

NIA Small Business Funding: Applicant Assistance Program



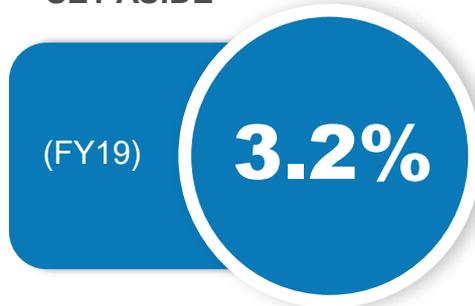
National Institute
on Aging



About SBIR and STTR

Congressionally Mandated Programs

SET ASIDE



Small Business Innovation Research (SBIR) Program

Set-aside program for small businesses to engage in federal R&D—with potential for commercialization



Small Business Technology Transfer (STTR) Program

Set-aside program to facilitate cooperative R&D between small businesses and U.S. research institutions—with potential for commercialization



Why Seek SBIR/STTR Funding

- Provides seed funding for innovative technology development
 - Not a loan
 - No repayment required
 - No impact on stock or shares (non-dilutive)
- Small business retains intellectual property rights
- Provides recognition, verification, and visibility
- Helps attract additional funding or support (e.g., venture capital, strategic partner).

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Eligibility

- ✓ Applicant must be a small business
- ✓ Organized for-profit U.S. business
- ✓ 500 or fewer employees, including affiliates
- ✓ > 50% U.S.-owned by individuals and independently operated
 - OR**
 - > 50% owned and controlled by another (one) business that is > 50% owned and controlled by one or more individuals
 - OR (SBIR ONLY)**
 - > 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these



**AWARDS
ALWAYS MADE
TO THE SMALL
BUSINESS**



Critical Differences

AWARD IS STILL MADE TO THE SMALL BUSINESS!



SBIR	STTR
<p>Permits research institution partners (e.g., universities)</p>	<p>Requires research institution partners (e.g., universities)</p>
<p>Small business may outsource ~33% of Phase I activities and 50% of Phase II activities</p>	<p>At least 40% of the work should be conducted by the for-profit small business, and at least of 30% by a non-profit U.S. research institution</p>
<p>Eligibility: PD/PI primary employment (i.e., > 50%) MUST be with the small business for the duration of the project</p>	<p>Eligibility: IP agreement providing necessary IP rights to the small business to carry out follow-on R&D and commercialization</p> <p>PI primary employment not stipulated (at least 10% effort to project)</p>



SBIR & STTR Program Phases and Funding Levels

Phase I	Discovery & Feasibility	<ul style="list-style-type: none"> • Up to 1 year • Awards up to \$300,000, or up to \$450,000 for AD/ADRD • Establish technical merit, feasibility, and potential for commercialization
Phase II	Development & Full R&D	<ul style="list-style-type: none"> • 2 years • Awards up to \$2 million, or up to \$2.5 million for AD/ADRD • Continues Phase I R&D efforts • Requires a commercialization plan
Fast Track		<ul style="list-style-type: none"> • One combined application for Phases I and II (SBIR only)
Direct-to-Phase II (SBIR only)		<ul style="list-style-type: none"> • Apply directly for Phase II funding • Demonstrated feasibility through other funding sources
Commercialization Readiness Pilot		<ul style="list-style-type: none"> • Funding for late-stage R&D and technical assistance for commercialization
Phase IIB	Competing Renewal	<ul style="list-style-type: none"> • 3 years • Awards up to \$3 million



The SBIR & STTR Programs at NIA



NIA SBIR & STTR Seeks

- Innovative solution to significant unmet **clinical needs**
- Solutions that have **significant commercial potential**
- Projects should:
 - Leverage **the expertise of the company/founder**
 - Seek funding to **produce feasibility data** (Phase I) or conduct **product-focused development activities** (Phase II)

Special Research Interests in AD/ADRD

NIA's SBIR & STTR programs have funding available up to **\$450,000 for Phase I** and **\$2.5 million for Phase II** in AD/ADRD topics.

