

# PROGRAM TO ACCELERATE CLINICAL TRIALS (PACT)

## FUNDING OPPORTUNITY DESCRIPTION

The PACT RFP supports IND-enabling studies 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
- Biomarker-based proof-of-concept studies (generally phase 1b or phase 2a trials) designed to assess target engagement and downstream pharmacologic effects

#### 2. Regulatory studies including:

- Non-GLP and GLP pharmacology and toxicology studies, pre-formulation, and GMP manufacture required for investigational new drug (IND) and clinical trial authorization (CTA) preclinical packages. Funding is available for preparation of traditional and exploratory IND applications
- Long-term toxicology studies to enable longer-term dosing in phase 2 trials
- GMP manufacturing and testing of clinical grade drug 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) being granted and full review of the data package.*

**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.

**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

## AWARD INFORMATION

## ELIGIBILITY

## EXPECTATIONS AND EVALUATION

## APPLICATION SUBMISSIONS

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

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

### For scientific inquiries, please contact:

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### For inquiries related to contracting and the online funding portal, please contact:

Grants and Mission-Related Investments Team

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Alzheimer's Drug Discovery  
Foundation



A GuideStar-Rated  
Charity

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