PARMELEE
CONSULTING GROUP, INC

SBIR/STTR

A program supporting innovation in R&D

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SBIR · STTR
America's Seed Fund

Topics for Today’s Presentation

1.Overview of the SBIR/STTR Program

2 Key Attributes of an Ideal SBIR/STTR

. Participating Agencies

3 Grants vs. Contracts, Topics and Abstracts

5.What‘s Next

4. Questions

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Presentation Rules

- Exception to every rule presented today
- Expect to be overwhelmed!
- Every agency is different, make no assumptions
- Future of program is always subject to change (September 2025 renewal)
- Most answers are “it depends”
- SBIR=STTR

Overview of SBIR/STTR Program

SBIR · STTR
America's Seed Fund

SBIR

Small Business Innovation Research

Promotes technical innovation and commercialization by small businesses

STTR

Small Business Technology Transfer

Promotes cooperative research and development between small businesses and U.S. research institution

Eligibility

- **500 or fewer employees**, ***including affiliates***
- For profit business
- Located/primarily operated in U.S. +50% owned/operated by U.S. citizens or permanent residents

OR

- Owned and controlled by a (one) for-profit small business that is +50% owned and controlled by a U.S. citizen or permanent resident

Eligibility of companies with VC investment varies

Overview of SBIR/STTR Program

- **Set aside program** based on extramural research budget of agencies (founded in 1982) Totaling **$4+ billion in non-dilutive**
- **funding**

- Designed to stimulate R&D, innovation and commercialization of new technologies to meet the needs of
  - oThe public **(Grants)**
  - oFederal agencies **(Contracts)**

Important! The best option for most projects is:

Phase I → Phase II → Phase III

Phase I

- Focused on feasibility
- ~$150K (or up to ~$275K+)
- 6 months to 1 year project period

Phase II

- Prototype
- ~$1 million (or up to ~$1.5 million/year or more)
- 2 year project period

Phase III

- Commercialization
- No SBIR Funds
- Sole-source procurement for contracts

Other mechanisms:

- Fast Track
- Direct to Phase II
- Phase IIB
- Administrative Supplements

Overview of SBIR/STTR Program

Why do it?

- Allows business to
  - Maintain control of operations
  - Retain all intellectual property
  - Safely explore new ideas
- Requires an inherent sense of **risk** in the work—there will be failures
- Success rate is greater than other sources; other sources are attracted to non-dilutive funding

4,500+ Phase I awards

made to

2,900+ firms

Award rate for Phase I is ~17% (NIH: 12%)

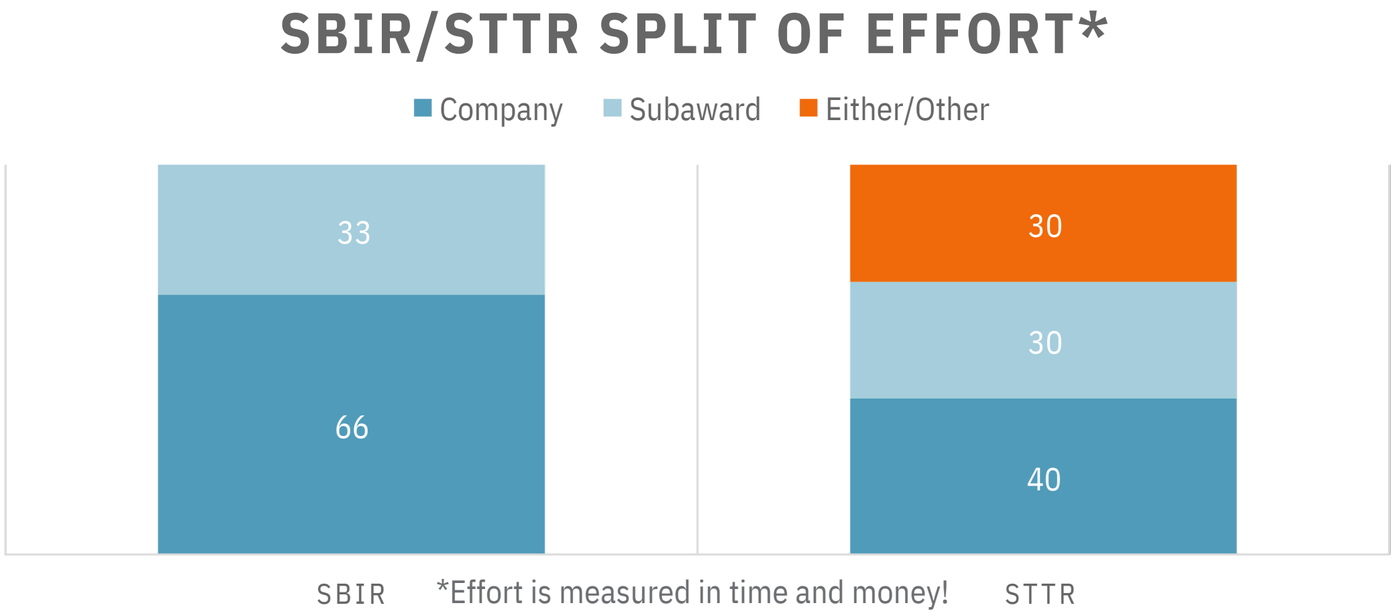
Phase II ~34% (NIH: 21%)

40% of winning companies have between 2 and 9 employees

Difference betweenSBIR and STTR

SBIR= *Allows*Research Institution as a partner | PI @ company

STTR=*Requires*Research Institution as a partner | PI @ company or sub



How do you choose?

