

NIA Small Business SEED Fund:

Accelerating Alzheimer's and Aging Research



National Institute
on Aging

NIA Office of Small Business Research: Core Activities

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

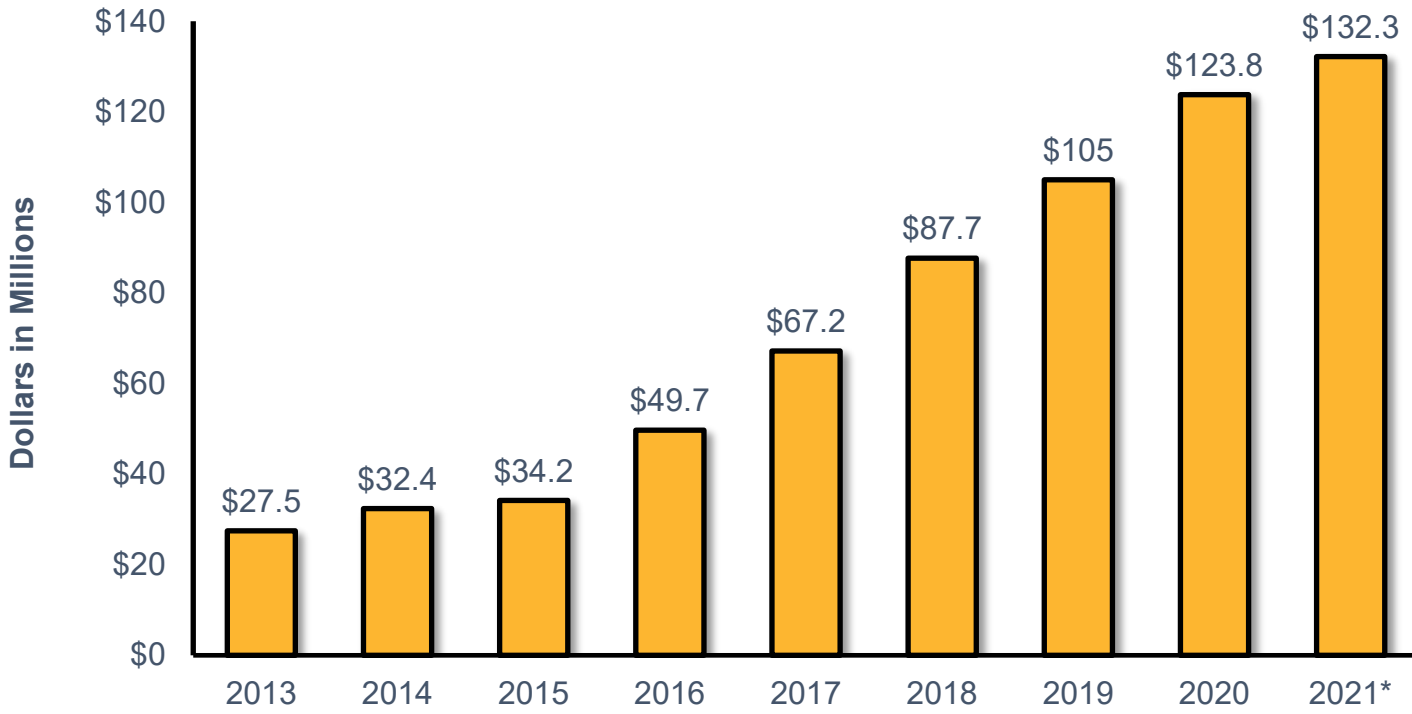


Provide entrepreneurship training as well as webinars on key commercialization-related topics

**Stakeholder
Engagement for
Cross- Leverage:
ADDF SBIR Bridge
Funding and
Longevity Innovation
Summits**



NIA SBIR/STTR Obligation



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 \$500,000 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
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



NIA Research Divisions

NIA provides SBIR/STTR support through 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—is one of the highest priorities.



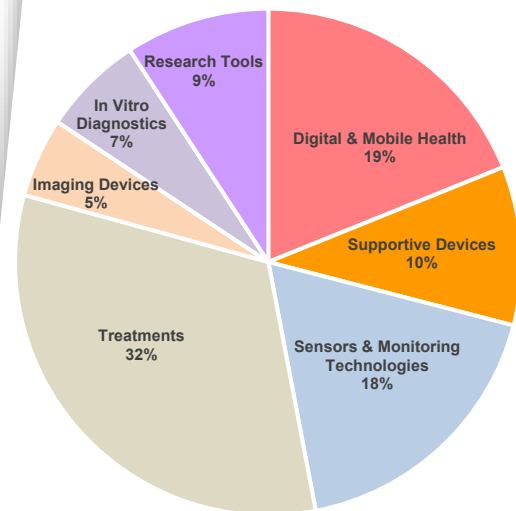
We Strategically Fund Innovations for:

