Winning SBIR/STTR Funding: Raising Your Chances for Success

University of San Diego BRINK
San Diego Contracting Opportunities Center (SDCOC)
San Diego PTAC Southwestern College Higher Education Center
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AMERICA'S SBDC CALIFORNIA
SAN DIEGO AND IMPERIAL NETWORK

SBIR · STTR
America's Seed Fund

1st in a Four-Part Series

Winning SBIR & STTR Grants: The Basics (July 12, 2018)

SBIR & STTR – Phase II: Beyond the Basics (August 23, 2018)

Funding Your Innovation (September 21, 2018)

Roadmap to Commercialization: I-Corps (October 18, 2018)

SBIR "Deal Killer" (Avoidance) Program

1) Registration for SBIR/STTR Applications
2) Presenting a Fundable Study Approach
   - Research Design/Protocol
   - Writing Hypotheses and Aims
3) Writing Your Phase II Commercialization Plan

Industry Specific: (e. g. Life Sciences)

Commercialization (Navigation Roadmap)

- Coding, Coverage, Payment (Reimbursement); 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 – 10 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

Candidacy to National Cohort

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 & other aspects
10) Strategic & Tactical planning

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

America's SBDC California – San Diego and Imperial Network
Brink University of San Diego
UC Riverside University of California
UCI Applied Innovation

NSF I-CORPS NSF Innovation Corps
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, Coulter, Drexel; University of California
5) Times Mirror, American Healthcare Systems, General Electric, Roche Diagnostics, Toshiba America Medical Systems
6) **$33.8 MM** in Capital & Grants 2016 – Q1 2018


What is Your Odyssey?
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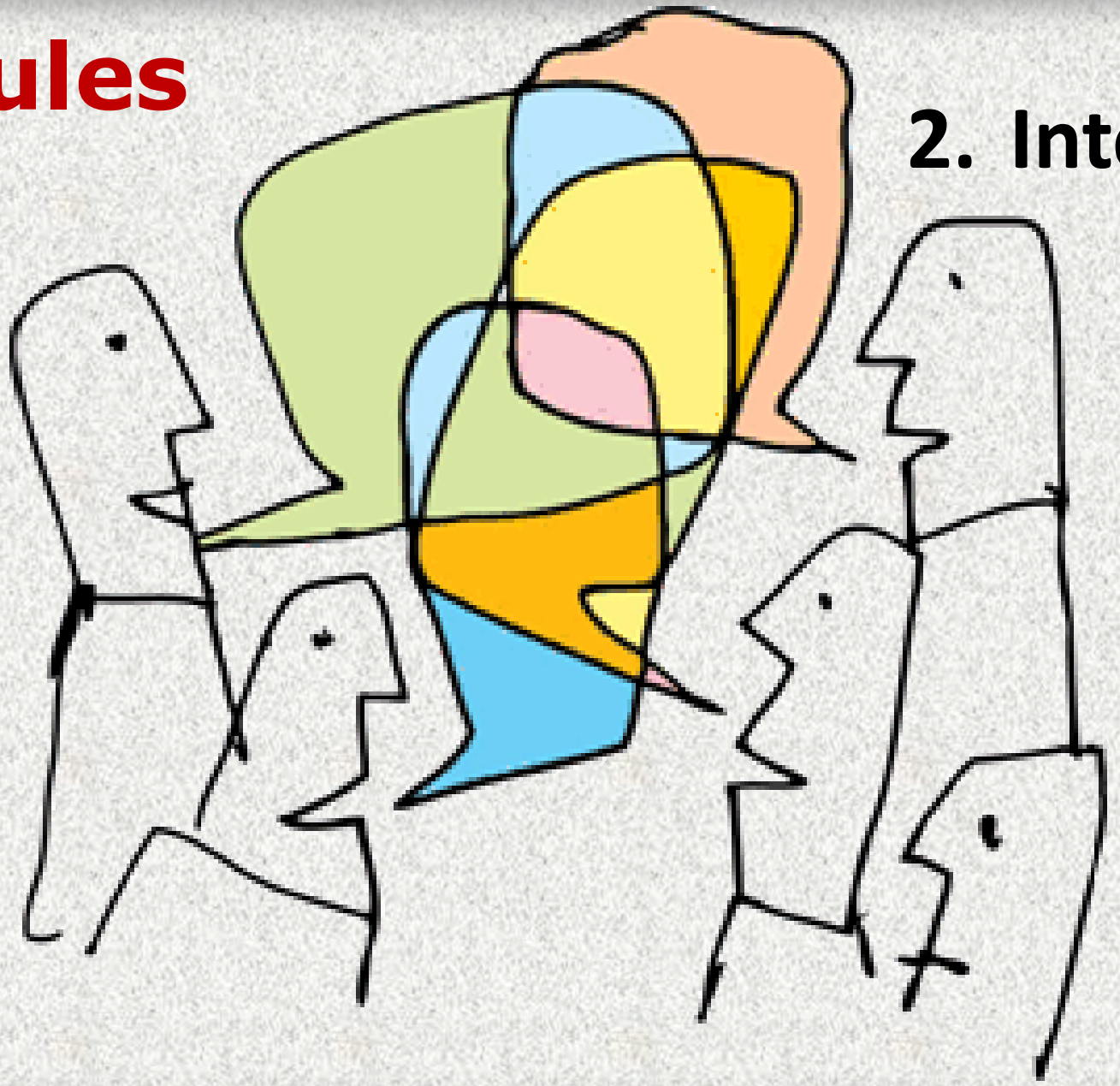
Essential Rules

1. Ask Questions

2. Interrupt

3. Challenge



SBIR/STTR: The Basics

I. The PROGRAM BASICS (DOE, NIH, DoD, NSF et al.)

- Legislative/Regulatory Affairs; Registration; Funding

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 (extended: 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
  - Extended in December 2016 through Sep 2022
  - 0.45% of Agency Budget (Budget > $1B)
  - Collaboration Between Small Business and NFP Research

U.S. Research Groups Going to War Again Over Small Business Funding

Jeffrey Mervis, May. 18, 2016 http://www.sciencemag.org/news/2016/05/us-research-groups-going-war-again-over-small-business-funding

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 extended, not 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 March 23.

Base Program Remains . . .

. . . “pilot” programs expire

No More (Pilot Programs Expired):

- **Direct to Phase II**

- **Phase 0 Proof of Concept Partnership** (Commercialization Readiness Program: CRO Studies; IP Strategies; FDA Guidelines)

DoD Commercialization Readiness Program (CRP) stays in force through 09/30/2022

DoD Rapid Innovation Fund (RIF): $250 MM in Phase III funds is now 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

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; higher per agency)
- 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; varies per agency)
- Phase IIB (NIH; DOE: Sequential) or Special/Supplemental (e.g. DOE, NSF)
- Commercial Potential: Past Record; Funding + "Commitments" (P II & III)

PHASE III: Commercialization

- Unfunded; Non-Cash; In-Kind Support

To Be Eligible (SBIR) . . .

1. SBC* Organized For-Profit; based in the U. S.
2. No more than 500 employees (incl. Affiliates, PT & Temp.)
3. ≥ 50.1% directly-owned or controlled by 1 or more permanent citizens or resident aliens ('Green Card' & 'Substantial Presence')
   - Other small businesses meeting the above criteria
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

* Legal form of a Proprietorship, Partnership, LLC, Corporation, Joint Venture, Association, Cooperative

Eligibility (STTR) . . .

