INTRODUCTION & OVERVIEW
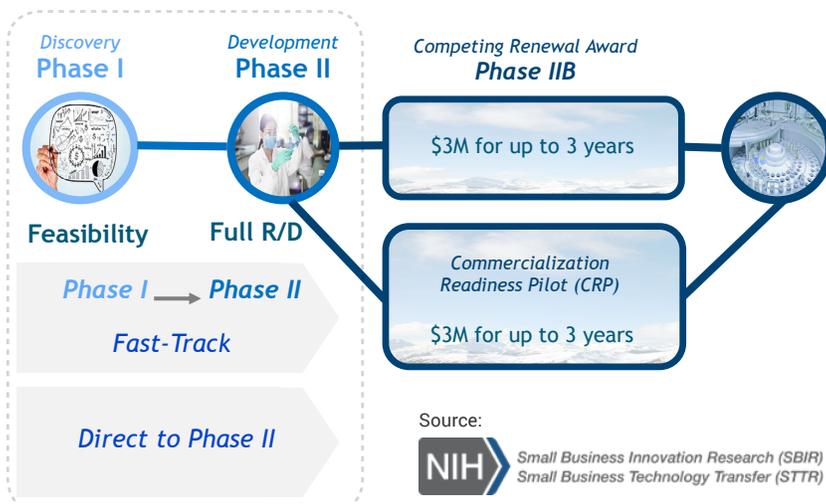
The National Institutes of Health (NIH) is the largest government research agency in the world and spends more than $30 billion annually to fund research that advances scientific discovery. A portion of the money spent goes towards non-dilutive funding programs, which enable early-stage medtech and other life science companies to advance and de-risk product development, while also providing scientific and technical validation that attracts investors and supports reimbursement.
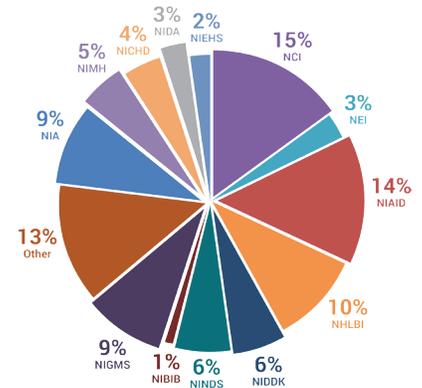
$1B

Over $1B invested in life science companies.

The NIH offers non-dilutive funding through the **Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs**. In FY18, these programs invested over $1 billion in life science companies ($941M for SBIR and $132M for STTR); approximately 30% of this funding was awarded to medical technology companies.

NIH SBIR/STTR is set up as a **Three-Phase Program** that covers a product's lifecycle from proof of concept to feasibility.

Discovery **Phase I**
Feasibility

Development **Phase II**
Full R/D

Competing Renewal Award **Phase IIB**

$3M for up to 3 years

Commercialization Readiness Pilot (CRP)

$3M for up to 3 years

Phase I → *Phase II*
Fast-Track

Direct to Phase II

Source:

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

NIH SBIR/STTR PROGRAMS

Approximately $300M in SBIR/STTR funding in FY18 for medtech

- 3% NIDA
- 2% NIEHS
- 15% NCI
- 4% NICHD
- 5% NIMH
- 9% NIA
- 13% Other
- 9% NIGMS
- 1% NIBIB
- 6% NINDS
- 6% NIDDK
- 10% NHLBI
- 14% NIAID
- 3% NEI

FY18 SBIR/STTR Funding by IC
Source: NIH RePORTER

Institutes and Centers (IC) 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 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)](#)

Additional Resources

[NIH Grant Submission Guidance](#)

[NIH Review Criteria](#)

[SBIR/STTR Application Infographic](#)

[Clinical Trials Decision Tree](#)

[SBIR/STTR Tutorials](#)

[Develop Your Budget](#)

[Entrepreneurial Finance Course](#)

[SBIR/STTR Annual Conference](#)

APPLICATION PROCESS, TIMELINES, AND AWARD MANAGEMENT

1 | Determine **program eligibility** and understand **differences** in SBIR and STTR.

2 | **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).

