

Phase I/II Proposal Development: Beyond The Basics

University of San Diego, MRH Warren Auditorium
May 1, 2019; San Diego, California

Disrupting

Old

Habits

Martin Kleckner III PhD MBA



2nd of a Four-Part Series

April 18: SBIR STTR – The Basics

May 1: SBIR/STTR Phase II – Beyond the Basics

May 23: Funding Your Innovation: SBIR Phase I & II Grants, SBIR III Support, Business Alliances, Private Equity

June 13: Business Model Discovery & Validation for Capitalization; the I-Corps Way

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: TBD
Fee: \$350.00

**SBIR Writer's
Work Group**
**- Curt Becker, Brink
SBDC Advisor**

Program Format: Multi-session Course

- 1) A facilitated peer-learning work group – Target: the NIH
September 5, deadline**
- 2) In each session, instructors and peers work in concert on the
same topics**
- 3) Not a guarantee that you will receive a SBIR; we will not write
or submit an application for you**

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

2) Six Launches; Two Exits

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



The Brink SBDC



The I-Corps™ at NIH

USC, Caltech, U C Irvine, Georgia Tech, Ohio State, U C Riverside, NSF-Arlington, NIH-Bethesda

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

4) **SBIR/STTR**: NSF, NIH, DoD, DOE, Commerce, Trans., Coulter, Drexel; Univ. of Calif (San Diego, Merced, Irvine, Riverside, Los Angeles); USC

5) Times Mirror, AmHS, General Electric, Roche, Toshiba America (La Costa Group LLC)

6) **\$55.8 MM** in Capital & Grants 2016 – Q2 2018

What is Your Odyssey?



WEDNESDAY

TODAY

1

MAY

Agenda

APPOINTMENTS

TASKS

8

9

10

11

12

1

2

3

4

5

6

7

8

**USD the Brink: SBIR
STTR Phase I/II –
Beyond the Basics**

JOURNAL

For Our Discussion

1. Reiterations (Phase I)
2. Phase II Award Criteria
3. Designing and Defending a **Fundable Study Approach**
4. **Commercialization Plan/Business Model Essentials.**

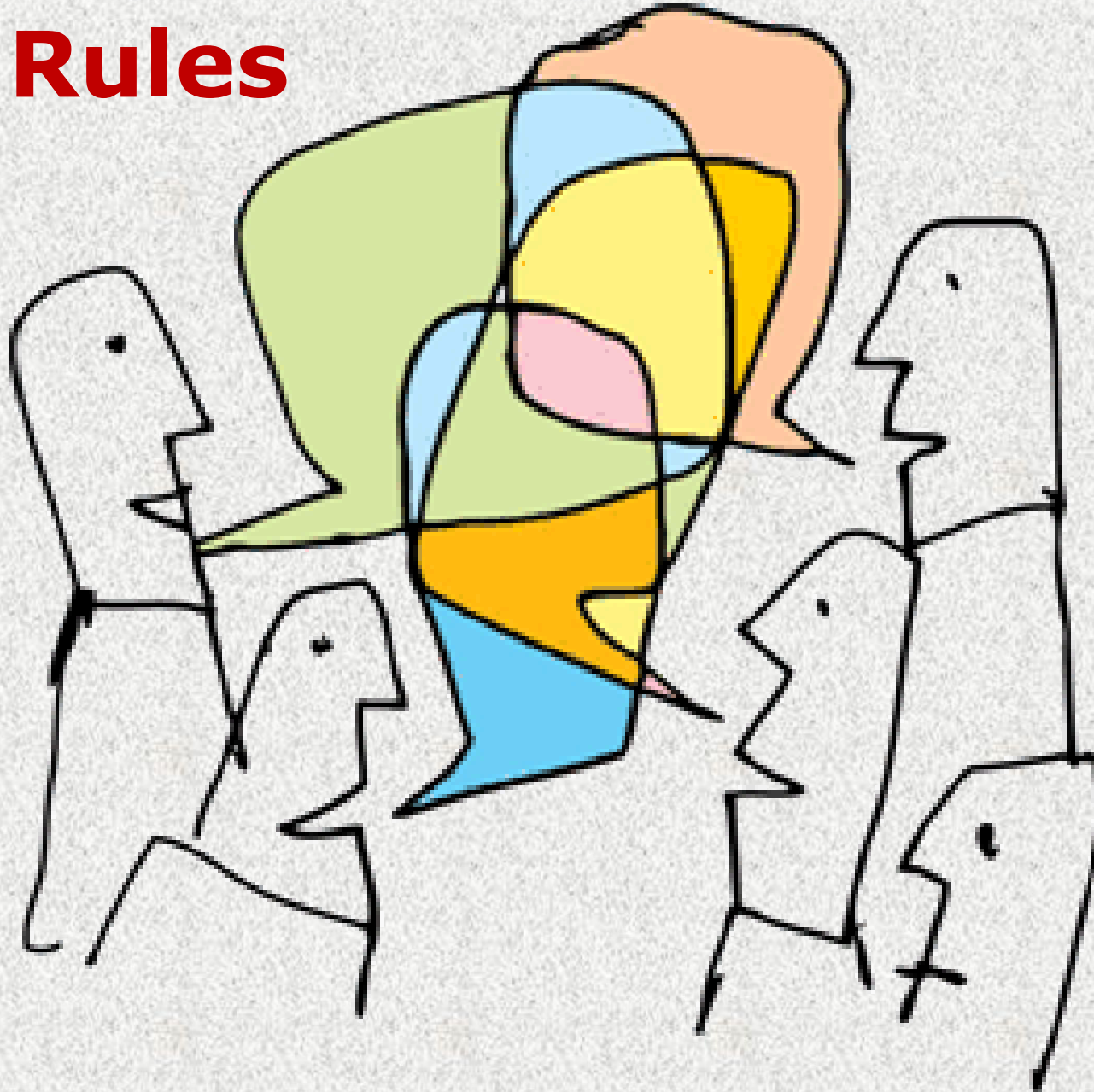
Addendum

**Budgeting, Accounting &
Government Audits**

Essential Rules

1. Ask
Questions

3. “Your
Take”



2. Jump-In

4. Discuss

The Phase II “Sniff Test”

- 1) You Meet **Eligibility** Requirements
 - Size, United States Based; For Profit
- 2) You have the **Facilities**
- 3) You have the right Research & Commercialization **Team**
- 4) **Awarded Phase I** or have in-house equivalent data for a **Direct-to-Phase II**
- 5) **Phase I Aims Achieved** (or will be)
- 6) **Fast Track**

**This workshop pertains
to both Phase I & II**

PART I:

REITERATIONS
(from April 18)

They're still here



- Eleven (11) Agencies Have an SBIR Program
- Five (5) Have an STTR Program (✓)
- High Risk – Innovative – Transformative
- Strong Chance For Commercial Success
 - Credible Commercialization Plan w/ Evidence
 - (I-Corps Programs “Linked to” SBIR)
 - Partnerships for Innovation (NSF)
- Well-Designed Study, Strong Team



Characteristics (again)

PHASE I (Proof of Concept): Merit, Feasibility, Commercial Potential

- ALSO: Your Quality & Performance w/ a small amount of money
- Amounts Vary; 6 – 12 Months: \$75,000 - \$225,000 + + (inflation)
- There may be a **Hard Cap Waiver**

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

- Amounts Vary; 24 Months: \$750,000 - \$2.25 MM + +
- 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 (except for the DoD); Non-Cash; In-Kind Support

To Be Eligible (SBIR) . . .

1. 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" Test)
 - 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**

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** - No Need To Be Primarily SBC Employed

And (Again)...

- **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 (It's Back!)**

- **All Phase I Awardees** Must be Allowed To Apply For Phase II

- **Second Sequential Phase II** May Be Awarded

**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): 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 March 23.

Base Program Remains . . .

. . . “pilot” Programs Return

Re-instated (NIH):

- **Direct to Phase II**
- **'Phase 0' Proof of Concept Partnership**
 - NIH Centers for Accelerated Innovations (3)
 - Research Evaluation and Commercialization Hubs (3)

**DoD Commercialization
Readiness Program** stays
in force through **09/30/2022**



DoD Rapid Innovation Fund
**\$250 MM in Phase III funds now
permanent**



“Can Your Dog Hunt?”

Supplemental Funds

**Phase II Match Funding
(NSF “Phase IIB”) - 50% of 3rd
Party Investment Funds Up To
\$500,000**

#

**Commercial/Strategic
Partnerships - 20% of the Phase
II award, up to \$150,000**

#

**Commercialization Assistance -
\$10,000 per Phase II award (one
per active Phase II grant)**



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
TOTAL	\$3.2B	\$430M	\$3.6B	\$756

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 - > 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, perm. 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**

PART II:

Reviewer Decision Criteria

PROPOSAL PLANNING & DEVELOPMENT



National Institutes
of Health



CONTENT: WHAT'S IMPORTANT



Reviewer Criteria Synopsis



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

Phase I/II Preparations

- **'Scientific' Literature & Market Research**
- **Commercialization Plan (I-Corps, Validation)**
- **Phase 0/I Findings/Data Analysis**
 - **Have Confirmed/Demonstrated Feasibility?**
- **Phase I/II Study Approach; Research Design**
- **Facilities & Other Resources**
- **Accounting/Management System (Phase II)**
- **Convene Your Phase I (& II) Team**

Questions

- What are you going to do?
- Why is it worth doing?
- Who is going to do the work?
- Where are you going to do the work?
- How much will it cost?
- How are you getting it to market?



What Question* Do You Want to Answer?

- **What is Known already** - literature review: relevant findings
- Where is there **missing information** (“unknowns“)?
- **Your Aims** – what do you want to find out; how will you achieve the answer (**Study Approach**)?
- **Impact** – how this project will substantially add to science or technology, change practice, save money, save lives or improve quality of life in substantial numbers of people. Include an **Economic Impact (Quantify)** if possible.

* Problem that you want to solve

Reviewers Should Understand:

1. What is your Research **Question**,
2. Is it **Original** and **Relevant**,
3. How will it help **Fill the Gap** (in research, our lives, un-met needs, value. . .)?

Important for Phase II . . .

4. How did you **Manage Phase I**?
 - Aims
 - Communications
 - **Relationships** with Program Managers
5. Can you handle a Larger **Budget**, tougher **Objectives**, and . . .
6. Execute an “evidence-based”
Commercialization Plan

When Are Phase II Award Decisions Made?