1. Organized For-Profit; based in the U. S.; ≤ 500 employees
2. ≥ 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 Primarily 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
- ~~**Direct to Phase II (Pilot)**~~
  - FY 2012 – 2017, NIH, DoD, and ED May Issue Phase II SBIR Awards To Pursue Phase I Solicitation Topics/No Phase I Required
- **All Phase I Awardees** Must be Allowed To Apply For Phase II
- **Second Sequential Phase II** 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 ≤ 500 employees)
2) Can a Single VCOC (HF, PEF) hold a majority share - own more than 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) 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**

2018 SBIR & STTR Budgets (Est.)

Agency	SBIR	STTR	Total
Defense (DoD)	$1,050	$148	$1,198
HHS/NIH	795	109	904
Energy (DOE)	205	29	234
NSF	190	26	216
NASA	193	26	225
USDA	21	-	21
Homeland	18	-	18
Education	15	-	15
DOT	8	-	8
Commerce	9	-	9
EPA	5	-	5
TOTAL	$2.5B	$338M	$2.8B

2018/19 Where The Interest Is

- EPA: Climate Change/Green House Gas
- DOE: Clean Energy –Vehicles/Buildings
  - ❖ Advanced Research Projects: Fossil Fuels/Carbon Capture/Nuclear
- NASA – Land-Use Monitoring; Asteroid Capture
- NIH – Precision Medicine; Biotic-Resistant Bacteria; Anti-Microbials; BRAIN
- USDA - Food Safety
- NSF – Basic Research

*** Brain Research through Advancing Innovative Neurotechnologies - National Institute of Neurological Disorders and Stroke (NINDS)**

2018: More Specifically

- Biodefense
- Biosensors
- Nanotechnologies
- Bioinformatics
- Diagnostic & Therapeutic Devices
- Telehealth
- Proteomics / Genomics

- Biosilicon Devices
- Biocompatible materials
- Acousto-Optics/Opto-Electronics
- Health IT
- Imaging Devices
- Genetically Engineered Proteins
- . . .

U.S. DEPARTMENT OF ENERGY

GOAL 1: Clean Energy Technologies

GOAL 2: Science & Engineering Leadership

GOAL 3: Nuclear Security

See: FY 2018 DOE SBIR/STTR Phase I Release; Available Funding Topics (31) https://www.sbir.gov/node/1308571

Program Offices Participating in the DOE SBIR/STTR Programs

- Electricity Delivery & Energy Reliability
- Energy Efficiency & Renewable Energy
- Fossil Energy
- Nuclear Energy
- Advanced Scientific Computing Research
- Basic Energy Sciences
- Biological & Environmental Research
- Fusion Energy Sciences
- High Energy Physics
- Nuclear Physics
- Defense Nuclear Nonproliferation
- Environmental Management

America's SEED FUND SBIR.STTR

https://seedfund.nsf.gov/portfolio/

TECHNOLOGY TOPIC AREAS

- Advanced Manufacturing and Nanotechnology (MN)
- Advanced Materials and Instrumentation (MI)
- Biological Technologies (BT)
- Biomedical Technologies (BM)
- Chemical and Environmental Technologies (CT)
- Digital Health (DH) and Medical Devices (MD)
- Educational Technologies and Applications (EA)
- Electronic Hardware, Robotics and Wireless Technologies (EW)
- Internet of Things (I), Semiconductors (S), and Photonic (PH) Devices/ Materials
- Information Technologies (IT)

Some Examples, but . . .

Predict Patient pt-Chemo Resistance
Automated Tourniquet Systems
Human Organ Simulation
Continuous Subcutaneous Insulin
Engineering Human Livers
Persistent Platform, GeoSync Orbit
Exotic Bird Stimulation
Ocular Surface Disease

Glaucoma Prediction
Energy Use – Ceramic Insulation
Waste Water Treatment
Autonomous Vehicles
Personal Flotation Device
Bird Strike Avoidance
Pre-Birth Fetal Movement
BoTox-E – Opioid Avoidance
Asteroid Mining

https://www.sbir.gov/news/success-stories

Most FY 2018 Solicitations Have Been Closed (FY 2019 Pending; see below e.g.)

DoD: https://www.acq.osd.mil/osbp/sbir/

DOE: https://www.sbir.gov/node/1308571

USDA: https://www.sbir.gov/node/1306641 (dated 2017; also: July 24, U C Riverside, Scott Dockum, USDA)

NIH: https://grants.nih.gov/funding/index.htm & grants.gov

NSF: https://seedfund.nsf.gov/portfolio/

Commerce (NIST): https://www.nist.gov/tpo/small-business-innovation-research-program

Not Required (except for the DOE)

Letter of Intent/Inquiry

Communicating Research Intent and Value in Applications

- Problem Statement
- The Purpose of Your Proposed Research Project
- Specific Objective(s)
- Specific Aim(s)
- Study Approach (Qualitative/Quantitative Method(s))
- Anticipated (Targeted) Impact(s)

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 (e.g. 13 c)
- 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

So, for the Department of Energy . . .

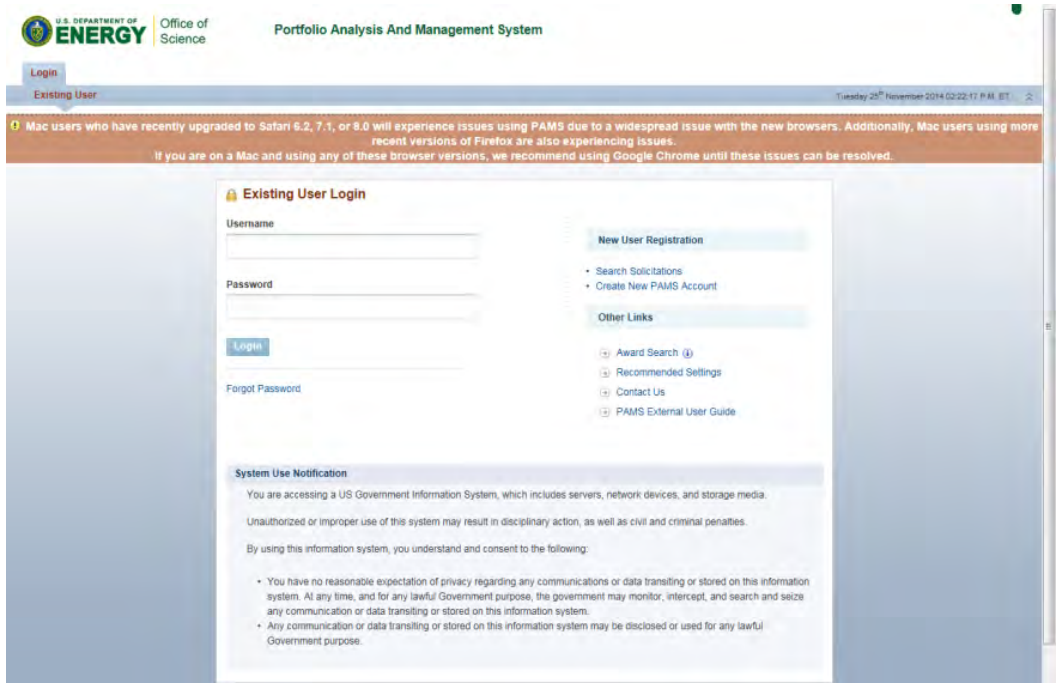
All Times are ET	Release 1	Release 2
Topics Issued	Monday, July 16, 2018	Monday, October 29, 2018
Webinar(s)	Week of July 30, 2018	Week of November 05, 2018
FOA Issued	Monday, August 13, 2018	Monday, November 26, 2018
Webinar(s)	Friday, August 17, 2018	Friday, November 30, 2018
Letters (LOI) Due	Tuesday, Sept 04, 2018 5:00 PM	Monday, Dec 17, 2018 5:00 PM
Non-responsive LOI Feedback Provided	Tuesday, Sept 25, 2018	Monday, January 7, 2019
Applications Due	Monday, Oct 15, 2018 11:59 PM	Monday, Feb 04, 2019 11:59 PM
Award Notification	Monday, January 07, 2019	Monday, Apr 29, 2019
Projected Grant Start	Tuesday, February 19, 2019	Monday, June 10, 2019
PI Meeting		

