BIO Office Hours

Grant Applications with: PSC Biotech®

PSC Biotech Contacts:

Dr. Charles Heldebrant

CSO, Subject Matter Expert

cheldebrant@biotech.com

Dr. Conor Smith

Professional Services

csmith@biotech.com

Brandon Clough

CRO

bclough@biotech.com

John Clapham

CEO

jclapham@biotech.com

PSCBiotech®

Grant Application Process

01 Opportunities

02 Composition

03 Project Management

Grant Application Process

BIO Office Hours: Ask an Expert for Grant Writing Tips

1. Identify opportunities that match your companies R&D
2. Draft the proposal
3. Ensure the application meets deadlines and complies with all necessary requirements

PSC Biotech can provide support when it comes to engaging in the grant writing and application process:

- Best practices
- Strategies

Introduction

Government grants provide a critical source of capital to many early-stage biotechs. Successfully winning grant funding also signals to potential investors that the science underpinning your companies R&D has been vigorously vetted and shows promise.

Bridging the gap:
Basic research ← → Commercialization

←Basic research funding [←**Grants**→] Product sales, licensing, etc.→
(SBIR/STTR)
←Venture capital→

Identify Opportunities

Overview
Ensure alignment between the opportunity and the project/organization.

Strategy

Funding Opportunity		Project & Organization
Search: • For US grants, a good starting point: https://www.grants.gov • There are many additional related US government grant sites. For the focus of this presentation, see: https://www.sbir.gov • There are many additional grant opportunities, including private organizations: https://candid.org	Align	Identify and match to the opportunity: • The project, product, idea, study, etc. • The organization, company, institution, etc. Establish: • Clear definitions • Goals • Strengths • Weaknesses

Focus and Rationale

Focus

This presentation highlights Small Business Innovation Research (SBIR) grant proposal submissions to the Department of Health and Human Services (HHS) - National Institute of Health (NIH).

Rationale

BIO Emerging Member Companies:

- Likely to meet the criteria for small business – type grants: **SBIR**/STTR.
- Life sciences / biotech industry.
  - e.g., grant proposal submission to: **NIH**, NSF, DoD, USDA, ED, NASA

NSF: National Science Foundation, **DoD**: Department of Defense, **USDA**: United States Department of Agriculture, **ED**: Department of Education, **NASA**: National Aeronautics and Space Administration.

SBIR / STTR

"The mission of the SBIR/STTR programs is to support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy"

SBIR: **S**mall **B**usiness **I**nnovation **R**esearch **STTR**: **S**mall Business **T**echnology **Tr**ansfer

- Company must be for profit, U.S. owned/operated, and under 500 people
- Work must be done in the U.S.
- Focus is on performing R&D - Not purchasing equipment, commercializing a technology that has already been developed, or one that has very low risk and only needs capital

Budget allocation by type, year:

	SBIR	STTR
FY2019	$3.28B	$453M
FY2022	$3.83B	$529M

Strategy

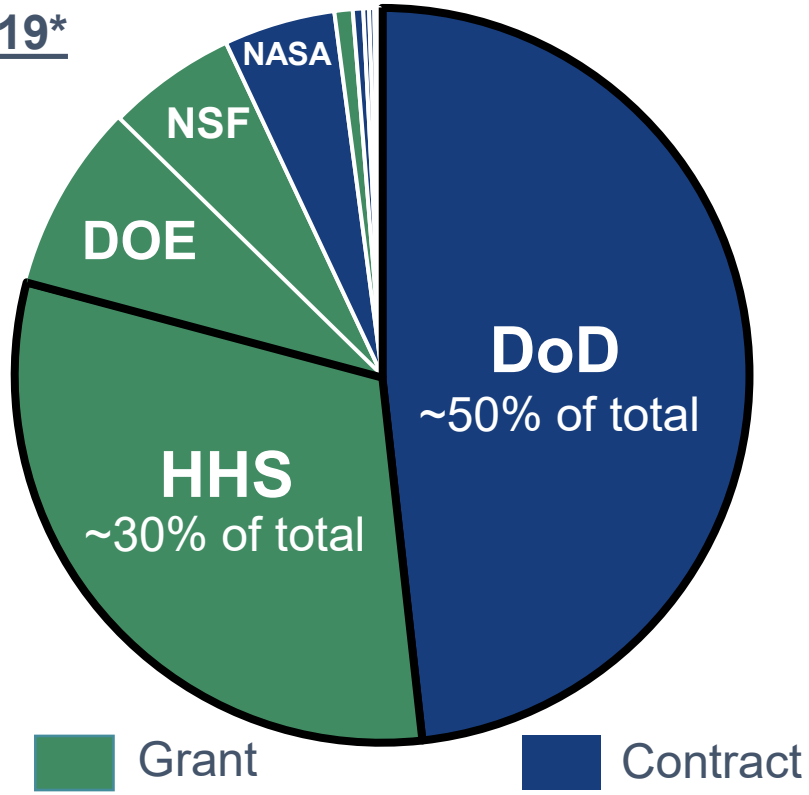
- The goal is to develop a product (technical innovation) to solve a problem.
- There are significant differences in criteria: SBIR vs. STTR, and grants vs. contracts.
- Refer to: https://www.sbir.gov
- In short: SBIR: *permits* partnering; STTR: **requires** a non-profit research institution partner.
  Grants: Allows upfront payment; Contracts: Invoiced on progress.