Part III: Study Approach

What are you going to do? Why, How?

- Specific Aims
- Project Description; Research Strategy
- Team, Expressly Relevant to the Study
- Commercialization Plan



NIH Reviewer "Marching Orders"

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

Title
Abstract
Problem
Solution
Specific Aims
Research Strategy
Facilities
Biographies



Key Criteria

Phase II

- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
- Research Strategy (12 Pgs.)
 - Significance
 - Innovation
 - Approach
- Inclusion Enrollment Report
- Progress Report/Publication List
- Protection of Human Subjects
- Inclusion of Women & Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Select Agents
- Multiple PD/PI Plan

- 1494
- Consortium/Contractual Arrangements
 - Letters of Support
 - Resource Sharing Plans
 - Appendix
 - Bibliography & References Cited
 - Project Summary/Abstract (30 Lines)
 - Public Health Relevance Statement
 - Senior/Key Person Profiles
 - Biographical Sketches (4 Pgs. Each)
 - Facilities & Other Resources
 - Equipment
 - Project Budget
 - Cover Letter
 - Commercialization Plan (12 Pgs.)
 - Forms

Phase II

- Introduction To Application (1 Pg)
- **Specific Aims (1 Pg.)**
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Statement of Aims



- Very Important Page
- Establishes Objectives/Value
- What Question are . . .

. . . you answering?

AIMS – APPROACH - IMPACT

Anatomy of an Aims Page

The most vital part of any (NIH) grant application . . .
central to our proposal.

Difficult to write - gain reviewer trust and confidence
- simultaneously convince them that our work is
important to fund & we are the right ones for the job.

Source: [Michelle S., Ph.D., E.L.S.](#) "The Anatomy of a Specific Aims Page" (April 09, 2015)

Category: *Scientific Grant Writing*

Opening Paragraph

- 1) First Sentence – The Hook (Importance/Urgency)
- 2) Introduce your Research Topic – Why is it Critical
- 3) Significant Knowledge Gap Relative to the Critical Need

Necessary Details Only: Be Concise & Focused

Hook

**What is
Known**

**Knowledge
Gap**

**Critical
Need**

Second Paragraph

Your Solution

- 1) **WHAT** are you going to do
- 2) **WHY** are you doing it
- 3) **HOW** you will do it – Simple, Relevant, to the Point
- 4) Long-Term **GOAL** – Hypothesis & Proposal Objectives –
Rationale – Your Qualifications

Goal

Proposal

Rationale

Hypothesis

Payoff

3rd Paragraph: Your Aims

- 1) What aims will you use to test your hypothesis (2 – 4 Aims)
- 2) Describe your experimental approach
- 3) What are your anticipated outcomes from this test?
- 4) How will this answer your hypothesis, develop a new tool, or establish a new technique?

Aim

**Experimental
Strategy**

**Outcome or
Impact**

Example Aims

- **Establish** an innovative mouse model for HTLV-1 Tax tumorigenesis
- **Create** a novel, scalable energy storage and power boost system for 100 kW and larger solar PV arrays.
- **Develop and evaluate** an opioid use disorder chatbot that administers a patient version of MINI
- **Verify** the feasibility of an innovative, computer-based program to improve cognitive skills in mTBI subjects.
- **Increase** the use of the five major components of a brief tobacco cessation intervention

Aim 1: Develop algorithms for *C. elegans* viability assays to identify modulators of pathogen infection. **Challenge:** To identify individual worms in thousands of two-dimensional brightfield images of worm populations infected by Microsporidia, and measure viability based on worm body shape (live worms are curvy whereas dead worms are straight).

Approach: We will develop algorithms that use a probabilistic shape model of *C. elegans* learned from examples, enabling segmentation and body shape measurements even when worms touch or cross. **Impact:** These algorithms will quantify a wide range of phenotypic descriptors detectable in individual worms, including body morphology as well as subtle variations in reporter signal levels.

Closing Paragraph

- 1) **Innovation:** What is innovative/transformational?
- 2) **Expected Outcomes:** What do you expect to see?
- 3) **Impact:** How will this be beneficial?

Innovation

**Expected
Outcomes**

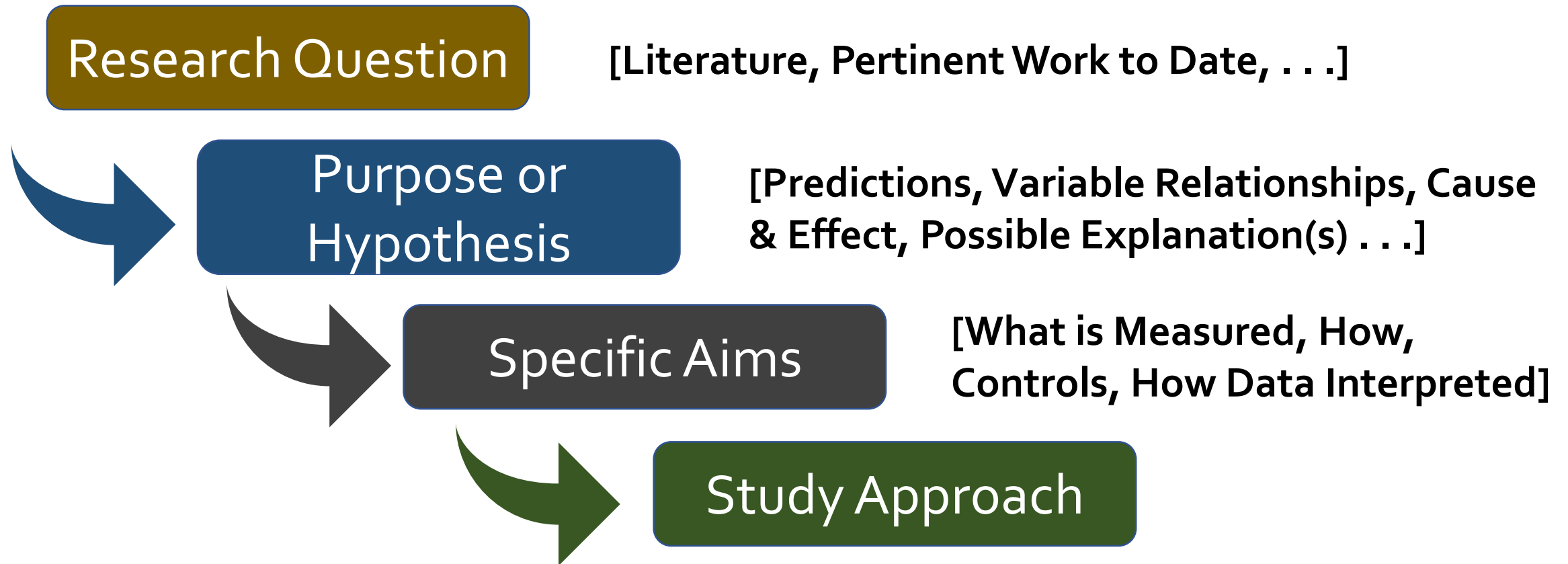
**Impact or
Payoff**

Objective (Aim) & Endpoints (Example)

Objective (Aim) may be to assess the accuracy (effectiveness, impact) of (a Proposed Solution) in determining the foods to be eliminated from your diet that measurably lower symptom severity of your IBS.

Endpoints (or Outcomes) are the **Quantitative Measurements** that tell you that you have attained your Objectives. For example, what measurements of change in IBS symptom severity would you use to evaluate a favorable result?

“Deal Killers” for Some



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

Phase I & II

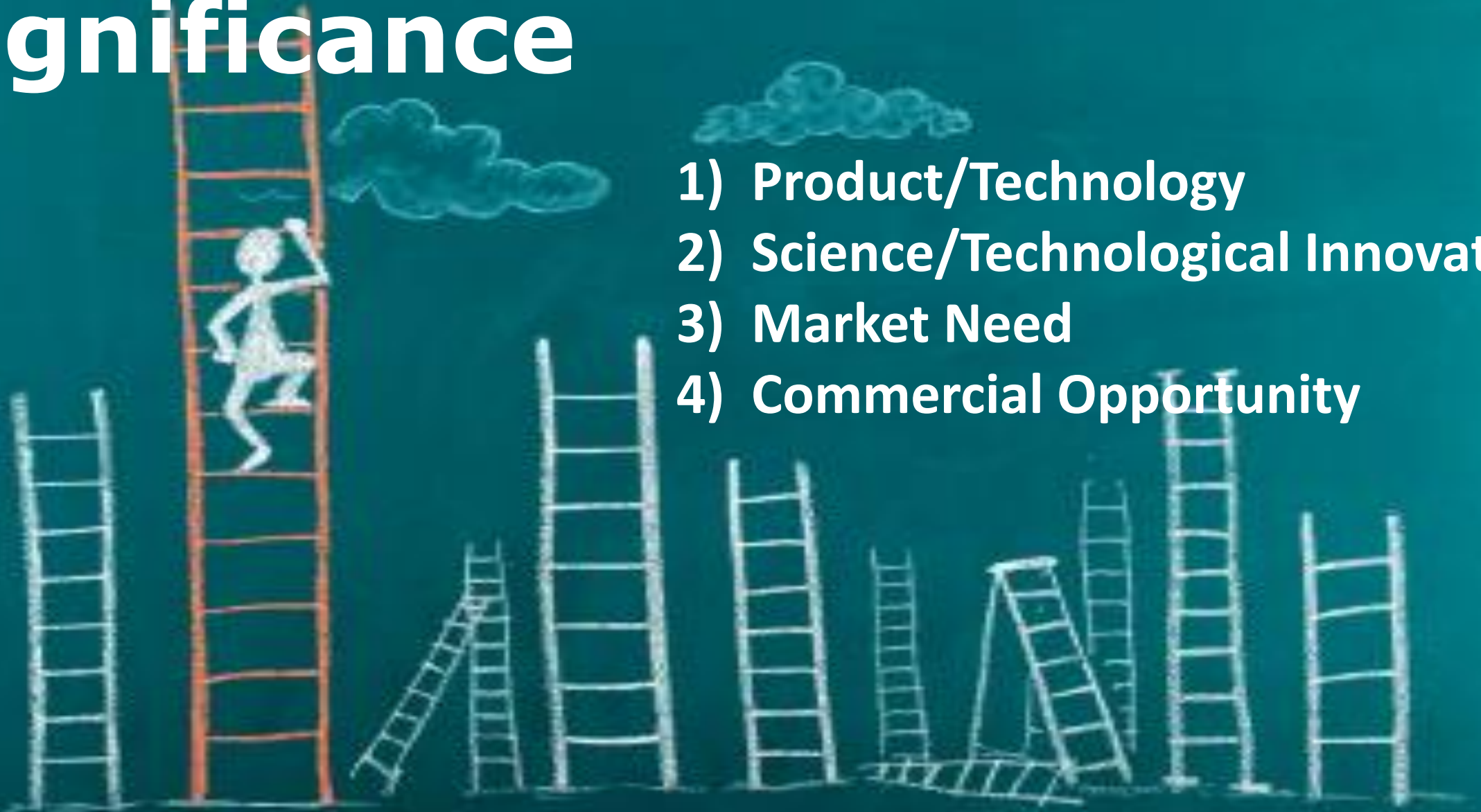
- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
- **Research Strategy (Pages vary)**
 - **Significance**
 - **Innovation**
 - **Approach**
- Inclusion Enrollment Report
- Progress Report/Publication List
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 - Commercialization Plan (12 Pgs. +/-)
 - Forms