https://science.energy.gov/sbir/funding-opportunities/

Submit LOI online

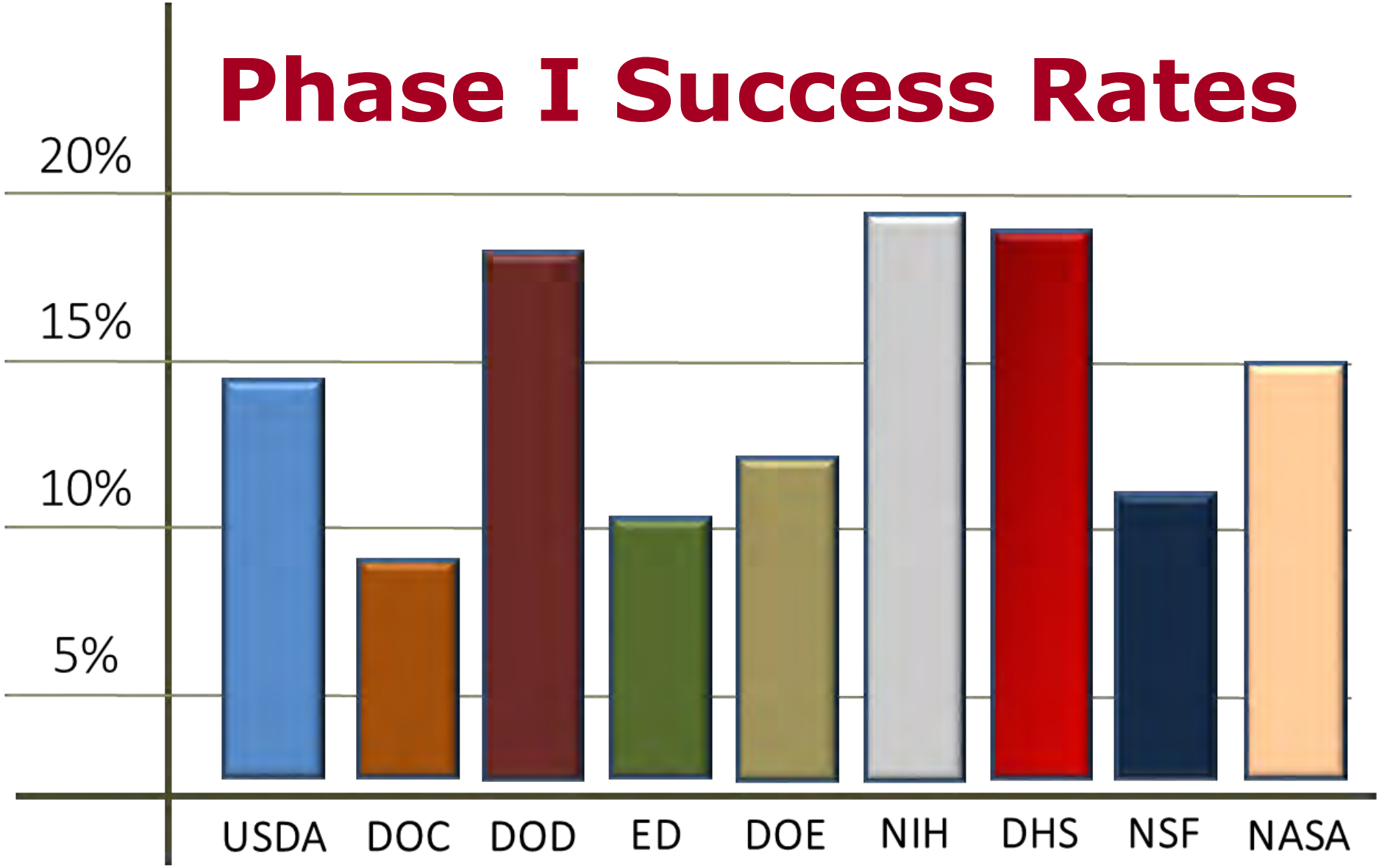
directly to the DOE Portfolio Analysis and Management System (PAMS) website:

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

Phase I Success Rates



http://www.sbir.gov/competitiveness

So, When Do I Get My Money?

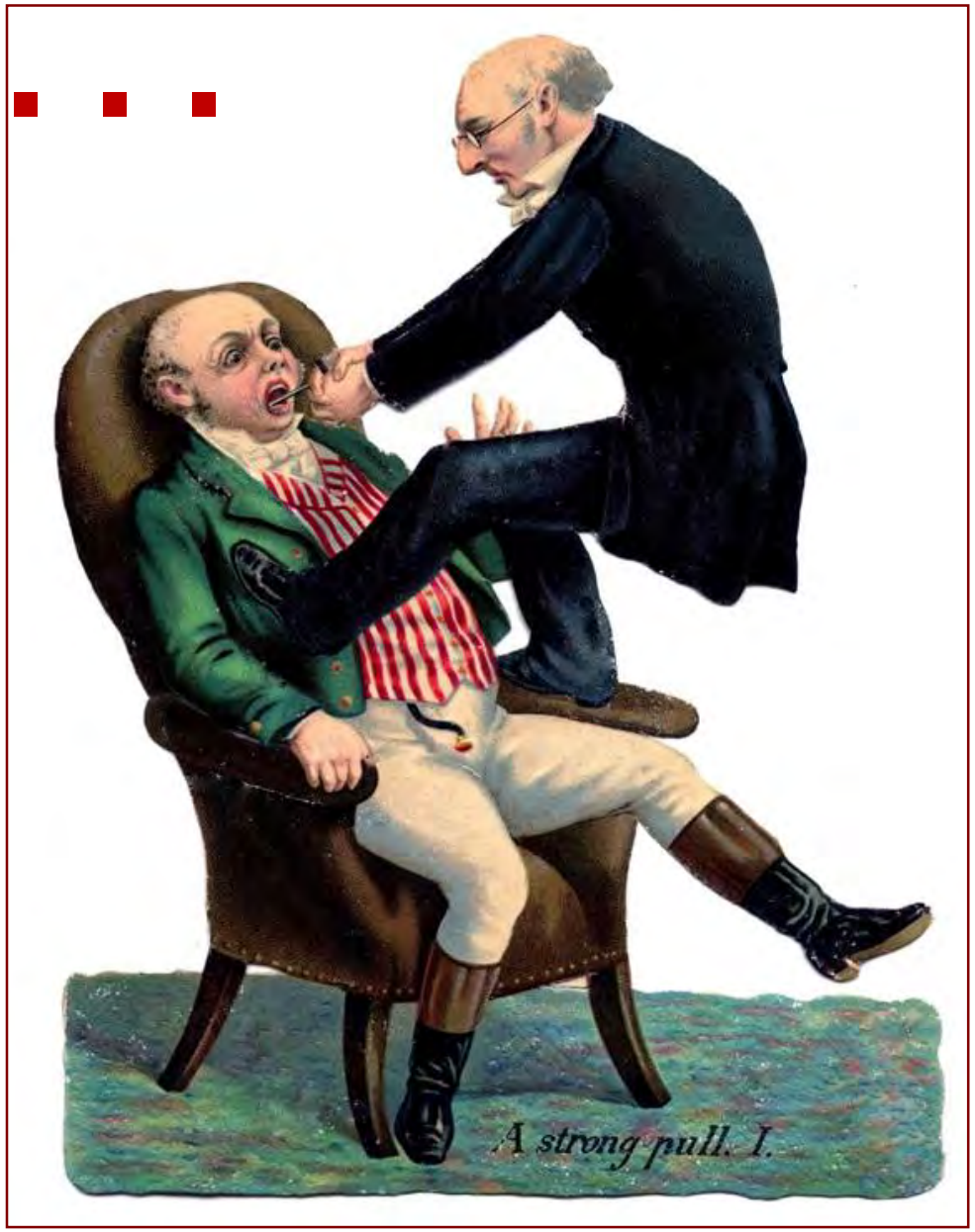
Timelines	USDA	DOC	DOD	ED	DOE	NIH	NSF	EPA
Avg. Months Deadline – $$	8.6	5.8	5.3	5.6	5.0	10.6	8.9	10.1
% P1 Awards dispersed < 6 Mo.	0%	75%	69%	100%	100%	8%	0%	0%
Avg. Mo. P1 to P2	9.3	5.3	10.8	1.8	4.7	8.1	8.5	7.8
Avg. Mo. P2 Award – P2 Start	2.8	1.0	0	5.2	1.5	-	2.3	1.0
% P2 Awards Dispersed < 3 Mo.	0%	100%	100%	100%	100%	0%	41%	100%

Register, Register . . .