- Team structure
- Budget
- Scope of work

Challenges of STTR?

- Required company effort
- NSF restrictions
- University overhead
- PI required % effort

Key Attributes of an Ideal SBIR/STTR

What makes a good SBIR/STTR?

Innovation—not just incremental improvement, but something new: new market, new use, new method, new solution, or building a better mouse trap

Commercial Potential—must be able to identify customer(s), the buyer, the competition. A market must exist, someone must want to buy the solution

Phased Development—must fit in the Phase I, Phase II, Phase III process (otherwise not worth the fight)

Structure—a team with a lead, a PI with experience, a company (formed, bank account, registrations complete), partners, collaborators

NSF Says a Good Project Is

- ***Game-changing:*** innovation could make a difference to people worldwide or revolutionize an industry
- ***High Risk:*** based on unproven technology that needs further testing (and funding for that testing)
- ***Market Pull:*** evidence that your product or service could meet an important, unmet need for your customers
- ***Scale:*** if successful it could form the foundation for a scalable business and make a large impact on your target market

…add solid IP position!

What Kind of Projects are Right for SBIR/STTR?

- An alternate device for cervical insufficiency—offering safer, faster, better outcomes than current method of cerclage

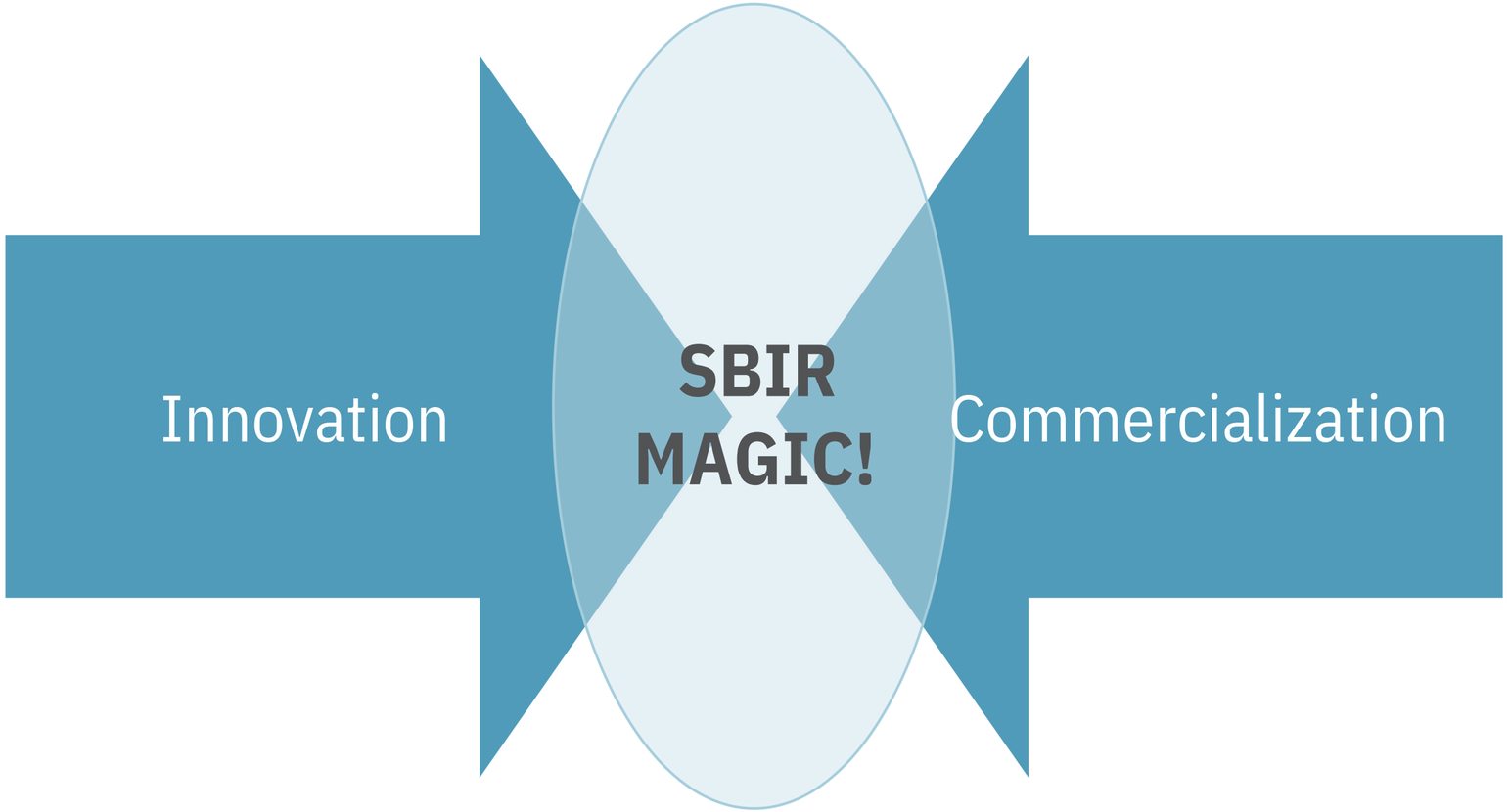
- A new technology developed for licensing to major trauma suppliers, who will market the device as part of their internal fixation product portfolio