Research Strategy

Significance
Innovation
Approach

Significance



- 1) Product/Technology
- 2) Science/Technological Innovation
- 3) Market Need
- 4) Commercial Opportunity

Use References, Citations

Significance

This is a Sales Pitch

- **Problem** to be Solved
- **Effects/Impact/Ramifications** if not Addressed
- **Solution Needed**; Product/Technology Planned
 - Impact of Proposed Product
 - Effect of Innovation on Science/Technology
- **Solution Value/Value Proposition**
- **Commercial Potential** (Summary)
 - Market Analysis; Competition; Commercialization Plan
- **Other Applications/Indications**

Innovation

- **Description**
- **It's Relevance to Current Science/Our Understanding**
 - **Why** is it Innovative? Transformative?
 - How does it **Move the Field Forward**?
 - What future **Advancement** will this Innovation Enable?
- **It's Value** to Targeted Customers/Stakeholders

Approach

- **Phase I (or in-house) Progress Report**
 - Beginning and Ending Dates of Phase 0/I
 - Summarize/Reiterate Phase 0/I Aims
 - **Findings, Results & Conclusions/Aims Achieved**
 - Any changes to Aims/New Directions?
 - Appraisal of Findings
 - Demonstration of Feasibility (Proof of Concept or Principle)
 - **How do/will the outcomes Support Transition to Phase II?**
 - Technology Developed, Intended Use, Product Development Status

Approach (continued)

Experimental Design & Methods (in Detail)

- **Study Population**, Characteristics, Source(s), Criteria
 - Detail Discussion of **Experiments to be Performed** to complete Aim
 - Study **Procedure/Methods** to be employed in each Experiment
 - **Is there a shift** in how things will be/have been studied?
- Data Collection, Analysis & Interpretation, Management, Safety
 - Potential Pitfalls/Alternative Approaches
 - What could go wrong; how will that be dealt with?
 - Expected Outcomes
 - Statistical Analysis; Finance/Resource Use (Direct v. Indirect Costs)

Review of the Literature . . .

. . . Relevant Research, Methods, Findings

- 1) Some of us ignore this part, or overdo it, which could be a “death sentence”.
- 2) Some of us overplay “Disruption” and ignore “advancement” of quality work.



“We’re turning the industry upside down”

Summary

- **Specific Aims**
 - What are they?
 - Why (Significance, Innovation, Phase I Feasibility)
- **How will Research Strategy be Performed?**
- **Who, When & Where (Summary)**
 - **Gantt Chart**
 - Detailed Timeline
 - Who will be responsible for each Aim's Completion?
 - Where will the work be done (Company, Contractor, etc.)

What, Who, When, Where

Specific Aims	1	2	3	4	5	6	7	8	9	10	11	12	13
Specific Aim 1	Green	Green											
Experiment 1			Green	Green	Green	Green	Orange	Orange					
Researcher, Facility	Green	Green											
Experiment 2			Green	Green									
Researcher, Facility					Green	Green							
Specific Aim 2	Green												
Experiment 1		Green	Green										
Researcher, Facility									Orange	Orange	Orange		
Specific Aim 3												Orange	
Experiment 1													Orange
Researcher, Facility													Orange

Phase I/II

- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
- Research Strategy (12 Pgs. +/-)
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Biosketch Format

- **Use a Personal Statement** to highlight work/performance
- Describe **Five (5) most significant contributions** to science with historical background
- Central findings of prior work/influence of those findings on the field
- Per Description, accompany with a list of up to four (4) **relevant peer-reviewed publications** or other non-research publication research
- You can include a link to a full list of published work in [MyBibliography](#) or [SciENcv](#)

BIOGRAPHICAL SKETCH
DO NOT EXCEED FIVE PAGES.

NAME: Hunt, Morgan Casey

eRA COMMONS USER NAME (credential, e.g., agency login): huntmc

POSITION TITLE: Associate Professor of Psychology

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/1999	Psychology
University of Vermont	Ph.D.	05/1996	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/1998	Public Health and Epidemiology

A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neurophysiological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

- Merryle, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. *Psychology and Aging*, 23(4), 10-22.
- Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-

Biosketches for PI & Key Persons

Position Title where you
will do the funded work

Customize to fit each
proposal

B. Positions and Honors

Positions and Employment

1998-2000	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001	Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2007-	Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995-	Member, American Psychological Association
1998-	Member, Gerontological Society of America
1998-	Member, American Geriatrics Society
2000-	Associate Editor, Psychology and Aging
2003-	Board of Advisors, Senior Services of Eastern Missouri
2003-05	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11	NIH Risk, Adult Addictions Study Section, members

Honors

2003	Outstanding Young Faculty Award, Washington University, St. Louis, MO
2004	Excellence in Teaching, Washington University, St. Louis, MO
2009	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Contribution to Science

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.
 - a. Gryczynski, J., Shaft, B.M., Merryle, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.
 - b. Shaft, B.M., Hunt, M.C., Merryle, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. *International Journal of Drug Policy*, 30(5), 46-58.
 - c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. *Journal of Applied Gerontology*, 28(2), 26-37.
 - d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. *Addiction*, 104(9), 1436-1606. PMID: PMC9000292
2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance

Don't forget the small business (SBC) for personnel who will be working there on the project

New Since 2015: Replaces Publications

Phase I/II

- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
- Research Strategy (12 Pgs.)
 - Significance
 - Innovation
 - Approach
- Inclusion Enrollment Report
- Progress Report/Publication List
- Protection of Human Subjects
- Inclusion of Women & Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Select Agents
- Multiple PD/PI Plan

- 1494
- Consortium/Contractual Arrangements
 - Letters of Support
 - Resource Sharing Plans
 - Appendix
 - Bibliography & References Cited
 - Project Summary/Abstract (30 Lines)
 - Public Health Relevance Statement
 - Senior/Key Person Profiles
 - Biographical Sketches (4 Pgs. Each)
 - **Facilities & Other Resources**
 - Equipment
 - Project Budget
 - Cover Letter
 - Commercialization Plan (12 Pgs.)
 - Forms

Phase I/II

- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
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 - Equipment
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 - Cover Letter
 - Commercialization Plan (12 Pgs.)
 - Forms

- **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

NSF Phase II

- Cover Sheet
- Table of Contents
- Project Summary
- **Project Description (15 Pgs.)**
- Proposal Budget
- References Cited
- Biographical Sketches
- Facilities, Equipment & Other Resources
- Current & Pending Support
- Data Management Plan
- Mentoring Plan

- 1494
- Other Supplementary Documents
 - Payment Schedule
 - Project Milestone Chart
 - Commercialization Plan*
 - Commercialization History
 - Phase I Technical Report
 - STTR Cooperative Agreement
 - Letters of Support (Max 5)
 - Humans/Vertebrate Animals

*Number of pages may vary per FOA

Project Description

I. Phase 0/I Results, Findings

- Feasibility Established

II. Phase II Technical Objectives, Approach

- Objective (1, 2, 3 . . .)
 - Rationale
 - Experimental Methods
 - Data Analysis & interpretation
 - Potential Pitfalls/Alternative Approaches
 - Anticipated Outcomes
 - Project Development Chart

III. Organization Information

- Income Statement/Staffing profile; Plans/Phase I/II/III Team

IV. Consultant Sub-awards

Who is going to do what work?

Where will the work be done?

How much will it cost?



National Institutes
of Health



Biographical Sketches

Facilities and Resources

Letters of Support

Budget and Justification





Strong Team Needed

-
PI(s)

Employees

Subcontractor(s)

Consultants

Other Significant
Contributors

(Think Ahead to
Commercialization)

NSF Phase II

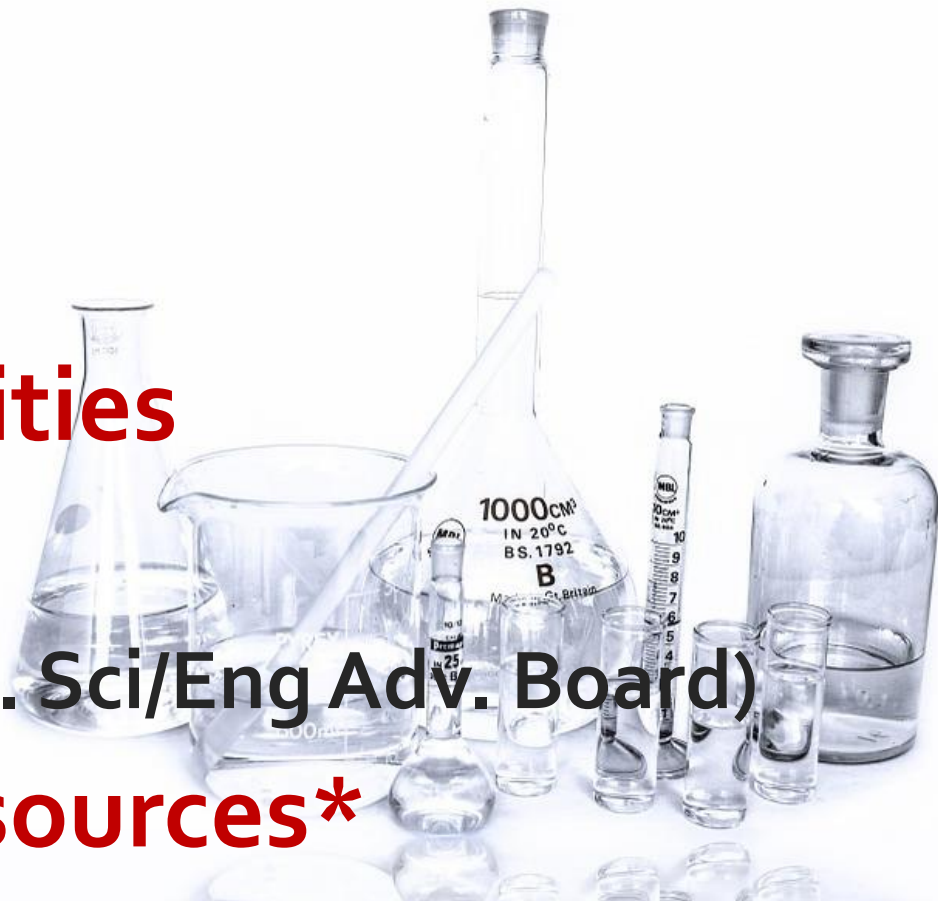
- Cover Sheet
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 - Letters of Support (Max 5)
 - Humans/Vertebrate Animals



