

2021 HHS Small Business Program Conference
Diverse Perspectives SEEDing Impactful Innovations



Secrets to a Successful Submission

Speakers:



Eva Garland, PhD
Eva Garland Consulting, LLC



Patti Weber, DrPH
NCI SBIR Development Center

Start Early

Strong proposals take time to develop

- Refine your product
- Gain access to equipment, facilities, other resources
- Assemble a strong scientific team
- Obtain letters of support from collaborators

Complete the administrative registrations

- Five required registrations (<https://sbir.nih.gov/infographic>)
- Send specific aims to Program Director at least a month before due date



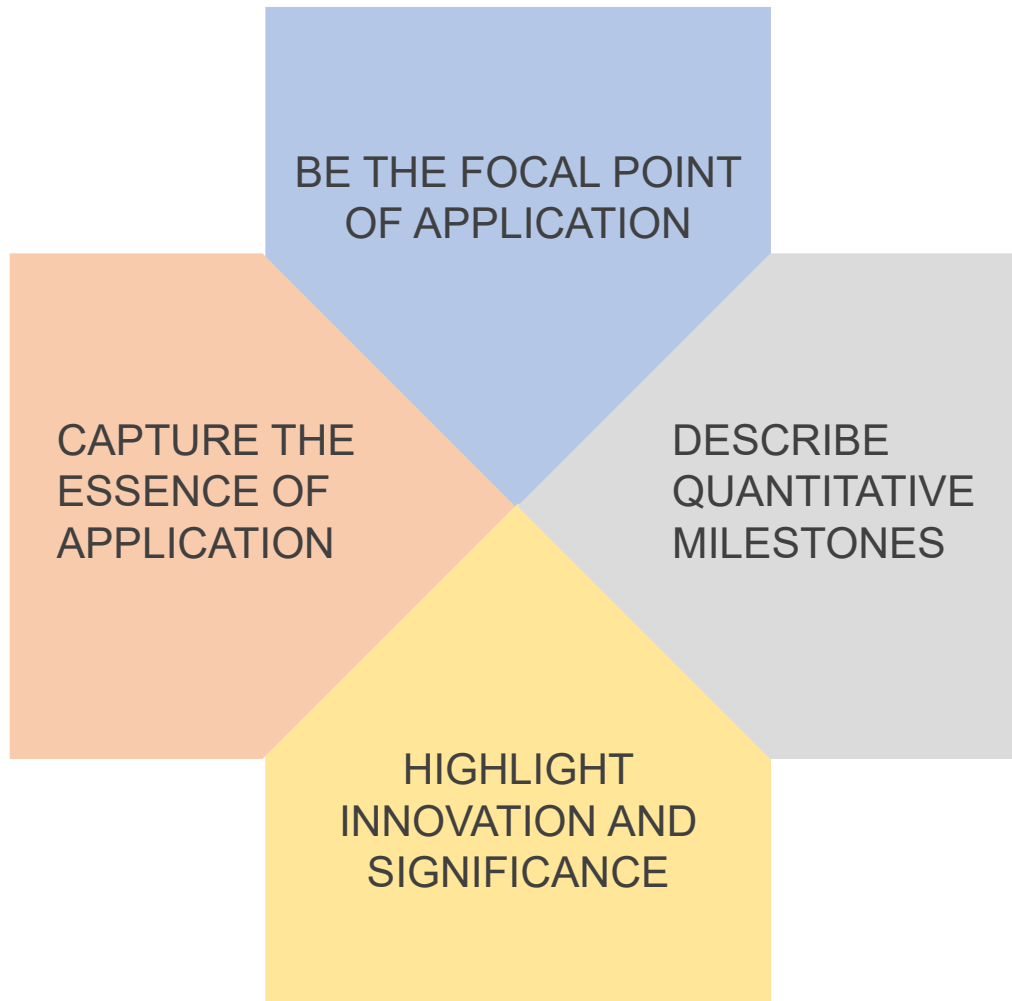
Discuss Your Specific Aims With a Program Director