- A non-pneumatic device to prevent DVT during in-patient stays
- Intelligent clinical pathway decision support tool for pre-authorization documentation in oncology care

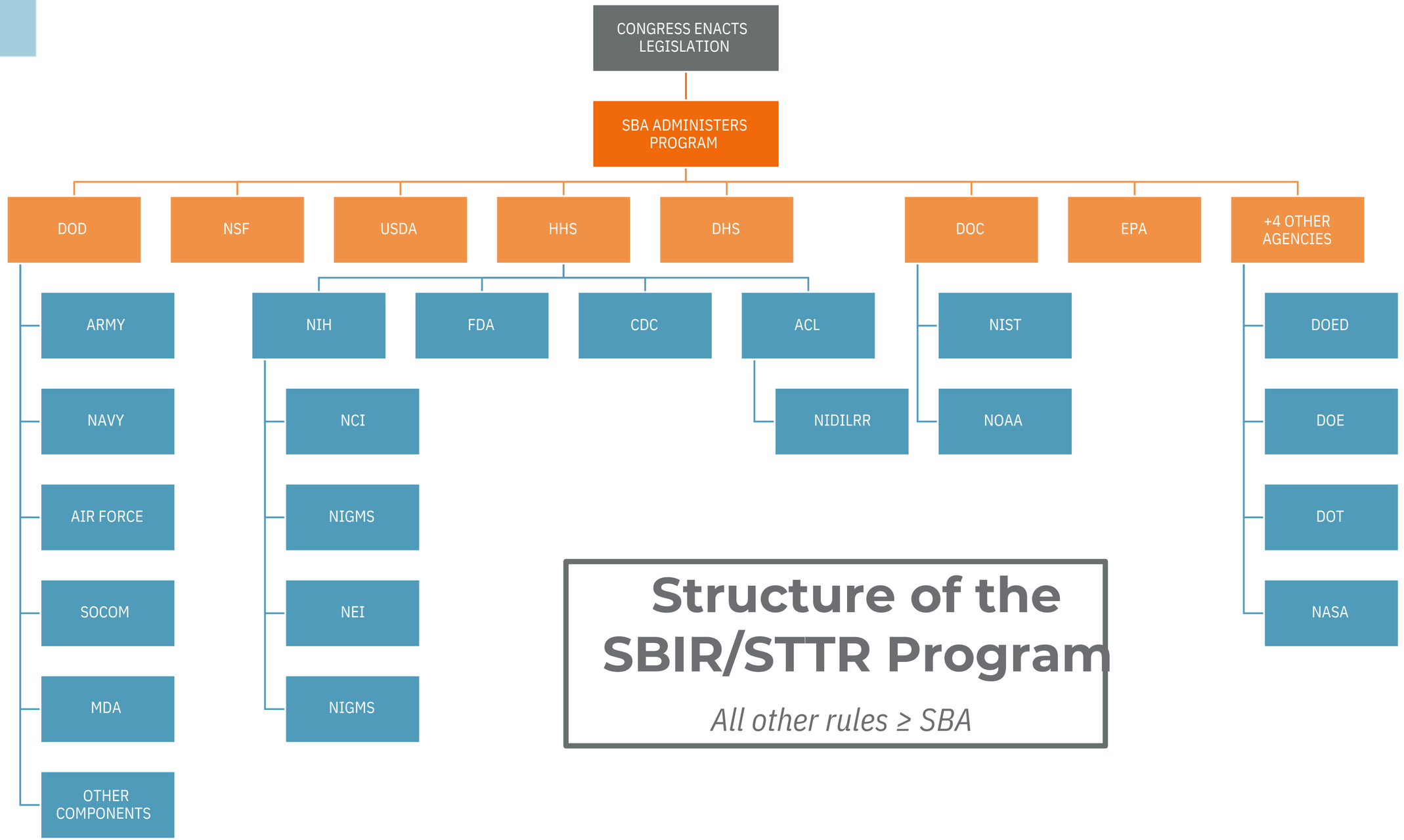
Key Attributes of an SBIR/STTR

1. Innovation
2. Commercial

   Market



Participating Agencies



Structure of the SBIR/STTR Program

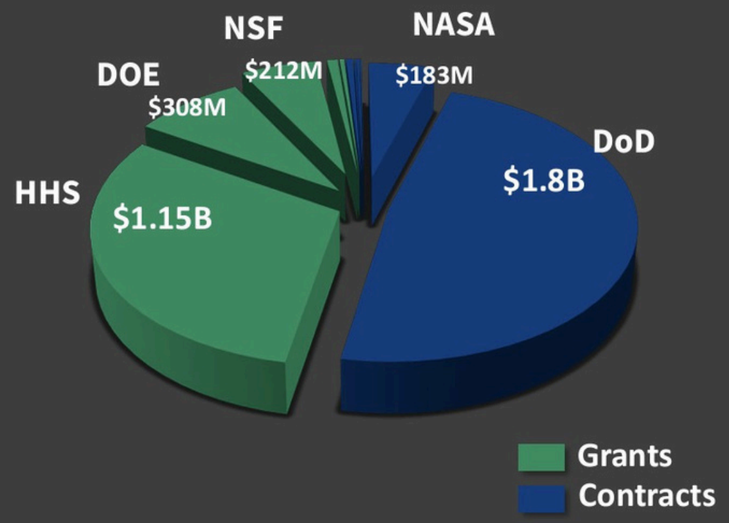
All other rules ≥ SBA

Participating Agencies

FY2019 SBIR/STTR Budgets by Agency

Agencies	Budget
Department of Defense (DoD)*	$1.80 B
Department of Health and Human Services (HHS)**, including the National Institutes of Health (NIH)	$1.15 B