NIA seeks AD/ADRD research focusing on:

- Prevention
- Diagnosis
- Treatment
- Care & Caregiving
- Research & Clinical Tools
- Analytical Tools
- Digital Health
- Novel Devices

Available Opportunities

OMNIBUS FUNDING

Investigator-initiated
Standard application due dates:
Jan. 5, Apr. 5, Sept. 5

NIA-FOCUSED FUNDING

Focused priority areas in aging
Includes higher AD/ADRD budgets
Application due dates vary



Budget Specifics

TOTAL COST BUDGETS

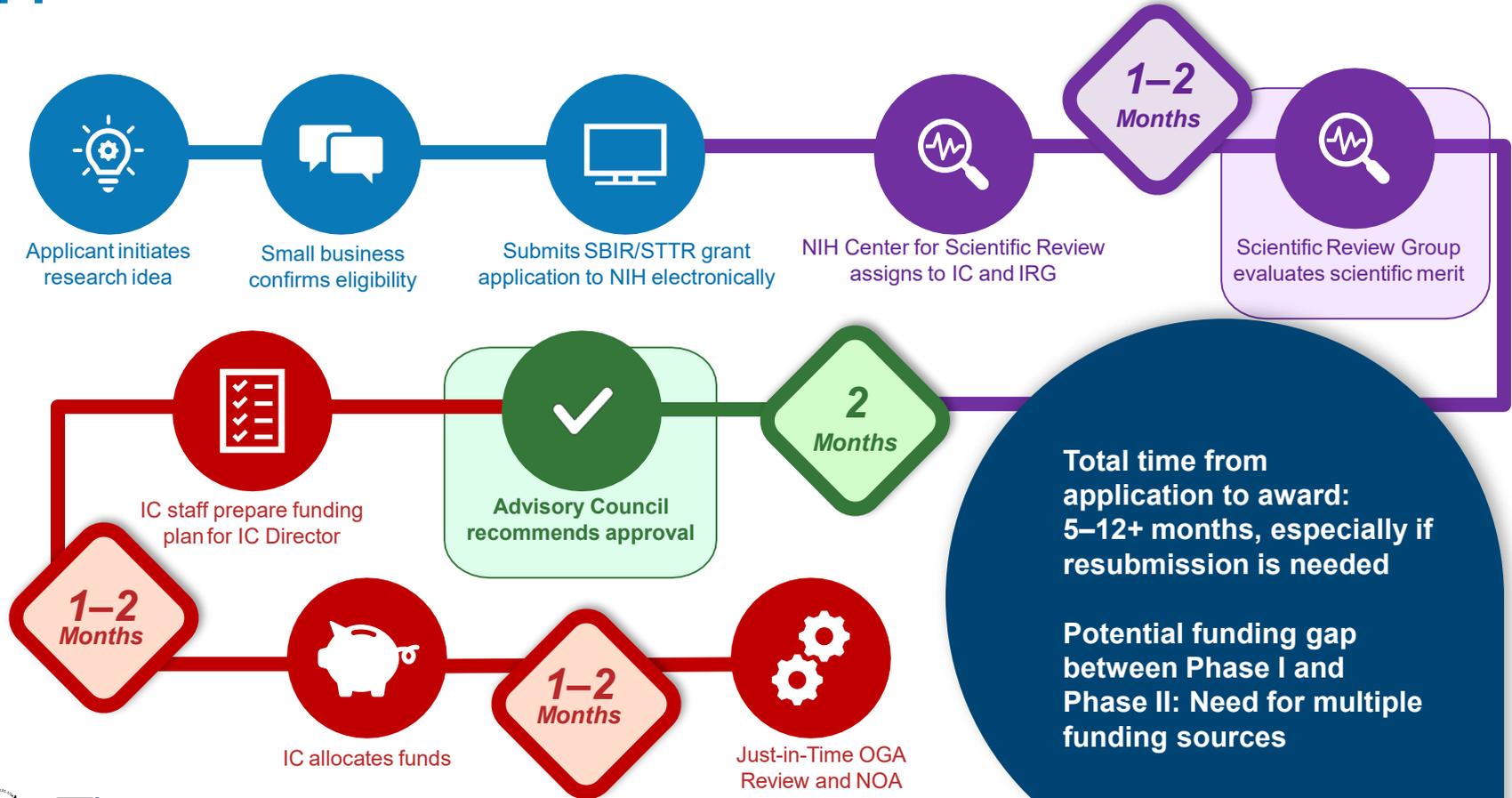
- SBIR budgets are defined by **total cost**, and subcontracting is limited. Know the rules and the criteria.
- Check budget allowance in each funding opportunity.