- **Your Facilities**
- **Subcontractor(s') Facilities**
- **Other R & D Resources**
(Significant Contributors, e.g. Sci/Eng Adv. Board)
- **Commercialization Resources***
(Management, Strategic Partners, Funding, Regulation, Coding & Reimbursement), Environment, Topic Specialists

*** Critical for Phase II**

Phase II

- Cover Sheet
- Table of Contents
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- Proposal Budget
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- Other Supplementary Documents
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 - Commercialization Plan
 - Commercialization History
 - Phase I Technical Report
 - STTR Cooperative Agreement
 - **Letters of Support (Max 5)***
 - Humans/Vertebrate Animals

*** Excludes those from subcontractors & consultants (included with Budget Justification)**

Letter of Support

[Your Street Address]

[Your City, ST Zip Code]

[Month Day, Year]

[Recipient Name]

[Title]

[Company Name]

[Street Address of Company]

[City, ST Zip Code of Company]

To Whom It May Concern:

This letter is written as a reply to any advertisement in [Source of Information] that appeared on [Date of Advertisement].

In this paragraph you will write your intent for writing this letter or state what you have decided to respond in response to that specific advertisement etc. In this paragraph you will write your intent for writing this letter or state what you have decided to respond in response to that specific advertisement etc. In this paragraph you will write your intent for writing this letter or state what you have decided to respond in response to that specific advertisement etc. In this paragraph you will write your intent for writing this letter or state what you have decided to respond in response to that specific advertisement etc.

In this paragraph try to convince the recipient that you can best perform that job or how your intention can be beneficial for the advertising person. In this paragraph try to convince the recipient that you can best perform that job or how your intention can be beneficial for the advertising person. In this paragraph try to convince the recipient that you can best perform that job or how your intention can be beneficial for the advertising person. In this paragraph try to convince the recipient that you can best perform that job or how your intention can be beneficial for the advertising person. Thank you.

Sincerely,

[Signature]

[Your Name]

Validate Your Resources & Commercial Opportunity

- Consultants (required) – incl. rate/time
- Subcontractors
- Other Significant Contributors
- Research Resources (Facilities, equipment not on budget or owned by the company)
- **Commercialization (Critical)**
 - Strategic Partners
 - Investors
 - Key Customers
 - Potential Licensees
 - Key Opinion Leaders

*Convincing;
well-thought
out; why are
they buying-in?*

Letters of Support AND Commitment

PHASE I

- Market Validation by Third Parties
- Evidence that you have been communicating with stakeholders

PHASE II

- **Evidence of Commitment** of follow-on resources from investors, partners, licensees, customers, and other stakeholders
- **Contingent** on Technical Success

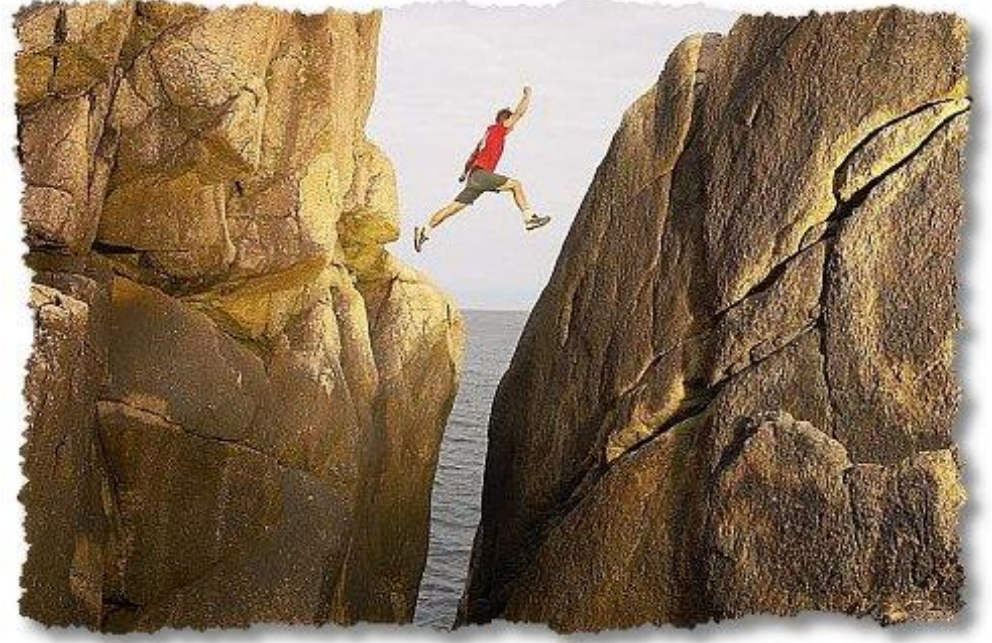
DON'T FORGET: NSF has Matching Funds

Letters of Commitment – Phase II

- From prospective investors, strategic partners, customers, licensees, et al.
- Commitment of tangible resources (e.g. funding, services, business agreements)
- Estimated dollar/economic value
- Describe **achievements necessary** to secure the commitment

PART IV:

“Crossing The Chasm”



COMMERCIALIZATION

Congress Loses Sense of Humor

Reauthorization Act of 2011

- 1) **More Emphasis on Commercialization**
- 2) **Requirements**
 - SBC Applicant Registers at SBIR.gov (**Commercialization database**)
 - Phase II Awardee Commercialization History
 - Phase II – Commercialization Process
 - Phase III Acquisition Preference
- 3) **Added Agency Flexibility**
 - **VC/HF/PEF – Ownership Stakes**
 - **Commercialization Assistance** programs
 - **Option for Non-Agency Commercialization Support**

“Can Your Dog Hunt?”

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



Commercialization Plans

Agency	Phase I	Phase II
NIH/HHS	1/2 page	12 Pages
DOE	3 -5 Pages	15 Pages
NSF	6 – 8 Pages	15 Pages
USDA (SBIR-Only)	1 Page +/-	10 Pages

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 Launch Pad”)
 - The Business Model Canvas
 - The Customer Discovery & Validation Process
 - Supplemental (e.g. Matching Funds)
- IV. DOE, DOT:** Commercialization Assistance Program

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**
- **50% of 3rd Party Investment Funds Up To \$500,000**
- Must Start Process At least 30 Days Prior to Phase II Award Expiration; 3rd 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” (TECP)
- 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 Executive 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 (one per active Phase II grant)

