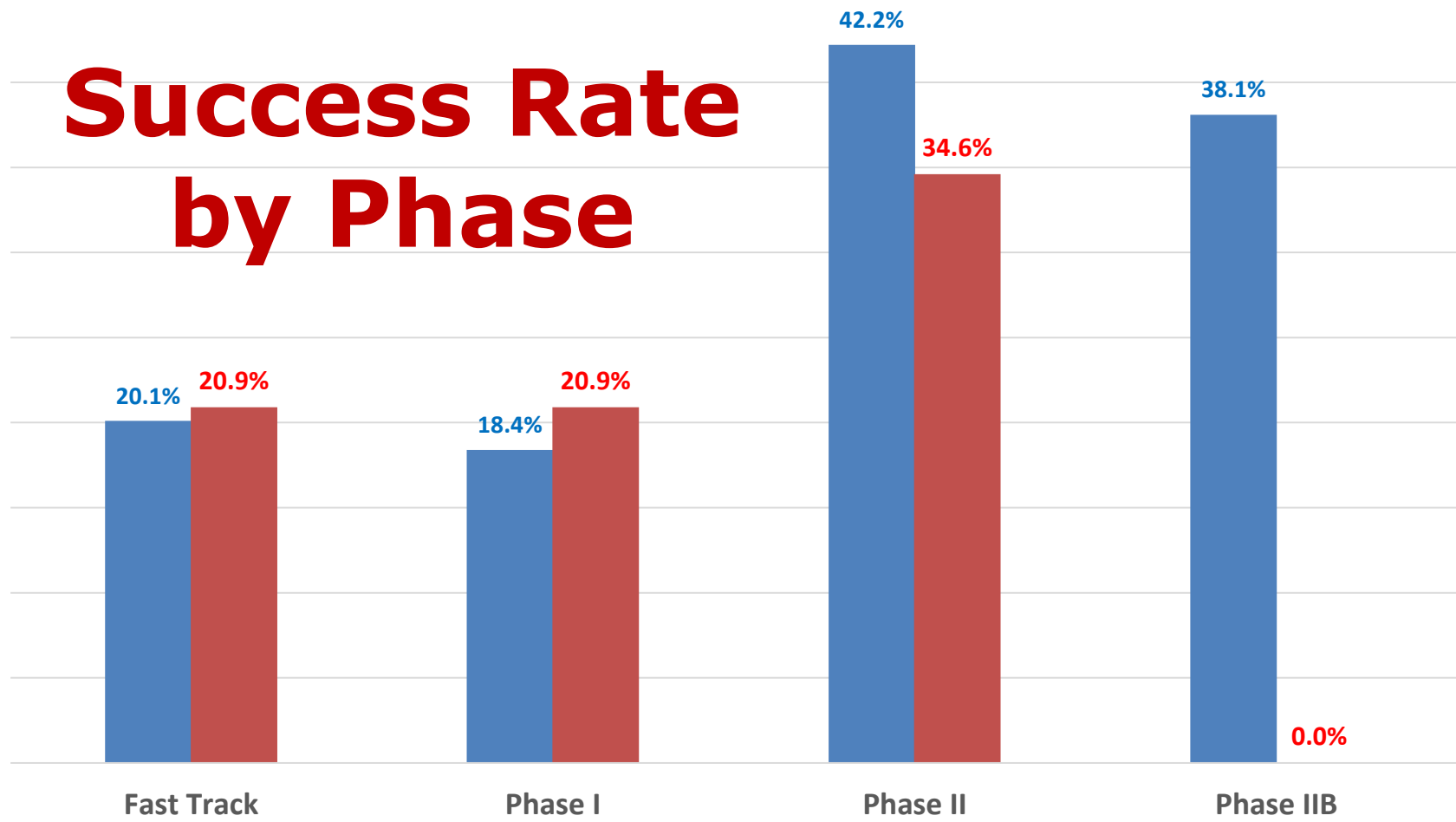


**National Institutes  
of Health**

# NIH Budget Has Increased for 2019

2019 Budget	SBIR	STTR
NIH	\$1B	\$141M
CDC	~\$12M	N/A
ACL (NIDILRR)	~\$3M	N/A
FDA	~\$1M	N/A

# Success Rate by Phase

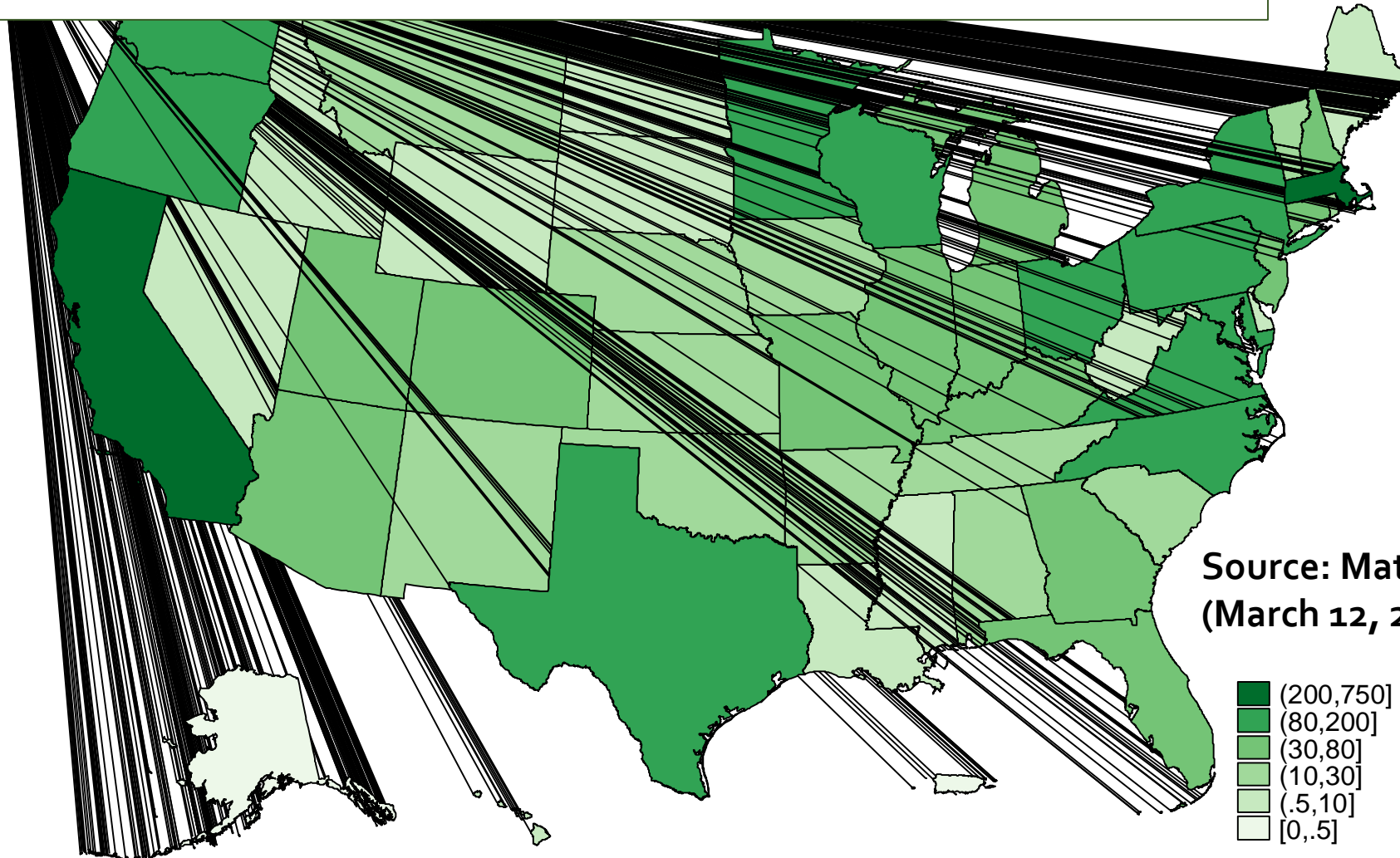


Source: Matthew Portnoy (March 12, 2019)

