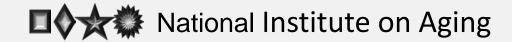
National Institute on Aging Small Business (SBIR/STTR) Awards to Advance Research on Alzheimer's Disease and Alzheimer's-Related Dementias (AD/ADRD)

NIA-AABC May 9th, 2018 Webinar Lorenzo Refolo & Yuan Luo



Overall Goal of Small Business Award Program

The NIA SBA Program (SBIR/STTR) aims to support the discovery, development and commercialization of new therapies, novel devices, analytical tools, health care programs and practices that will improve prevention and treatment, as well as caregiving for patients with AD/ADRD.

- Small Business Innovation Research (SBIR)
- Small business Technology Transfer Research (STTR)
- ➤ A Small Business is defined as a company with ≤ 500 employees

Difference between SBIR and STTR

	SBIR (R43, R44)	STTR (R41,R42)
PI(s)	Must be employed with the small business.	Employed with small business or University
Collaboration	Not required, can have university collaborators < 33% for phase I, <50% for phase II.	Require collaboration, Small business perform >40% R&D University >30% R&D
Phase I	Feasibility studies, De-risk	~ \$150K for 6 mon -1 yr Higher for AD-related topics
Phase II	Full R&D, NIH Phase I awardee, <u>Commercial plan required</u>	~\$1.0M for 1-2 yr Higher for AD-related topics
Fast Track	Combined Phase I and II PO will determine "successful enter	Phase I + Phase ₂ II

Application Types

- Phase I- feasibility and proof-of-concept
- Phase II-continue R&D initiated in Phase I funding is based on results achieved in Phase I + scientific and technical merit and commercial potential of the project proposed in Phase II
- Fast Track- 1 application for Phase I and Phase II that is submitted and reviewed together
- Phase IIB Competing Renewal- for projects that require additional funding beyond the original Phase II award. These applications require competitive peer review.

Timetable for SBIR & STTR Grant Applications

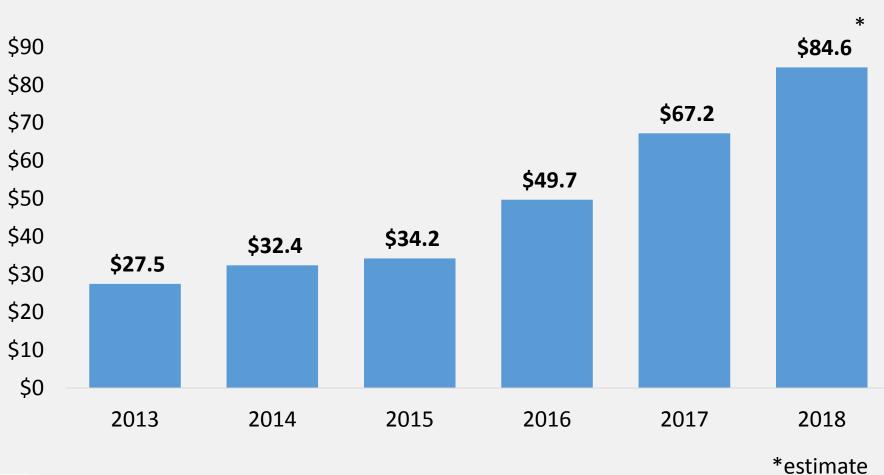
Due Dates	Review meetings	Advisory Council Round	Earliest Project Start Date
January 5	March	May	July
April 5	June 23	August	September- December
September 5	November	January	April

Broadly speaking, the NIA SBA Program will support research that address the following topics:

- Prevention
- Diagnosis
- Treatment
- Care
- Analytical Tools
- Mobile Technology

NIA SBIR/STTR Obligations

Dollars in Millions





PAR-18-187 (SBIR)

Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R43/R44 Clinical Trial Optional);

PAR-18-188 (STTR)

Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R41/R42 Clinical Trial Optional)

Award Budget

- -Statutory guidelines -\$150K (Phase I), \$1.0M (Phase II)
- -For specific waiver topics and with appropriate justification ->\$225K (Phase I), >\$1.5M (Phase II)

PAR-18-186 (SBIR)

<u>Development of Socially-Assistive Robots (SARs) to Engage Persons with</u> <u>Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and their Caregivers (R43/R44 Clinical Trial Optional);</u>

PAR-18-185 (STTR)

<u>Development of Socially-Assistive Robots (SARs) to Engage Persons with</u> <u>Alzheimer's Disease (AD) and AD-Related Dementias (ADRD), and their Caregivers (R41/R42 Clinical Trial Optional)</u>

Award Budget

-Statutory guidelines -\$350K (Phase I), \$2.0M (Phase II)

PAR-17-067 (SBIR)

Tools for Clinical Care and Management of Alzheimer's Disease (AD) and its Commorbidities (R43/R44);

PAR-17-066 (STTR)

Tools for Clinical Care and Management of Alzheimer's Disease (AD) and Its Comorbidities (R41/R42)

Award Budget

- -Statutory guidelines -\$150K (Phase I), \$1.0M (Phase II)
- -For specific waiver topics and with appropriate justification ->\$225K (Phase I) , >\$1.5M (Phase II)
- **Applicants are strongly encouraged to contact NIH program officials prior to submitting any application in excess of the guidelines

PAR-18-512 (SBIR)

<u>Testing Lifespan/Healthspan-Extension Interventions in the Models of Alzheimer's Disease (AD/ADRD) (SBIR R43/R44 Clinical Trial Not Allowed)</u>

PAR-18-514 (STTR)

Testing Lifespan/Healthspan-Extension Interventions in the Models of Alzheimer's Disease (AD/ADRD) (R41/R42 Clinical Trial Not Allowed)

Award Budget

-Statutory guidelines -\$350K (Phase I), \$2.0M (Phase II)

PAR-18-329 (SBIR);

Technology to Detect, Monitor and Assess Daily Functions in Individuals with Cognitive Decline, Alzheimer's Disease and/or Alzheimer's Disease Related Dementias (AD/ADRD) (SBIR R43/R44 Clinical Trial Not Allowed);

PAR-18-326 (STTR)

Technology to Detect, Monitor and Assess Daily Functions in Individuals with Cognitive Decline, Alzheimer's Disease and/or Alzheimer's Disease Related Dementias (AD/ADRD) (R41/R42 Clinical Trial Not Allowed)

Award Budget

-Statutory guidelines -\$350K (Phase I), \$2.0M (Phase II)

Other Funding Opportunities Open to SBCs

- PAR 18-505: Assay Development for Neuroscience –Relevant Targets
- PAR 17-336: Discovery of in vivo Chemical Probes (R01)
- PAR 18-541: Blueprint Neurotherapeutics Network: Small Molecule Drug Discovery for Disorders of the Nervous System (U44)
- PAR 18-174: Alzheimer's Drug Development Program (U01)
- PAR 16-041: Drug Discovery for Nervous System Disorders
- PAR 18-175: Pilot Clinical Trials for the Spectrum of Alzheimer's Disease and Age-related Cognitive Decline (R01)
- PAR-18-028: Phase III Clinical Trials for the Spectrum of Alzheimer's Disease and Age-related Cognitive Decline (R01)

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