- Alzheimer's disease (AD), AD-related dementias (ADRD), and age-related change in brain function
- Aging in place
- Age-related diseases and conditions
- Research tools

Additional Areas of Interest

- Companion diagnostics and other forms of personalized medicine
- Bioinformatics, public health informatics, or data science technologies/methods (e.g., machine learning, artificial intelligence) to better understand and predict health outcomes
- Novel cell and gene therapies, as well as other novel therapeutic approaches to AD/ADRD
- Biomarkers and diagnostic tools for the early detection of disease
- Prevention and therapeutics that directly target mechanisms related to aging biology
- Assistive technology, devices, and mobile applications for older adults and caregivers
- Tools, technologies, and analytic methods to address health disparities among older adults

Portfolio Classifications (AD & Non AD)



NIA Funding Opportunities

	Omnibus FOAs	AD/ADRD-Focused FOAs
SBIR	<p><u>PA-20-260</u> (clinical trial not allowed)</p> <p><u>PA-20-262</u> (clinical trial required)</p> <p><i>Budget limits: Phase I \$300,000; Phase II \$2 million</i></p>	<p><u>PAS-19-316</u> (Advancing Research on AD/ADRD)</p> <p><i>Budget limits: Phase I \$500,000; Phase II \$2.5 million</i></p>
STTR	<p><u>PA-20-265</u> (clinical trial not allowed)</p> <p><u>PA-20-261</u> (clinical trial required)</p> <p><i>Budget limits: Phase I \$300,000; Phase II \$2 million</i></p>	<p><u>PAS-19-317</u> (Advancing Research on AD/ADRD)</p> <p><i>Budget limits: Phase I \$500,000; Phase II \$2.5 million</i></p>



NIA Funding Opportunities (Continued)

Commercial Readiness Pilot (CRP) Program	Budget Limits
<u>PAR-20-128</u> (CRP Technical Assistance; clinical trial not allowed)	\$300,000
<u>PAR-20-129</u> (CRP Technical Assistance and Late Stage Development; clinical trial not allowed)	\$1.75 million/year for 2 years (\$3.3 million total)
<u>PAR-20-130</u> (CRP Technical Assistance and Late Stage Development; clinical trial required)	\$1.75 million/year for 2 years (\$3.3 million total)
Supplements & NIA Participating Initiatives	Budget Limits
<u>PA-18-837</u> (Administrative Supplements to Promote Diversity in Research and Development Small Business; clinical trial not allowed)	\$250,000 in direct costs
<u>PA-18-705</u> (SBIR Technology Transfer; clinical trial not allowed)	Phase I \$300,000; Phase II \$2 million
<u>RFA-AG-22-011</u> (clinical trial required)	No limit

We also participate in additional funding opportunities that can be found here: www.nia.nih.gov/research/osbr/nia-small-business-funding-opportunities



ADDF Phase 1 Bridge Support

Alzheimer's Drug Discovery Foundation funding opportunity for NIA grantees:

- **Eligibility:** U.S.-based companies previously awarded NIA SBIR/STTR Phase I grants or applicants with scored but unfunded applications
- **Purpose:** NIA SBIR/STTR awardees can receive interim funding from ADDF to:
 - Serve as bridge funding as NIA funding decisions are finalized
 - Enable investigators to continue to generate additional data in support of SBIR/STTR Phase II grants or other NIH grants

Questions? Contact Dr. Zane Martin: zane.martin@nih.gov

Apply: <https://bit.ly/3c9nqMz>



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

- Free application preparation **assistance**
- Participating ICs: NIA, NCI, NHLBI, NINDS, NCCIH, NCATS, NIEHS and NINR

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

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



NIH Applicant Assistance Program Eligibility and Process

- 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



Technical and Business Assistance (TABA)

Phase I Needs Assessment Report

- **TABA Needs Assessment Report** provides a third-party, unbiased assessment of progress in 10 technical and business areas that are critical to market success and suggests the highest priority steps companies can take to improve the commercial potential of a product or service.
- **Goal:** To help small businesses identify and address their most pressing product development needs
- **Deadline:** Requests are accepted on a rolling basis. Reviews take place monthly, with notification of status within 60 days of submission.
- **Eligibility:** Active Phase I SBIR/STTR award within the past two years



Technical and Business Assistance (TABA) Budget Allowance

- **Purpose:** Help small businesses make better technical decisions, solve technical problems, minimize technical risks, and develop and commercialize new products and processes
- **Examples:**
 - Technology expertise
 - Product sales expertise
 - IP protections expertise
 - Market research and validation
 - Development of regulatory plans
 - Development of manufacturing plans
 - Technical and business literature
- **Best fit for Phase II awardees**
- Awardees who request the TABA budget allowance cannot participate in other NIH technical assistance opportunities, such as the TABA Needs Assessment Report

