CTC Center For Technology Commercialization

NATIONAL INSTITUTES OF HEALTH

Module 2

https://wisconsinctc.org/

CONTENTS

Specific Aims Strategy

If you see this button

or yellow text

click on them to follow a link.

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What are Specific Aims?

These are the goals that you want to achieve, and essentially, why you need the funding. They are “What you want to achieve;” rather than “What you want to do.” Probably the most common error seen in proposals overall, is that the Aims or Objectives are weak and don’t have quantitatively measurable endpoints.

Think of the Specific Aims page as an abbreviated version of the full grant. By having this page well written and well-thought out, the remainder of the grant application will be easier to write. Put strategic thought into every sentence on the specific aims page.

The Specific Aims section is central to your grant proposal and should be the first section written to send to the program manager. This is the “first impression” reviewers get about your grant proposal. Eventually, it’s rewritten in its final form after the rest of the document is written.

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Feasibility

Determine the most difficult aspect of the proposed technology that must be overcome to show that it's technologically feasible. Proving feasibility is the point of Phase I. If there is only enough time and money to answer one question for Phase I, focus on feasibility.

Determine Aims by:

Working backwards

- What is your final product?
- What do you have to do in Phase II to have a prototype?
- What needs to be done in Phase I to enable Phase II?

Working forwards

- What are 2-3 research questions to reduce technical risk?
- What are the shortfalls in the state of the art?
- What do you do to address these shortfalls?

Check out related videos

- What's the point?
- What do you want to accomplish?
- List the objectives in bold type.
- What do you need to achieve?
- Make your milestones market-relevant.
- Proposal Roadmap and Pitfalls.

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SPECIFIC AIMS HOMEWORK

PROVIDE THREE TECHNICAL RESEARCH QUESTIONS BELOW

SPECIFIC AIMS EXAMPLES

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AIM

Construct a system to measure substance X in plasma to improve data simulations. We plan to use tool Y to measure because it has been shown to be most accurate.

MILESTONE

The future product must have a minimum sensitivity of X picomoles/mL, and have an accuracy of XY%. These specifications have been determined to be necessary by [insert market reason or standard benchmark justification].

TIPS

Try to make a simple statement with 1 or 2 sentences. Include quantifiable criteria in your milestones that demonstrates when you are done with this phase of Product Development.

Aims demonstrate product feasibility. These MUST BE successful to advance to Phase II.

Specific Aims

Meningitis and encephalitis are inflammatory, often infectious, processes of the central nervous system (CNS) that can result in significant morbidity and mortality for those affected. Prompt, appropriate therapy is crucial, but determining the infectious etiology can be difficult and time-consuming. A wide-range of pathogens can be involved, including both bacteria and viruses, and therapy varies between etiologies. At present, culture is the gold standard for diagnosis of bacterial meningoencephalitis (ME), while amplification of viral DNA by the polymerase chain reaction (PCR) is the standard for many viral ("aseptic") causes. Though employed in clinical laboratories, most real-time PCR assays for viruses causing ME are not FDA cleared and may require considerable skill or resources to perform. New technologies for rapid detection of pathogens that cause acute ME are critical for accurate diagnosis and facilitation of effective treatment for these life-threatening infections.

Idaho Technology (ITI) has developed the FilmArray, an easy to use "lab in a pouch" PCR-based diagnostic system that can rapidly and simultaneously test for large panels of infectious agents. We propose to apply the FilmArray technology to the problem of ME diagnosis.

SA1: Develop a FilmArray Meningoencephalitis (FAME) panel (0-18 months)

We will combine assays from existing FilmArray panels with five new viral assays (in bold below) to construct a panel that can detect the following ME-causing organisms directly from cerebrospinal fluid (CSF):

Bacteria: *Enterobacteriaceae, Escherichia coli, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa, Enterococcus* species, *Listeria monocytogenes, Mycoplasma pneumoniae, Staphylococcus* species (including *S. aureus*), and *Streptococcus* species (including *S. agalactiae, S. pneumoniae, S. pyogenes, viridians streptococci*)

