

DRUG DEVELOPMENT RFP

FUNDING OPPORTUNITY DESCRIPTION

The Drug Development RFP supports investigational new drug (IND)-enabling studies (or the international equivalent) and early-phase clinical trials that test promising pharmacological interventions and devices for Alzheimer's disease (AD) and related dementias. Both disease-modifying and symptomatic agents will be considered.

This funding opportunity prioritizes diverse drug mechanisms and modes of action related to the biology of aging and other emerging therapeutic areas for dementia. For this reason, amyloid targeted approaches and cholinesterase inhibitor proposals will not be considered for this RFP.

Stage of development:

1. Early-stage human clinical trials including:

- Phase 0 micro- or sub-therapeutic-dosing studies
- Phase 1 trials in healthy subjects or patients
- Biomarker-based proof-of-concept studies (generally phase 1b or phase 2a trials) designed to assess target engagement and downstream pharmacologic effects

2. IND (or international equivalent) – enabling studies including:

- Non-GLP and GLP pharmacology and toxicology studies, pre-formulation, and GMP manufacture of API and/or drug product required for regulatory packages. Funding is available for preparation of traditional and exploratory IND (or international equivalent) applications
- Long-term toxicology studies to enable longer-term dosing in phase 2 trials
- GMP manufacturing and testing of API and/or drug product required to move into phase 2 or phase 3 trials

For clinical trial applications, if IND-enabling work is in progress, funding for clinical studies would be contingent upon an IND (or equivalent) successfully going into effect.

Type of therapy: Novel, repurposed and repositioned drugs, as well as natural products and devices will be considered. Therapeutic modalities of interest include small molecules, peptides, antibodies, gene therapies, antisense oligonucleotides, and stem cells. Other non-pharmacologic interventions, such as diet, meditation, and exercise, will not be considered. A detailed landscape analysis to compare competition related to the mode or mechanism of action is strongly encouraged.

Drug mechanisms or modes of action: Novel drug mechanisms and modes of action related to the biology of aging and other emerging therapeutic areas for dementia are considered high priority. These include, but are not limited to:

- **Epigenetics**
- **Inflammation**
- **Mitochondrial & metabolic function**
- **Neuroprotection**
- **Proteostasis**
- **Synaptic activity and neurotransmitters**
- **Vascular function**
- **Other mechanisms and modes of action related to the biology of aging (e.g. senescent cells)**
- **Other novel mechanisms or modes of action that are supported by compelling evidence demonstrating a rational biological connection to the disease process**
- **Please note: Anti-amyloid approaches (e.g., anti-amyloid aggregation, beta-amyloid vaccines, beta- or gamma-secretase inhibitors) and cholinesterase inhibitor proposals will not be considered**

UPCOMING DEADLINES

ELIGIBILITY

AWARD INFORMATION

EXPECTATIONS AND EVALUATION

APPLICATION SUBMISSIONS

Review the [Application Instructions](#) for steps on applying.

[LOG IN OR CREATE ACCOUNT](#)

We encourage you to contact us if you would like to discuss your proposed project and receive initial feedback.

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For inquiries related to contracting and the online funding portal,
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