Discuss your Specific Aims page with Program Director

- *Program contact information for each NIH Institute is in the solicitation*

Specific Aims Page



SPECIFIC AIMS PAGE ADVICE

The Aims Page

The specific aims page is a critical page in an SBIR/STTR application. The aims page should be treated as a standalone page from which a reviewer can gain a reasonable understanding of the project's critical components without needing any other parts of the application. Applicants are only allowed one page for their specific aims. Applicants are assigned to 3 or 4 primary reviewers who are responsible for initial scoring and acting as primary discussants during the larger peer review panel. Often the primary reviewers are the only members of the peer review panel to read the application in its entirety. For applications that are discussed, the final priority score will be set after discussion by a panel of 30+ peer reviewers. Many of the peer reviewers will likely only read the aims page of an application. Therefore, it is critical that the aims page clearly convey why this application should be selected out of the roughly thousand applications received by NCI SBIR the program annually.

The first half to two-thirds of the aims page should cover key background information. The background should clearly convey three things:

1. **The product.** A clear product description is critical to an SBIR application and is often a key difference separating an SBIR application from a basic science or discovery science application. SBIR grants are intended primarily for product development, whereas basic/discovery grants are primarily intended for the advancement of knowledge.
2. **The Significance.** A problem/proposed solution format often works well to convey significance. If there is an unmet clinical need, it will help the application for this need to be clearly stated.
3. **The Innovation.** How will the product change the current paradigm or practice? How will those affected by cancer benefit from this product being commercially available? The aims page should convey this information as well as provide some textual highlights of the preliminary data as supporting evidence that the product will perform as proposed.

The second half to one-third of the aims page should state your specific aims. An often-successful format for the aims is one in which a clear bolded aims statement is made, followed by key assays and models proposed to complete each aim, with appropriate milestones. It is critical that each aim have clearly articulated success criteria. Whenever reasonable, the success criteria should be defined by quantitative metric(s). However, in cases where only qualitative success criteria are appropriate, they should be clearly stated. For fast-track applications, a go/no-go decision at the end of the phase I component should be obvious.

A statement of next steps is often a nice way to wrap-up an aims page. A statement about what will be accomplished during phase II (for phase I applications) or after the award ends (for phase II applications) allows reviewers to judge if the aims will adequately prepare the project for the next step. A statement of next steps also provides an opportunity to show the reviewers that the company is focused on moving the product forward on a path to commercialization.

Overall, an SBIR application should focus on the product. Each section of the application should focus on how the proposed work will improve product commercialization. Successful SBIR/STTR applications clearly describe how the product will benefit a population affected by cancer, and identify the customer.

IMPORTANT: This guide page is meant to be used as advice for applicants and is not intended as program requirements. This advice page was developed based only on the opinions of several NIH SBIR Program Directors and successful SBIR awardees.

BACKGROUND:

Product
Innovation
Significance

AIMS:

Goals-based statements
Key assays and models
Quantitative milestones

CONTEXT:

These studies will get us to...
Next, we will...
This data will be used for...

Understand the Peer Review Process

INVESTIGATOR

Are the investigators, collaborators and consultants appropriately trained and **capable** of completing all project tasks?

ENVIRONMENT

Does the **scientific environment** contribute to the probability of success? **Facilities**? Independence?

COMMERCIALIZATION

Is the company's **business strategy** one that has a high potential for success?



SIGNIFICANCE

Does the product address an important **problem**, and have commercial potential? Is there a market pull for the product?

APPROACH

Are **design and methods** well-developed and appropriate? Problem areas addressed? Potential pitfalls and alternative approaches provided?

INNOVATION

How novel is the **technology/product** and **approaches** proposed to test feasibility?

Resources: Know Before You Go



Read the solicitation & SF424 carefully to understand the requirements

- <https://sbir.cancer.gov/funding>
 - <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/sbir-sttr-forms-f.pdf>
-



Review similar, currently-funded NIH SBIR/STTR projects

- <https://projectreporter.nih.gov/reporter.cfm>
-



Look at some sample applications

- <https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44>
- <https://sbir.cancer.gov/resources/forapplicants>

NIH Applicant Assistance Program (AAP)

AAP is a **FREE** application preparation **ASSISTANCE** program.