- **Can request a 7% fee:**
 - Company profit
 - Part of total budget

- **Fee for service: CRO-type activities can count as small business costs, providing that:**
 - 1) It is a commercially available service.
 - 2) All analysis is done by the small business.
 - 3) It is a fee per basis (no indirect costs by fee for service providers).



Application to Award



Resources to Help Research Entrepreneurs

FIRST-TIME AND NEVER-FUNDED APPLICANTS

Applicant Assistance Program. A 10-week coaching program to help develop your application. Offered once each standard funding period.

ALL AWARDEES

Technical Assistance Budget Allowance. Supports services such as access to technologies, IP protections, and market research. Offers up to \$6,500 for Phase I and up to \$50,000 for Phase II when requested in the grant application.

Diversity Supplement. Helps increase the diversity of the research workforce by supporting students, postdocs, and eligible investigators from underrepresented groups.

C3i Program for NIH. Supports medical device innovators in commercializing their products through a 24-week entrepreneurial training course.

SEED Resources. Support from the NIH Small Business Entrepreneurial Education and Development (SEED) Office including access to Entrepreneurs in Residence and regulatory support.

PHASE I AWARDEES

I-Corps™ at NIH. An 8-week intensive course that offers real-world, hands-on entrepreneurship training and customer discovery in life sciences and biotechnology.



NIH Applicant Assistance Program

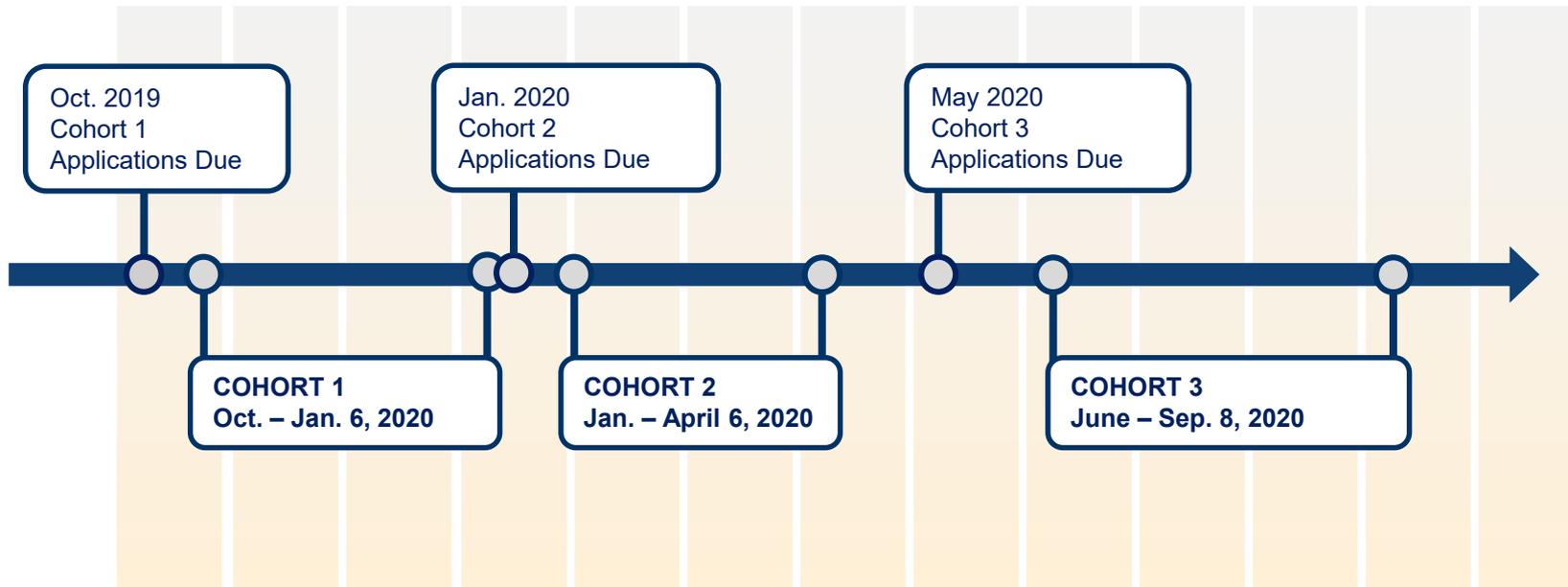
Goal: Provide a mentor for applicants with great technology, but little NIH experience and limited NIH experience in their network.