■ SBIR ■ STTR

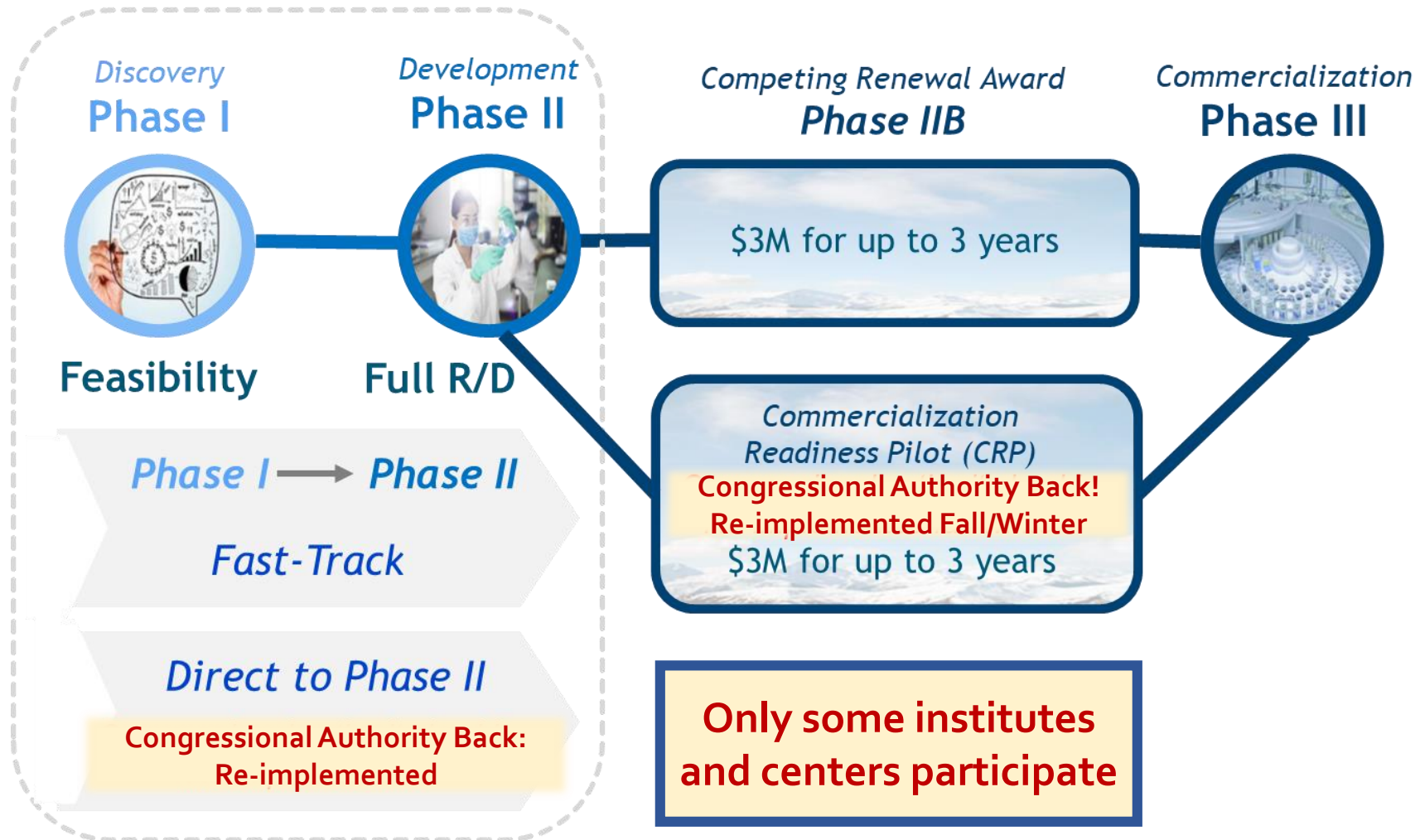
Note: STTR Ph2B 1 application, no award.

# Award Dollars in Millions 2012-2016





# Three-Phase Program



# NIH Reviewer “Marching Orders”

1. Significance
  2. Innovation
  3. Approach
  4. Investigators
  5. Environment
- Overall Impact

Title  
Abstract  
Problem  
Solution  
Specific Aims  
Research  
Strategy  
Facilities  
Biographies



## Focus: Key Criteria

# Overall Impact

**Assessment of the likelihood for the project to  
*exert a sustained, powerful influence on the  
research field(s) involved***

# Additional Review Criteria

- Commercial Potential (Phase I)
- Commercialization Plan (Phase II)

1. Project Value, expected outcomes, societal & educational benefits
2. Company information
3. Market, customer, and competition information
4. Intellectual property protections
5. Finance plan
6. Production and marketing plan
7. Revenue stream generation



# Scoring System and Procedure



National Institutes of Health

Overall Impact or Criterion Strength	Score	Description
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

Other	
AB	Abstention
CF	Conflict of Interest
DF	Deferred
ND	Not Discussed
NP	Not Present
NR	Not Recommended for Further Action

- 1) Preliminary Scores
- 2) Criterion Scores
- 3) Impact Score
- 4) Non-Numeric Scores
- 5) Final Impact Score

- 
- See “What’s Next?”
  - Program Officer

\* [http://grants.nih.gov/grants/peer/reviewer\\_guidelines.htm](http://grants.nih.gov/grants/peer/reviewer_guidelines.htm)

# DoD Evaluation Factors



- 1) Military & Program Relevance
- 2) PI/Key Personnel Qualifications
- 3) Research Objectives
- 4) Scientific Excellence
- 5) Impact/Outcomes
- 6) Facilities
- 7) Budget
- 8) Commercialization Strategy

**SBIR/STTR Desk Reference:**  
**“Evaluation & Selection”-**  
([http://www.acq.osd.mil/osbp/sbir/sb/resources/deskreference/02\\_eval.shtml](http://www.acq.osd.mil/osbp/sbir/sb/resources/deskreference/02_eval.shtml))



# We need YOUR solutions

Robert Smith, Director, DON SBIR/STTR & Special Programs  
robert.l.smith6@navy.mil



# BAA Schedule

- DoD BAAs are released 3 times per year. The FY19 schedule is listed below.
- The .1/A BAA typically has the most Agency participation and the largest number of topics.
- <https://sbir.defensebusiness.org/>

2019 BAA Schedule			
BAA	Pre-Release	Open	Close
FY19.1/A	28 November 2018	8 January 2019	6 February 2019
FY19.2/B	12 April 2019	13 May 2019	19 June 2019
FY19.3/C	23 August 2019	24 September 2019	23 October 2019