APPLICANT
ASSISTANCE
PROGRAM

PROGRAM GOAL:

Provide a **mentor** for applicants with great technology, but little NIH experience and limited NIH experience in their network.

APPLICATION PERIOD:

- Opens April 26 and **closes May 20, 2021 at 5 p.m. EDT**

evagarland.com/aap

- Outreach webinar:
May 4, 12:30-2:00 pm EDT
- Q & A Session:
May 20, 2:00-3:30 pm EDT

AAP PROVIDES ✓

Phase I SBIR/STTR application preparation support and review

Specific Aims page review and advice

Submission process coaching

AAP DOES NOT PROVIDE ✕

Grant writer

Research plan development

Small business registration or NIH application submission services

NIH Applicant Assistance Program (AAP):

Currently Participating Institutes/Centers

- The National Cancer Institute (NCI)
- The National Institute on Aging (NIA)
- The National Heart, Lung, and Blood Institute (NHLBI)
- The National Institute of Neurological Disease and Stroke (NINDS)
- The National Center for Complementary and Integrative Health (NCCIH)
- The National Center for Advancing Translational Sciences (NCATS)
- The National Institute of Environmental Health Sciences (NIEHS)
- The National Institute of Nursing Research (NINR)

*NINR is not participating in the September 5, 2021 cohort



Application Assistance Program (AAP)

Program Benefits

- **Program Benefits:**

- ✓ 10 weeks of free one-on-one mentoring by an experienced Ph.D.-level SBIR/STTR coach
 - A weekly call to discuss key tasks and ask questions
 - Emails outlining weekly tasks and highlighting key resources
 - Written feedback on the grant components
- ✓ A free copy of EGC's grant writing guide, *Winning SBIR/STTR Grants*
- ✓ Specialized webinars to introduce the SBIR/STTR mechanism, help participants convey technology fitness and unmet need, and help companies build entrepreneurial networks
- ✓ Free copy editing for the Specific Aims page and Research Strategy





Application Assistance Program (AAP)

Weeks 1-3

Grant preparation is structured in a manageable 10-week plan

WEEK 1

- Develop a project scope and Specific Aims that are appropriate for a NIH Phase I SBIR/STTR application.
- Contact your Program Officer (PO) to schedule a call for Week 4 to discuss your Specific Aims.
- Download Application Guide.
- Initiate all registrations.

WEEK 2

- Compose your title.
- Write or revise the Specific Aims section of your Research Plan
- If a resubmission, plan how you will respond to reviewers' comments from the Summary Statement.
- Prepare an initial outline of your budget and identify all work that will be done at outside institutions.
- Identify expertise needed for team/individuals.
- Request letters of support from consultants, key opinion leaders, and/or potential customers.
- For STTR proposals, arrange for a letter from the partnering research institution.

WEEK 3

- Finalize your Specific Aims page and share with PO 1 week prior to call.
- Identify the most appropriate Scientific Review Group (SRG) for your proposal.
- Create a list of questions to ask your PO.
- Review the competitive landscape for your project.
- Assess whether you will be required to include information for Vertebrate Animals and/or Human Subjects.
- Begin preparing Biographical Sketches.





Application Assistance Program (AAP)

Weeks 4-7

Grant preparation is structured in a manageable 10-week plan

WEEK 4

- Identify references to include in your Significance and Innovation sections.
- Identify references to include in your Approach section.
- Discuss your Specific Aims with your PO (scheduled in Week 1).