- Free Application Preparation *ASSISTANCE*
- Participating ICs: NIA, NCI, NINDS, and NHLBI

PROVIDED	NOT PROVIDED
Phase I preparation support and review	Grant writer
Specific Aims page review and advice	Development of research plan
Submission process coaching	Register small business for you Apply to NIH for you



AAP Timeline



Calendar Year 2019–2020



AAP Eligibility and Application

- Simple eligibility criteria:
 - **Never received a small business grant award from NIH**
OR
 - **Received an award prior to 2010**
- Interested in applicants who are currently underrepresented in the biosciences (not a requirement)
 - Women-owned small businesses
 - Minority-owned small businesses
 - Small businesses operating in an underrepresented (IDeA) state

AAP application portal:

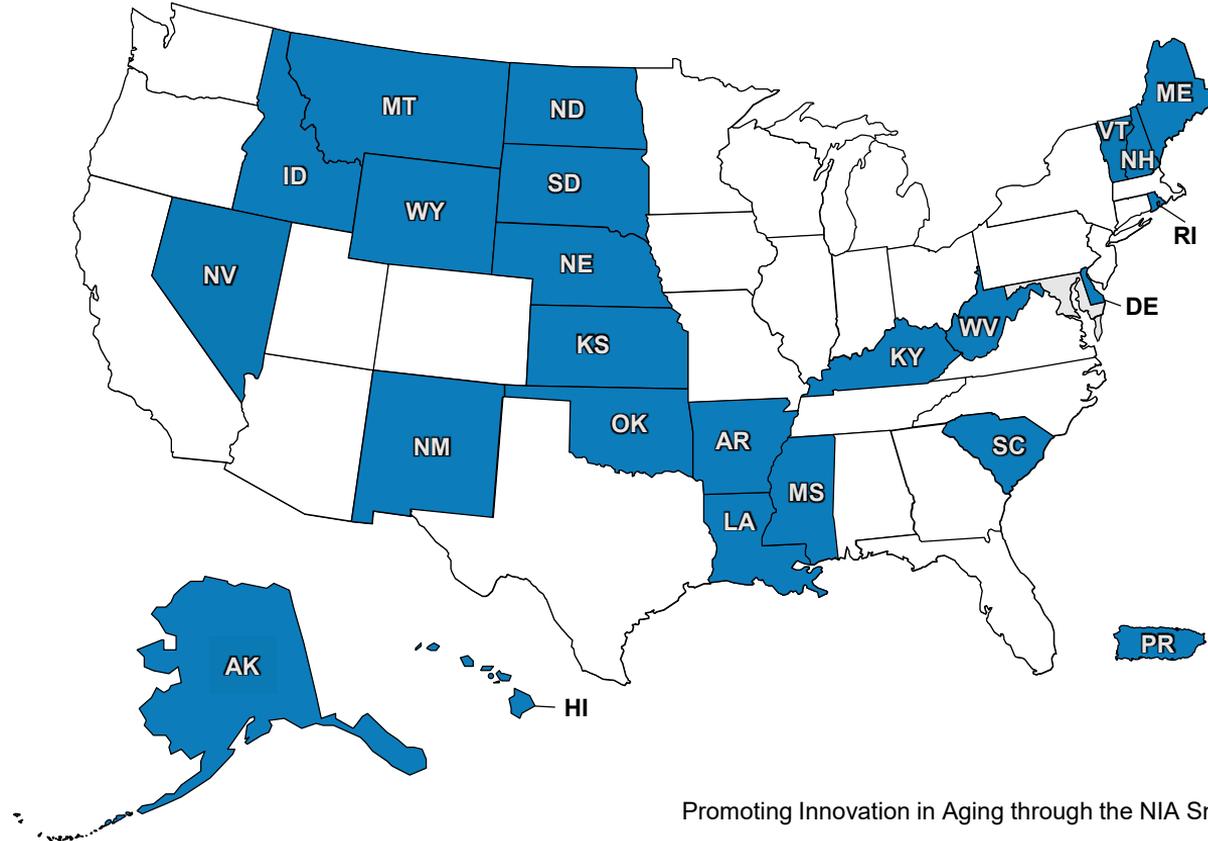
<http://bit.ly/2020AAP>

- Answer a series of structured questions
- Upload supporting documents (e.g., abstract)
- Submit



Recognizing IDeA States

Institutional Development Award (IDeA)



NIA OSBR: Core Activities

<https://nia.nih.gov/sbir>

Central Coordination



Administer all SBIR/STTR awards at NIA

Guidance



Help applicants prepare for application/resubmission, and discuss funding options

Outreach



Attend conference/workshops and visit regional organizations to raise awareness of the program