- **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



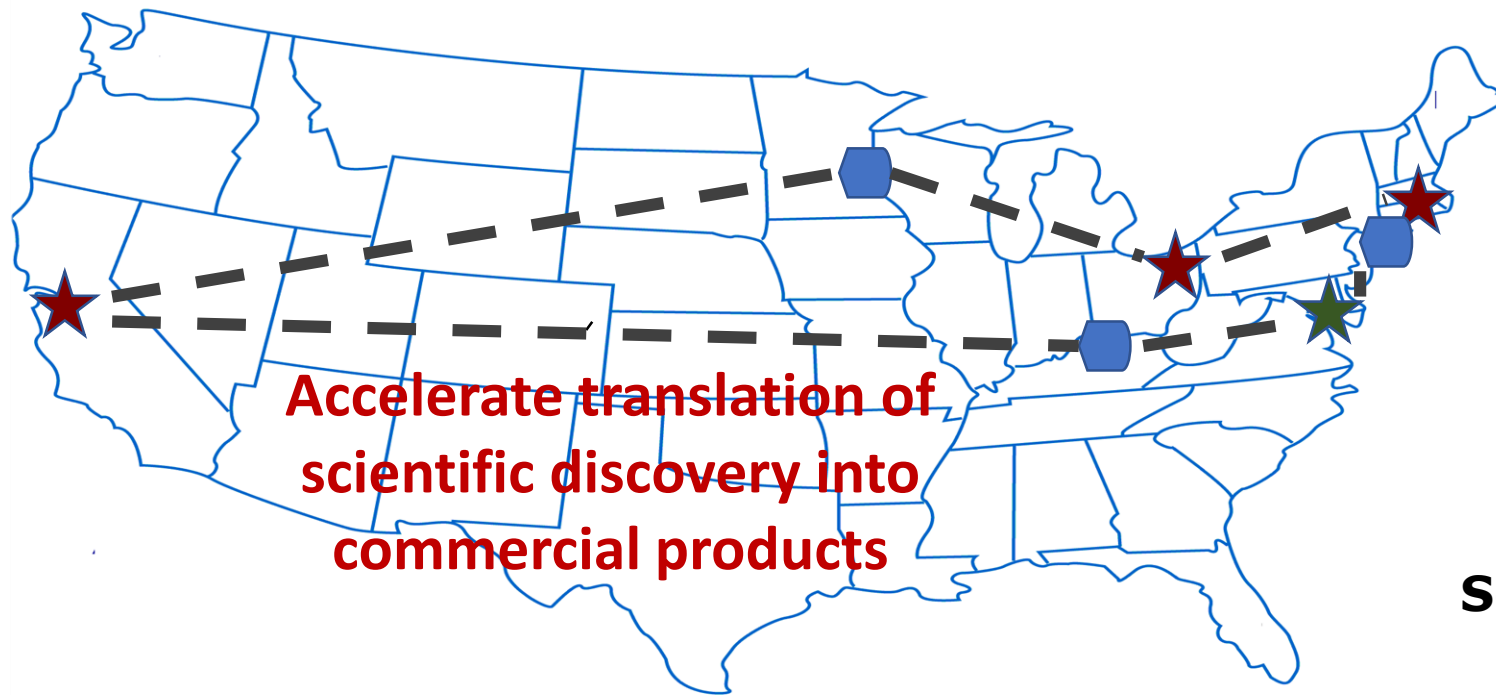
National Institutes
of Health

*Matthew Portnoy PhD

Program Manager

Office of Extramural Research

<https://ncai.nhlbi.nih.gov/ncai/aboutncai/mission>



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



**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

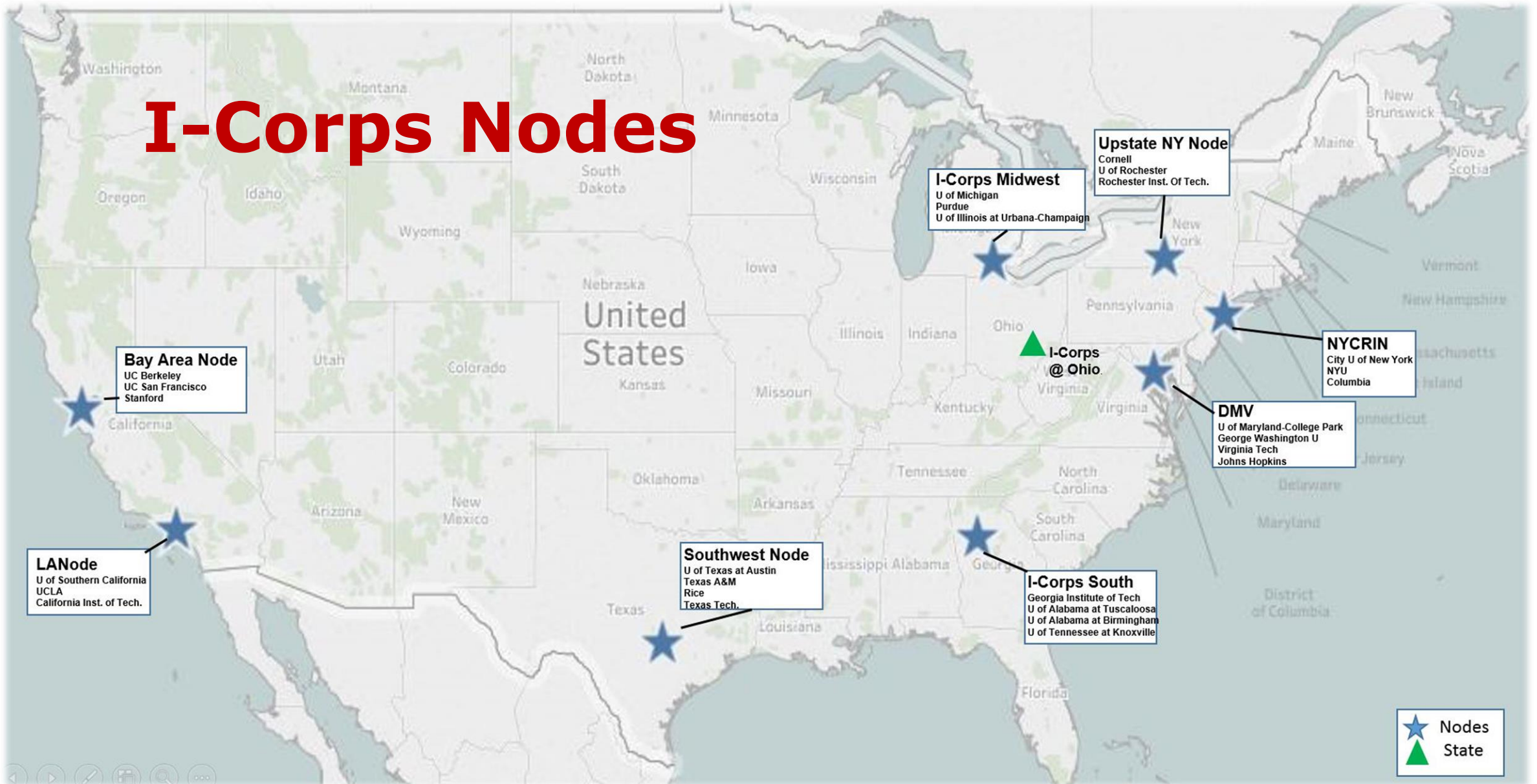
National Institutes of Health: NSF, FDA, USPTO, CMS, Kaiser



I-Corps™ at NIH

Innovation Corps @ Department of Defense
(I-Corps @ DoD)

I-Corps Nodes

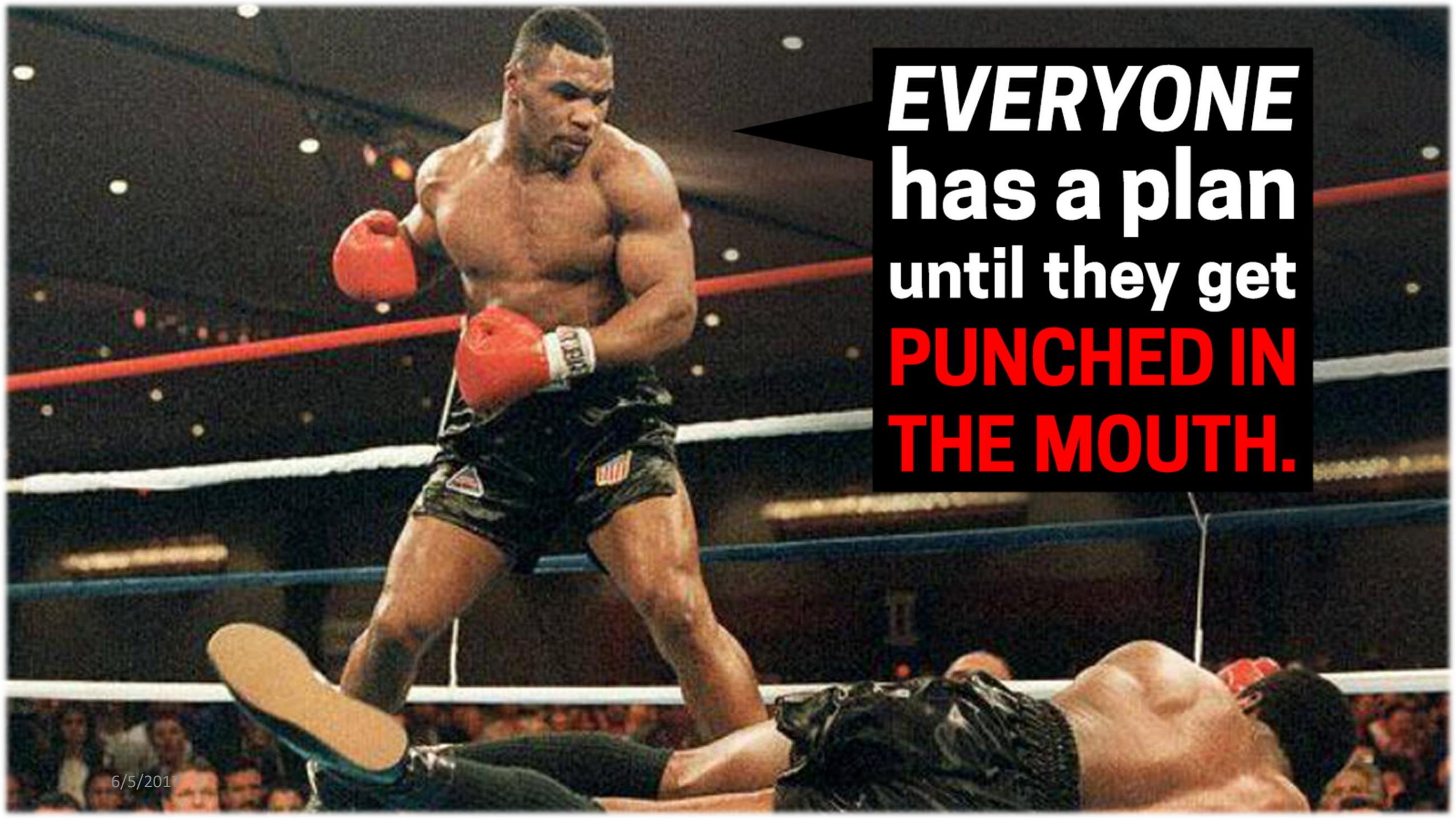


I-Corps Sites



What We Used to Believe

Start With an Business Plan
and Financial Model



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

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

- Helmuth von Moltke¹

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

- Steve Blank²



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

Five - Year Plans

Venture Capitalists

Soviet Union



BUSINESS PLAN

Prepared by:
Clayton J. Woodard
P.O. Box 2249
Frederick, MD 21702
(301) 697-0200

BUSINESS PLAN

Prepared by:
Claudia Accoradio
P.O. Box 2246
Frederick, MD 21702
(301) 697-6500

	A	B	C	D	E	G	H	I	J	K	L	M	N
32	Balance Sheet										Year		
33									1999	2000	2001	2002	2003
34	Assets												
35		Cash and cash equivalents*							\$4.27	\$6.38	\$7.62	\$8.83	\$7.00
36		Accounts receivable*							\$20.58	\$24.39	\$28.77	\$34.11	\$32.00
37		Inventories*							\$26.73	\$30.45	\$36.75	\$43.27	\$38.00
38		Deferred income taxes*							\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
39		Total current assets							\$51.58	\$61.22	\$73.14	\$86.21	\$77.00
40		Fixed assets											
41		Cost*							\$331.64	\$423.92	\$503.87	\$613.28	\$650.00
42		Accumulated Depreciation*							\$98.72	\$105.09	\$112.40	\$122.26	\$115.00
43		Net fixed assets							\$232.92	\$318.83	\$391.47	\$491.02	\$535.00
44		Goodwill*							\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
45		Intangible assets*							\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
46		Other assets*							\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
47		Total assets							\$284.50	\$380.05	\$464.61	\$577.23	\$612.00
48	Liabilities												
49		Accounts payable*							\$31.83	\$63.43	\$83.84	\$94.41	\$80.00
50		Current debt*							\$30.86	\$43.83	\$44.85	\$79.49	\$0.00
51		Total current liabilities							\$62.69	\$106.46	\$148.69	\$173.90	\$80.00
52		Long-term debt*							\$40.00	\$46.92	\$53.41	\$73.57	\$214.54
53		Other long-term liabilities*							\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
54		Total liabilities							\$102.69	\$153.38	\$202.10	\$247.47	\$294.54
55	Shareholders' equity												
56		Common Stock and Additional Paid in Capital*							\$90.00	\$130.00	\$160.00	\$220.00	\$200.00
57		Retained Earnings*							\$91.81	\$96.67	\$162.51	\$169.76	\$117.46
58		Total Shareholders' Equity							\$181.81	\$226.67	\$322.51	\$389.76	\$317.46
59		Total liabilities and shareholders' Equity							\$284.50	\$380.05	\$464.61	\$577.23	\$612.00