WEEK 5

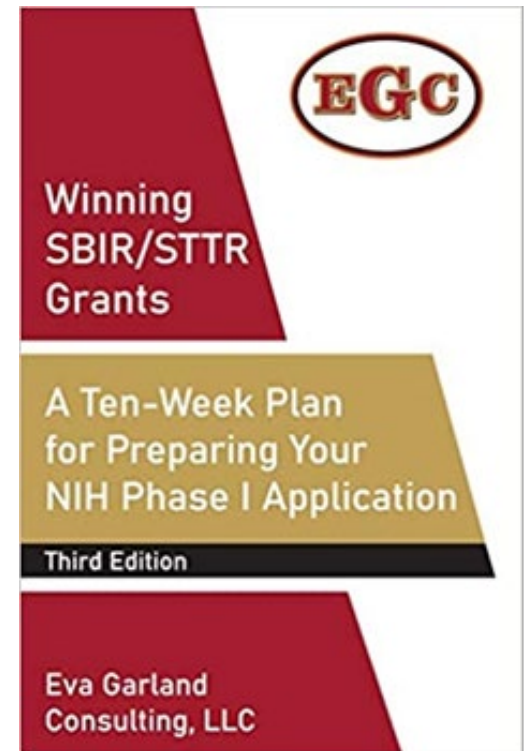
- Write the Significance section of your Research Strategy.
- Write the Innovation section of your Research Strategy.
- Follow up on quotations, Biographical Sketches and letters of support.

WEEK 6

- Write the Approach section of your Research Strategy.
- Edit the Specific Aims section of your Research Plan.
- Identify the Vertebrate Animals information that will be required to support your approach.
- Identify the Protection of Human Subjects/Clinical Trial information that will be required to support your approach.
- Familiarize yourself with ASSIST and begin filling out the administrative sections of the application.

WEEK 7

- Have your proposal reviewed.
- Confirm that you have received all materials requested from external sources.
- Write your Facilities and Equipment sections.
- Prepare your Budget.
- Complete your Vertebrate Animals, Human Subjects, Authentication of Key Resources, and/or Select Agents sections.





Application Assistance Program (AAP)

Weeks 8-10

Grant preparation is structured in a manageable 10-week plan

WEEK 8

- Make final corrections to your Research Plan.
- Write your Project Summary.
- Write your Project Narrative.
- Fill out the PHS Assignment Request form.

WEEK 9

- Verify that your required registrations are in place for submission.
- Collect and complete any outstanding items from previous weeks.
- Assemble and systematically review your final application.

WEEK 10

- Submit your proposal.
- Review your submitted application in the eRA Commons.





NIH AAP's *Impact* by the Numbers

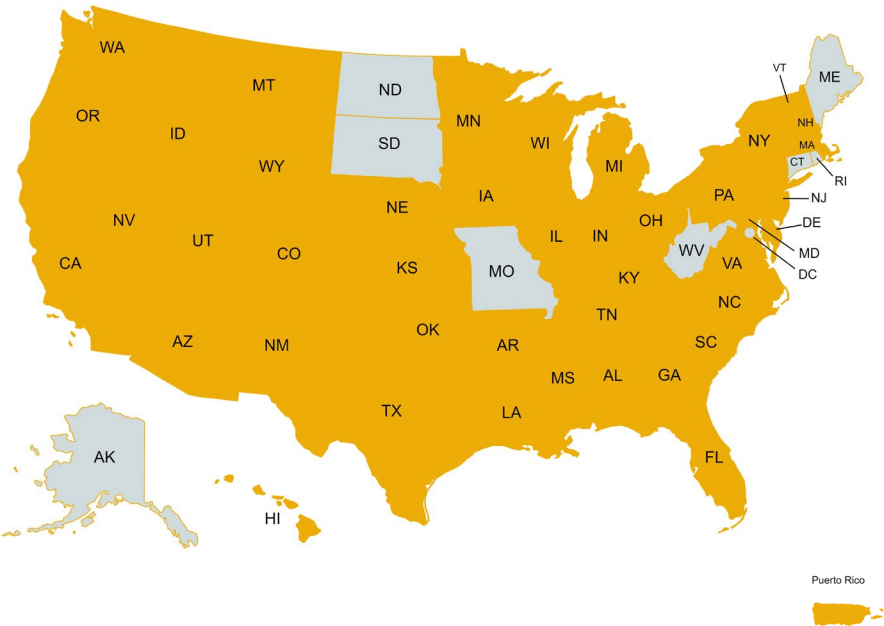
349
small business concerns

70%
women-owned
or operated

36%
under-represented group
owned or operated

27%
HUB Zone

Participants from 44
States and 1 US Territory



(*Participants from 6 submission cycles in 2019-2021)



NIH AAP's *Impact* by the Numbers (cont'd.)