1. Get a DUNS #
2. Register on SAM.gov*
3. Register on Grants.gov or FastLane

   3a. DOE: Portfolio Analysis & Management System (PAMS)
4. (Register on eRA Commons, NIH)
5. SBA Registry
6. Can take 6 – 8 weeks

. . . Register



Online Access Sites

1. DUNS:http://www.sba.gov/content/getting-d-u-n-s-number: (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”.

2. SAM: Grants Registrations User Guide at http://www.sam.gov for additional information. (“Register” is located on the upper right corner of the web page.)

Online Access Sites

3. **Grants.gov:** (http://grants.gov/applicants/get_registered.jsp).

   Questions? 1-800-518-4726 or by e-mail at support@grants.gov.

4. **(eRA Commons - NIH)**: https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp

5. **SBA Registration** (SBC Control ID): https://www.sbir.gov/registration

System for Award Management (sam.gov)

ALERT - June 11, 2018: Entities registering in SAM must submit a notarized letter appointing their authorized Entity Administrator.

Alleged Fraudulent Activity (GSA measures taken):

(1) Masking specific data elements in the entity registration even for authorized entity users;

(2) Requiring "parent" approval of new registrations for their "child" entities; and

(3) Requiring the formal appointment of the Entity Administrator by original, signed notarized letter (no longer needed prior to activation).

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=kb0013183

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 entity's legal business name and physical address at the top of the letter before printing.

Comprehensive Guides

e. g. NIH Application Format etc. (SF424 SBIR/STTR Guide)
http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_Adobe_VerB.pdf

e. g. DOE Instructions - http://science.energy.gov/sbir/applicant-and-awardee-resources/grant-application/

Large Documents

- How to Register
- Required Software (PDF Document Creator)
- Using the Application "Package", Filling in Forms
- Fonts, Margins, Headers, Page Limits . . .
- Organization of Your Application
- How to Submit

PART II

CONTENT: WHAT'S IMPORTANT

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%)

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

Your NIH Reviewers & Their "Marching Orders"

National Institutes of Health

- Title
- Abstract
- Problem
- Solution
- Specific Aims
- Research
- Strategy
- Facilities
- Biographies

Focus: Key Criteria

Scoring System and Procedure

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

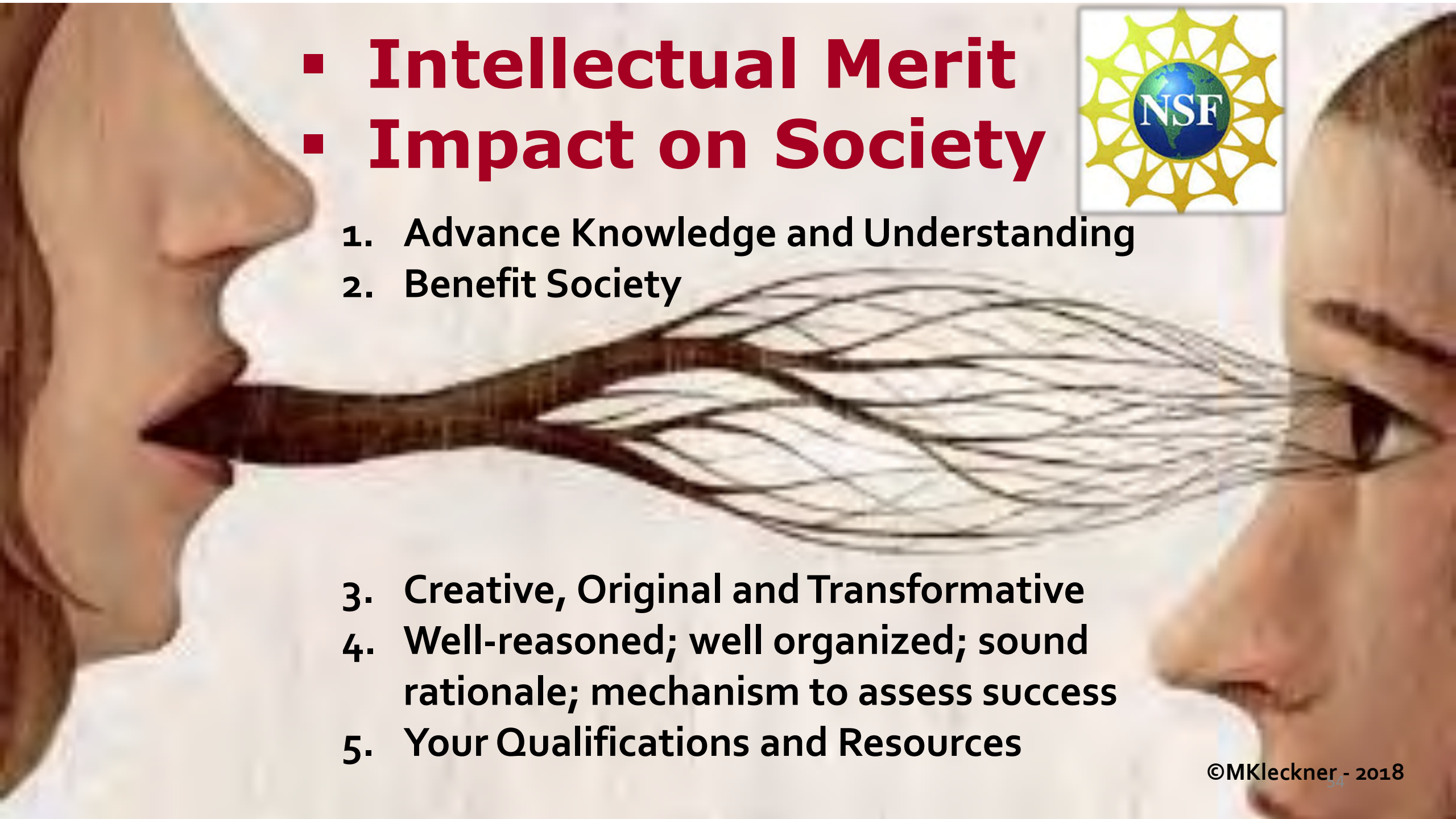
*** http://grants.nih.gov/grants/peer/reviewer_guidelines.htm**

DoD Evaluation Factors

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

Source Selection Authority & selected team; specified factors noted in Program Solicitation; includes performance history.

SBIR/STTR Desk Reference:
"Evaluation & Selection"-
(http://www.acq.osd.mil/osbp/sbir/sb/resources/deskreference/02_eval.shtml)



- **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

Reviewer Criteria Synopsis

Study Approach
Ability/Credentials
Impact

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

Final Award Decisions Based Within Context

1. PUI – Primarily Undergraduate Institutions *(www.nsf.gov/pubs/2014/nsf14579/nsf14579.htm)*
2. EPSCoR – Experimental Program to Stimulate Competitive Research *(www.nsf.gov/od/iia/programs/epscor/index.jsp)*
3. Career Stage
   - Beginning Investigator
   - Mid-Stage
   - Late-Stage

Additional Criteria

1. PHASE II
2. Phase I/II FAST TRACK
3. Protection of Humans
4. Vertebrate Animals
5. Biohazards

- PHASE I OBJECTIVES MET: feasibility demonstrated; solid foundation for moving ahead?
- FT: P1 CLEAR, MEASURABLE, APPROPRIATE GOALS TO ACHIEVE prior to P2?
- LETTERS OF INTEREST: additional funding commitments; private sector resource support to enhance commercialization odds

Additional Criteria

- Re-Submissions
- Phase IIB Competing Renewals
- Revisions

- Application as now presented; RESPONSES to comments from the previous scientific review; CHANGES made to the project
- PROGRESS MADE in the prior funding period
- APPROPRIATENESS of the proposed expansion of the project scope; responses to reviewer comments: adequate

PART III: 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

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/Offering being Developed
   - 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