Department of Energy (DOE), including Advanced Research Projects Agency – Energy (ARPA-E)	$308 M
National Science Foundation (NSF)	$212 M
National Aeronautics and Space Administration (NASA)	$183 M
U.S. Department of Agriculture (USDA)	$30 M
Department of Homeland Security (DHS)	$17 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA)	$9.5 M
Department of Education (ED)	$8.4 M
Department of Transportation (DOT)	$5.2 M
Department of Commerce: National Institute of Standards and Technology (NIST)	$3.9 M
Environmental Protection Agency (EPA)*	$3.6 M

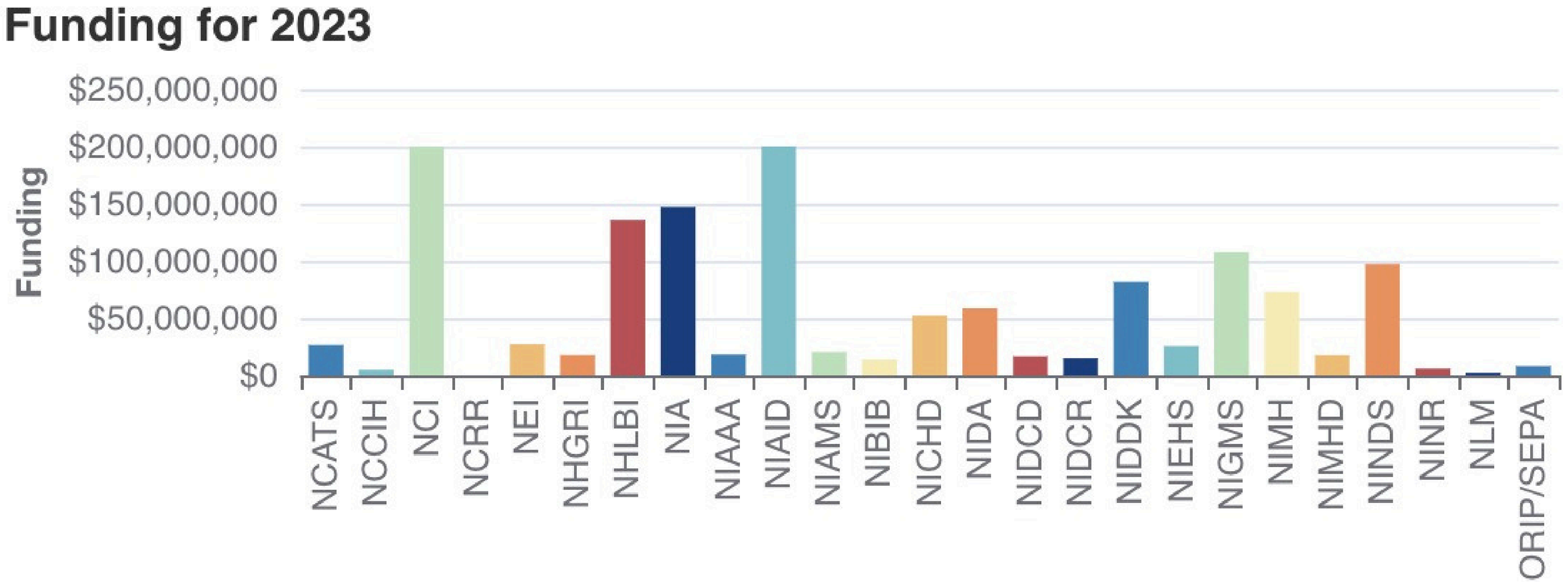
* Budgeted Amount; other Agencies Obligated Amount
** Provides grants and contracts