93%

**Successfully
completed AAP**

\$20.5M

**Raised in *non-dilutive
funding* after AAP
participation**

\$165.8M

**Raised in *venture
capital, angel and other
equity investments***

*(*Participants from first 4 submission cycles in 2019-2021)*



AAP Superstar: Mulberry Biotherapeutics

Success stories from AAP and beyond



Susan Luo, CFA, MBA
Director, Mulberry Biotherapeutics
Wellesley, Massachusetts

- Completed January 2020 AAP round (NINDS)
- **NIH Phase I STTR Award: \$700,000**
- Received funding through AAP to support the **development of a next-generation bacteria-medicated therapy** for the rare genetic disorder neurofibromatosis Type 2 (NF2).
- In parallel, Mulberry Bio is **in the process of closing a Series A financing** to fund its lead program to IND in 2022.

“Our experienced EGC consultant provided actionable guidance under NIH’s Applicant Assistance Program (AAP) that ultimately led to a successful STTR application. The award was an important validation as the company attracted seed funding and top-flight scientific and industry talent.”



AAP Superstar: Doric Pharma

Success stories from AAP and beyond



Maria Lambros, PhD
Founder, Doric Pharma, LLC
Irvine, California



- Completed September 2019 AAP round (NCI)
- **NIH Phase I STTR Award: \$299,559**
- Received NIH Phase I STTR grant funding to develop **targeted lipid nanoparticles (TLNs) to selectively bring chemotherapy only to cancer** and avoid healthy tissues.
- In parallel, Doric Pharma has been admitted into the **I-Corps program** and has also been **awarded an NIH diversity supplement**.

“The AAP program provided the needed guidance and helped us find answers to our questions during the grant writing process.”



AAP Superstar: PETcoil

Success stories from AAP and beyond



Chenming Chang, PhD
Co-Founder and CEO, PETcoil, Inc
Sunnyvale, California



- Completed September 2019 AAP round (NCI)
- **NIH Phase I STTR Award: \$494,652**
- Received funding to **develop a portable positron emission tomography (PET) system** that can be inserted into existing MRI systems for cost-effective simultaneous PET/MR imaging.
- Raised **additional seed funds of ~\$400k from grants, angels, and a VC to supplement the STTR grant.** Strengthened partnership with Stanford University and submitted an NIH R01 Academic-Industrial Partnerships proposal for clinical translation of the portable PET insert technology.

“The Applicant Assistance Program (AAP) is instrumental in securing our first STTR grant.

During the 10-week program, an experienced consultant guided us through every step of the grant application process toward its submission.

Winning the STTR grant helps us hire the R&D team and purchase the materials required to validate the technical feasibility of a portable positron emission tomography (PET) system that can be inserted into any existing MRI systems to cost-effectively achieve simultaneous PET/MR imaging.”



AAP Superstars: Oncodisc, Inc.

Success stories from AAP and beyond



James Mitchell, MD
CEO, Oncodisc, Inc
Walnut Creek, California



- Completed January 2020 AAP round (NCI)
- Won an **NSF SBIR Phase I grant** (\$223,881)
- Received grant funding to develop an **intelligent implantable vascular access device** embedded with advanced sensor and communication technology.
- Closed a \$1.2M private financing round.

“The NIH Application Assistance Program (AAP), Eva Garland Consulting, and Stephen Rego [AAP coach] were instrumental in ongoing success at Oncodisc.

Through AAP, our team learned the intricacies of grant writing and refined our value proposition, providing benefits with both non-dilutive and private financing.”



AAP now accepting applications!

May 20, 2021
(5pm ET)

DEADLINE
for applying
to AAP

June 21 – August 30, 2021

10-week AAP Program

www.evagarland.com/aap

September 7,
2021
(5pm local time)

NIH
SBIR/STTR
Submission
deadline