See: <https://sbir.defensebusiness.org/topics>





- **Intellectual Merit**
- **Impact on Society**



1. Advance Knowledge and Understanding
2. Benefit Society

3. Creative, Original and Transformative
4. Well-reasoned; well organized; sound rationale; mechanism to assess success
5. Your Qualifications and Resources



# **NATIONAL SCIENCE FOUNDATION**

## **New SBIR/STTR Protocol**

# **NEW: Submit a “Project Pitch” (required)**

## **Invitation Process:**

- NSF “only accepts proposals from companies that have been officially invited to submit (via the Project Pitch process).”
- See the current [SBIR solicitation](#) or [STTR solicitation](#) to get a sense of NSF’s objectives.
- Processing time: About three (3) weeks

# Three-Page Project Pitch



- 1) *Each small business can only submit **one Project Pitch at a time** and up to **two Project Pitches per submission window**.*

*Submission windows: (a) March 4-June 13 & (b) June 14-December 12*

- 3) *Those with a pending Project Pitch must **wait for a response before submitting another Project Pitch**.*
- 4) *Any small business that has **received an invitation to submit a full proposal** must **wait for a resolution of the full proposal** before submitting a new or revised Project Pitch.*



# Four Key Elements:



1. The Technology Innovation. (500 words)
2. The Technical Objectives and Challenges. (500 words)
3. The Market Opportunity. (250 words)
4. The Company and Team. (250 words)

# Upon Invitation



1) Register your company

2) Submit your full proposal

- **Submission window will close on June 13, 2019**
- Another submission window will open on June 14
- 1-3 (July – September) months after the window closes: Applications undergo merit reviews.
- 4-6 (October – December) months after the window closes: Notification whether proposal is accepted or declined.
- Funding 5-6 months after the window closes

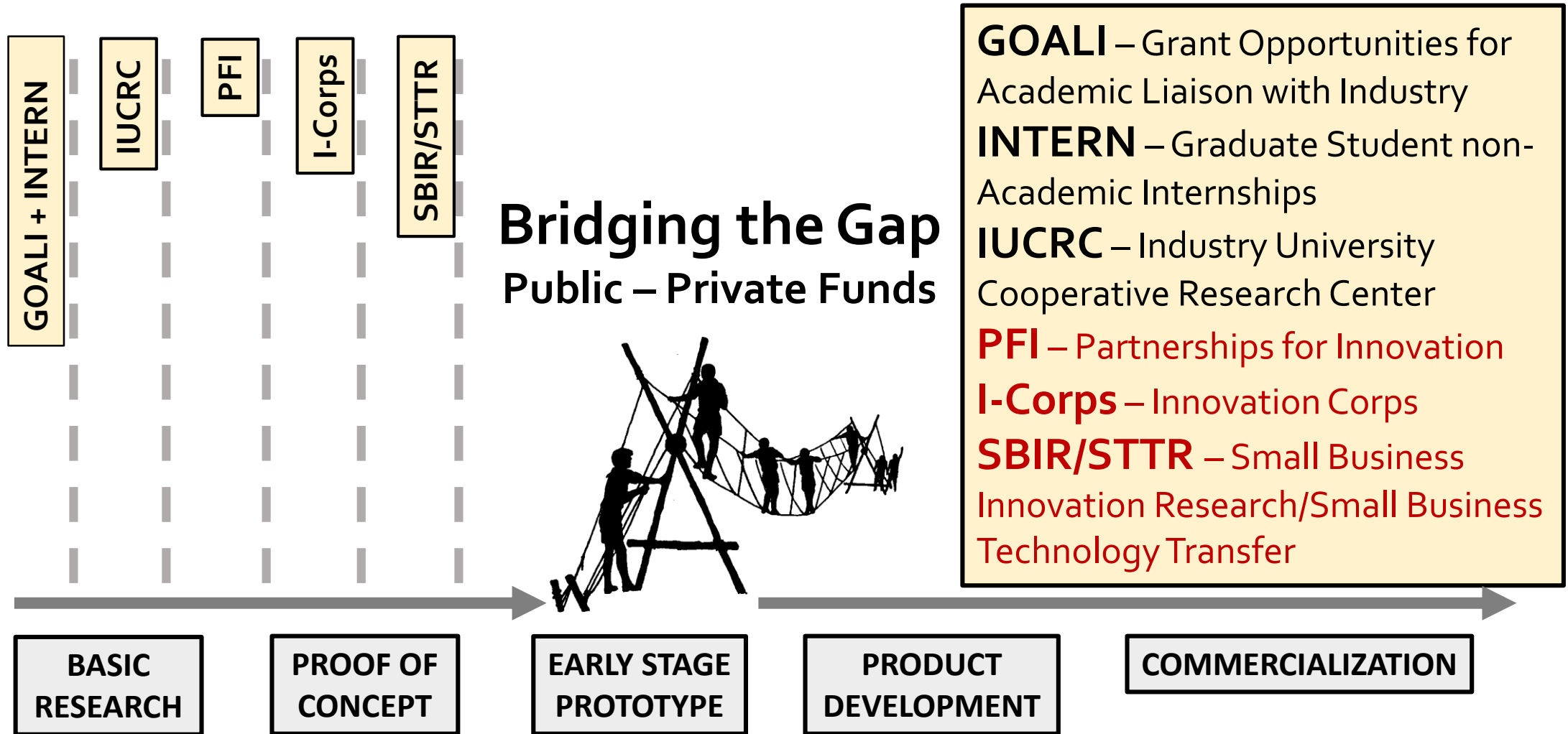
# Partnerships for Innovation (PFI)



Source: Jesus Soriano Molla MD PhD MBA  
Program Director  
National Science Foundation  
Industrial Innovation & Partnerships

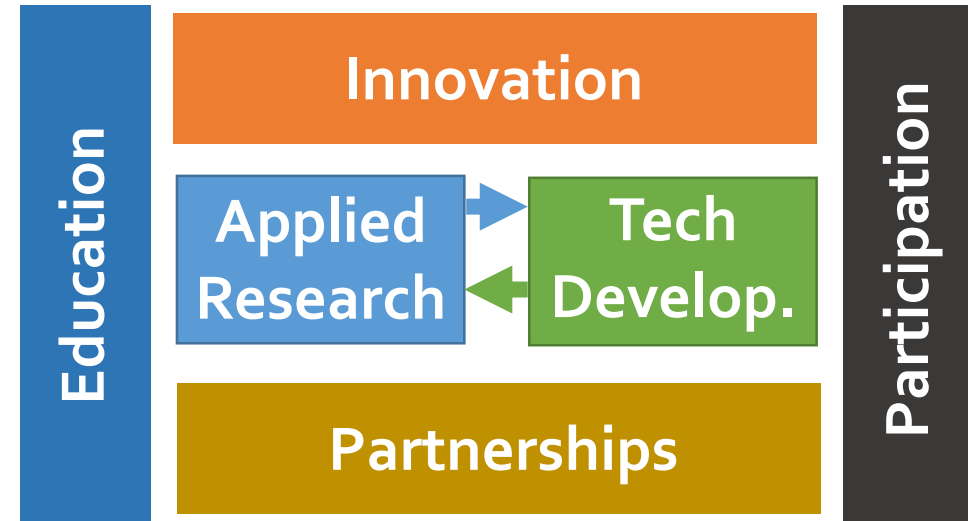


# NSF Innovation Programs





# Partnerships for Innovation (PFI)



## Congressionally Mandated<sup>1</sup>:

- Accelerate translation of research results to societal impact.
- Promote a sustainable university-based innovation ecosystem.
- Train faculty and students in technological innovation.
- Engage women and other underrepresented groups in innovation.