Viruses: Enterovirus, **Parechovirus**, HSV1, HSV2, **VZV, EBV, CMV, HHV-6**

For each FAME panel assay, we will implement a corresponding published, or in-house developed singleplex real-time PCR assay. This will allow us to compare the sensitivity of the FAME pouch to that of established PCR assays when tested on CSF spiked with dilutions of organism(s). Those assays in the pouch that perform less well than conventional assays will be modified or replaced. **Milestones:** Development of a FilmArray pouch comprised of assays for the pathogens listed with demonstration of sensitive and specific pathogen detection in spiked CSF samples

Example

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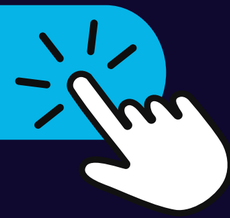
SPECIFIC AIMS HOMEWORK

FILL IN YOUR INFORMATION BELOW

Aim 1: Goal and Quantifiable Milestone	
Aim 2: Goal and Quantifiable Milestone	
Aim 3: Goal and Quantifiable Milestone	

Tie Aims to Significance



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DRAFT SPECIFIC AIMS PAGE

The following pages will outline this single page document required to submit to the program manager.

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Outline of Specific Aims Page

CONSIDER THESE STARTER PHRASES WHEN WRITING

- Introduction
  - Company (One sentence): We are a X University startup formed to commercialize Y technology from the medical center.
  - Goal: The goal of this SBIR is to develop [product] to address [state problem].
- Significance:
  - Problem to be solved: The problem is … and as a result [defined group of people] suffer.
  - Gap in knowledge: Existing solutions fall short because…
  - Prelim Studies: We have discovered [1-2 sentences on innovation and promise to solving problem]
- Product: The product of this SBIR is ..(1 sentence)
- Long term impact: We envision [product] being used to…[1 sentence]
- Specific Aims: Include your drafted aims.
- Expected Outcomes: Completion of the above aims prove feasibility of product to [meet a market need] (2 -3 sentences)
- Plans for Phase II: Upon successful completion of Phase I, Phase II will focus on [1-2 sentences on scaling goals]
- Commercial Application: This product addresses the $XX market of [identified markets]. 1-3 sentences on market path, partnership, and regulatory milestones.

PAGE REQUIREMENTS

Introduction
- The Company
- The Goal

Significance
- Problem to be solved
- Gap in knowledge
- Prelim studies

The Product
- Technological Innovation

Long Term Impact
- Rationale for the goal

Phase I Project:
- Phase I Hypothesis
- Specific Aim 1…
  - Acceptance Criteria
- Specific Aim 2…
  - Acceptance Criteria
- Expected Outcomes
  - Proof of Feasibility

Plans for Phase II

Commercial Application

ONE PAGE!

Formatting

Single Spaced
11-point Font (Arial*)
4 point space between paragraphs*
Left aligned*
0.5" margins on all sides

*our recommendations

Tips:

- **Use these section headers.**
- **Inspire your reviewer to read the whole application with Specific Aims 1 page.**
- **Tell a compelling story about problem, need, your solution.**

Introduction

Establishes that you are a legitimate for-profit company with the skills and resources to do the research. Immediately describes the problem addressed and describes the technology that is the subject of the research.

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BASICS

- State the company name and status: startup, existing, etc.
- List relevant partners and licenses.
- Briefly state focus of research.
- Include home city & state like this: “Alpaca Biosciences (Milwaukee, WI) intends to commercialize…” This provides reviewers with info as to where the company is located.

TIPS

Potentially include the tradename of the product. “Alpaca Biosciences (Milwaukee, WI), has developed PANDA, a new at-home diagnostic test for UTIs.” Introducing the tradename early on can save space later, as you can simply refer to the tradename throughout instead of repeating “the at home diagnostic test for UTIs”.

STRATEGY

Short, concise and full of information.

Every word has a purpose.

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INTRODUCTION HOMEWORK

PROVIDE THE INTRODUCTION BELOW

Example:

XYZ LLC is a startup that is working to address lung cancer mortality using modified cytokine research licensed from the University of Wisconsin-Madison.

Goal

Briefly tell the reader what the point or your work is as well as identify the health issue being addressed.

BASICS

- List your goal results in a measurable way: to what extent will there be change?
- Be very specific in what task you will perform to provide a solution.
- Clearly and articulately describe the final product and where it will be used.
- Plainly describe the benefit, not just the feature.