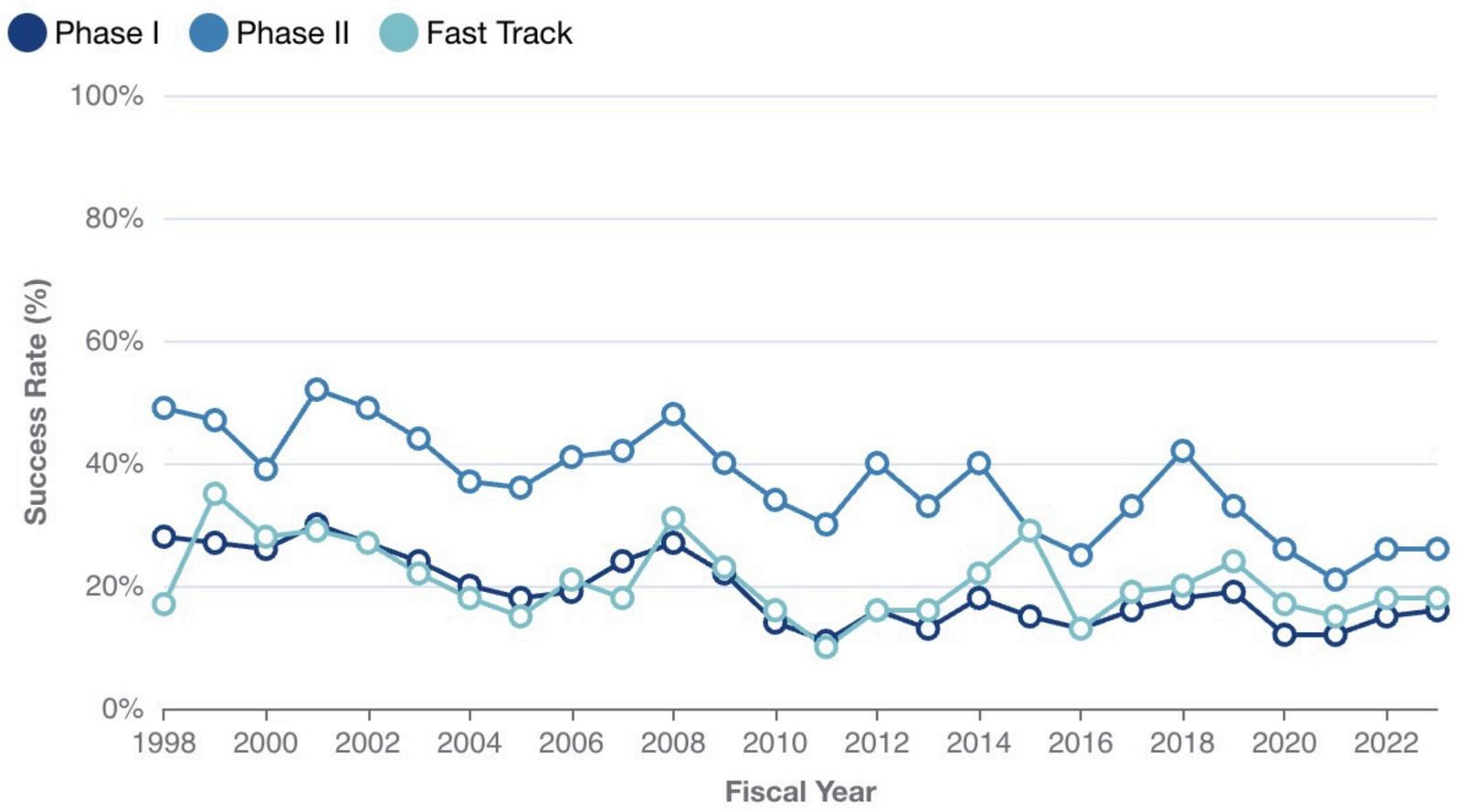
SBIR: $3.28 Billion
STTR: $453 Million

Health& Human Services (NIH, FDA, CDC)		
	Grants	**Contract**
Solicitations:	Varies—ongoing	Once a year
Grants v. Contracts:	Both	
Topic Areas:	Investigator-initiated	Agency-specified
Contact with Staff:	Always encouraged	Restrictive periods
Budget:	Budget flexibility	Firmfixed price
Submission Method:	Grants.govor ASSIST	Separate portal
Review Process:	Peer review process	Internal review
Resubmissions:	Permitted	Not permitted
Fun Fact:	24 Institutes/Centers	

NIH Award Statistics



NIH Award Statistics



Trends in Award Rates

Award Rates 2023
Phase I: 16%
Phase II: 26%
FastTrack: 18%

3,014 Phase I
1,323 Phase II
applications

Award Rates 2018
Phase I: 18%
Phase II: 42%
FastTrack: 20%

3,607 Phase I
618 Phase II
applications

Award Rates 2008
Phase I: 27%
Phase II: 48%
FastTrack: 31%

2,926 Phase I
598 Phase II
applications

National Science Foundation	
Solicitations:	Rolling—requires“Project Pitch”
Grants v. Contracts:	Grants (act likecontracts)
Topic Areas:	Investigator-initiated (broad) in 30 areas
Contact with Staff:	Permitted, encouraged
Budget:	Firm $275,000 ceiling (Phase I)
Submission Method:	NSF’s FastLane(Research.gov) system
Review Process:	Peerreview process
Resubmissions:	Permitted (1 at a time; requires new Pitch)
Fun Fact:	PI onSTTR must be at small biz

NSF Award Statistics

303

Number of companies with active awards

Phase I seed funding

$273,283

Average amount of funding awarded for each company

45

Total states and territories

59%

of the companies from the most recent 2017 cohort are <3 years old

#	Topic		#	Topic		#	Topic
19	Biological Technologies		12	Digital Health		21	Artificial Intelligence
24	Environmental Technologies		**37**	**Biomedical Technologies**		21	Medical Device