<sup>1</sup>. American Innovation and Competitiveness Act (Public Law No. 114-329)

# Partnerships for Innovation

**PFI-TT<sup>①</sup> grants are up to \$250,000 over 18-24 months.**

- Applied Research.
- Proof-of-concept demonstrations or prototypes.

**PFI-RP<sup>②</sup> grants are up to \$550,000 over 36 months.**

- Same Goals as PFI-TT.
- Focused on Multidisciplinary, Multi-Organizational Teams.
- Requires an Industry Partner.

(1) PFI-TT – Partnerships for Innovation-Technology Translation

(2) PFI-RP – Partnerships for Innovation-Research Partnerships

**Submission Deadlines: January and July**

# Not For All Of Us

- **Academic / Research US institutions**; includes universities and two- and four-year colleges (including community colleges) accredited in, and having a campus located in the US, acting on behalf of their faculty members
- **Public or Non-profit, Non-academic US organizations** located in the US that are directly associated with technology transfer activities
- **Non-profit US organizations** located in the US that partner with an institution of higher education
- **A US consortium of 2 or more** of the organizations described above

# The Industrial Partner (I)

- **Mandatory in PFI-RP track, encouraged in PFI-TT**
- **U.S.-based**
  - Foreign Public Entities or Foreign Organizations do not qualify.
- **Established record of commercial revenue.**
  - From sales or licensing
  - Majority of revenues cannot be from grants/government contracts
- **For-profit or not-for-profit.**
  - Non-profit, technology transfer organizations must meet revenues requirement
- **Proven experience in bringing products or services to the proposed target market sector**



# The Industrial Partner (II)

- Demonstrates **strategic commercial interest** in PFI technology
- **Does not include** budgeted Vendors/Service Providers
- **SBIR/STTR companies** may act as Industrial Partner.
- **Subawards only to SBIR/STTR – funded businesses**
  - Small businesses must be eligible for SBIR/STTR
  - Must not be owned and/or controlled by proposing team/institution.
  - Subawards are not intended to complement or circumvent SBIR/STTR awards to small businesses or as a standing source of revenue for the small business

# Intended Outcomes of PFI

- **Commercialization of IP** derived from NSF-funded research.
- **Licensing** of NSF-funded research outputs.
- **Foster collaborations** with industry.
- **Training** future innovation and entrepreneurship leaders.
- Increased participation of **women, minorities, and persons with disabilities** in innovation & entrepreneurship.

Read solicitation NSF 19-506

<https://www.nsf.gov/pubs/2019/nsf19506/nsf19506.htm>

# Synopsis: Reviewer Criteria



**Study Approach  
Ability/Credentials  
Impact**



**National Institutes  
of Health**

**Significance  
Innovation  
Approach  
Investigators  
Environment  
Impact**



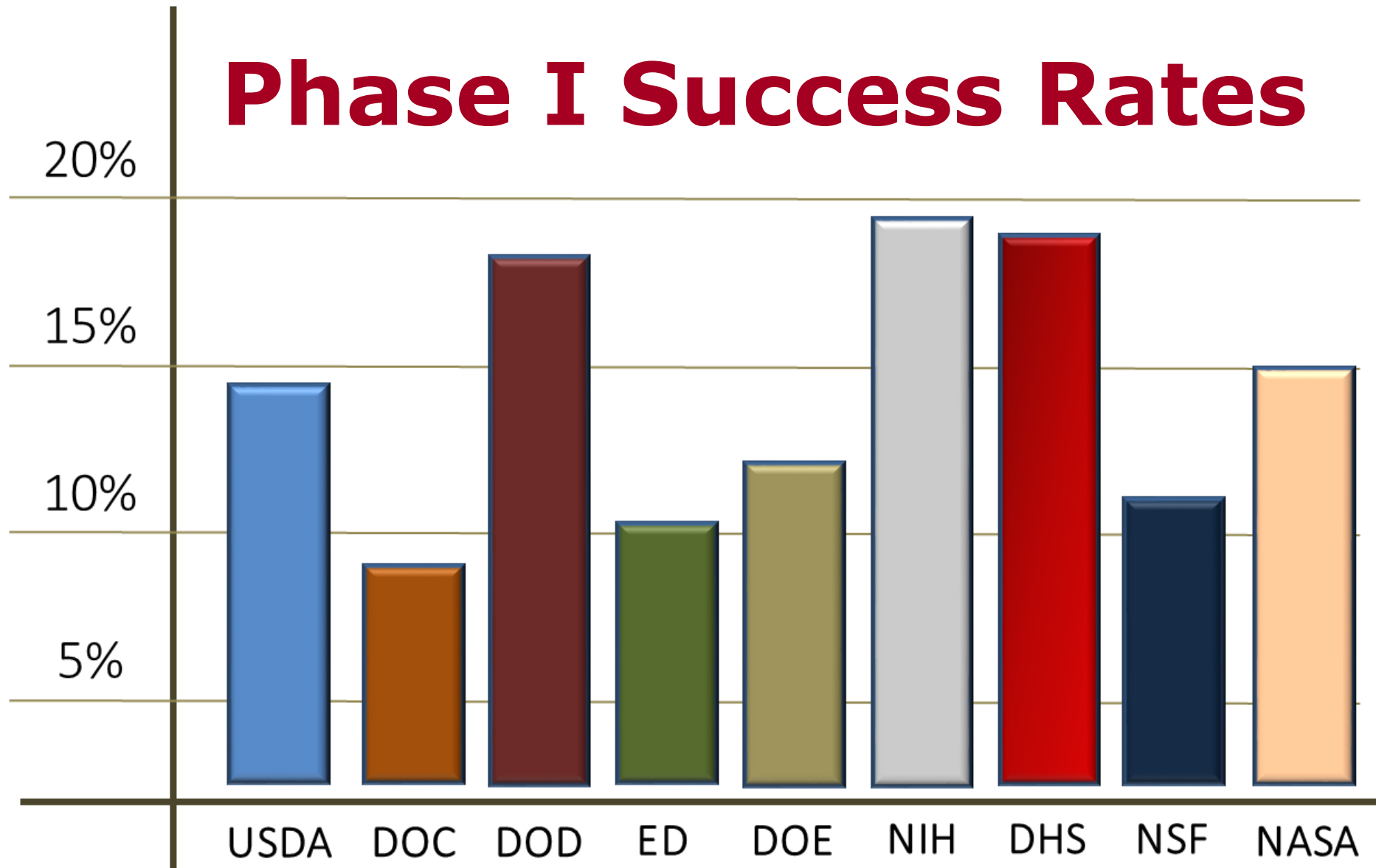
**Relevance  
Objectives  
Scientific Excellence  
Impact  
Qualifications  
Facilities  
Budget  
Commercialization**



**Intellectual Merit  
Impact/Benefit  
Advance Knowledge  
Creative, Original,  
Transformative  
Well-Reasoned  
Qualifications  
Resources**

**Similar Criteria for  
the Other 7 Agencies**

# Phase I Success Rates





# PART IV: REJECTED?



## Common Problems

- 1) They Don't "Get It"
- 2) Problem Is Not Significant (Enough)
- 3) Not Innovative
- 4) We're Not Qualified
- 5) Approach Needs Work