TIPS

You can also provide additional information that emphasizes at least one advantage over current solutions, like “PANDA is a faster, cheaper alternative that allows women to accurately self-diagnose UTIs at home.”

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GOAL HOMEWORK

PROVIDE GOALS BELOW

Example:

Our work is intended to result in a measurement device used in the surgical suite to more precisely graft vessels during by-pass surgery, resulting in reduced mortality and fewer complications.

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Significance

Provide information to validate that the problem addressed is important to stakeholders and to convey the size and extent of the problem. The health condition addressed should be important enough for funding when compared to other proposals. Detail the specific group helped by your solution.

BASICS

- State the type of population affected: age range, gender, race, occupation, etc.
- Measurable effect on that population: number of annual deaths, hospitalizations, fees, recovery time, etc.
- Pull on society, provide input from experts by including a direct quote fragment from a subject matter expert stating the significance: Director of Johns Hopkins says this issue is “wasting time and money”.
- Costs/funds currently spent on the issue.

STRATEGY

If known, include the Medicaid/Medicare costs, because the NIH is always looking to reduce those costs.

Good language to use is “There is a critical need for better…” Emphasizing the critical need will enhance the importance of your significance.

TIPS

Small problems that are nearly addressed are less interesting than larger problems that affect a lot of people and cost a lot of money and lives.

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SIGNIFICANCE HOMEWORK

PROVIDE THE SIGNICIFANCE BELOW

Example:

“Pneumonia accounts for over a million hospitalizations and more than 50,000 deaths per year. It can affect anyone of any age, but is more insidious for older adults, young children or those with compromised immune systems….”

Gap in knowledge

Address current solutions for the problem. Focus on providing reasons that current strategies are not ‘good enough’. If you don’t already know current solutions or your competition, start researching. There is ALWAYS competition, even if no one else does what your innovation does.

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BASICS

- Summary of current solution including failure rate, cost, length of time to complete, etc.
- Describe the specific problem that isn’t addressed by current methods, provide quantitative numbers of those affected by the failings of the current method.
- State the current flaw being addressed that your product will improve.
- Reference back to significance section to convey that the status quo is allowing significant setbacks, human suffering, etc.
- Explain what the “ideal solution” is and how your product fulfills or comes closer to that, using quantitative numbers of what the ideal solution should reach. This sets up the targeted milestones for the specific aims.

STRATEGY

Use a list of identifiers that make up the “Ideal Solution”. For example, “The ideal solution would be an at-home test that allows women to rapidly and accurately determine if they have a UTI.” Then, use the same descriptors for your product. “PANDA is an at-home test that is both rapid and accurate.”

TIPS

Even if there isn’t a way to currently treat the disease at all, there is a way that people are dealing with the disease. A competing strategy could be to just ‘live with the problem’ or ignore it. If the current solutions are ‘good enough’ than it’s harder to fund your project.

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GAP IN KNOWLEDGE HOMEWORK

PROVIDE GAP IN KNOWLEDGE INFORMATION

Example:

Preliminary diagnosis of Lyme's disease is often suggested by physical evaluation of a central clearing rash. However, up to 40% of cases do not manifest a rash leading to severely underreported diagnosis and treatment. Definitive diagnosis for Lyme's disease is through an ELISA assay which is complex enough to require samples be sent to a central laboratory for testing and analysis, resulting in as much as a week-long delay in treatment. An ideal solution would be a more rapid test that can be done at the point of care with results in as little as 10 minutes….."

Preliminary Studies

If space allows, briefly describe what research your team has done already that shows your eventual product can be successful. Detail the specifics of the success rate of your past research and convey why this success would translate to an eventual product.

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BASICS

- List partners of the university or organization involved in your research and detail why they are reputable experts.
- Emphasize the best points that have emerged from your prior research using quantifiable measurements. You will have more space later to discuss any shortcomings.
- Describe the specific and measurable endpoints that must be reached to prove feasibility.

STRATEGY

Explain how the preliminary findings lead to the requirement of more work. “While our initial work on PANDA is promising, we still need to prove efficacy and accuracy of or methodology.”
Show that this is not a ‘fishing expedition’ to find to find something that should be completed in academia, but rather selects the potential targeted components for commercial development.

