



REQUEST FOR PROPOSALS

Digital Assessment Tools for FTD and ALS Deadline: July 14, 2023

Frontotemporal degeneration (FTD) and amyotrophic lateral sclerosis (ALS), once considered separate neurodegenerative disorders, are now recognized to have many commonalities at the molecular, cellular, and clinical level. Behavioral and language symptoms characteristic of FTD can appear concurrently or over time in persons diagnosed with ALS; similarly, symptoms of motor neuron disease can occur in persons diagnosed with FTD. In addition, the hallmark pathological feature in both disorders is the aggregation of the RNA-binding protein TDP-43, while a hexanucleotide repeat expansion in C9orf72 is the most common genetic mutation in hereditary FTD, ALS, and FTD-ALS (also known as FTD-MND). As a result, experts have proposed that these disorders constitute a clinical spectrum, with some patients exhibiting primarily ALS symptoms, some exhibiting primarily FTD symptoms, and still others with overlapping symptom profiles. This intersection of FTD and ALS is a compelling argument for prioritizing the development of diagnostic tools and therapeutics applicable to both disorders to facilitate the alignment of clinical care practices as well as drug and biomarker development.

FTD and ALS present challenges to clinical care and research. For example, the small number of potential participants in clinical trials for these rare disorders increases the probability they will be underpowered. Symptoms observed in the clinical setting may not accurately reflect behavior in the home environment, while travel to clinical sites is burdensome. Digital assessment tools have the potential to overcome these challenges. Remote monitoring methods utilizing wearable sensors or handheld devices would allow for more frequent assessments, improving power. Data collection either in-home or in local clinics with a non-specialized clinical team member could increase frequency, accuracy and intraindividual reliability; and in addition, assessment in a local setting could also facilitate recruitment, increase diversity, and reduce travel burden. Despite these advantages and many innovative attempts, no digital assessment tool has yet been validated for non-exploratory use in regulatory-grade clinical trials for any neurodegenerative disorder. And despite the commonalities between FTD and ALS, the fields of ALS and FTD use different assessment tools to measure clinical severity and little effort has been devoted to the development of digital measures with relevance to both disorders. Advancing the development of digital tools with broad applicability across the FTD-ALS spectrum beyond the discovery stage toward validation would therefore be advantageous for both researchers and clinicians.

The Association for Frontotemporal Degeneration and the ALS Association have launched the **Digital Assessment Tools for FTD and ALS Awards** to drive progress in digital tool development at the intersection of ALS and FTD. This one-time funding opportunity will support projects seeking to refine, evaluate, adapt, or validate promising digital tools that have already undergone preliminary testing in humans, with a focus on aligning approaches across ALS and FTD.

Scope

Two types of applications will be considered:

Advancing tool development

These applications should clearly indicate the stage of development of the digital tool to be utilized and its relevance to FTD and ALS. Example of suitable research topics include but are not limited to:

- Adaptation or testing of a digital assessment developed for ALS in an FTD cohort or vice versa
- Further development, verification, or analytical validation of a digital assessment tool already tested in both ALS and FTD cohorts
- Head-to-head comparison of digital assessment tools developed for ALS or FTD across both disorders
- Evaluation or development of a digital tool from a related disease space in both ALS and FTD cohorts
- Harmonization of digital assessment tool data across FTD and ALS clinical cohorts to enable maturation of tools applicable to the populations and clinical settings of both disorders

Projects focused on the above topics can utilize existing data as well as data collected *de novo*.

Creating a conceptual model as a guide for digital outcome assessment development

To strengthen long-term development of digital assessment tools, this RFP will consider proposals to fund the development of a conceptual model that could in turn serve as the foundation for the creation of measurement models to quantify patient experience. The conceptual model should be inclusive of ALS and FTD, for example for the prodromal C9orf72 mutation or FTD-ALS. All projects should adhere to the [FDA guidance](#) series on Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments and should clearly explain how their project plan will address specific recommendations within that guidance.

