National Institutes of Health

NIH National Institutes of Health
Turning Discovery Into Health

Introduction

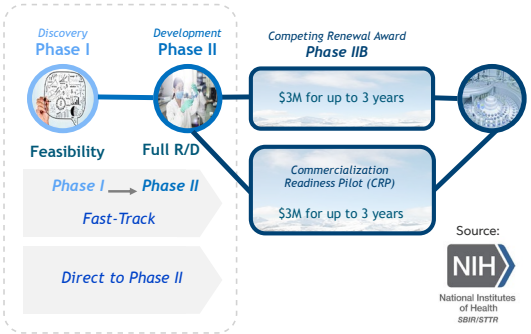
The NIH SBIR/STTR Programs invest over $1 billion in life science companies annually.

The National Institutes of Health (NIH) is the largest government research agency in the world and spends more than $32 billion annually to fund research that advances scientific discovery. A portion of the money spent goes towards non-dilutive funding programs, which enable early-stage medtech and other life science companies to advance and de-risk product development, while also providing scientific and technical validation that attracts investors and supports reimbursement.

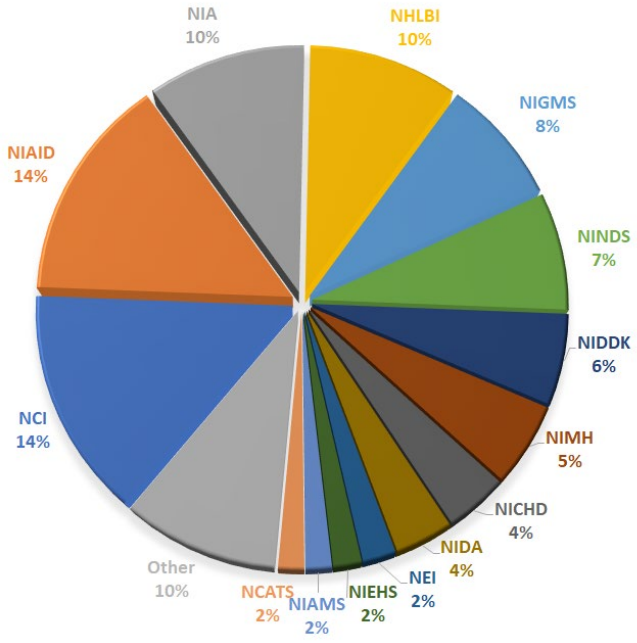
The NIH offers non-dilutive funding through the highly-competitive **Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs**. In FY20, these programs invested over $1.2 billion in life science companies (over $1 billion in SBIR projects and nearly $150 million in STTR projects). Approximately 30% of this funding was awarded to medical technology companies.

Source: NIH RePORTER

NIH SBIR/STTR is a [Three-Phase Program] that covers a product's life cycle from proof-of-concept and feasibility to advanced product development and clinical studies.



Over $300 million in SBIR/STTR funding for medtech in FY20



FY20 SBIR/STTR Funding by Institute/Center

Source: NIH RePORTER

Key institutes and centers that extensively fund and collaborate with medtech companies

- National Cancer Institute (NCI)
- National Eye Institute (NEI)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute of General Medical Sciences (NIGMS)
- National Institute of Neurological Disorders and Stroke (NINDS)

NIH SEED
Helping Innovators Turn Discovery Into Health

NIH Small business Education and Entrepreneurial Development (SEED)

SEED coordinates early-stage product development activities across the NIH, and develops relationships with universities and research institutions, small businesses, trade associations, societies, angel investors, venture capitalists, and strategic partners to build opportunities for NIH-funded innovators to further their product development efforts. SEED oversees multiple programs to support small businesses including Technical and Business Assistance, Commercialization Enhancement Programs, and Funding to Diversify Your Workforce.

Small businesses are encouraged to contact the SEED team for questions on eligibility, applications, and funding opportunities. SEED can help small businesses connect with the right NIH staff depending on where they are in the process. SEED also hosts and promotes numerous educational events with information on funding opportunities and the application and review process. Subscribe to the mailing list for the latest news from NIH SEED.

Five Scored Review Criteria

Significance

Addresses critical problem and advances scientific knowledge with commercially-viable technology

