DIAGNOSTICS ACCELERATOR: PERIPHERAL BIOMARKERS PROGRAM

FUNDING PRIORITIES

Modalities: Blood and other peripheral markers, including saliva, urine, and ocular biomarkers are encouraged. The development of CSF and neuroimaging biomarkers will not be considered for this program; however, we encourage the use of these modalities to validate proposed biomarkers.

Biomarker targets: Proposed approaches will be evaluated on biological plausibility linking the biomarker to disease pathophysiology. Examples of target areas of interest include, *but are not limited to:*

- Vascular injury and blood-brain barrier integrity
- Neuroinflammation
- Neuroprotection and Neurodegeneration
- Biomarkers of interest in fronto-temporal degeneration (FTD)
- Protein misfolding
- Synaptic integrity and/or activity
- Mitochondria and metabolic function

Other novel approaches that are supported by compelling evidence that **demonstrate a rational biological connection** to the disease process are encouraged.

Sample sharing program: Clinical validation of a biomarker requires well characterized samples across multiple cohorts. The Diagnostics accelerator has partnered with Janssen/Shionogi, Eisai and Roche pharmaceuticals to make available samples from their clinical trials to our researchers.

The peripheral RFP is open to all biomarker categories that will advance drug development for Alzheimer's and related dementias. The expected context of use, which defines a biomarker's intended use clinically as a diagnostic or in drug development, should be described in the application. These categories, **as defined by the FDA**, include diagnostic, monitoring, predictive, prognostic, pharmacodynamic/response, safety, and susceptibility/risk biomarkers. Additionally, the applicant should articulate where in the path to commercialization the study falls and what is the proposed plan forward.

PROJECT DETAILS

All proposals will be evaluated on scientific and technical merit, level of innovation, and investigator and organizational capabilities. Additionally, proposals will be evaluated on the following criteria:

- **Context of Use** concise description of the biomarker's specified use in in drug development
- **Methodological considerations** including sample collection and storage, quality and reliability of the assay used, and strategy for maximizing reproducibility
- **Samples** should be obtained from well-characterized cohorts and when possible, should include individuals from minority and disparity populations

The following types of projects will be supported through this RFP:

1. **Exploratory** awards will support pilot studies that aim to test the utility of an existing fluid biomarker approach for the first time in an Alzheimer's disease or related dementia population. These projects should already have preliminary human data from another disease indication. A limited number of awards will be considered in this category.

   Generally, projects at this stage will be awarded up to approximately $250,000 based on stage and scope of research. However, this is not a cap and higher funding levels will be considered if the proposed budget is well justified.

2. **Proof-of-principle** awards will support exploratory analyses of biomarkers at a small scale (e.g., 50-100 human samples) that are supported by human data demonstrating that the candidate markers correspond with disease pathophysiology. Preliminary assay validation data for the proposed studies should be included.

   Generally, projects at this stage will be awarded up to $500,000 based on stage and scope of research. However, if there is a compelling reason to go above this level, please justify this in your full proposal if invited.

3. **Validation** awards will support biomarkers that need to be tested at a larger scale (e.g., 500-1000 samples) and are supported by a significant body of human data demonstrating that the biomarker(s) correspond with disease pathophysiology. Applicants should be able to address how validation studies would move the biomarker towards the clinic and should define their strategies for regulatory approval and commercial scale-up. Assays should be well developed. Proposals should consider compatibility with existing sampling infrastructure, scalability, and intellectual property position, and standard operating procedures should be in place. Validation studies should compare peripheral analytes to quantitative measurements using PET and/or CSF, going beyond comparisons to cognition alone.

   Award amounts will be based on stage and scope of research.

Projects that succeed in the exploratory or proof-of-principle stage may be eligible for follow-on funding.

ELIGIBILITY

ACCESS TO CONSULTANTS

DATA SHARING

APPLICATION SUBMISSIONS

Review the **Application Instructions** for steps on applying.

For program-related inquiries, please contact:

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For application submission inquiries, please contact:

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