US Department of Agriculture	
Solicitations:	Once a year (SBIR/STTR) (~July/ due ~ Oct.)
Grants v. Contracts:	Grants (act likecontracts)
Topic Areas:	10 broad categories
Contact with Staff:	Permitted, encouraged
Budget:	Firm $100,000 ceiling (Phase I, 8 months)
Submission Method:	Grants.gov
Review Process:	Peerreview process
Resubmissions:	Permitted
Fun Fact:	Rural and Community Development

- Forests and Related
- Resources
- Plant Production and Protection -Biology
- Animal Production and Protection
- Conservation of Natural
- Resources
- Food Science and Nutrition
- Rural Development
- Aquaculture
- Biofuels and Biobased Products

Small and Mid-Size Farms

Plant Production and Protection --Engineering

Department of Defense	
Solicitations:	3x pear year + off-cycle solicitations
Grants v. Contracts:	Contracts
Topic Areas:	Very focused (submitting to component)
Contact with Staff:	Public forum only
Budget:	Firm fixed price (progress payments/options)
Submission Method:	DoD's own portal
Review Process:	Internal technical experts
Resubmissions:	Not permitted
Fun Fact:	Wide range of topics

Largest participant in SBIR/STTR

13 separate components

No VC owned companies

New flexible topics

End customer!

Grants vs. Contracts, Topics + Abstracts

Grants vs. Contracts

- Some agencies are **granting agencies**—a problem to solve not the end customer
- Some agencies are **contracting agencies**—an urgent problem to solve and if you can solve it, you will be their (sole source) supplier
- Some agencies are **one and act like another**
- Some are **both**!

Points that Vary:

- Contact with program staff
- Topic selection at time of submission
- Agency involvement during project period
- End customer
- Resubmission of proposals

Topics

Topics in NIH

- 24 Institutes and Centers participate
- Do not need to have a topic selected to submit
- 200+ pages of topics and interest areas (plus special interests on websites)
- If meets SBIR/STTR requirements and relates to public health, can submit
- Ideally contact IC/Program Officers prior to submission (not required)
- Topics listed in Omnibus and Special Solicitations

https://seed.nih.gov/

Topics in NSF

- 30 broad topic areas, many have subtopics
- Make suggestion on topic area at submission of Project Pitch (will reassign if not correct)
- Contact information provided for each topic (but most staff will not comment in advance on projects)
- No clinical trials but limited human subjects permitted
- All topic areas have “Other” category as general catch-all

https://seedfund.nsf.gov/

- Preliminary data needed
- Ideas and approaches rooted in literature
- Risk-adverse
- Supports clinical trials
- Focused on health outcomes (saving money, time, lives)—cool technology is secondary

- Preliminary data not required
- Loves cutting-edge ideas
- Embraces risk
- Does not support clinical trials/drug development
- Focused on cool technology—health outcomes are secondary

NIH vs. NSF

“The Watch Example”

Abstracts & Success Stories

SBIR.gov

- Select PortfolioApplyfilters: Agency, state, phase, year, program (SBIR/STTR)

Furopyrimidines as novel inhibitors of henipaviruses

SBC: Chicago Biosolutions, Inc. *Topic: NIAID*

The emergence and reemergence of pathogenic viruses represent continuous infectious disease threats to public health. Among these, the paramyxoviruses, which include many important human and animal pathogens, also include two excellent examples of emerged, zoonotic viral pathogens of importance: the henipaviruses; Hendra virus (HeV) and Nipah virus (NiV). HeV and NiV have a uniquely broad host tro ...

STTR | Phase I | 2021 | Department of Health and Human Services | National Institutes of Health