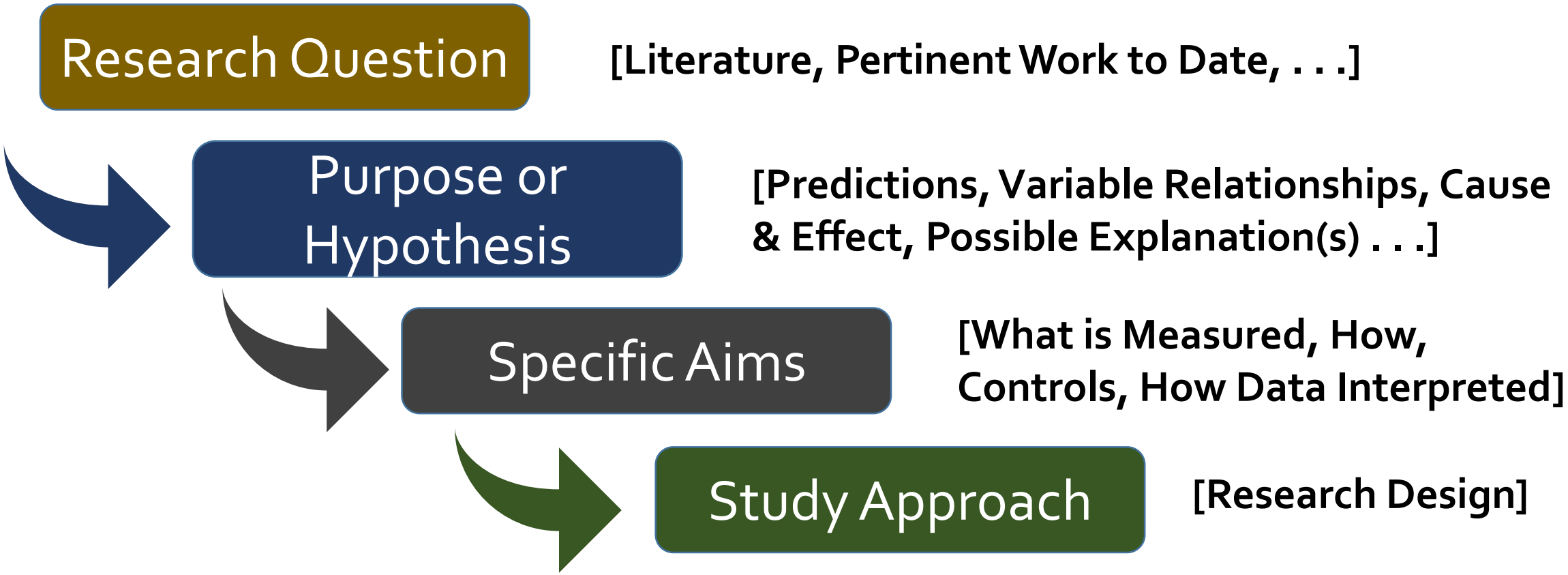
Study Approach

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

Study Design
e.g. Single/Double Blind
Study Population
Sample Size/Power Anal.
Outcomes/Endpoints

Study Procedure
e.g. Sampling Plan, Criteria
Recruitment Procedure
Screening
Randomization (if applicable)
Study Intervention
Assessments & Activities

Analysis Plan
Statistical Methods
Background

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

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 Plan

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

Commercialization Support

I. **NIH:** Phase I "Technology Niche Analysis" (TNA)

II. **NIH, NSF:** Commercialization Assistance Program (Phase II)

III. **All:** 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)

CAP for Phase II Awardees (NIH)

(https://sbir.nih.gov/cap#cap-home)

Managed through a contract with Larta, Inc. (www.larta.org) of Los Angeles, CA - individual mentoring and consulting sessions, training workshops, access to domain experts

1) Commercialization Training Track (CTT)
2) Accelerated Commercialization Training Track (ACT)
3) Regulatory Training Track (RTT)

DAWNBREAKER®

Phase I Awardees

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

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)

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)

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

~~Phase 0 POC: NCAI and REACH~~

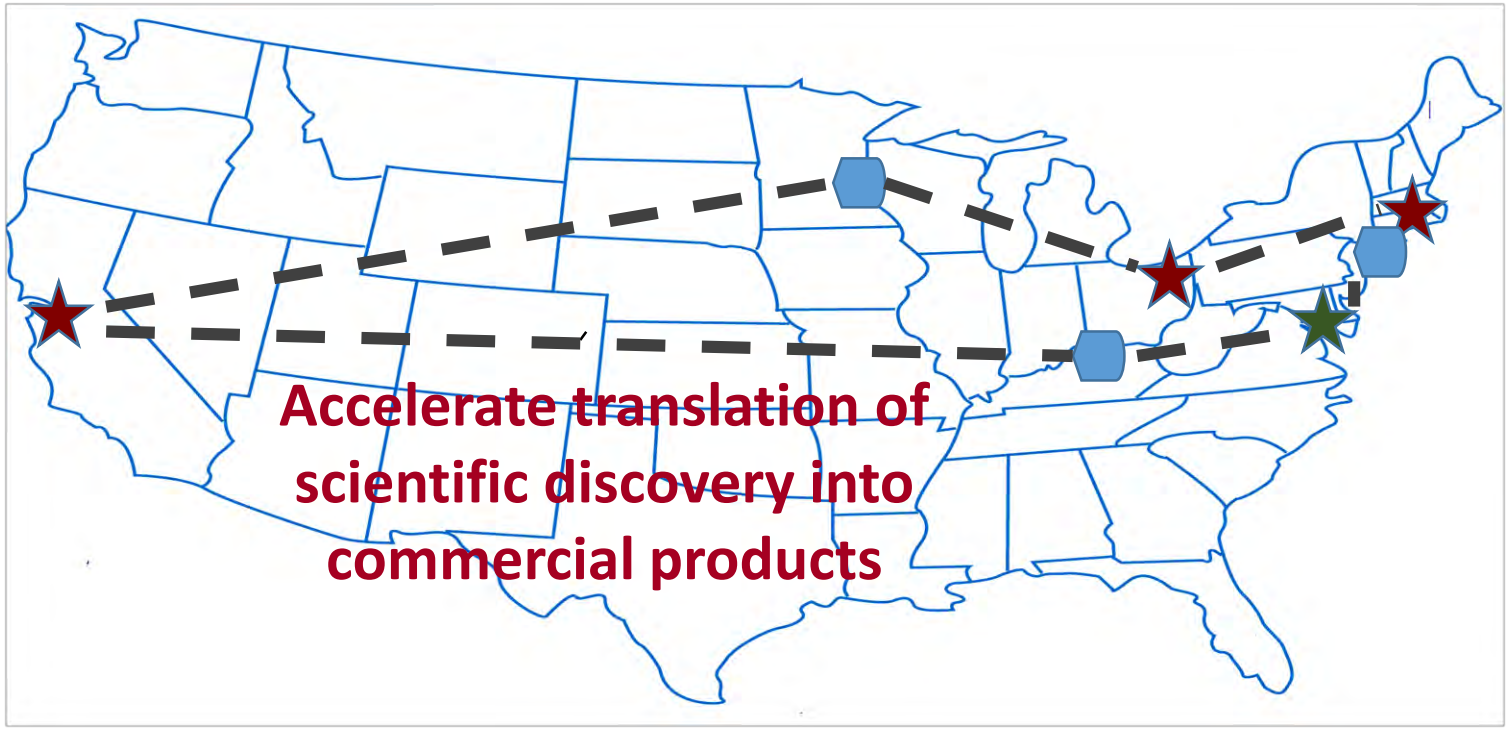
Proof-of-Concept Centers (Hubs)*

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

Source: Matthew Portnoy PhD

NIH Centers for Accelerated Innovations: Boston Biomedical Innovation Center, Cleveland Clinic Innovation Center, UC BRAID Center for Accelerated Innovation