This RFP does not support:

- Discovery-stage or pilot studies of a digital assessment tool not yet tested clinically
- Projects primarily designed to develop or expand a clinical database for future algorithm or tool development

Researchers and companies with ideas that are not included in the list of suggested topics above but could advance the development of digital assessment tools for research or care across FTD and ALS populations are encouraged to contact AFTD to discuss whether the project under consideration is within the scope of this funding opportunity.

Eligibility

The AFTD-ALS Association Digital Assessment Tools for FTD and ALS Awards are open to investigators worldwide at:

- Academic or other nonprofit research institutions
- For-profit organizations such as biotechnology or digital technology companies
- Other types of organizations may be eligible.
- Collaborative arrangements, e.g., between academia and industry or ALS and FTD researchers, are encouraged.

Applications must include evidence of clinical or research expertise in both ALS and FTD. This expertise may be provided by one individual with dual expertise or any combination of the principal investigator, co-principal investigator, another member of the research team, and outside collaborator/advisors.

Postdoctoral researchers cannot apply as the lead PI but can be co-PIs on a project team.

AFTD and the ALS Association are committed to increasing the diversity of the scientific workforce and encourage applications by researchers from underrepresented or historically excluded populations.

Award Information

Funding period: 2 years (January 1, 2024 – December 31, 2026)

Number of awards: Between 2-4 grants will be awarded based on the budgets of the top-ranked proposals.

Award Amount: Budget requests between \$150,000 to \$400,000 will be considered depending on the stage of development and scope of the project. All applications require submission of a detailed budget and corresponding budget rationale. A template for this purpose is provided in the application. Applicants contemplating project budgets outside the specified range should contact AFTD to discuss prior to submission.

Grant applicants at academic or non-profit institutions may request up to 10% of the approved budget to be allocated to indirect costs.

Sources of any supplemental funding from other organizations should be specified as noted below under “Submitting an application.”

Selection Process

Applications will be reviewed confidentially by AFTD and the ALS Association as well as a Scientific Review Panel of external experts from the ALS and FTD research community. Applications from for-profit companies will also be evaluated by a business reviewer.

The review panel will prioritize projects that:

- Demonstrate the requisite experience and scientific resources to support tool development
- Are likely to lead to demonstrable progress toward verification and eventual validation of a digital assessment tool to improve clinical care and/or research for people with FTD-ALS or FTD-MND

- Clearly define the context of use for the digital assessment tool being tested
- Increase alignment between the FTD and ALS fields of clinical research and clinical care
- Describe a clear and specific plan for responsible data management and data sharing with the research community

Funding decisions will be communicated by mid-October 2023.

Submitting an Application

The submission portal and detailed application instructions will be available on the AFTD website by May 26, 2023.

Applications should include the following elements:

- Executive lay abstract providing a concise overview of the project
- Research plan describing (A) rationale and background; (B) project plan and objectives; (C) experimental design and methods.
- Preliminary data
- Summary of the follow-on product development plan (beyond the specific project proposed) required to bring the digital assessment tool into widespread use
- Bibliography (most relevant references only)
- Biosketches for the principal investigator and co-PIs or collaborators
- Budget and justification, including any sources of supplemental funding as well as plans for financing further tool development beyond the funding period.
- Organization or individual holding the rights to the digital tool under development. If the PI does not hold the rights, describe any licensing or other agreements governing the continued development of the tool.
- Business overview (industry applicants only) to include:
 - Company description and history
 - Staff size and management structure
 - Evidence of financial stability (e.g., financial statement)
- Data management and sharing plan to include:
 - Platform or repository where the data will be stored
 - What precautions will be taken to ensure data privacy
 - Who can access the data and how requests for access will be reviewed

All applications must be submitted through the portal by the July 14 deadline to be considered for funding.

Submission deadline: July 14, 2023

Contact information

You are welcome to contact us to discuss your proposed project prior to submission or for answers to questions about eligibility, the submission process, or the online portal.

For questions on the application

process or submission portal contact:

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