Funding



Seed emerging technology areas by developing targeted funding opportunities and Omnibus interest topics

Networking



Facilitate connections between awardees and potential strategic partners (NIA programs/external partners)

Entrepreneurship



Provide entrepreneurship training as well as webinars on key commercialization-related topics



NIA Funding Opportunities

	Omnibus FoAs	AD/ADRD-Focused FoAs
SBIR	<p><u>PA-19-272</u> (clinical trials not allowed)</p> <p><u>PA-19-273</u> (clinical trials required)</p>	<p><u>PAS-19-316</u> (Advancing research on AD/ADRD)</p> <p><u>PAR-18-512</u> (Lifespan/healthspan-extending Interventions for AD/ADRD patients)</p> <p><u>PAR-18-186</u> (Development of socially-assistive robots for AD/ADRD patients and their caregivers)</p>
STTR	<p><u>PA-19-270</u> (clinical trials not allowed)</p> <p><u>PA-19-271</u> (clinical trials required)</p>	<p><u>PAS-19-317</u> (Advancing research on AD/ADRD)</p> <p><u>PAR-18-514</u> (Lifespan/Healthspan Extending Interventions for AD/ADRD Patients)</p> <p><u>PAR-18-185</u> (Development of socially-assistive robots for AD/ADRD patients and their caregivers)</p>

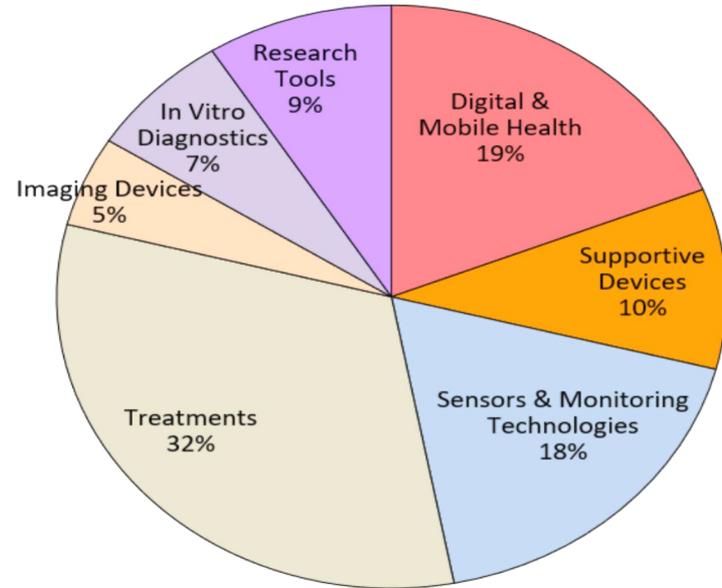


NIA Priority Areas and Portfolio

Priority areas are covered by NIA's four main divisions:

