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](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

**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

**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?

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

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

**INVESTIGATOR**
Are the investigators, collaborators and consultants appropriately trained and capable of completing all project tasks?
Resources: Know Before You Go

Read the solicitation & SF424 carefully to understand the requirements
• https://sbir.cancer.gov/funding

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.

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

evagarland.com/aap

AAP PROVIDES

AAP DOES NOT PROVIDE

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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
• 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
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.
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.
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)
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-mediated 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.”
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.”
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)

June 21 – August 30, 2021

10-week AAP Program

September 7, 2021 (5pm local time)

DEADLINE for applying to AAP

NIH SBIR/STTR Submission deadline

www.evagarland.com/aap