# Common Problems (I)

- 1) Lack of new or **original ideas**
- 2) No **Significance**: unimportant problem, unconvincing case for commercial potential or societal impact
- 3) Inadequate consideration of **scientific premise & rigor**
- 4) Absence of an **acceptable scientific rationale**
- 5) Questionable reasoning in **experimental approach**
- 6) Diffuse, superficial, or unfocused **research plan**
- 7) Lack of sufficient **experimental detail**
- 8) Failure to consider **potential pitfalls** and alternatives
- 9) Lack of **knowledge of published relevant work** &/or technologies
- 10) **Lack of experience** in the essential methodology
- 11) **Unrealistically large** amount of work



# Common Problems (II)

## 1) Proposal Is **NOT CLEARLY WRITTEN**

- Use peer review improve solution and pitch

## 2) Proposal is **Not Innovative**

- **NOT CLEARLY DIFFERENTIATED:** Position Technology Solution Relative to Current Standard & Alternative Solutions/Offerings
- **NOVEL COMBINATION** Of Existing Approaches: emphasize Novelty AND Unmet (Evidence-Based) Need

## 3) Team is **NOT QUALIFIED**

- Add collaborators and consultants
- Create a Multi-PI Group (To Address Experience Issues)

# More Common Problems

## 4) Not Working on a **SIGNIFICANT PROBLEM**

- Sell on Problem Importance: Repercussions/Ramifications
- Be More Specific and Quantitative
- Get Letters of Support in re Problem and Buyers/End users

## 5) Reviewers Are Critical of **OUR APPROACH**

- Respond to Their Criticisms
- Revise the Approach
- Have Others Review and Critique Approach



# **What We Often Find . . .**

**Evidence of Innovation &  
Sustainable Value is Lacking . . .**

**. . . Carefully Written Letters from  
Targeted Stakeholders are Vital**

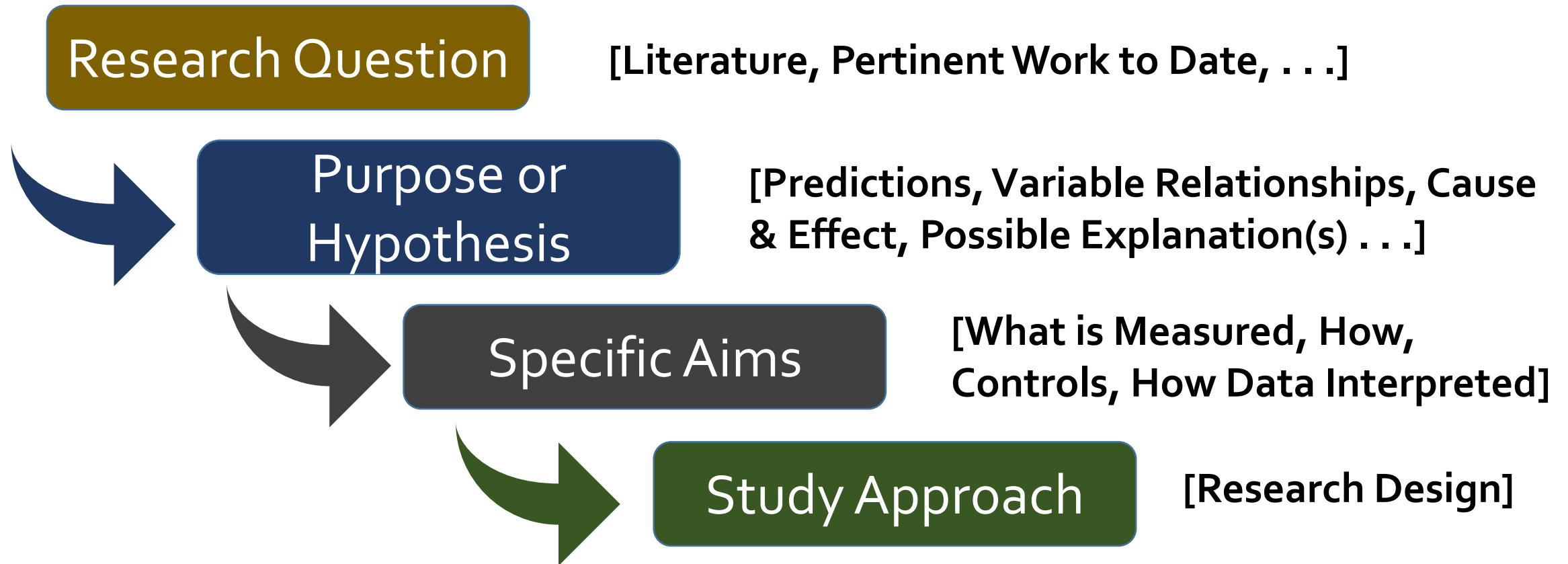
# **Study Approach**

**Statement of Aims**

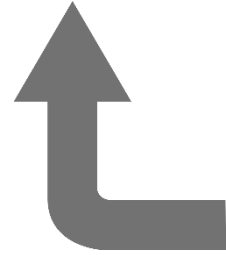
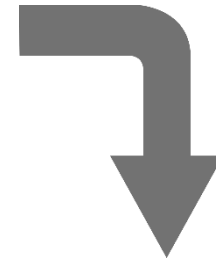
**-**

**Project Description**

# “Deal Killers” for Some



**Letter of Intent**



**Statement of Aims**

Question – Aim(s) – Approach - Impact



# Our Credentials



# Our Team

-

PI(s)

Employees

Subcontractor(s)

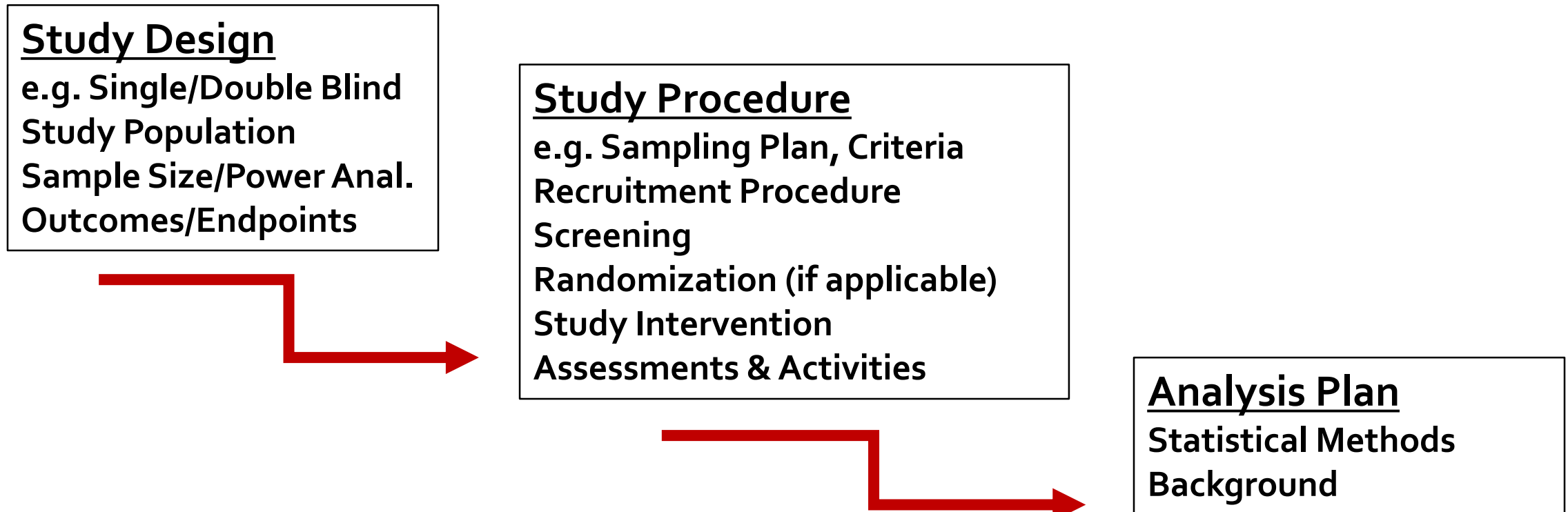
Consultants

Other Significant

Contributors

(Think Ahead to  
Commercialization)