Approach

Well-reasoned strategy, methodology, and milestones

Innovation

Novel concept presents value over current standard of care

Investigators

Clinical and technical expertise and experience in the field

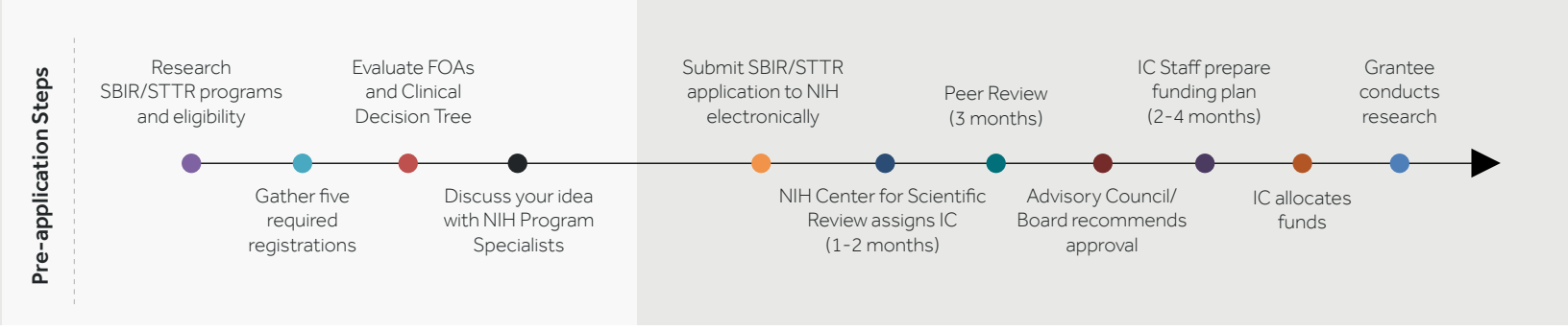
Environment

Appropriate facilities, equipment, and institutional resources

Key Application Components

- **Specific Aims**
  Executive summary of review criteria; can submit in advance to confirm project fit with funding priorities of individual ICs.
- **Research Strategy**
  Addresses the most critical scored review criteria of Significance, Innovation, and Approach, including detail on the scientific and clinical impact, as well as project methodology and milestones.
- **Biographical Sketches**
  Includes a personal statement along with CV, which allows a place for startups companies to capture industry experience and demonstrate strength of team.
- **Letters of Support**
  Optional but critical component to provide technical and commercial validation for proposed project (no limit on the number of letters; 2-5 recommended).
- **Commercialization Plan**
  Offers a clear and concise description of the proposed work's market potential and path to commercialization *(Phase II and Fast Track only; not required for Phase I)*.

NIH SBIR/STTR Application and Review Timeline



Commercialization Plan

Application Submission and Review

1 | Understand the basics of the SBIR and STTR programs, the different funding paths and phases, and eligibility criteria for small businesses.

2 | Talk through your idea with NIH staff at relevant Institutes and Centers (ICs) – share a 1-page concept paper or specific aims document in advance of a phone consultation. Each IC has different rules, contacts, and budgets. The NIH Center for Scientific Review will assign each application to an IC.

3 | Prepare to apply by understanding the various application systems and allowing sufficient time to obtain the required registrations (DUNS Number, System for Award Management, Grants.gov, eRA Commons, SBA Company Registry at SBIR.gov).

4 | Identify the right funding opportunity - SBIR and STTR omnibus grant solicitations have three standard application cycles per fiscal year (September 5, January 5, and April 5) and targeted solicitations on specific research areas are issued by individual ICs.

5 | Understand the Review Process, including Peer Review (panels of outside experts) and the role of the NIH Center for Scientific Review, which reviews most applications and gives an overall impact score on five scored review criteria as well as additional criteria (not scored; vary by application type and aspects of research project).

6 | Prepare your application, paying close attention to the content and format of key documents: Specific Aims, Research Strategy and Letters of Support. Use ASSIST (the NIH online application preparation and submission system) to submit and eRA Commons (NIH electronic Research Administration) to track your application.

7 | Know the reporting and financial management requirements for an award. Develop and maintain a budget – know what type of budget will be required, understand various components, and track expenditures for project reporting. Note the requirements for registering & reporting NIH-funded clinical trials in ClinicalTrials.gov.

AdvaMed Member Recommendations

- **Focus on the Five Review Criteria:** Significance, Approach, Innovation, Investigators, Environment.
- **Follow the application guides:** prepare application side-by-side with the NIH SBIR/STTR Instructions and the NIH Grants & Funding Application Guide.
- **Spend time developing your budget,** and be as specific and inclusive of the project costs as possible.
- **Plan accordingly for the significant time required to prepare application** (over 100 hours on average per application, according to company applicants).
- **Emphasize the real-world impact** and commercial potential of the project.
- **Seek strong academic partners,** who can provide research assistance and access to facilities, labs, equipment, personnel.
- **Clearly define roles** for collaborating Primary Investigators.
- **Bring in outside talent or experience** to support specific project objectives, when necessary.
- **Employ a finance grant specialist** to make funding requests, gather evidence, develop budget.
- **Allow sufficient lead time** to gather strong letters of support from key opinion leaders and investors.

Pointers from NIH Program Managers

- **Contact NIH Program Specialists** to gauge relevance of a specific project to individual IC's priority areas of interests.
- **Start early** to gather required registrations and build relationships with key opinion leaders and NIH Program Specialists.
- **Be prepared to resubmit –** majority of first-time applicants do not get awards (12% success rates for Phase I applications in FY20); all applicants receive feedback from review panel.

Potential Pitfalls:

- **No significance –** no compelling case for commercial potential and societal impact.
- **Lack of innovation –** does not present value over current technology or standard of care.
- **Diffuse research plans –** superficial or unfocused research plans.
- **Overly ambitious scope of work –** exceeds reasonable milestones and budget resources.
- **Weak or unsubstantiated Commercialization Plan –** lack of clarity on go-to-market strategy.

Additional Resources

- Small business Education and Entrepreneurial Development (SEED)
- HHS Small Business Program Managers
- How to Apply
  - Step-by-Step Instructions
  - Application Guide
  - Develop Your Budget
- Application Assistance Program
- Forms Library
- Clinical Trial Requirements
- Technical and Business Assistance Programs
- Commercialization Enhancement Programs
- Entrepreneurial Finance Course