3 | Identify relevant Institutes and Centers (ICs) within NIH. Companies may submit an executive summary (or Specific Aims document) to relevant IC prior to submission to determine strategic fit, as different ICs have different rules, contacts, and budgets. The NIH Center for Scientific Review will assign each application to relevant IC.

4 | Examine **Funding Opportunity Announcements (FOAs)**, consider **clinical trial requirements**, and submit applications in response to specific FOAs. Standard application due dates: January 5, April 5, September 5 (or next business day if on holiday or weekend).

5 | When preparing an application, pay close attention to the content and format of key documents: Specific Aims, Research Strategy and Letters of Support.

6 | Understand 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).

7 | Develop and maintain a budget – know what type of budget will be required, understand various components, and track expenditures for project reporting.

Five Scored Review Criteria

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

Approach
Well-reasoned strategy, methodology, and measurable milestones

Innovation
Novel concept presents value over current standard of care
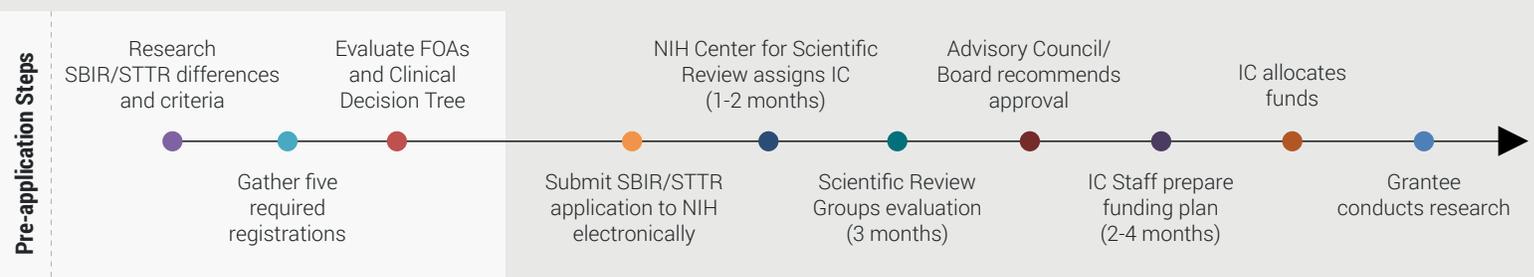
Investigators
Clinical and technical expertise and experience in the field

Environment
Appropriate facilities, equipment, and institutional resources

NIH SBIR/STTR Application and Review Timeline

Pre-application Steps

- Research SBIR/STTR differences and criteria
- Gather five required registrations
- Evaluate FOAs and Clinical Decision Tree
- Submit SBIR/STTR application to NIH electronically
- NIH Center for Scientific Review assigns IC (1-2 months)
- Scientific Review Groups evaluation (3 months)
- Advisory Council/Board recommends approval
- IC Staff prepare funding plan (2-4 months)
- IC allocates funds
- Grantee conducts research

SBIR/STTR Application Tips From the Experts

AdvaMed Member Recommendations

- **Seek strong academic partners**, who can provide research assistance and access to facilities, labs, equipment, personnel.

- **Emphasize the real world impact** and commercial potential of project.

- **Clearly define roles** for collaborating Primary Investigators.

- **Spend time developing your budget,** and be as specific and inclusive of the project costs as possible.

- **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.

- **Bring outside talent or experience** to support specific project objectives, when necessary.

- **Prepare application side-by-side** with NIH Grant Submission Guidance and NIH Review Criteria.

- **Plan accordingly for the significant time required to prepare application** (over 100 hours on average per application, according to company applicants).

Pointers from NIH Program Specialists

Commercialization Plan

Value of SBIR/STTR Project	Company Info	Market, Customer, Competition	Intellectual Property Protection	Finance Plan	Revenue Stream

- **Confirm project relevance –** contact NIH Program Specialists to discuss project's relevance to individual IC's priority interest areas.

- **Start early –** 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 (16% application success rate for Phase I in FY18); 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.

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 startup 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 to number of letters, but 2-5 recommended).

- **Commercialization Plan** *(Phase II and Fast Track only; not required for Phase I)* **–** offers a clear and concise description of the proposed work's market potential and path to commercialization.