TIPS

Do not claim the ‘company’ has done the preliminary studies when it was the work of the University researchers. It is more correct to say “Our collaborators at XYZ University have done this.”

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PRELIM STUDIES HOMEWORK

PROVIDE PRELIMINARY STUDIES INFORMATION BELOW

Example:

XYZ Biotech researchers in collaboration with our partners at the Medical College of Wisconsin have identified a class of antibiotics that are effective against Methicillin Resistant Staph. Aureas (MERSA) in the rat model. Of note, we have identified three potential molecules in this class that are particularly effective in reducing bacterial counts by 92% after five days treatment.....

Product

This gives a sense of what your ultimate commercial product will be. Describe what the product will be and who will use and/or buy it. Describe how far along you expect to be with your Phase I research.

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BASICS

- Describe your product in layman's terms as if advertising your product to high schoolers using numbers to convey the appeal of your product.
- State what you will do with the awarded money to turn your research into a product.
- Detail how established or complete your expected prototypes will be.
- Include the measurement of feasibility that will apply to your product in Phase I.
- If this is a Phase II grant, explain what will result from the Phase II work (a prototype, a miniaturized prototype, etc.).

STRATEGY

State your end user and product purchaser. Tie the purchaser back to significance because you've shown that a subject matter expert has an interest related to your product.

Explicitly set the goal of what is defined to 'prove feasibility'. You might be able to say 'In order to prove feasibility in phase I, we need to demonstrate…".

TIPS

The product may be used by a person with a disease but is purchased by an insurance company. The product may be used by a nurse but is purchased by a hospital.

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PRODUCT HOMEWORK

PROVIDE PRODUCT INFORMATION BELOW

Example:

The product will be a software package used by cigarette smokers to monitor and reduce their nicotine cravings. To prove feasibility in Phase I we will demonstrate that the prototype software will be spontaneously accessed by smokers 50% of the time during a craving 7 weeks after training.

Long-Term Impact

Provide a sense of how your product will be used and how it ties back to the health problem you've identified. Detail what the problem will look like in five or ten years with and without the solution you provide.

BASICS

- Detail what a successful version of your product looks like in use.
- Describe how it will directly reduce or solve the issue if commercialized.
- Define the subset of people who will actually be helped by the product and how their lives will improve.

STRATEGY

Address the problem that you previously stated and not a subset or a superset of that problem's symptomology. For example, if the problem that you stated was "Pneumonia kills X people/year." Then, your solution should address pneumonia and its mortality rate, not a subset of its symptoms.

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LONG-TERM IMPACT HOMEWORK

PROVIDE THE LONG-TERM IMPACT BELOW

Example:

The product is a non-invasive image test for diagnosing NCRD where patient morphology prevents use of traditional methods. Of the 10 million suspected NCRD patients, 15% are estimated to be missed during traditional examinations. We target that subset of patients and expect to identify 80% of the missed cases. This results in over 1.3 million cases identified that would otherwise be untreated.

Specific Aims

You can have 1-3 specific aims, each about one or two sentences that summarize what you want to prove, demonstrate, or achieve. This is NOT what you want to do, or what experiments you want to carry out. These are the things you need to prove in order to convince reviewers your project is feasible.

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BASICS

- Describe the things you need to prove in order to convince reviewers your project is feasible. This can be tied back to your feasibility statement.
- List your objective and measurable milestones with your short and clear specific aims.
- Milestones should be a go/no-go criteria and are NOT tasks or methodologies, but are a goal of what needs to be proven, demonstrated or achieved, etc.
- Include a solid measurable milestone that is clear, and that can be proven to be reached or not. It is not a vague milestone that can be disputed as being achieved or not.

STRATEGY

Try NOT to make your aims dependent on each other, such that if Aim 1 fails, then Aim 2 is impossible to complete.

TIPS

Include benefits of the potential tech into sentences with quantitative impact potential.

Work goals into the statement - "target that subset of patients and expect to identify 80% of missed cases".

End with a punch - "1.3M would be missed without this product I'm making".

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SPECIFIC AIMS HOMEWORK

PROVIDE THE SPECIFIC AIMS BELOW

Example:

Aim 1: Demonstrate EG-137 remains in the blood at therapeutic levels over for extended times.
Milestone: EG-137 levels will be between 1ng/mL and 5ng/mL between 12 hours and 120 hours after injection.