BUSINESS PLAN

Prepared by:
Olson & Associates
P.O. Box 2249
Frederick, MD 21702
(301) 697-6200

		Year				
		1999	2000	2001	2002	2003
	Cash and cash equivalents	\$4.27	\$6.38	\$7.62	\$8.83	\$7.00
36	Accounts receivable*	\$20.58	\$24.39	\$28.77	\$34.11	\$32.00
	Inventories*	\$26.73	\$30.45	\$36.75	\$43.27	\$38.00
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59	Shareholders' Equity	\$284.50	\$380.05	\$464.61	\$577.23	\$612.00

Startups Search

Companies Execute

Memo: Larry Bossidy, Execution – The Discipline of Getting Things Done (2002)
“Execution is a systematic way of exposing reality and acting on it.”

**More startups fail from
a lack of customers than
from a failure of product
development**

**Therefore,
Investors, SBIR Reviewers
And Our Customers
Need Us To
DISCOVER & VALIDATE**

Seven (7) Week Curriculum (Agency Grant-Funded: \$50K)

- **Precursor or Regional Competitive Programs**
 - IN-LA “Zap” & “Boom” (USC, Caltech, UCLA)
 - U C Riverside (Jay Gilberg; Alexandra Orozco)
 - U C Irvine (Doug Crawford)
 - U C San Diego (Dennis Abremski)
 - SDSU BioTech Focus (Susan Baxter)

- **Five + Week Site-Based Programs**

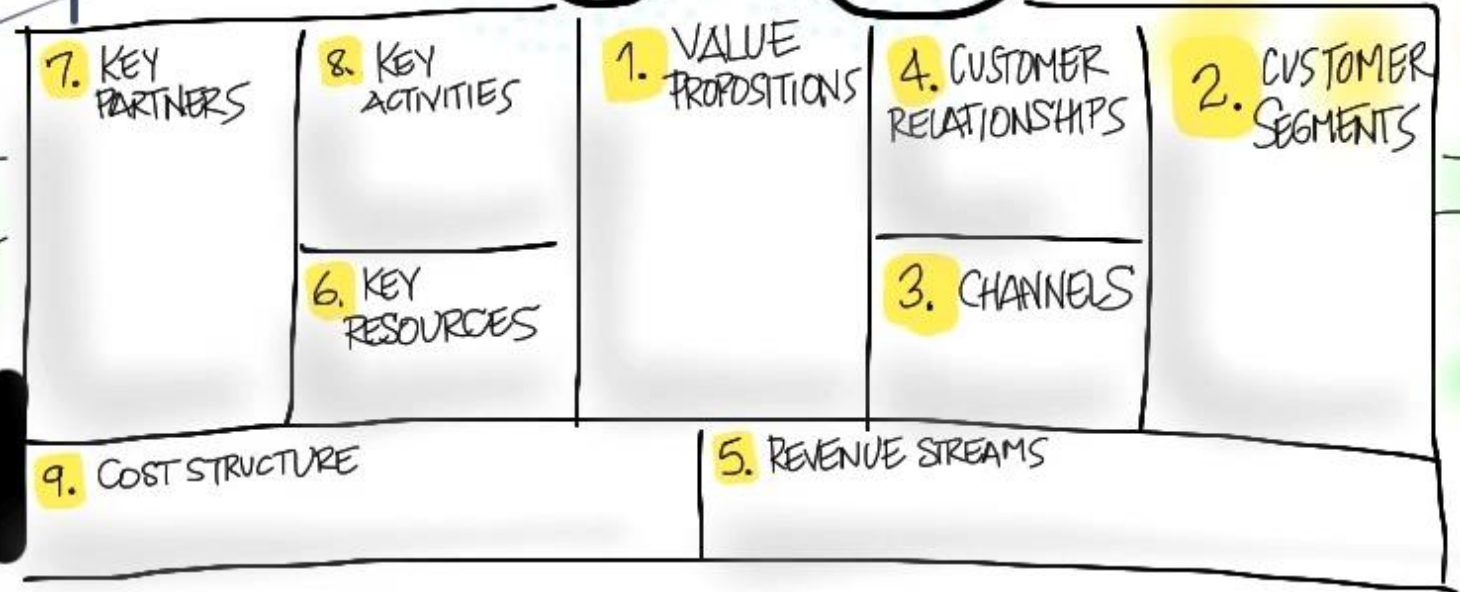
Business Model Generation **(Customer Discovery & Validation)**

Alexander Osterwalder & Yves Pigneur, Business Model Generation (2010)

WHAT is a BUSINESS MODEL?

How a company **CREATES VALUE** for **ITSELF** while delivering products or services for customers.

