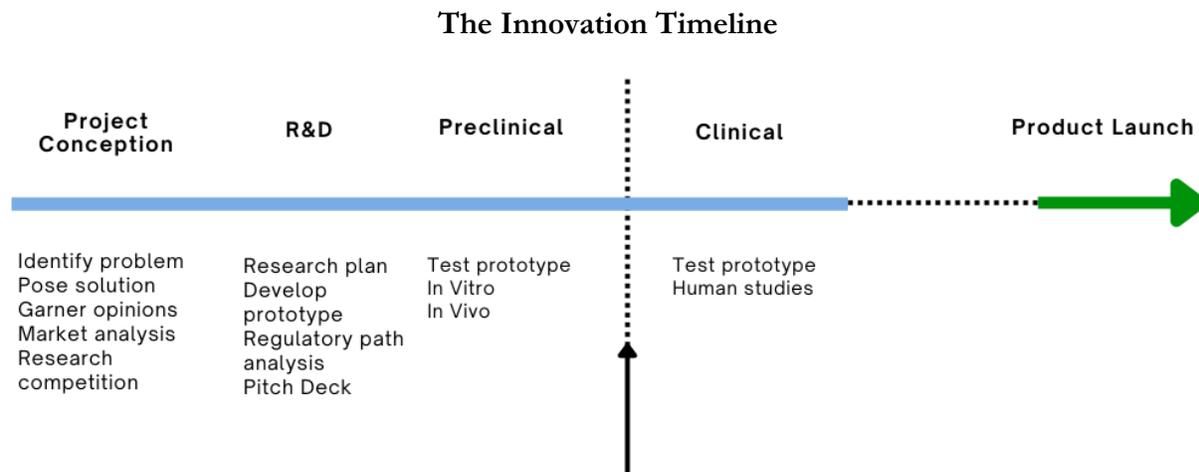


## Primer for the PSF Translational and Innovation Research Grant

This document serves as an introduction and primer to writing the innovation and translational research grant. It is intended to help the writer be more competitive since the grant is a departure from traditional discovery grants or other mechanisms funded by PSF. Brief descriptions are included, and examples are provided to help educate applicants on different components in the development and commercialization process. The grant should be thought of as an expression of an overall multi-layered project plan in a moment in time. It conveys information typically found in a pitch deck and is the basis for ongoing project development and even future fundraising if the goals of the grant are met. Before diving into specific sections of the grant, a brief discussion on commercialization, the innovation process, and potential timelines are presented to frame the project and intention of the grant.



### Apply for PSF Translational and Innovation Research Grant

The timeline above provides a rudimentary breakdown of the innovation process. This is not a strict sequence of events, but rather it provides a general framework for potential innovators. Each of these steps is essential in the innovation process, but they can often be done in parallel. To be competitive for the PSF Translational and Innovation Research Grant, the tasks under Project Conception, Research and Development, and Preclinical Testing should be underway or completed.

## Project Conception

### Need Identification

What is the clinical problem that needs addressing? How many patients are affected, how often are the surgeries performed, perhaps what are the costs? What is thought to be causing the problem (e.g., lack of knowledge, or lack of a sufficient tool)? Why would the proposed approach solve the problem when other approaches have failed—what are the distinguishing characteristics and how is there a compelling way to solve this problem?

### Early Connection with Colleagues

A successful innovator garners opinions from peers and scientific leaders on their proposed project, collecting critical feedback early in the development process. Start thinking about which trusted colleagues would help turn an idea into reality. These same colleagues may later be early adopters, investors, and supporters. A non-disclosure agreement may be appropriate but is not always necessary.

#### Tip

Speak with colleagues early to garner critical feedback

### Early Market Research and Competitive Analysis

Market research helps an inventor understand consumer behaviors and economic trends.<sup>1</sup> Accessing online market reports or collaborating with consultants and business advisors can help facilitate this process. Contacting sales representatives from companies that sell products in the space and from whom you have existing relationships can be a valuable source for market data.

Key market parameters to research include:

- Market size: identify clinical need. How many suffer from the relevant clinical condition? How many relevant procedures are performed yearly already?
- Market saturation: How many similar options are currently available to consumers?
- Pricing: What is the addressable market revenue and what are market trends in terms of revenue?
- Competitors: market share, strengths/weakness of their products (strengths and weaknesses is super important to understand the need for the invention)

#### Tips

1. Use published literature to support market analysis and revenue
2. Move forward with a project if several surgeons agree that the need and approach is compelling. Avoid solving a problem in a vacuum. Avoid creating a solution that would be uniquely valued by a few individuals or not widely accepted.

**Examples:** Hernia mesh market analysis: <https://www.grandviewresearch.com/industry-analysis/hernia-repair-devices-market>

Small business administration resources: <https://www.sba.gov/business-guide/plan-your-business/market-research-competitive-analysis>.

## Research and Development

### Early-Stage Prototype

Once the need has been established and a potential solution has been advanced with a compelling rationale, a prototype needs to be created and tested. Testing should be relevant and accurate but is often preliminary in nature. The story and data should be exciting and compelling, it is why grant reviewers want to fund a project. Note it is difficult for a reviewer to want to fund a concept or idea without a compelling story that includes a working prototype and preliminary data. One can think of the grant as funding to advance an early prototype.

Benchtop models, small animals, cadavers, or end user conversations can all be used to validate the value or potential impact of the product. Consideration of manufacturing costs are important.