# Why 65% of SBIRs are Partnerships



# ***We don't need no stinking budgets!***



Alfonso Bedoya ("Gold Hat"), The Treasure of Sierra Madre (1948)

"Budgets? We ain't got no budgets. We don't need no budgets. I don't got to show you no stinking budgets!"

## **Budget Preparation Guide & Salary Validation:**

- <https://seedfund.nsf.gov/fastlane/form-prep-2/>
- <http://www.bls.gov/bls/blswage.htm>



# **PART IV: “Crossing The Chasm”**

## **Commercialization**



# Commercialization Plan

1. Company Information
2. Customer & Competition
3. Market
4. Intellectual Property
5. Financing
6. Assistance & Mentoring

# From the NIH Reviewers Guide\*

- 1) Your Project's **Value**, Expected Study Outcomes, **Market Benefits**
  - Key Technology Objectives, Commercial Applications, Competitive Advantages
- 2) Corporate Objectives, Core Competencies, **Business Development Plans** (PLUS Background: History of Previous Funding; Regulatory Experience; Commercialization)
- 3) **Market, Customer, and Competition**
  - Segment(s) Targeted; Competition(or) Analysis
- 4) Intellectual Property Protections (Patent & Provisional Status)

\*"R41, R42, R43, R44 Guide For Reviewers" (February 8, 2011)

# From the Reviewers Guide (continued)

## 5) Financial Plan

- Letters of Commitment; Letters of Support; Specific Steps Taken for Phase III

## 6) Production & Marketing Plan

- Manufacturing, Marketing, Licensing, and Internet Sales

## 7) Revenue Stream Generations (aka “sales”)

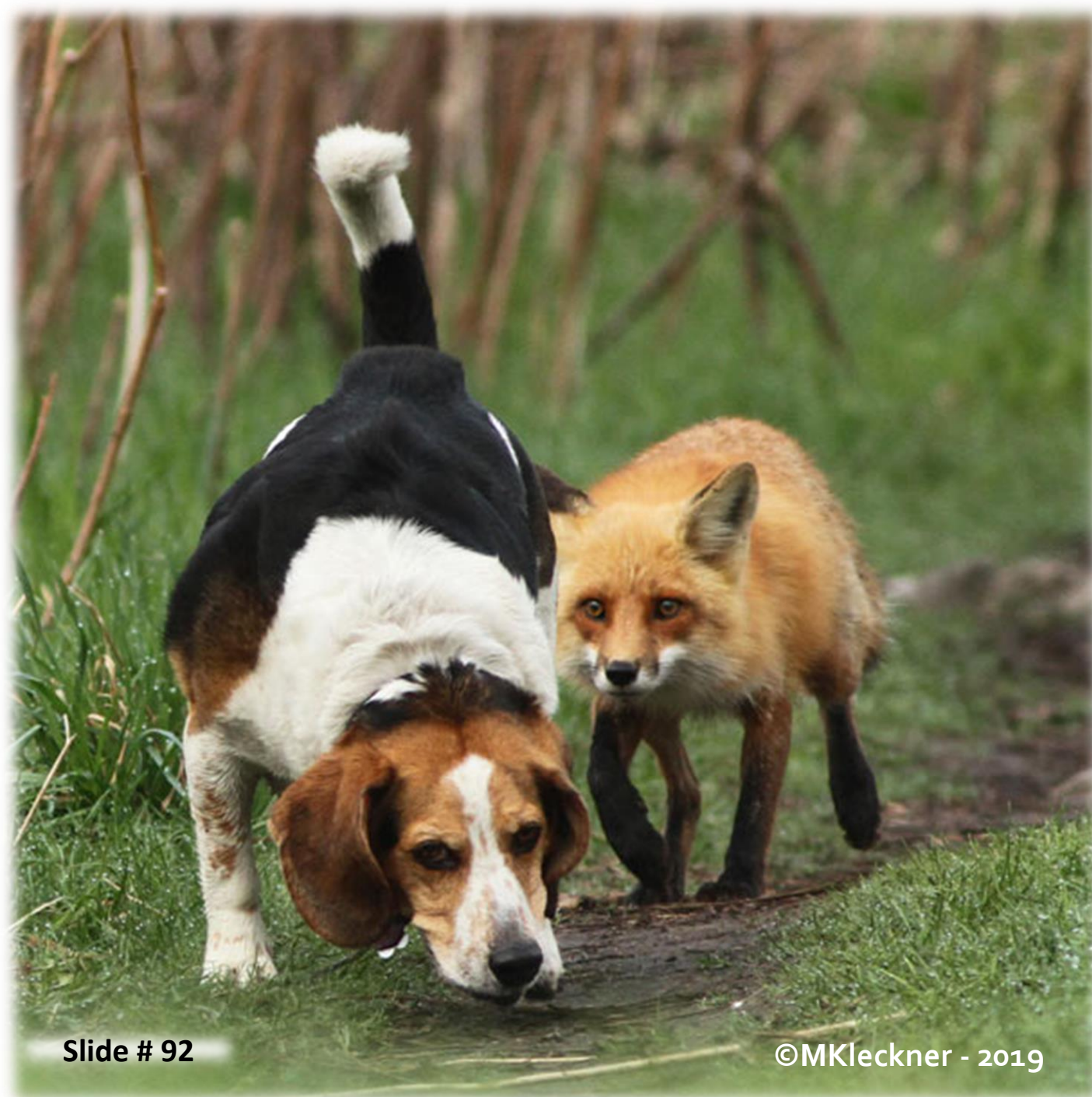
- Manufacture & Direct Sales, Distributors, Joint Ventures, Licensing, Internet

**(Reviewers evaluate Commercialization Plan in SIGNIFICANCE Criteria Section— Comment on its Strengths/Weaknesses)**



# **“Can Your Dog Hunt?”**

- 1) Your Past Record**
- 2) Phase II Funding Commitments**
- 3) Phase III Follow-On Commitments**
- 4) Other Indicators**



# Commercialization Support

- I. **NIH:** Phase I “Technology Niche Analysis” (TNA)
  - NCAI, REACH (centers/hubs) as noted previously
- II. **NIH, NSF, DOE:** Commercialization Assistance Program (P II)
- III. **NSF, NIH, DoD:** The I-Corps Program - Innovation & Technology Commercialization Methodology (“Lean LaunchPad”)
  - The Business Model Canvas
  - The Customer Discovery & Validation Process
- IV. **NSF:** Supplemental (e.g. Matching Funds)
- V. **DOE, DOT:** Commercialization Assistance Program (CAP)

# NIH Technical Assistance Programs



## Phase I Awardees

Niche Assessment Program  
Foresight Science & Tech

- Jump-start commercialization efforts
- Determine competitive advantages
- Develop market entry strategy



## Phase II Awardees

Commercialization  
Accelerator Program  
Larta, Inc.