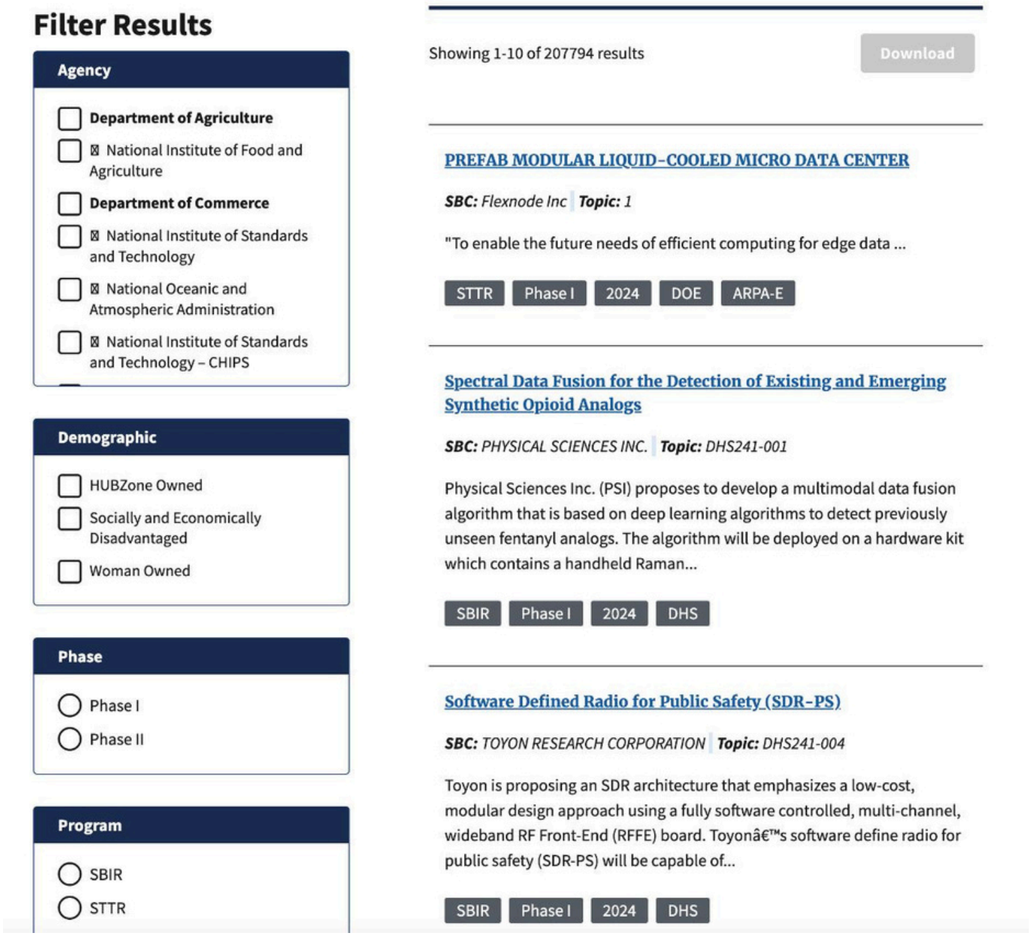
Development of Coccidioides Cytokine Release Assay

SBC: MiraVista Diagnostics, LLC *Topic: NIAID*

Coccidioidomycosis (CM) is an endemic mycosis caused by the fungi Coccidioides immitis and Coccidioides posadasii, which is native to arid regions of North and South America. It is estimated that up to 350,000 infections occur annually in the U.S. Additionally, up to a third of community acquired pneumonia cases in these areas are thought to be a result of CM. Morbidity associated with CM is subst ...

SBIR | Phase I | 2021 | Department of Health and Human Services | National Institutes of Health

+ Agency websites for success stories, abstracts + sample proposals



Beginning a Phase I NIH Proposal

Designing Your Phase I

How much time do you have?

- Phase I projects run 6-12 months (some I/Cs allows up to 2 yrs)
- Reviewers sensitive to overly aggressive project timelines
- Work delays into timeline

Propose a project that comfortably fits within allowable Phase I timelines

How much money is available?

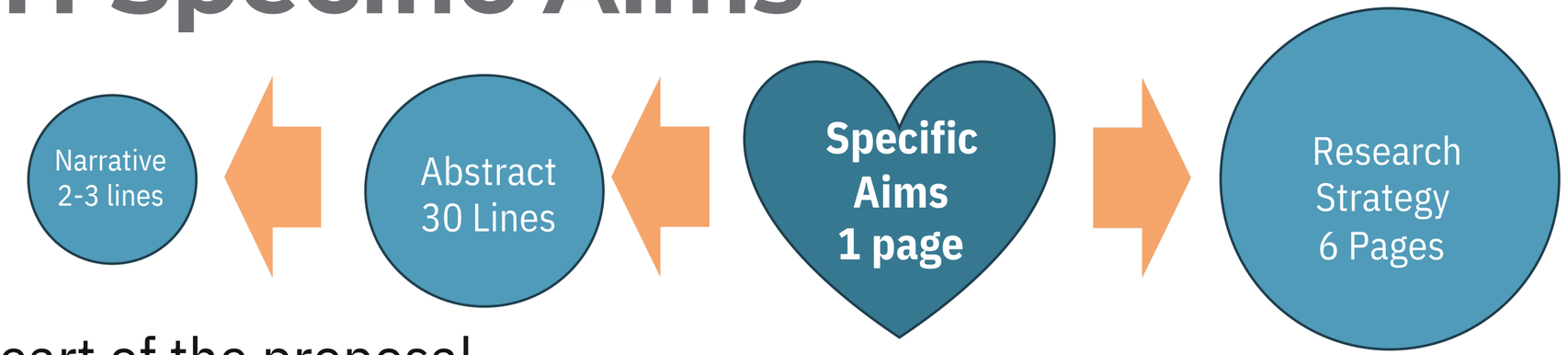
- Check guidelines of opportunity
- Look at I/C budget guidance
- Look at SBA Waiver Topics
- Consider splits for SBIR/STTR

Propose a project that is achievable with allowable funds

3 Key Elements

Specific Aims **The Team** **The Budget**

NIH Specific Aims



- Heart of the proposal
- Consistent with the funding opportunity (timeline/funding available)
- Leverage skills and experience of assembled team
- Presented in chronological order
- Start with action words (verbs) and should represent a series of tasks that share a common purpose and lead to an overall goal/outcome (i.e., Phase I—demonstrating feasibility)
- Aims are not tasks—they involve solving a technical issue (tasks are how you achieve the Aim)
- Include measurable (quantitative) milestones

Specific Aims Outline

- Paragraph 1: The problem
  - Why should anyone care?
  - What is it costing in lives, $$, time, resources, etc.
- Paragraph 2: Current state of the art
  - What's currently used to deal with the problem?
  - Why is it not working/what are its shortcomings?
- Paragraph 3: Your solution
  - What do you do better?
  - What are the benefits (cost savings, improved quality of life, etc.)?
- Paragraph 4: The Project
  - What is your overall goal in the total project?
  - What did you accomplish in Phase I?
  - Who will be involved (if you have a research partner, mention them here)
  - ➢ Enumerate your Specific Aims with brief description and milestone
- Paragraph 5: Summary
  - What will have have/know/have demonstrated by the end of Phase I (expected outcome)?
  - What comes next (Phase II)?
  - How big is the opportunity (market size, potential customers, etc.)?