- Design drawings and data are the backbone of intellectual property.
- An initial prototype can be improved upon further iterations but is often essential to gathering further funding.

### Examples:

Park, H., Islam, M. S., Grover, M. A., Klishko, A. N., Prilutsky, B. I., & DeWeerth, S. P. (2018). A Prototype of a Neural, Powered, Transtibial Prosthesis for the Cat: Benchtop Characterization. *Frontiers in Neuroscience*, 12, 471. <https://doi.org/10.3389/fnins.2018.00471>

Vélez-Guerrero, M. A., Callejas-Cuervo, M., & Mazzoleni, S. (2021). Design, Development, and Testing of an Intelligent Wearable Robotic Exoskeleton Prototype for Upper Limb Rehabilitation. *Sensors*, 21(16), 5411. <https://doi.org/10.3390/s21165411>

### Building a Start-Up Team

Initially, a surgeon and engineer may be all that is needed to create a working prototype and garner data; however, in parallel with this a regulatory expert can assist with the regulatory path and an entrepreneur can help with market assessment, funding, and other key aspects of the project. As a project grows, people with different expertise may be recruited. Understanding equity and cash compensation, as well as expectations and fair market value are important for team building.

### Intellectual Property

Intellectual property (IP) is a term used to describe unique creations or inventions. Patents and copyrights protect IP as they are used to legally define ownership and safeguard the financial interests of inventors. Obtaining legal counsel is instrumental in applying for intellectual property rights.

As one develops their invention, they should consider filing for a provisional patent. This form of early protection can help secure IP before an innovator has the resources to further develop it. Although garnering opinions of colleagues is important in developing an idea, consider avoiding excessive public disclosures of an idea before first developing it and applying for a provisional patent. Eventually, when a functioning prototype is created, consider filing a patent application,

### Tips

1. Engage engineers early. Sharing a portion of the invention to achieve invention is better than having no invention. This may mean spending money or sharing equity.
2. Never underestimate the value of early compelling data.

which is a document that contains details about the designs, functions, and operations of a device. In applying for a patent, seeking counsel may help fortify an application to anticipate future modifications or expansions of your product or invention.

**Example:**

Cardiac pacemaker patent <https://patents.google.com/patent/US20080009910A1/en>

### **Develop a Pitch Deck**

A pitch deck is a slideshow that presents the most pertinent aspects of a company in visual format. Many of the aforementioned topics are included in a pitch deck, including a prototype, market analysis, competition analysis, business plan, among other things. A pitch deck can be used in many scenarios, but is often used to obtain funding from investors. In addition, much of the information in a pitch deck can be used to apply for grants. For example, The Plastic Surgery Foundation Translational Grant application intentionally seeks information commonly found in a pitch deck to evaluate the potential impact of a project and help the project proceed successfully.

**Resources:**

<https://piktochart.com/blog/startup-pitch-decks-what-you-can-learn/#Airbnb>

<https://visme.co/blog/what-is-a-pitch-deck/>

### **Apply for the Plastic Surgery Foundation Translational and Innovation Research Grant**

A strong grant application will include a functional prototype, market analysis, and preliminary data. Make sure to read the requirements for the grant before applying, as other grants may be more suitable for other stages in the innovation process.

#### **A Note on Grants**

Grant applications may at first seem complex, but they are in fact organized project plans. Having a good project plan is the basis for writing a good grant. Weak project plans cannot be turned into good grants. Strong project plans can be turned into weak grants but this is unlikely. One way to think of a grant is as a planning tool. The process will expose strengths and weaknesses. When complete, the document serves as a vehicle to obtain critical external feedback. How well the story is told is reflected in the grant score. If the story is compelling, money is often awarded to proceed with the project plan. Irrespective of funding, there is still much to be gained through the process of grant writing and receiving a review.

For grant instructions, refer to the webpage below:

<https://www.thepsf.org/documents/Research/Grants/Translational-Research-Guidelines.pdf>

## How can ASPS/PSF help you develop your translational research into a medical device?



### Hot Topics at PSTM

Become a part of the discussions surrounding the latest cutting-edge research and applied technology. This session at PSTM is a great opportunity to stay updated on the latest innovations in the specialty and a good chance to network with like-minded plastic surgeons.

### Grant Application Mentorship Program at PSTM

Meet with leaders in plastic surgery research to gain insights on writing strong research grants and get feedback on your draft research grant proposals and ideas.

### PSF Research Grants

Several grants including the pilot grants, the national endowment for plastic surgery grant, and the translational and innovation research grant, among others, can help drive your ideas forward.

### PSF Translational Research Grant

This grant can specifically help take your start up and aid in the development and commercialization process. Before applying for this grant, one should have a prototype and preliminary data demonstrating the utility of the medical device.

### The Tank: Plastic Surgery Innovation Challenge at PSTM

An innovation competition at Plastic Surgery the Meeting (PSTM) where competitors pitch their innovations and battle it out to be awarded Top Innovator of 2022 - and win up to \$10,000 grant to kick-start their pitch into reality.

### ASPS/MedTech Innovator Collaboration

A recent partnership between ASPS and MedTech Innovator, the largest accelerator of medical technology startups, gives members an arena to showcase their innovations. Winners benefit from the MedTech Innovator network, which may include access to corporate executives, investors, providers, payers, FDA, NIH, DoD, and other stakeholders. Winners showcase their technologies on the industry floor of ASPS. Beyond networking, workshop opportunities can help accelerate a start-up company.