- **Division of Aging Biology:** Provides a basis in basic biology for preventive and interventional strategies to increase resilience and extend healthy aging.
- **Division of Behavioral and Social Research:** Supports research and research training on the processes of aging at both the individual and societal levels.
- **Division of Geriatrics and Clinical Gerontology:** Supports research on health/disease in older people and research on aging over the human lifespan, including its relationships to health outcomes.
- **Division of Neuroscience:** Supports research to further the understanding of neural and behavioral processes associated with the aging brain. Research on dementias of old age—in particular Alzheimer's disease (AD)—is one of the highest priorities.

Portfolio Classifications (AD & Non AD)



Scored Review Criteria

Significance

Does the product address an important **problem**, and have commercial potential? Is there a market pull for the proposed product?

Approach

Are **design and methods** well-developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?

Innovation

How novel is the **technology/product** and the **approaches** proposed to test its feasibility?

Investigator

Are the investigators, collaborators and consultants appropriately trained and **capable** of completing all project tasks?

Environment

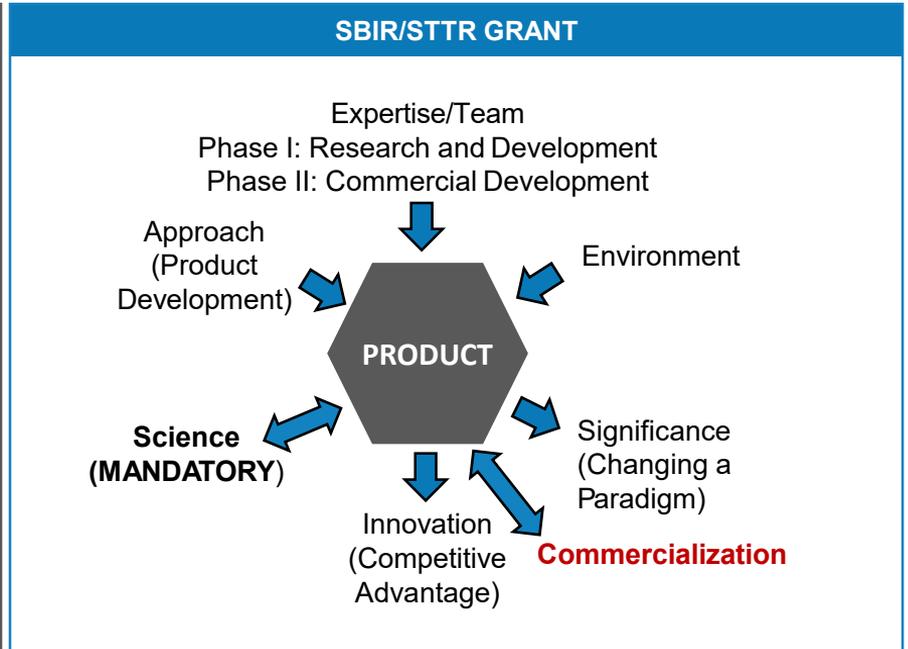
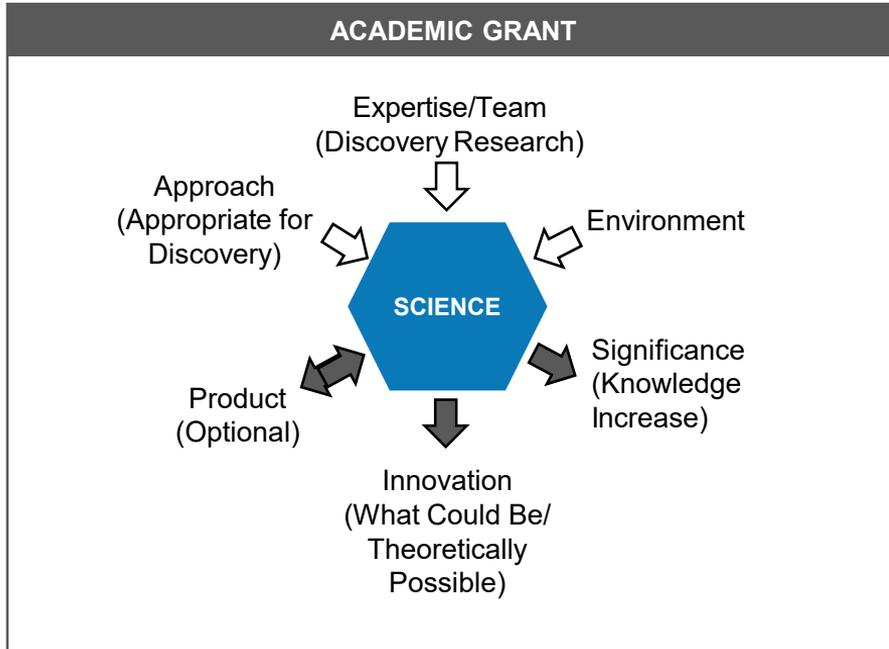
Does the **scientific environment** contribute to the probability of success? **Facilities**? Independence?

