



REQUEST FOR PROPOSALS (RFP)

The Treat FTD Fund – Funding for Innovative Clinical Trials for Frontotemporal Degeneration

The Alzheimer's Drug Discovery Foundation (ADDF) and The Association for Frontotemporal Degeneration (AFTD) have launched the *Treat Frontotemporal Degeneration (FTD) Fund* to support clinical trials testing novel or repurposed drugs for FTD and related disorders (bvFTD, PPA, PSP, CBD, FTD/ALS). *The Treat FTD Fund* will build on recent successes of both foundations in early-stage drug discovery and biomarker development and leverages new ongoing efforts under development by AFTD such as the recently launched FTD Disorders Registry and a \$5M FTD Biomarker Initiative. Running clinical trials in FTD patients will help investigators learn how best to target this unique patient population and will employ advances in biomarkers as they develop. Through this partnership, ADDF and AFTD propose to invest \$10 million dollars over 10 years to fund at least 5 innovative clinical trials subject to review by an appointed Joint Steering Committee.

Patient population: The population targeted by the clinical trial proposed should broadly include both genetic and sporadic forms of FTD and related disorders (bvFTD, PPA, PSP, CBD, FTD/ALS). The rationale for the mechanism of action of the drug/therapy for the specific FTD patient population proposed must be included in the application.

Therapeutic Focus: This RFP is agnostic to drug target, open to both symptomatic and disease modifying approaches and includes both novel and repurposed therapies. Behavioral and social interventions as well as lifestyle modifications will not be considered.

Clinical Phase: The RFP will support clinical proof-of-concept studies and pilot proof-of-mechanism clinical trials utilizing pharmacodynamic-based outcome measures in a patient population. Studies designed to solely test safety in healthy volunteers will not be considered, however Phase 0/Phase 1 studies in healthy volunteers that assess pharmacodynamics outcome measures relevant to FTD will be accepted for review. Innovative clinical trial design is encouraged as is inclusion of exploratory endpoints and/or novel biomarkers.

Resources: Leveraging of existing resources, clinical coordination centers/networks, and patient registries are highly encouraged.

Relevant resources include:

- Advancing Research and Treatment for Frontotemporal Lobar Degeneration ([ARTFL](#))
- Longitudinal Evaluation of Familial Frontotemporal Dementia Subjects ([LEFFTDS](#))
- Genetic Frontotemporal Dementia Initiative ([GENFI](#))
- Alzheimer's Disease Cooperative Study ([ADCS](#))
- Alzheimer's Disease Centers ([ADC](#))
- [The FTD Disorders Registry](#)



Alzheimer's
Drug Discovery
Foundation



The Association for
Frontotemporal Degeneration
Opening the gateway to help and a cure

Data Sharing: Applications should include a clear plan for data sharing and/or making available the results of the trial to the public.

Budget: Budgets can be flexible and in the range of \$500K to \$2M for trials ranging from 1-3 years. Leveraging other sources of funding or other ongoing trials is encouraged. Partnerships/co-funding with industry or other foundations is acceptable.

Applicant Eligibility: Applications may be submitted by non-profit or for-profit institutions, both public and private, worldwide. Please note that funding to for-profit entities is typically made as a program-related investment.

Application and Review Process:

Letter of Intent Deadline: Nov 15, 2016

Full Application Deadline: February 15, 2017

All letters of intent and applications must be submitted electronically at www.alzdiscovery.org following ADDF application guidelines. Applications should include confirmation of drug supply as well as an IRB-ready clinical trial protocol. Applications will be confidentially reviewed by a Joint Steering Committee appointed by the ADDF and AFTD. Applications from biotechnology companies will also be reviewed by ADDF's external Business Advisory Board.

To further discuss scientific or financial aspects of proposals, please contact:

Diana Shineman, PhD, *Senior Director, Scientific Affairs, ADDF*

Phone: 212-901-8007 / E-mail: dshineman@alzdiscovery.org

Nadine Tatton, PhD, *Scientific Director, AFTD*

Phone: 267-514-7221 / Email: ntatton@theaftd.org

For more information regarding the application process, please contact:

Heather Moore, JD, *Grants and Contracts Manager, ADDF*

Phone: 212-901-8019 / E-mail: hmoore@alzdiscovery.org