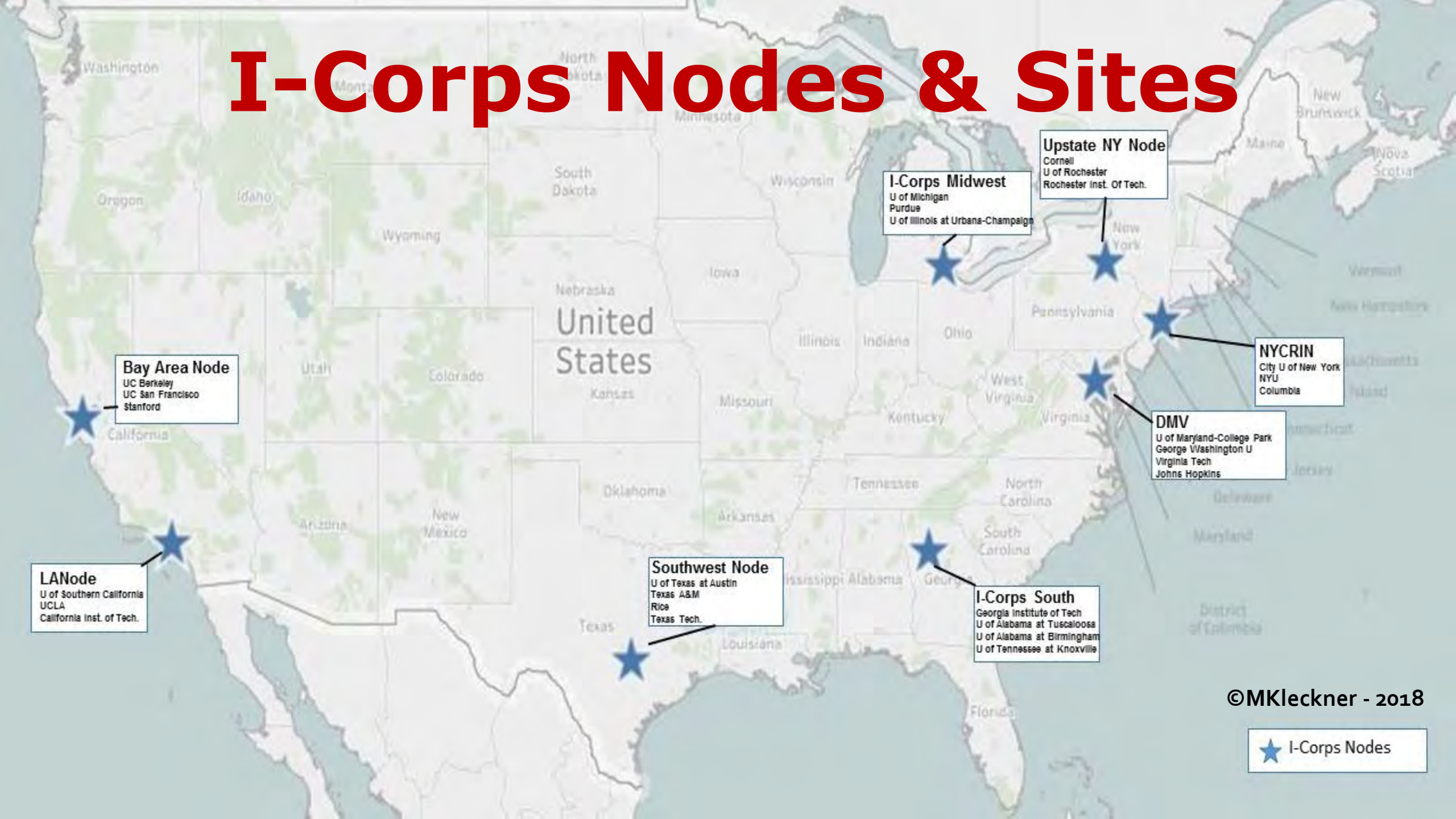
Research Evaluation and Commercialization Hubs: University of Minnesota, Long Island Biomedical Hub, University of Louisville

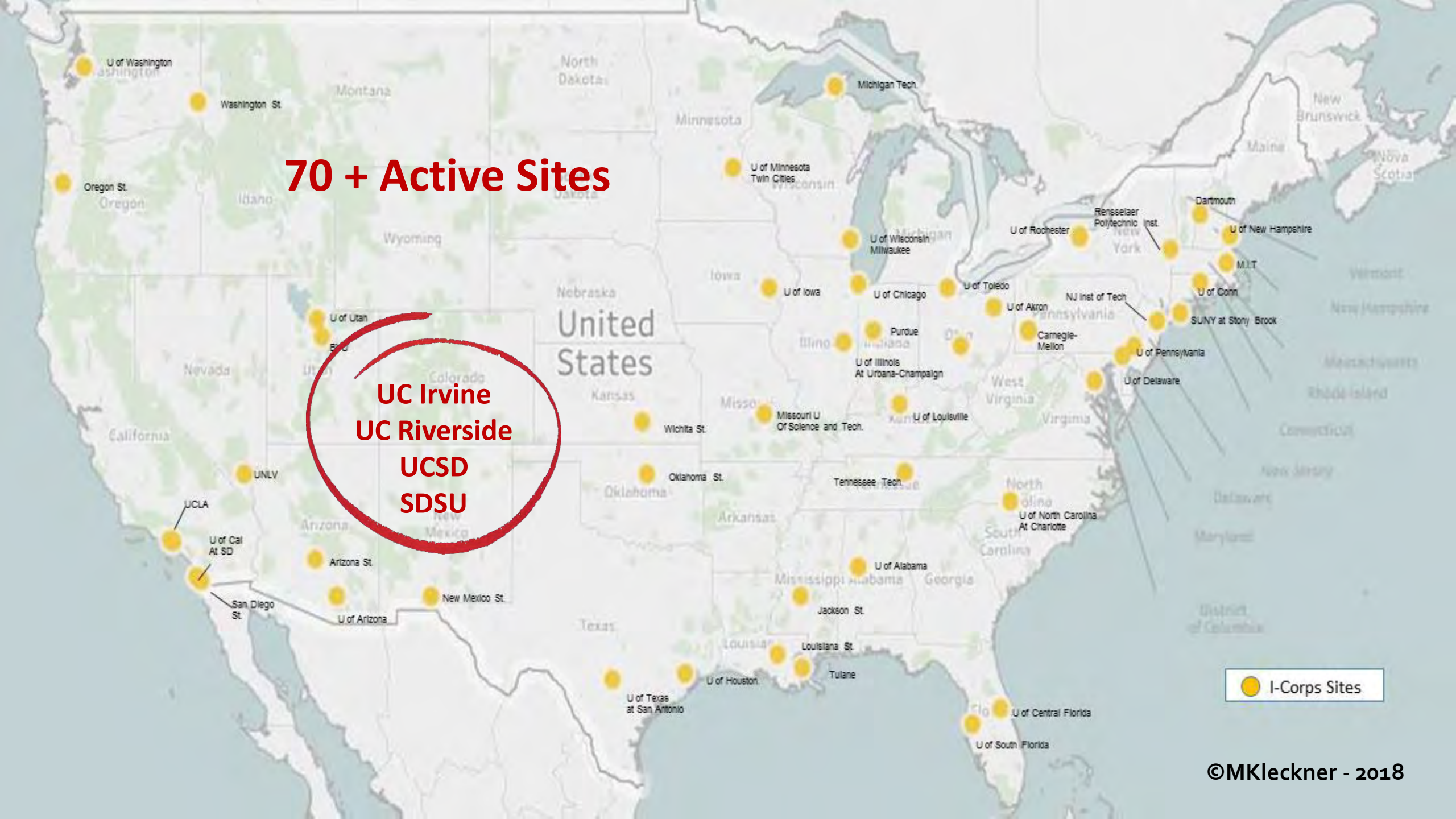
National Institutes of Health: NSF, FDA, USPTO, CMS, Kaiser

I-Corps™ @ NIH

(I Corps @ DoD)