9 Components...



7. KEY PARTNERS

8. KEY ACTIVITIES

1. VALUE PROPOSITIONS

4. CUSTOMER RELATIONSHIPS

2. CUSTOMER SEGMENTS

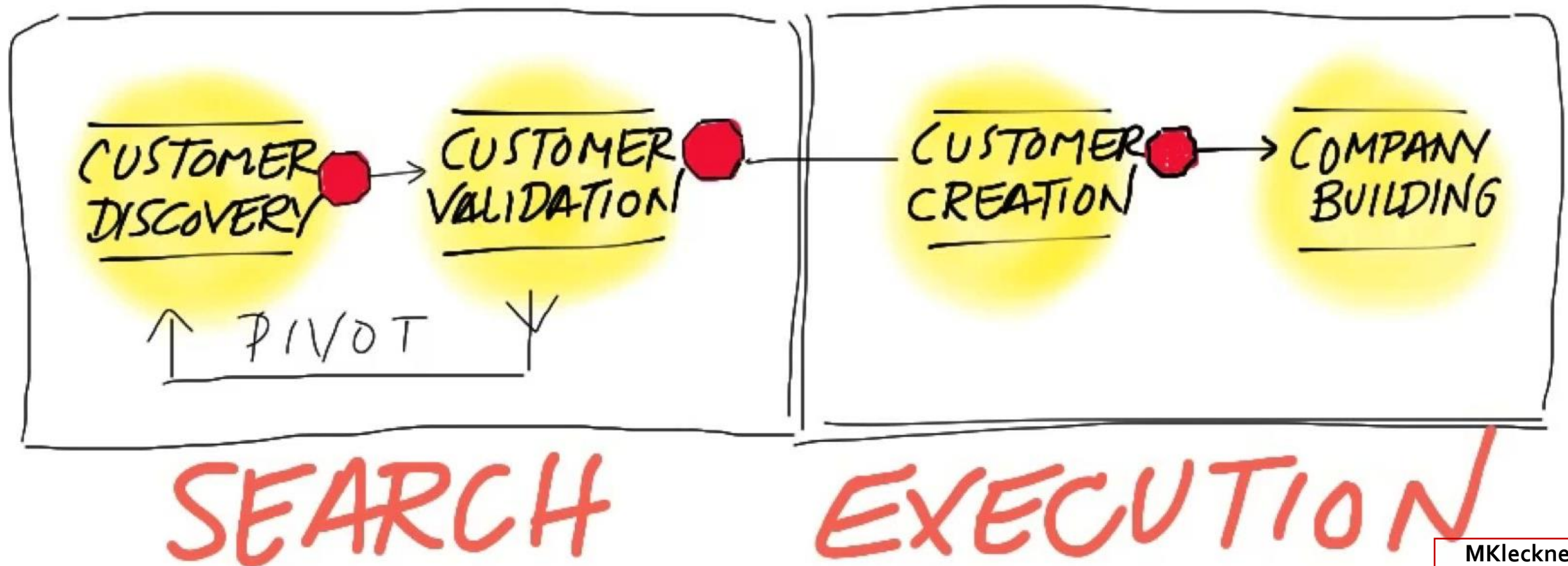
THE LOGIC OF HOW WE WILL MAKE MONEY
AKA HOW "THEY" WILL PROFIT

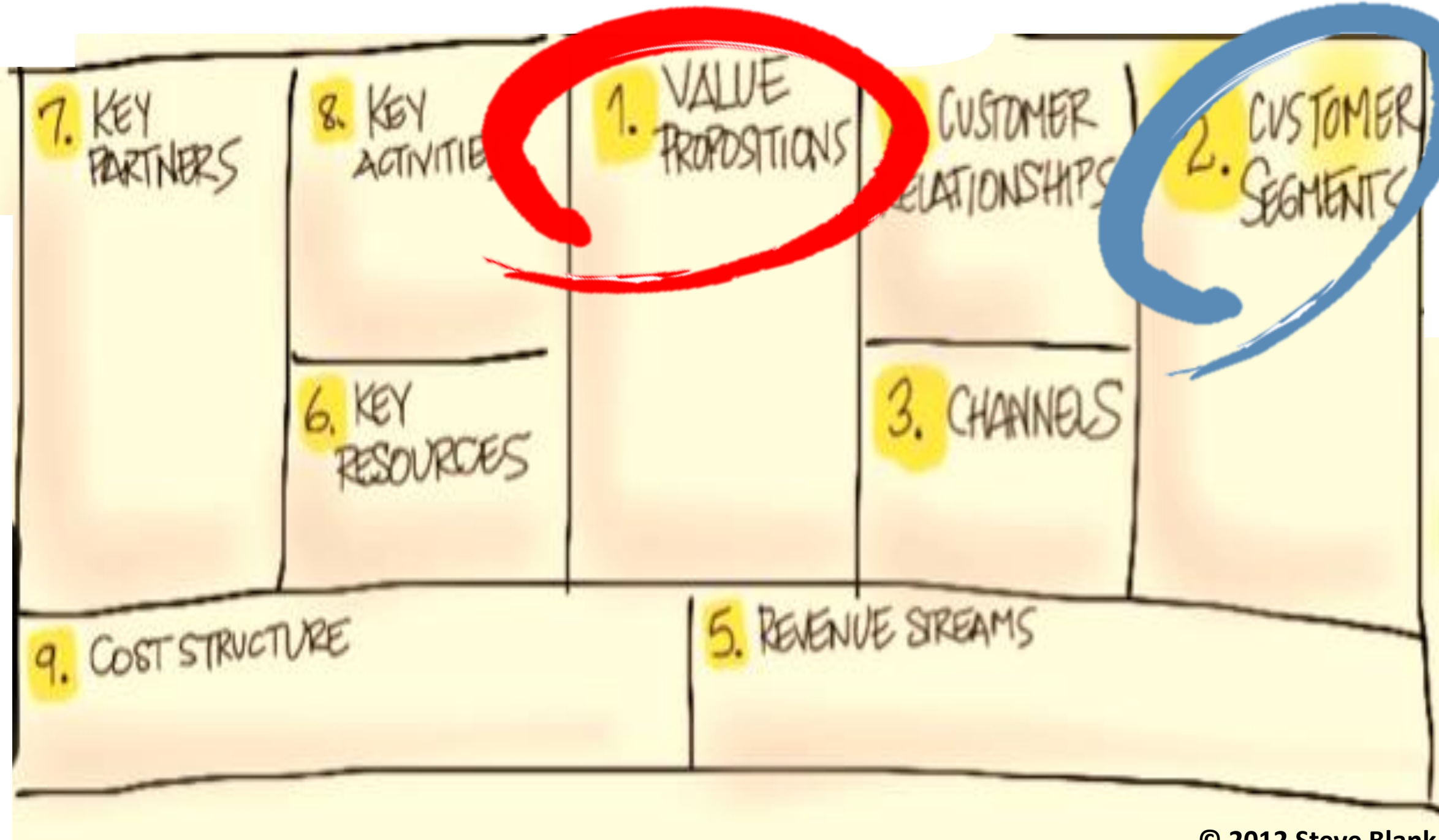
9. COST STRUCTURE

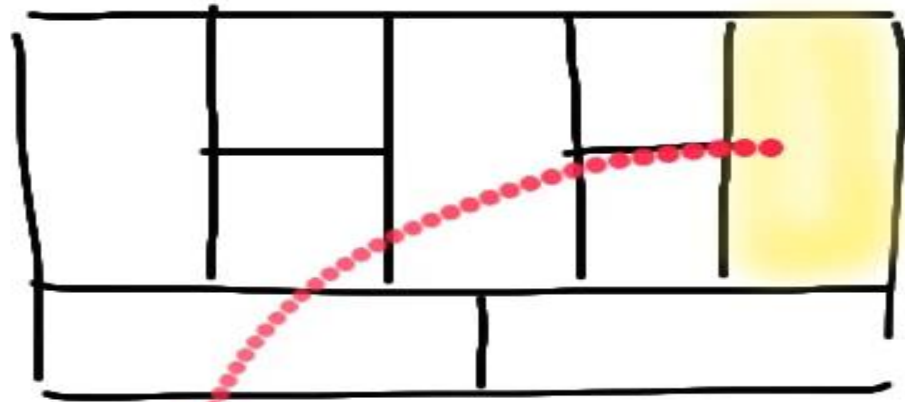
5. REVENUE STREAMS

Before Trying to Sell . . .

. . . Customer Development





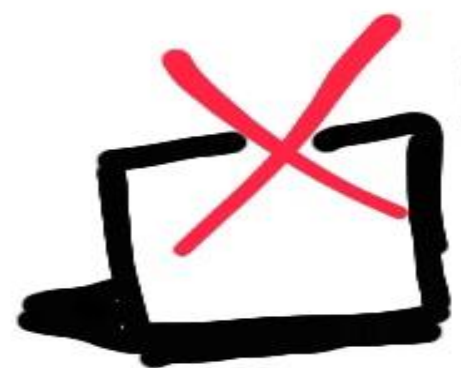


Customer
ARCHETYPE..

WHO are they?
WHY would they buy?

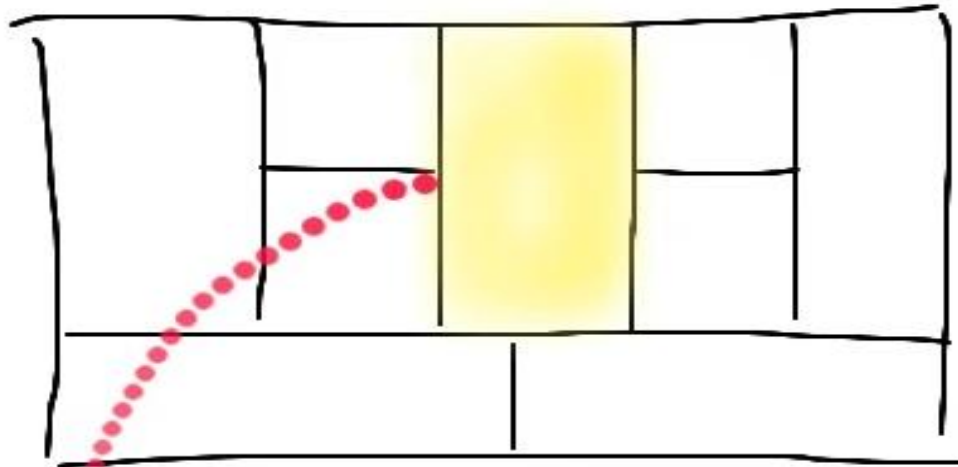
2. CUSTOMER SEGMENTS

- GEOGRAPHIC
- SOCIAL
- DEMOGRAPHIC



Your customers do not exist to **BUY**.
You exist for them.

- ← 24 years old
- ← Male
- ← City dweller
- ← Avid social media user
- Single
- inc



It's about SOLVING a **NEED** or **PROBLEM**.
HEAR YOU...
It's about SATISFYING a customer need.

It's about SATISFYING a customer need.
YAY! I'm DELIGHTED!

1. VALUE PROPOSITIONS

✗ "It's not about your IDEA or PRODUCT!"



...and **WHO** are your customers?

Investors are interested in this

After 5, 10,
... 100
Interviews:
What's
Your
Story?



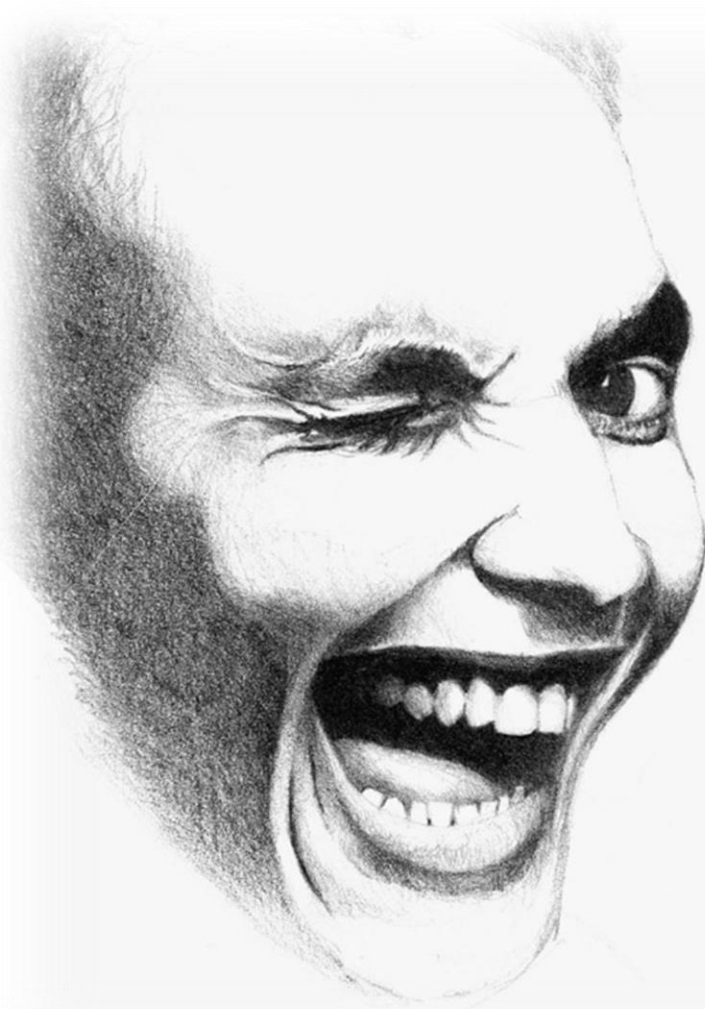
Cute Baby?