Expected Outcomes

Another place to say that proving these aims will show feasibility, as well as set you up for what needs to be done in Phase II and beyond.

BASICS

This is a restatement of the measures of success that you will have shown. For example, “By achieving these Aims, we will have shown that PANDA can accurately and rapidly diagnose UTI’s in an at-home, unsupervised setting.”

Reiterates what the expectation is for the outcome.

Clear and measurable and not disputable or subjective.

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EXPECTED OUTCOMES HOMEWORK

PROVIDE THE EXPECTED OUTCOMES BELOW

Example:

Successful completion of the Phase I aims will demonstrate that our software platform is feasible in identifying lesions within 15 seconds.

Plans for Phase II

This will allow the reviewers to see what your future plans are and what you need to do after Phase I success. Provide an idea of what is to be done in Phase II
Show you are thinking ahead beyond Phase I and have a roadmap in place.

BASICS

- Detail measurable ways in which the work that you do in your Phase I will meet qualification requirements for Phase II.
- List specific Phase II requirements that you will meet.
- Remember that the NIH will not hold you to your word – this is at best an estimation of what will happen. Your Phase I work could reveal very different outcomes than what you planned for.
- If this is a Phase II grant, tell them what remaining work will need to be done after this (such as during Phase IIb, etc.).

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PLANS FOR PHASE II HOMEWORK

PROVIDE THE PLANS FOR PHASE II BELOW

Example:

Phase II efforts will expand on Phase I in vitro work and demonstrate a significant anti-histamine response in a comprehensive rat model.

Commercial Application

This is less important in the specific aims page if you don’t have room and have mentioned the significance of the problem in terms of people and costs above.

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BASICS

- May not be necessary.
- If you have space, include commercial goals (like submission to the FDA or to other regulatory bodies, the date you anticipate initial sales to begin, or additional steps needed prior to full commercialization.).
- Gives an idea of what is the final product and what needs to be done.
- Includes partnerships or other resources beyond the SBIR/STTR funding.

STRATEGY

if you have space, describe what regulatory or partners and IP you are working on or need to work on, to make your ultimate product successful.

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COMMERCIAL APPLICATION HOMEWORK

PROVIDE THE COMMERCIAL APPLICATION BELOW

Example:

Ultimately, the resulting product is anticipated to pass FDA approvals as a class II device after partnership with a targeted medical device company, and is expected to address a $15million/year market need.

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Review

Get feedback from as many people as you can. Have several people review your page including CTC. Remember, this is a page that should clearly outline your plan to reviewers. After reviewers chime in and you are satisfied with your page, contact an NIH Program Manager for a meeting.

NIH PROGRAM MANAGER

Schedule a meeting with an NIH program manager to discuss Specific Aims Approach

Proposed agenda for the NIH Program Manager meeting:

1. Problem validation: Is this within the scope of interest of the institute? What are your pieces of evidence to support the qualitative and quantifiable claims?
2. Current gaps: Discuss your knowledge gaps important for this research/product development approach. Discuss a plan for additional justification with CTC. This could include letters of support content to justify your claims.
3. Program manager conversation: Discuss strategy with an HHS Program Officer.
4. Apply for CTC micro-grant: After HHS Program officer review and favorable feedback, apply to CTC's micro-grant program to hire a grant consultant.

Give yourself an accountability deadline of a week for this section. Schedule a CTC meeting today in preparation for a meeting in 1 week.

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Now What?

SBIR Assistance micro-grants are aimed at technology and research-based Wisconsin businesses who intend to apply for SBIR/STTR federal funds. The grants cover reimbursement of costs up to $4500.00, incurred by a business in hiring an independent, approved third-party to assist in the development of federal Phase I SBIR/STTR research and development proposal.

$4,500

CHECKLIST

At the end of module two you should have to following checklist completed.

- **Feasibility**
- **Specific Aims**
- **Draft of Specific Aims Page**

HAVE QUESTIONS?

Reach out to the CTC with questions or concerns here.

FINISHED WITH SESSION TWO?

It's time to reach out and check in with your CTC consultant to discuss the overview summary.

Todd Strother

Rob Baranowski