I-Corps Nodes & Sites




70 + Active Sites
UC Irvine
UC Riverside
UCSD
SDSU
U of Washington
Washington St.
Oregon St.
U of Utah
BYU
UNLV
UCLA
U of Cal At SD
San Diego St.
Arizona St.
U of Arizona
New Mexico St.
Wichita St.
Oklahoma St.
U of Minnesota Twin Cities
Michigan Tech.
U of Wisconsin Milwaukee
U of Iowa
U of Chicago
Purdue
U of Illinois At Urbana-Champaign
Missouri U Of Science and Tech.
U of Louisville
Tennessee Tech.
U of Alabama
Jackson St.
Louisiana St.
Tulane
U of Houston
U of Texas at San Antonio
U of Toledo
U of Akron
U of Rochester
Rensselaer Polytechnic Inst.
Dartmouth
U of New Hampshire
M.I.T
U of Conn
SUNY at Stony Brook
NJ Inst of Tech
Carnegie-Mellon
U of Pennsylvania
U of Delaware
U of North Carolina At Charlotte
U of Central Florida
U of South Florida
I-Corps Sites
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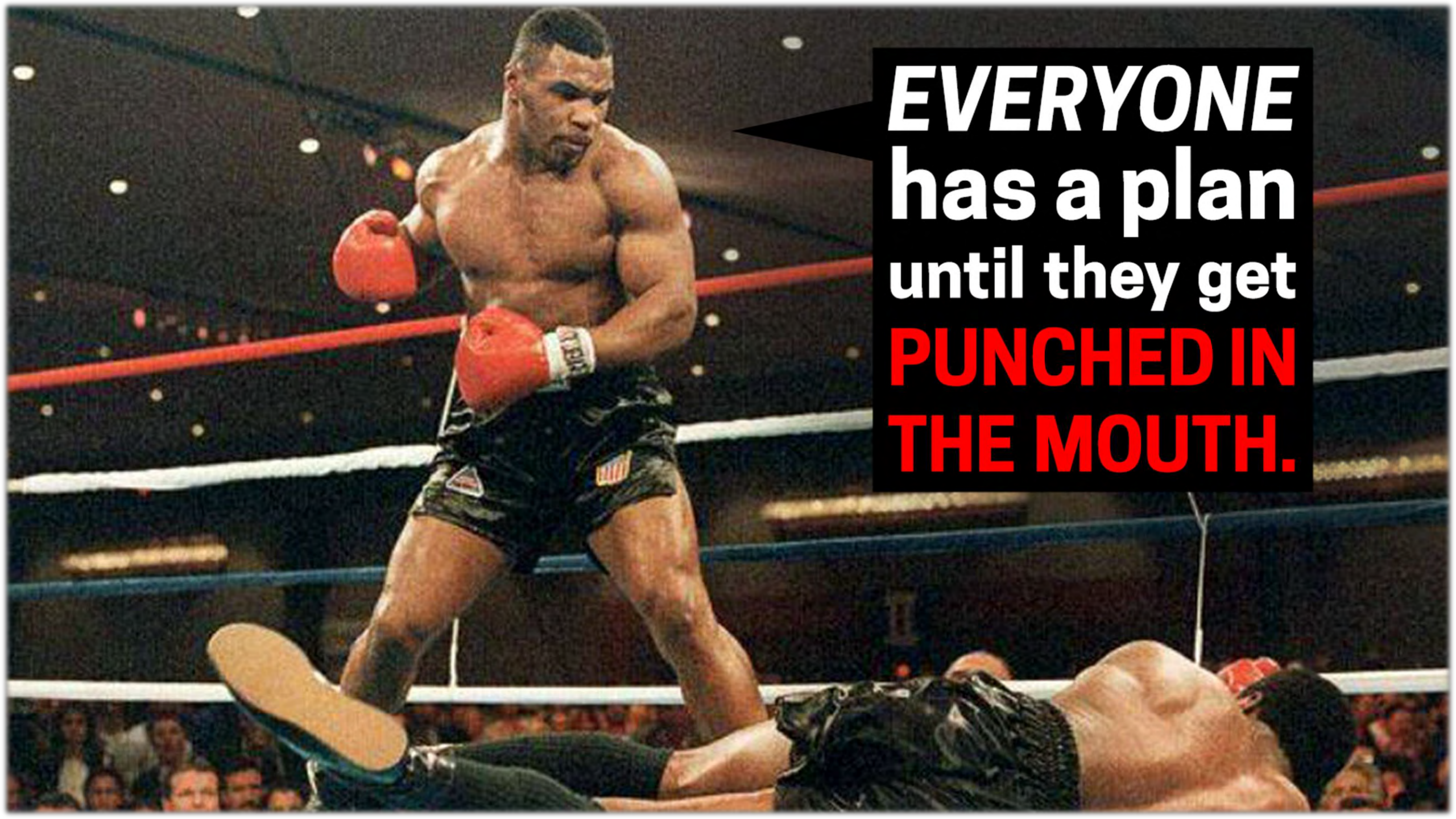
Seven (7) Week Curriculum
(Agency Grant-Funded: $40K - $70K)

- 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[1]

No Business Plan survives first contact with customers.

- Steve Blank[2]

(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

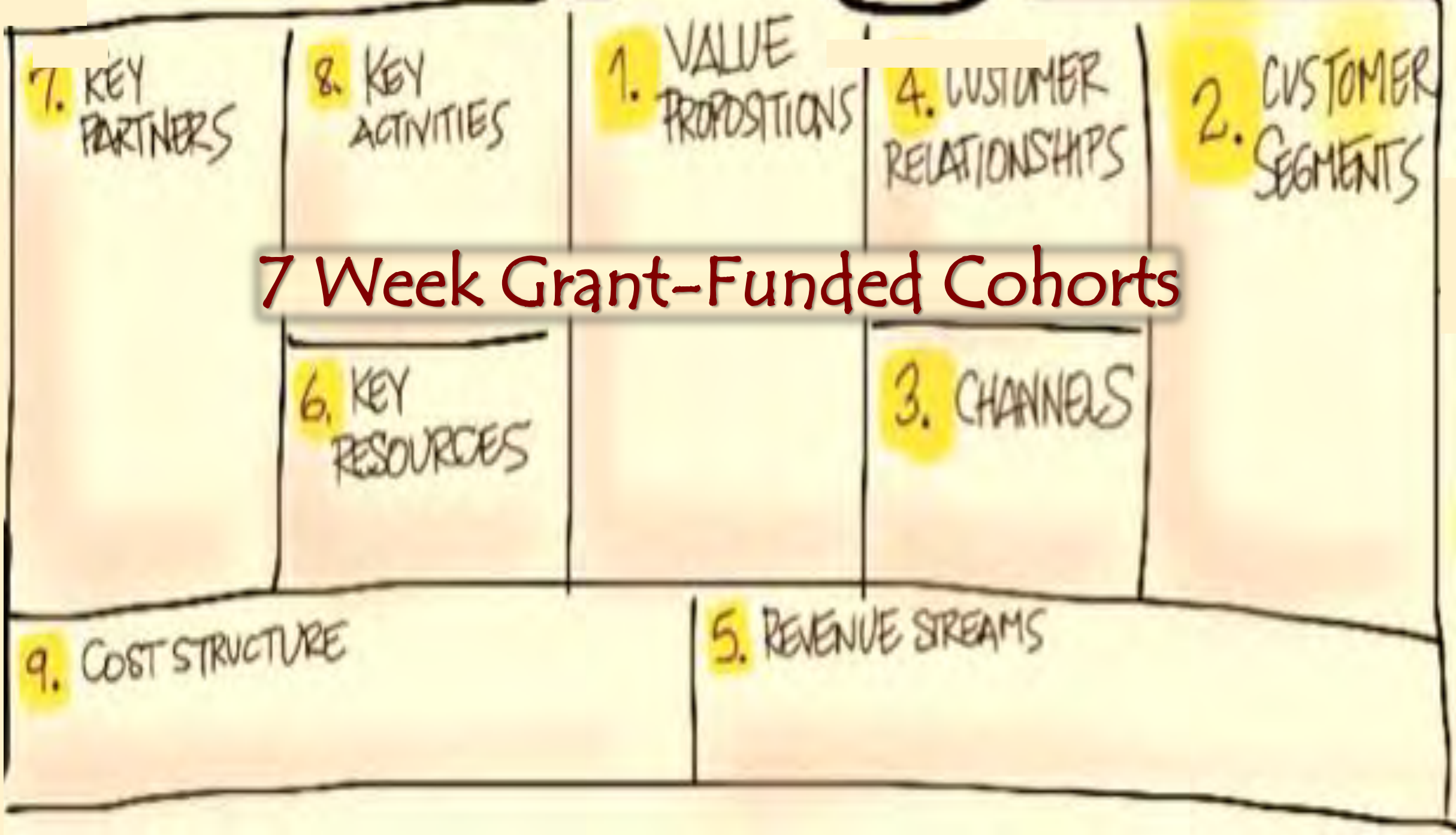
Venture Capitalists

Soviet Union

Instead of creating business plans...