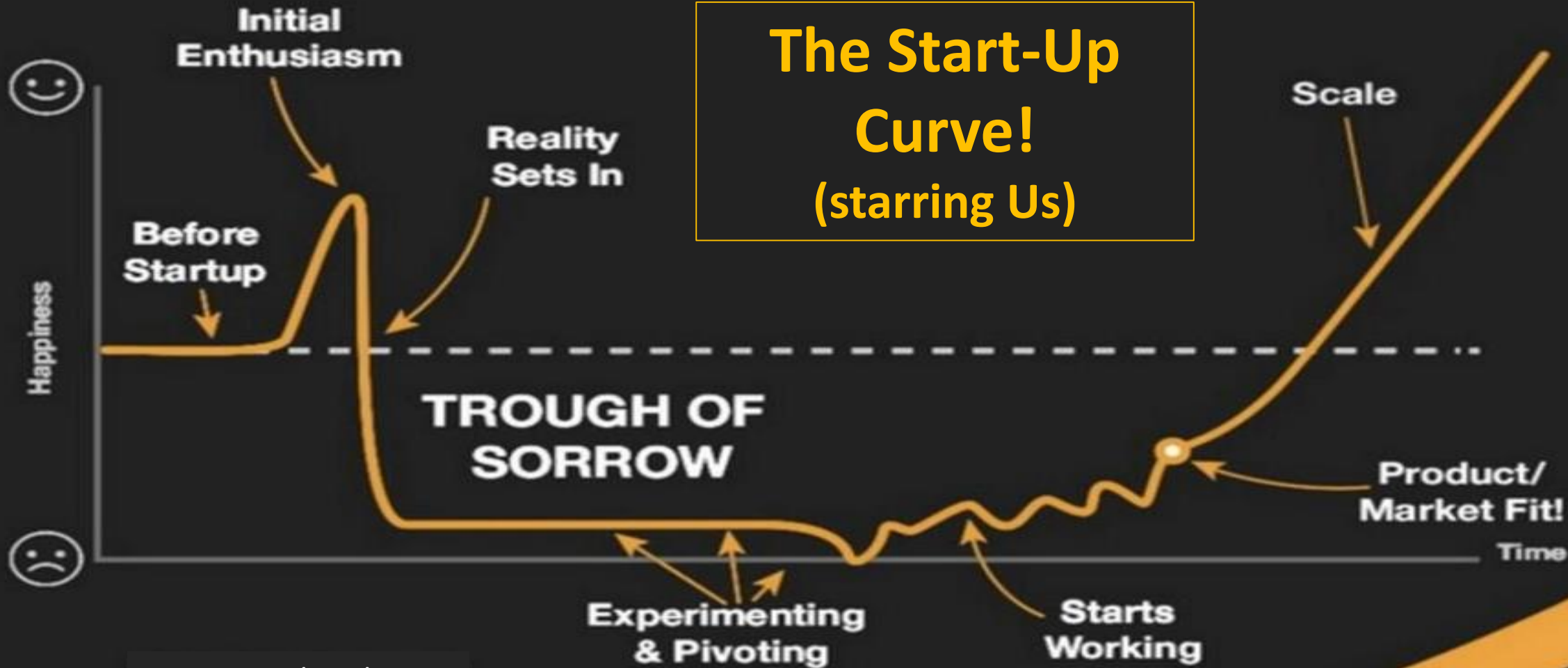
Confirmation Bias



Where may your first customers come from?



Behind Every Great Product is a Great Story



Source: Paul Graham

Hopefully some of this was helpful

**Martin S. Kleckner III PhD MBA
University of San Diego, The Brink SBDC, Innovation & Commercialization
NSF I-Corps Adjunct Faculty
5998 Alcalá Park, MRH 101
San Diego, CA 92110
mkleckner@cox.net
1 (619) 892-2565**

PART V (Addendum):

BUDGETING, ACCOUNTING, AUDITS

Direct v. Indirect Costs
Eligibility - Allowability

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!"

Yes, We Do

We will need an Approved Accounting System for Phase II

**Expectations Change
between Phase I & Phase II**

**Awarding Agencies & Contracting
Officers want you to be able to
distinguish Direct and Indirect Costs + also
isolate Unallowable ones**

Likely shift from (Firm) Fixed Price (FFP¹) to **Cost Plus Fixed Fee (CPFF²)**

1. FFP = Grant-Established Dollar Amount
 2. CPFF = Documented Costs
- (CPFF requires a “smart” accounting system)

DCAA & Pre-Award Surveys*

- 1) DCAA = Defense Contract Auditing Agency**
 - 2) NIH & NSF = External CPA Reviewer**
-
- **Assess Our Financial Stability (to complete a 2-Year Phase II project (not to mention Phase IIb))**
 - **Evaluate Our Accounting System**

***Audits**

Also . . .

3) Evaluate your proposed Indirect Rates

- Assess how they were calculated
- Determine if they are suitable for billing

4) Confirm that your Payroll Taxes are current

Memo: Take a look at the “DCAA Guide Information for Contractors”

http://www.dcaa.mil/DCAAM_7641.90.pdf, DCAA MANUAL NO. 7641.90 (June 26, 2012)

About that Accounting System . . .

1. Proper segmentation of Direct from Indirect costs
2. Identification & accumulation of Direct Costs by Contract
3. Logical & consistent method for Allocating Indirect Costs
4. Accumulation of costs under General Ledger Control
5. A Timekeeping System
6. Labor Distribution System charging direct & indirect labor correctly
7. Interim Determination of costs charged to contract/grant
8. Exclusion of Unallowable Costs
9. Identification of Cost by Contract Line Item
10. Segregation of Preproduction from Production Costs

Reference: "Standard Form SF 1408

Seriously, the Timesheet . . .

Need to document/prove where we incur the **largest single indirect costs**, namely employee time spent running the business, writing proposals, preparing & updating commercialization plans, & similar non-project activities (actual time/not %; do this daily)

*Must be kept by everyone, including the CEO – even if no work performed on grant/contract (see Enclosure 2, Section 4 of that DCAA Guide).

The Phase II Budget

Direct Costs
v.
Indirect Rates

A **Direct Cost** = Incurred when doing work expressly for the project; most common direct cost is labor

An **Indirect Cost** = Not directly accountable to the project; represents general costs of being in business: e. g. rent, employer portion of payroll taxes, phone bill, general operations

Indirect Costs?

- Overhead/Indirect Labor
- Pension Benefit Expenses
- Incentive Compensation
- Rent Expense
- Professional Fees
- Medical Insurance
- Patent Costs
- Payroll Expenses
- Office Supplies & Expenses
- Vacation, Holiday, & Sick (Earned)
- Depreciation
- Computer Supplies
- Trade Shows
- Telephone & Utilities
- Advertising – Recruiting & Hiring
- Postage and Shipping
- Contributions
- Penalties & Interest
- Claimed Expenses
- Travel, Lodging . . .

How should Start-Ups* Budget an Indirect Rate for an SBIR or STTR Proposal?

***No History of Operations**

Do the Best You Can*

1. List **ALL realistically expected** cost items – coming year
 - You can amend as you experience actual costs
 - Use a spreadsheet (e.g. MS Excel)
 - Don't think in terms of Direct v. Indirect yet
2. Estimate **anticipated annual costs** (do the best you can)
3. **Classify line items:** Direct, Indirect, Unallowable, Comments
4. What about **Independent Research & Development?**
 - NIH & NSF will not pay for it (Unallowable)

Eligible Costs

Limits: to help shape SBIR/STTR Direction

- Some agencies: can't direct-cost equipment
- Others: prohibit travel
- NIH limits Indirect Costs to 40% (% of Direct Costs)
- NSF limits indirect/fringe benefits to 150% of DC
- 7% Fee allowed; some: can't exceed; "normally"/average
- Unexpected Costs: "Contingency" allowed FFP; not allowed CPFF reimbursement
- Routine furniture and equipment: Nope for direct costs

So, let's say . . . "Total Plan = \$500K"

COSTS	TOTAL	DIRECT	INDIRECT	UNALLOWED
Labor	\$300,000	\$175,000	\$125,000	
Payroll Taxes	49,050		49,050	
Rent	24,000		24,000	
Office Supplies	6,000		6,000	
Telecommunications	6,000		6,000	
Consultants	15,000	10,000	5,000	
R & D Subcontractors	45,000	45,000		
Travel	12,000	4,000	7,000	1,000
Insurance	950		950	
Independent R & D	10,000			10,000
Equipment/Furniture				
Depreciation	32,000	10,000	22,000	
TOTAL	\$500,000	\$244,000	\$245,000	\$11,000

So,

Indirect (% of Direct Costs) = 100%

Indirect Rate (% of Direct Labor) = 140%

These rates are deemed equivalent

Use either one; read agency guidance

Actual Costs will, of course, change

NSF Budget Approach

Category	Budget \$	\$ Remaining	% Total
Total Budget Available	-	\$750,000	100%
Fee (Profit) = $\leq 7\%$	\$52,000	\$698,000	6.93%
Indirect Costs	250,000	448,000	33.3%
Direct Costs	448,000	-	59.7%

Indirect + Fringe = Maximum of 150% of Only Total Direct Salaries
From Your Forecasted Budget: Indirect Rate % of Direct Costs = 56%

What is a Good Rate (NSF, DOE)?

Allows us to **meet our grant-funded obligations** in our competitive environment while running our business. Government receives Value and Services it purchases – and **We are Sustainable**

A Good (and Reasonable) Rate

- **Fringe**
 - Payroll Taxes = 7.65%
 - Paid Time Off = 8%
 - Other Benefits = 0% - 10%
 - Total = 16% - 25%
- **General & Administrative**
 - 5% - 25%
- **50% Minimum**



**Can't be Too High;
but don't make it
Too Low.**

**Agencies like DOE,
no Absolute Cap;
NSF – 150%**

**Project Value
Prevails**

NIH Budget Approach With a Cap or Restriction

Budget Cap: \$1.5 MM		
Direct Costs		\$1,000,000
Indirect Costs*	$\$1,000,000 \times 40\%$	400,000
Fee	$(\$1.0 \text{ MM} + \$400,000) \times 7\%$	98,000
TOTAL	Direct + Indirect + Fee	\$1,498,000

Maximum NIH Indirect Costs w/o Rate Determination = 40%

***NIH IDC > 40% = Possible Audit**

About that 40% Rate

- We Can Propose an Estimated F&A Rate in our application
- If the requested F&A cost rate is **40 percent of total direct costs or less**, no further justification is required at the time of award
- If awarded at a rate of 40 percent or less of total direct costs, **we cannot charge actual F&A costs to projects that exceed this rate** unless we negotiate an indirect cost rate(s) with DFAS.
- **Division of Financial Advisory Services (DFAS)** — the office authorized to negotiate indirect cost rates with SBC's receiving NIH SBIR/STTR awards—will negotiate indirect cost rates

Allowable (Eligible) v. Unallowable

- **Allowable – defined in Federal Acquisition Regulation (FAR) 31.205.1-52**
 - Generally Allowable (e.g. Manufacturing/Production Engineering, Service & Warranty Costs)
 - Allowable w/ Limitations (Labor, Travel, Rent; Reasonable)
 - Generally Unallowable (Alcohol, Charitable Contributions)
- **FAR does not list or discuss all of the costs**

Allowable if Reasonable

Salaries and Wages if reasonable number of hours
with reasonable compensation

(Use, for example, professional association surveys, Bureau of Labor Statistics, or informal inquiries to companies with similar personnel)

Supplemental Regulations

Department of Defense (DoD) – DFARS

Dept. of Energy (DOE) – DOE Acquisition Regulations

NSF – Proposal and Award Policies & Procedures Guide

NIH – NIH Grants Policy Statement

(There may be additional limits: NIH Independent R & D);

NIH: Max Salary Rate; DOE is OK for Patent up to \$15,000)

Need Help?

C. P. Krishnan

CAK International, LLC

SBA Certified 8(a)/SDB/edWOSB Profile # 304315

GSA 8(a) STARS II GWAC Contract # GS00Q17GWD2176

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