Major contributing agencies to SBIR/STTR

There are 11 participating Agencies, each with unique goals, focus areas, and requirements.

Breakdown by Agency

FY2019*



*Relative proportion is equivalent in FY2022

Strategy

- The proposal must be tailored to the Agency – reference the Agency-specific SBIR and/or STTR webpages.
- THE major granting agency is the Department of Health and Human Services (HHS), including the National Institutes of Health (NIH).

SBIR / STTR Funding Agencies (Detail)

Agencies	Budget (FY2019)	SBIR / STTR	Grant / Contract
Department of Defense (DoD)*	$1.80 B	SBIR/STTR	**Contract**
Department of Health and Human Services (HHS)** including the National Institutes of Health (NIH)	$1.15 B	SBIR/STTR	**Grant**
Department of Energy (DOE), including Advanced Research Projects Agency – Energy (ARPA-E)	$308 M	SBIR/STTR	**Grant**
National Science Foundation (NSF)	$212 M	SBIR/STTR	**Grant**
National Aeronautics and Space Administration (NASA)	$183 M	SBIR/STTR	**Contract**
U.S. Department of Agriculture (USDA)	$30 M	SBIR/STTR	**Grant**
Department of Homeland Security (DHS)	$17 M	SBIR only	**Contract**
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA)	$9.5 M	SBIR only	**Grant**
Department of Education (ED)	$8.4 M	SBIR only	**Contract**
Departmentof Transportation (DOT)	$5.2 M	SBIR only	**Contract**
Department of Commerce: National Institute of Standards and Technology (NIST)	$3.9 M	SBIR only	**Contract**
Environmental Protection Agency (EPA)*	$3.6 M	SBIR only	**Contract**

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

Draft the Proposal

Strategy

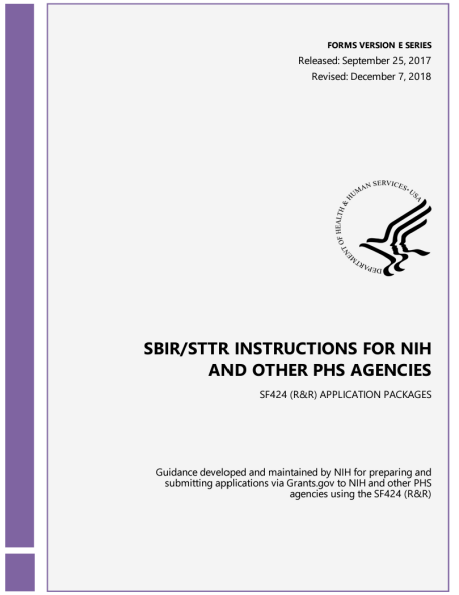
- The proposal must be tailored to the Agency – reference the Agency-specific SBIR and/or STTR webpages.

NIH – Mission:

"To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to **enhance health, lengthen life, and reduce illness and disability**."

"It is critical that applicants follow the SBIR/STTR (B) Instructions in the SF424 (R&R) SBIR/STTR Application Guide except where instructed to do otherwise."

https://grants.nih.gov/grants/guide/url_redirect.htm?id=32000



The instructions can be used to establish a submission checklist.

Draft the Proposal

A grant proposal will typically include the following components:

I. Executive Summary: A concise overview of the proposed project.

II. Background and Significance

III. Objectives: The goals and objectives of the proposed project and deliverables.

IV. Methods: How will you do it.

V. Timetable

VI. Budget

VII. References

Strategy

Consider the NIH review criteria:

- Significance
- Investigators
- Innovation
- Approach
- Environment

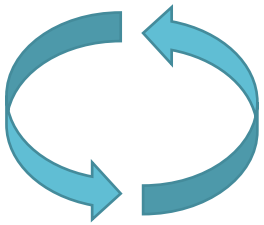
Overall impact: a rating on the likelihood that the project will have sustained, powerful influence on the applicable field of research.

NIH SBIR Grant:
Specific Aims + Research Strategy
7 pages total (Phase I)
13 pages total (Phase II)

Specific Aims: the most important page of the proposal.