- Technical Assistance/Training in:
  - Strategic/business planning
  - FDA requirements
  - Technology evaluation
  - Manufacturing issues
  - Patent and licensing issues
- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting

# DAWNBREAKER®

## Phase I Awardees (also prep support)

- Kickoff Webinar
- Commercialization Readiness Assessment (CRA)
- Market Research
- Specialty Webinars
- Business Mentoring: Phase II Commercialization Plan

[www.dawnbreaker.com](http://www.dawnbreaker.com)

<http://science.energy.gov/sbir/commercialization-assistance/>



# Phase II Match Funding (NSF “Phase IIB”)



- Aim: Extend R & D Efforts Beyond Current P-II Grant
- Further **Accelerate Commercialization**
- **Max Funding: 50% of Investment Funds up to \$500,000**
- Must Start Process At least 30 Days Prior to Phase II Award Expiration; Investment Minimum of \$100K
- (See: [https:// www.nsf.gov/eng/iip/sbir/Supplement](https://www.nsf.gov/eng/iip/sbir/Supplement))

# Commercial/Strategic Partnerships

- NSF: “Technology Enhancement for Commercial Partnerships”
- NSF Funding for additional **research that goes beyond the Phase II project’s objectives** to meet the technical specifications or additional proof-of-concept requirements. (Submit w/in 18 months of PII award)
- Additional research is anticipated to **enhance the commercial potential and lead to partnerships** with industrial partners & secure venture/angel investors.

▪ **Max Funding: 20% of the Phase II award, up to \$150,000**

▪ **Pre-submission Exec Summary + Letter from Commercial Partner**

(Reference: [www.nsf.gov/eng/iip/sbir/Supplement/instructions.jsp](http://www.nsf.gov/eng/iip/sbir/Supplement/instructions.jsp))

# Commercialization Assistance



- Funding to **secure the services of a third-party service provider** to assist in commercialization activities.
- **Max Funding: \$10,000** per Phase II award
- **Deadline: Within 12 months of the effective start date of Phase II award (*recommended*)**

<https://www.nsf.gov/pubs/2014/nsf14072/nsf14072.pdf>



**I-Corps™ @ NIH**  
**(I Corps @ DoD)**






# I-Corps Nodes & Sites



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**70 + Active Sites**

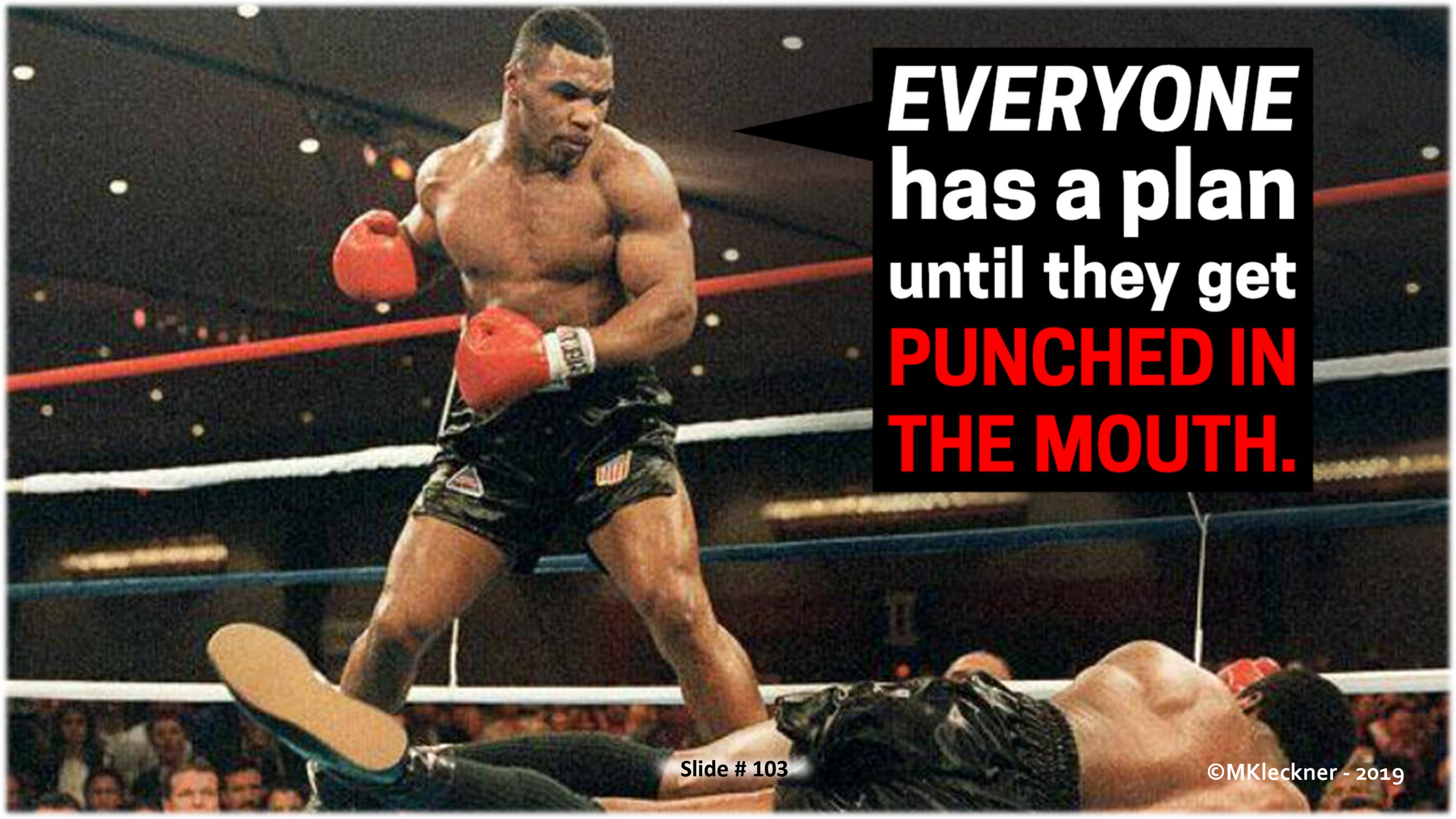
**UC Irvine  
UC Riverside  
UCSD  
SDSU/CSU  
USD?**

 I-Corps Sites

# **Seven (7) Week Curriculum (Agency Grant-Funded: \$40K - \$70K)**

- **Precursor Competitive Programs**
  - e. g. IN-LA “Zap” & “Boom”
  - e. g. U C Riverside Phase I & II
- **Five + Week Site-Based Programs**
- **Apply Directly to NSF, NIH, DoD**





***EVERYONE***  
**has a plan**  
**until they get**  
**PUNCHED IN**  
**THE MOUTH.**



**No battle plan  
survives first contact  
with the enemy.**

*- Helmuth von Moltke<sup>1</sup>*

---

**No Business Plan  
survives first  
contact with  
customers.**

*- Steve Blank<sup>2</sup>*



(1) 19th-century head of the Prussian army; (2) Stanford & U C Berkeley (I-Corps)