Commercialization

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



Remember: Focus on Product



Compose a Specific Aims Page

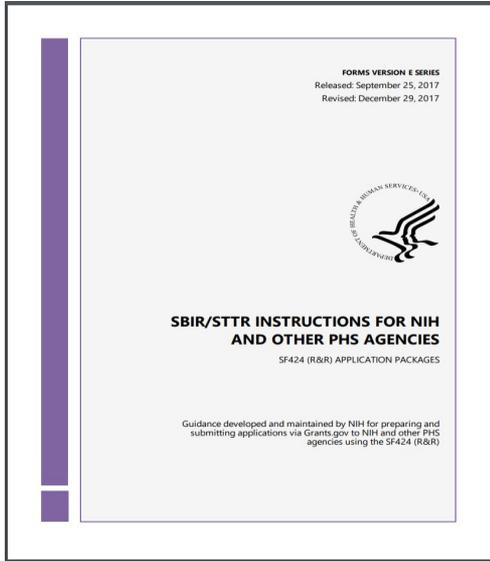
Specific Aims (1 page):

The Executive Summary and First Impression

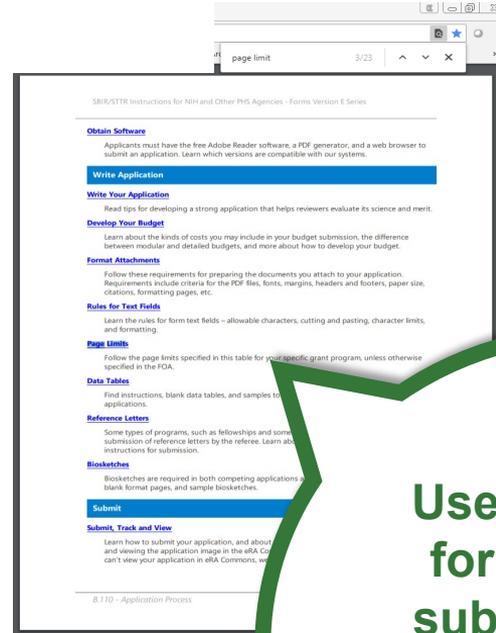
- **First 1/2 to 2/3: The elevator pitch—Why is it meritorious?**
 - The technology prototype to be developed
 - The technical innovation the development would represent, the unmet need being addressed, and technical challenges to overcome
 - The value proposition and competition
 - Textual highlights of preliminary data
 - The relevance of the R&D to NIA's mission
- **Last 1/3 to 1/2: Describe the specific aims for the project**
 - Include key models, assays, and metrics
 - Include quantitative performance milestones
- **Provide your draft Specific Aims page to NIA staff for feedback**



SF 424 Application Guide



Use "Ctrl F"
keyword search
on this
document.
That's what I do!



Use NIH ASSIST
for application
submission and
review the
annotated
application forms.



Connect with NIA

 [Visit the NIA Small Business Programs \(SBIR & STTR\) website.](#)

 View [upcoming events](#) and [funding opportunities](#).

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 Questions? Email: NIAsmallbusiness@mail.nih.gov

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