Request within the Application:

- F. Other Direct Costs, lines 8–10
- Label as “Technical Assistance”

Budget Allowance:

- Phase I up to \$6,500 per year
- Phase II cap of \$50,000



Commercializing Innovation (C3i) Program

- Open to all active SBIR and STTR awardees
- 24-week entrepreneurial training course designed to support medical device innovators in commercializing their products
- Provide specialized business frameworks and essential tools for successful transition of biomedical technologies from the lab (concept) to the market (clinic)



I-Corps™ at NIH

- Commercialization resource for **Phase I** awardees
- 8 week-intensive entrepreneurship immersion course
- Offers real-world, hands-on training and customer discovery in life sciences and biotechnology
- Program benefits include:
 - Provides up to \$55,000 to cover direct program costs
 - Training from biotech sector experts
 - Expanding your professional network
 - Building the confidence and skills to create a comprehensive business model
 - Gaining years of entrepreneurial skills in only weeks



Diversity Supplement Program

- Administrative Supplements to Promote Diversity in Research and Development Small Businesses— SBIR/STTR and SBIR Cooperative Agreements ([PAR-18-837](#))
- **Goal:** Improve the diversity of the research workforce by recruiting and supporting students, post-doctorates, and eligible investigators from groups that have been shown to be underrepresented in health-related research or in the SBIR/STTR programs.
- **Applications:** Include identification of the candidate as well as a strong career development plan.
- **Deadline:** Applications accepted on a rolling basis.



Research and Entrepreneurial Development Immersion (REDI)

NIA is developing dedicated programs to spur innovation and train the next generation of scientist-entrepreneurs.

This initiative provides multiple funding programs such as individual career development award, small business award, and National Research Service Award institutional funding programs to provide bio-entrepreneurship training to further enrich and diversify NIA training programs and allow trainees to acquire additional non-academic skills.

Note: This concept was formerly referred to as the Entrepreneurship and Innovation Training Program (ENRICH)



Entrepreneur Workshop Series

Goal: Support startups along the journey to commercializing novel scientific products and technologies through a 2021 series of **entrepreneurship workshops** for SBIR and STTR awardees and applicants.

Format: Topical presentation by NIA's Entrepreneur-in-Residence followed by breakout discussions with subject matter experts

Hosts:

- NIA Office of Small Business Research
- National Heart, Lung, and Blood Institute's Small Business Program



Investor Showcase and Partnering Opportunities

SBIR Awardee Opportunities to Attend Investor Events & Receive Pitch Coaching

Bio INVESTOR FORUM

AdvaMed

ACA ANGEL CAPITAL ASSOCIATION

RESI RESEARCH IN EARLY STAGE INVESTMENTS

Bio

LIFESCIENCES™ SUMMIT



Introducing our EIR: Don Rose, Ph.D.

As an Entrepreneur-In-Residence for NIA, Don Rose, Ph.D., provides valuable guidance and entrepreneurial coaching to NIA-funded companies. In addition to his current role as a Special Advisor at Hatteras Venture Partners, Don has extensive experience launching and building life-science start-ups, most recently at the University of North Carolina at Chapel Hill, where he helped spin out 80 companies. Prior to academia, Don held senior leadership roles at several life-science start-ups; he also holds six U.S. patents and has published eight papers and two book chapters. [Get in touch with Don today!](#)



Showcase Efforts at NIA

NIA maintains a virtual showcase for select NIA-funded companies that are chosen to participate in various investor showcases.

Learn more about the companies: <https://www.nia.nih.gov/research/osbr/nia-small-business-showcase>

Devices

Diagnostics

Therapeutics

Digital
Health and
Sensing
Technologies



Application Resources

- Small Business Resources:
 - [Sample SBIR Grant Applications from NIAID](#)
 - [Annotated Form Set for NIH SBIR Grant Applications](#)
 - [SBIR/STTR Application Process Infographic](#)
 - [Office of Small Business Research, National Institute on Aging](#)
- Database of NIH-Supported Research: [NIH RePORTER](#)
 - Find Similar Projects and Program Staff: [NIH Matchmaker](#)
- NIA-Supported Animal Model Resources:
 - [Alzheimer's Disease Preclinical Efficacy Database](#) (models, agents, and markers)
 - [MODEL-AD Consortium](#) focused on developing next-generation animal models for Alzheimer's
 - [Aged Rodent Colonies](#) Handbook



Connect with NIA

 Visit nia.nih.gov/sbir

 Follow us on Twitter: [@NIA_SBIR](https://twitter.com/NIA_SBIR)

 Follow us on LinkedIn: [NIA Office of Small Business Research](https://www.linkedin.com/company/nia-office-of-small-business-research)

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

 Join our [mailing list](#)

 Questions? Email: NIAsmallbusiness@mail.nih.gov





Thank you!