Draft the Proposal

- Write
- Read
- Edit



This is an iterative process.
During the process, consider the below:

George Orwell, Politics and the English Language:

"A scrupulous writer, in every sentence that he writes, will ask himself at least four questions, thus:

What am I trying to say?
What words will express it?
What image or idiom will make it clearer?
Is this image fresh enough to have an effect?

And he will probably ask himself two more:

Could I put it more shortly?
Have I said anything that is avoidably ugly?

… the following rules will cover most cases:

i. Never use a metaphor, simile or other figure of speech which you are used to seeing in print.
ii. Never use a long word where a short one will do.
iii. If it is possible to cut a word out, always cut it out.
iv. Never use the passive where you can use the active.
v. Never use a foreign phrase, a scientific word or a jargon word if you can think of an everyday English equivalent.
vi. Break any of these rules sooner than say anything outright barbarous."

Project Management

1. **Prepare in advance**
2. Comply with all necessary requirements
3. Submit

Strategy

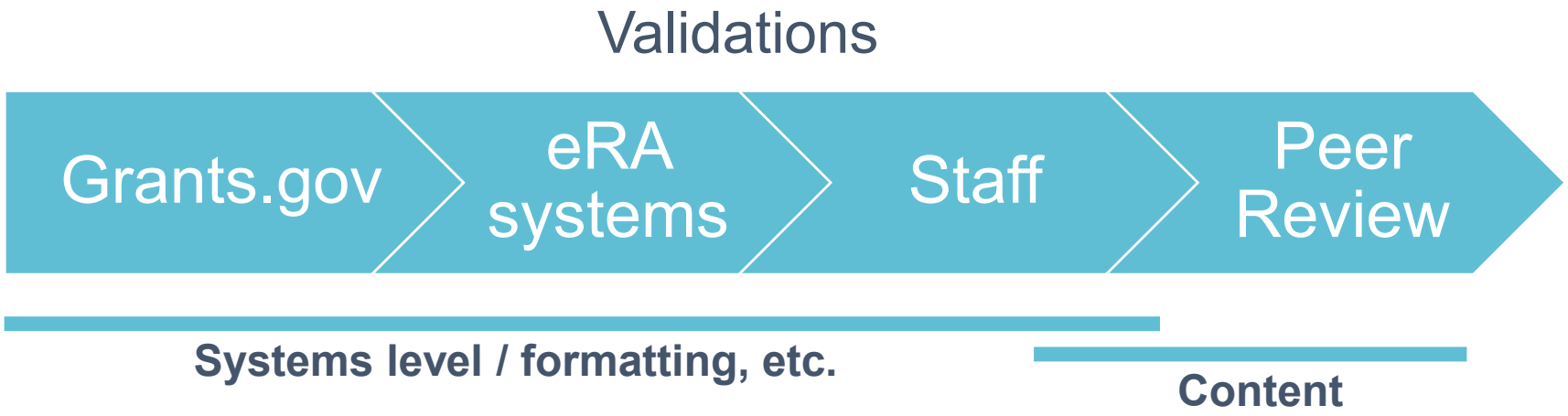
NIH SBIR Grant

- 75-150 pages
- 1 Month (full time) writing
    - If all required source information is available.
- *Opinion*: Time limitation is the root cause of grant rejections due to avoidable issues: missing/incorrect documents, formatting, etc.
- Find a comparable grant solicitation, use it to generate a template, then compose all sections that can be completed in advance.
- The organization* and product characteristics are independent of the grant, and can be completed (documented) in advance.

  *personnel, partner organizations may be variable.

Project Management

1. Prepare in advance
2. **Comply with all necessary requirements**
3. Submit



Strategy

- Government registrations – All are free
- Helpful overview: https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/how-we-check-for-completeness.htm
- Do: “Adhere to funding opportunity announcement (FOA) specific instructions”
- “Don’t rely on system checks to catch page limits and missing attachments specific to the announcement”

Project Management

1. Prepare in advance
2. Comply with all necessary requirements
3. **Submit**

Generate a submission checklist, and:

Don’t submit at the last minute.

In-depth Q&A:

What: BIO Office Hours: Ask an Expert for Grant Writing Tips
Where: Zoom Meeting
When: Wednesday, March 29, 2023, 3:00PM - 5:00PM ET | Thursday, March 30, 2023, 3:00PM - 5:00PM ET

See Email invite from BIO Office Hours for more information, including links to Schedule Office Hours:

Schedule Office Hour

PSC Biotech is BIO's Preferred Provider for consulting and professional services.
Learn More

Thank You!

Bio

Biotechnology
Innovation Organization

PSCBiotech®