Build the Team

Who is already engaged with company?

What roles can they play?

- Key persons (W2 employees who offer key expertise/skills)
- Other personnel (W2 employees offering general skills)
- Consultants
- Subawards/Subcontractors (research institutions)
- Advisors

- Make sure your team/available expertise aligns with planned efforts
- Need commercialization expertise!
- Regulatory/Reimbursement expertise needed?

- Who have you worked with in the past that has value to contribute?
- Who has been involved to date can help move things forward?

Sketch the Budget

Skeleton budget needed early to:

- Help determine SBIR or STTR
- See which staff and what % of time can be supported
- Provide subaward sites with available budget range
- Get commitments from
  - Consultants/Advisors
  - Contractors
    - Fee-for-service
- Make sure project scope is on target with Phase proposed

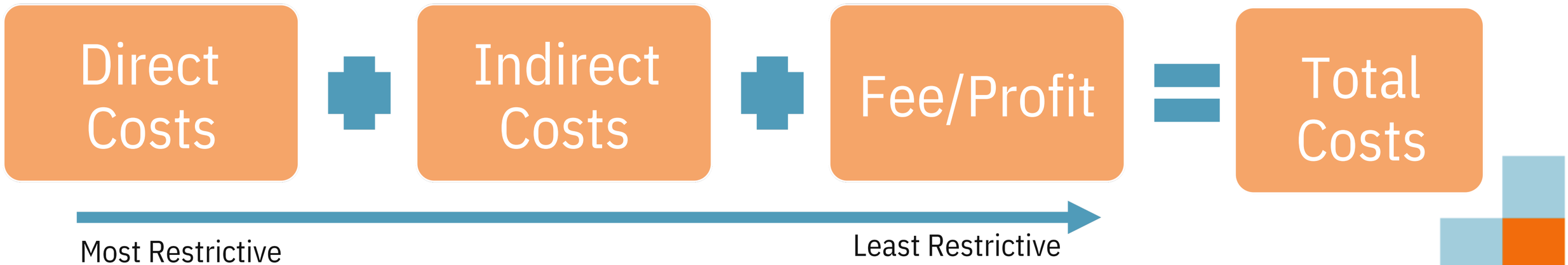
Sketch the Budget

- Based on the following:
  - Agency, Opportunity, I/C
  - Proposed work (Specific Aims)
  - Project period (how much time do you have?)
  - Team and resources required (facility usage, etc.)

NIH Budgets

"Normally may not exceed"
Phase I: $314,363
Phase II: $2,095,748

- Propose a budget that is reasonable, appropriate for and consistent with work proposed
- Budget is not a major factor of review
- Budget is always negotiated at time of award



Other Proposal Elements

- Narrative
- Abstract
- Facilities and Other Resources
- Equipment
- References Cited
- Research Plan
- Letters of Support
- Budget/Budget Justification
- Subaward (routed and approved) documents
- NIH-Compliant Biosketchesfor all Key Persons
- Data Management and Sharing Plan
- Other documents depending on project design (Vertebrate Animals, Human Subjects, Select Agents, Authentication, etc.)

...and more...

Other Considerations

- Consider timelines
- Contact Program Officer at NIH
- Complete required Registrations
  - SAM.gov
  - grants.gov
  - eRACommons
  - SBIR.gov
- Seek support from area resources (FAST Center)
- Read and re-read agency guidelines and application instructions
- Be prepared to submit more than once!

This program rewards persistence!

Questions?

APPLIED RESEARCH INSTITUTE

Helpful Resources

INFORM SERIES

POWERED BY ARI

Local Assistance

- Federal and State Technology Partnership Program (FAST)
- Small Business Development Center (SBDC)
- APEX Accelerator
- Small Business Administration (SBA)
- Indiana Regional Innovation Cluster
    - SBIR/STTR Support
    - Mentoring
    - Networking
    - Access to Capital

How ARI Can Help

1. Topic Identification
2. Proposal Assistance
3. Support Letters
4. Phase I & II matching funds
   - Phase I – Up to $50K
   - Phase II – Up to $75K

Go to our website, www.theari.us to see a list of our Initiatives and connect with our broader network.

Closing Thoughts

- Pay close attention to release schedule
- Review past awards to help determine which agency to pursue
- Use Pre-Release period as time to speak with topic authors
- Understand what your customer needs
- Make sure all necessary registrations are completed
- Follow Solicitation Guidelines
- Have multiple people review and edit your proposal

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