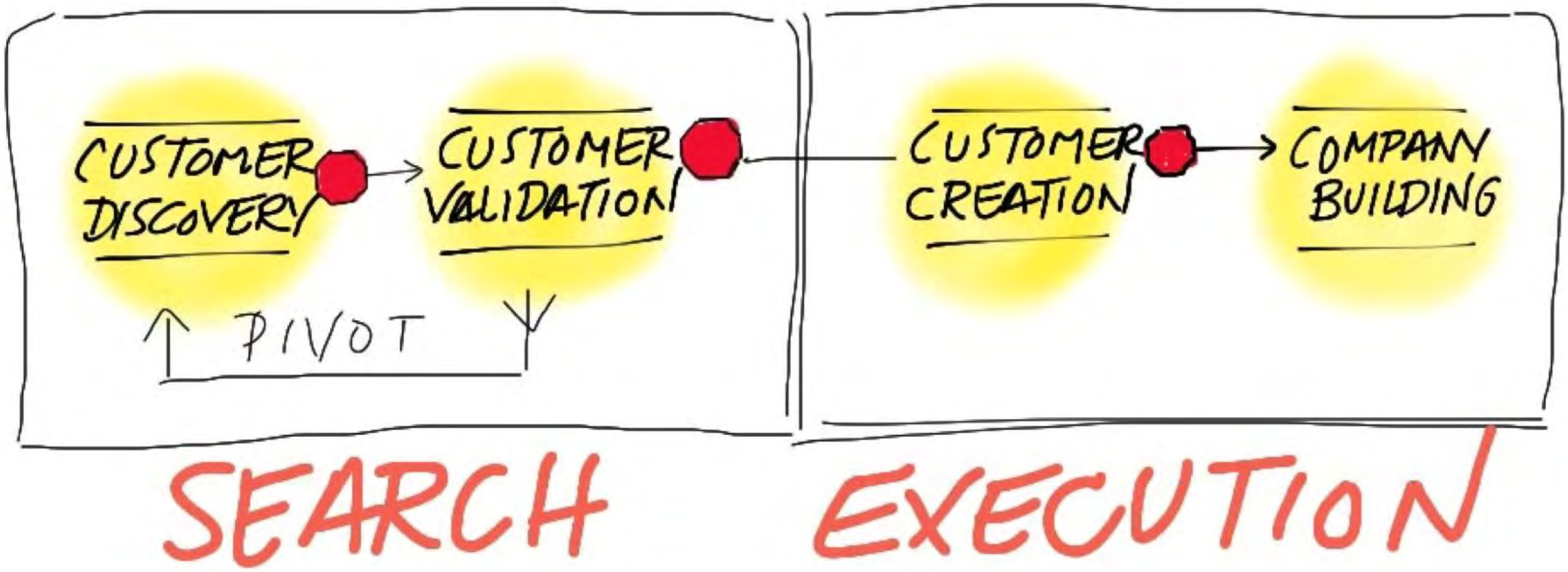
Today we discover *business models.*

Business Model Generation
(Customer Discovery & Validation)

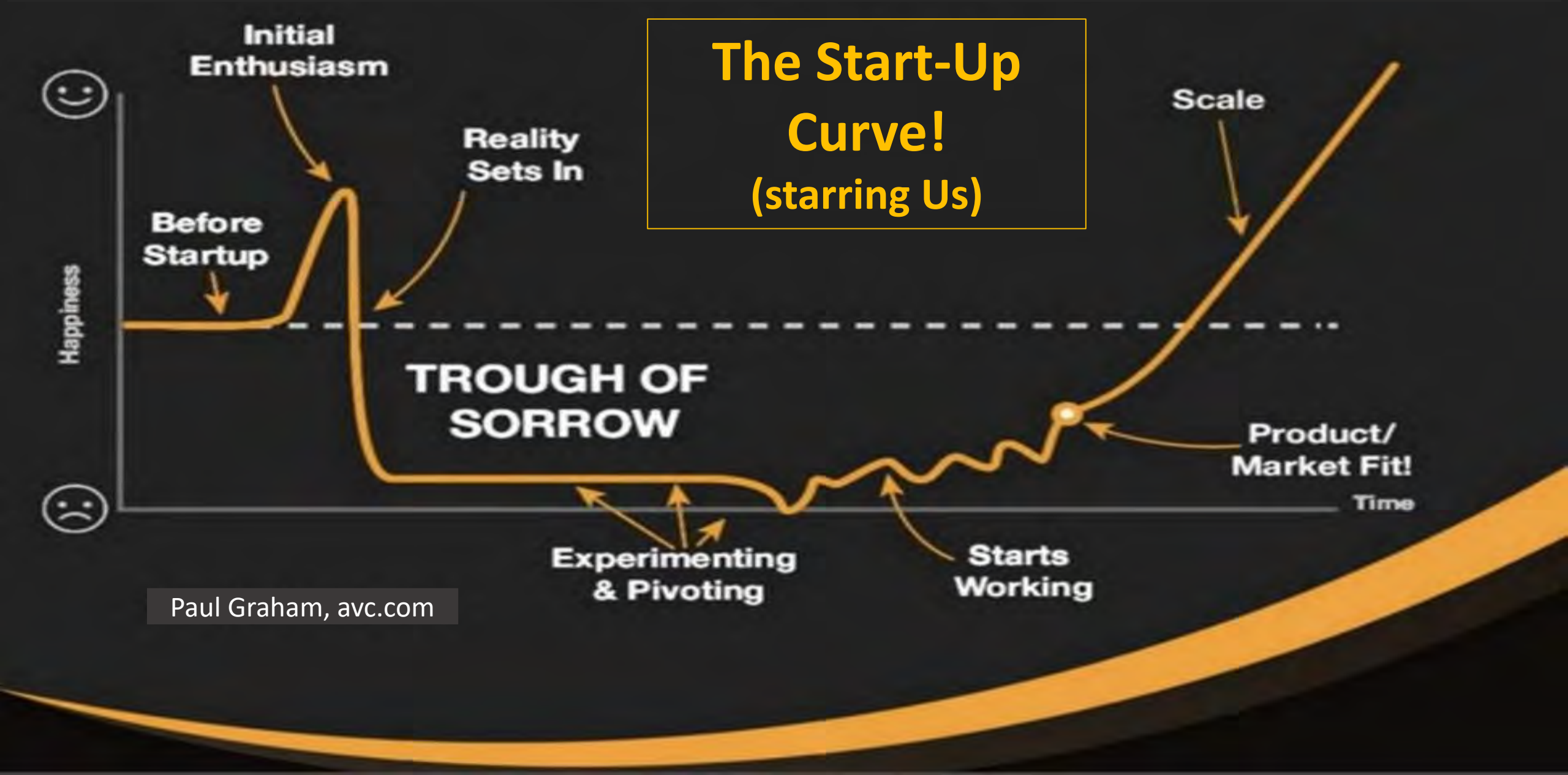


7 Week Grant-Funded Cohorts

Business Model Generation . . .
. . . Customer Development



Behind Every Great Product is a Great Story



Hopefully some of this was helpful!

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University of San Diego BRINK

Center for Innovation & Commercialization