**Plans are worthless, but  
planning is everything.\***

***- Dwight D. Eisenhower***

**\* National Defense Executive Reserve Conference, Washington DC, November 14, 1957**

# Five - Year Plans

Venture Capitalists

Soviet Union



**Instead of creating  
business plans...**

**Today we discover  
*business models.***



# **Business Model Generation** **(Customer Discovery & Validation)**

7. KEY PARTNERS

8. KEY ACTIVITIES

1. VALUE PROPOSITIONS

4. CUSTOMER RELATIONSHIPS

2. CUSTOMER SEGMENTS

## 7 Week Grant-Funded Cohorts

6. KEY RESOURCES

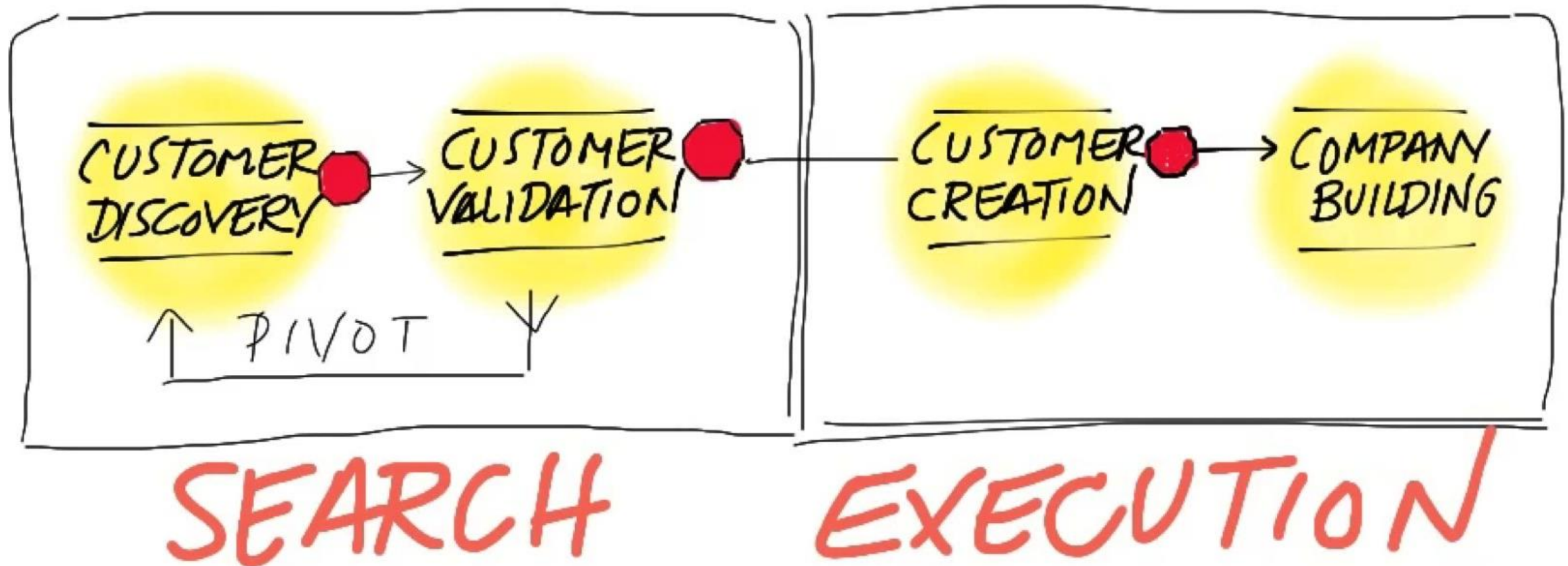
3. CHANNELS

9. COST STRUCTURE

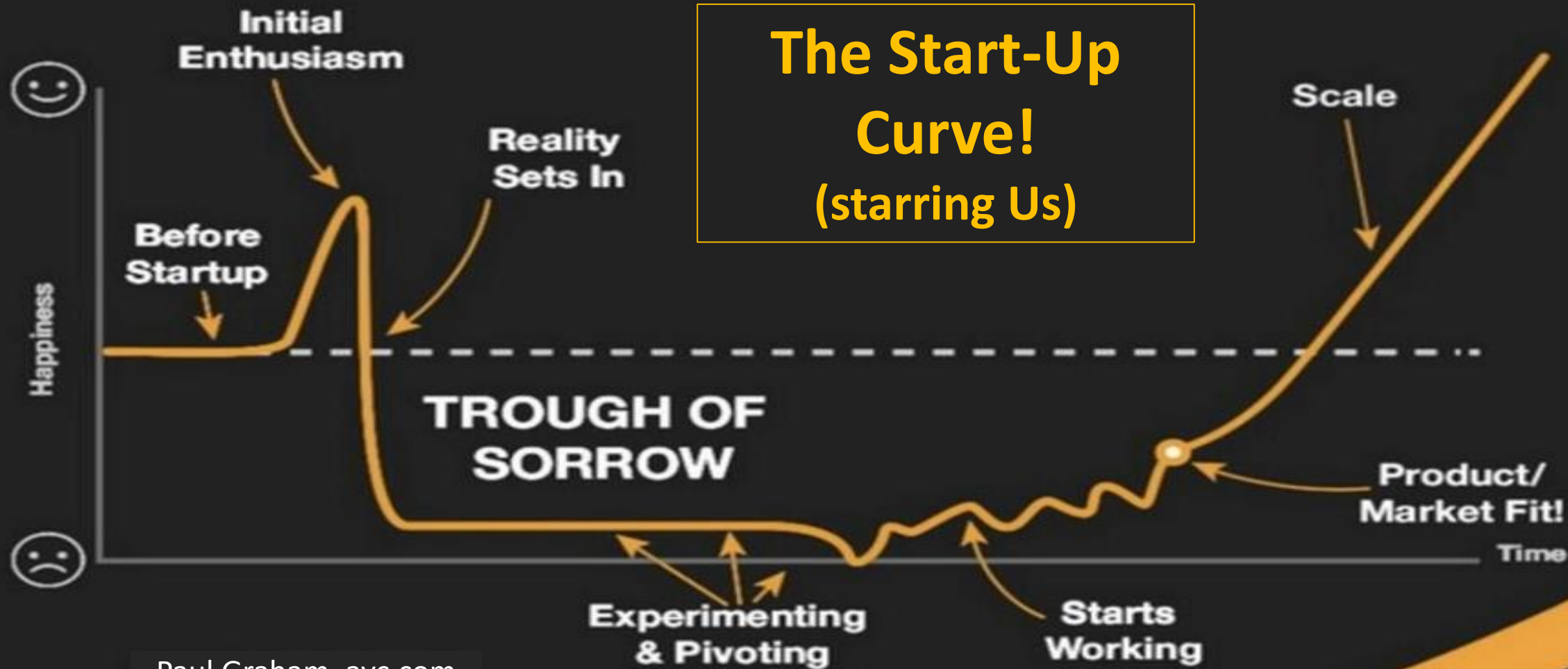
5. REVENUE STREAMS

# Business Model Generation . . .

## . . . Customer Development



# Behind Every Great Product is a Great Story



Paul Graham, [avc.com](http://avc.com)





**Hopefully some of this was helpful!**

**Martin S. Kleckner III PhD MBA**

**[mkleckner@cox.net](mailto:mkleckner@cox.net)**

**1 (619) 892-2565**

**University of San Diego BRINK  
Center for Innovation & Commercialization**