

DIAGNOSTICS ACCELERATOR: DIGITAL BIOMARKERS BODY OF THE APPLICATION INSTRUCTIONS

The Body of the Application should include the following:

- A. Project Narrative
- B. Study Population Questionnaire
- C. Budget and Justification
- D. Biographical Information

These four sections should be compiled into a single PDF and uploaded in the full proposal section of the [ADDF Funding Portal](#).

A. PROJECT NARRATIVE

The project narrative is the central part of the proposal and should contain the sub-sections 1-8 listed below (indicate each sub-section by number in the proposal). Expectations and evaluation criteria are listed in the [RFP](#). Sub-sections 1-6 should not exceed 15 pages of written text. *Legible* figures should be embedded in the text. Use at least 11pt. font and 1" margins.

1. Background and Rationale

This section should not exceed 2 pages.

- Provide the biological rationale that links the candidate biomarker(s) to disease pathophysiology. Refer to the [Diagnostics Accelerator Digital Biomarkers RFP](#) for expectations.
 - Describe the candidate biomarker's relevance to diagnosis or drug development for Alzheimer's disease and/or related dementias. Discuss related programs in the field; if any are known. Explain the advantages of your program.
 - Discuss the novelty of the proposed approach and its intended context of use (i.e. diagnostics, monitoring, prognostic, etc.).
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2. Supporting Data

Refer to the [Diagnostics Accelerator Digital Biomarkers RFP](#) for expectations and provide relevant supporting data.

- Include data that demonstrates how the symptom domain(s) measured by the candidate biomarker(s) is connected to the disease process.
 - Demonstrate the measurement's technical performance.
 - Include validation data for the methods used to quantify and qualify your digital test and include data collected in your target population for proof-of-principle and validation studies, or from another clinical population for exploratory studies.
 - Comment on available patient reactions to the device or technology (e.g. engagement, functionality, acceptability, interactivity, etc.).
 - **For validation projects**, provide data for the approach including accuracy, precision, consistency, and uniformity of the technology.
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3. Project Plan and Objectives

- **Objectives:** List specific aims and milestones with clearly defined go/no-go decision points for advancement of the project.

- Timeline: Provide a schedule for the completion of the proposed milestones/deliverables for each quarter of the year for each year of funding (this can be in table or Gantt chart format).
 - Discuss potential pitfalls of the program with sufficient risk assessment and criteria to substantiate continuation of the program at each milestone.
 - Discuss critical next experiments in order to advance the program to attract additional funding/licensing.
 - **For validation projects**, provide a clearly defined clinical context of use, outline strategies for commercial scale-up, manufacturing of wearables or sensors, possible cross-platform compatibility, and regulatory approval.
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4. Experimental Design and Methods

- Complete the [Study Population Questionnaire](#) (.doc).
- Provide details for each technology proposed and the measurement methodology (e.g. device properties, software information). Describe how the technology will be implemented and maintained. Include possible strategies if issues arise and any plans for the development of combined measures that may provide greater validity than an individual measure.
- Provide a statistical analysis plan. Include a power analysis to justify the number of subjects or samples per group. Has your power analysis accounted for previously observed variability in your outcome measures?
- Describe data collection methods, data analysis, storage, and security procedures. Outline the data sharing plan, including deidentification procedures, data storage, and process for accessing data.

Please note that it is the intention of the Diagnostics Accelerator that all data generated or used in each project should be made accessible to the research community through the ADDF/Gates Ventures digital data platform (under development). The funder may use these data to evaluate the validity of the digital biomarker. Noting that many cohorts have strict data sharing and standardization requirements, applications should include letters of support from the groups providing data sets that indicate agreement with this policy. In cases, where data sharing is not allowed due to regulatory issues or limitations related to informed consent, the investigator must provide a data sharing proposal describing the limitations on sharing and providing an alternative data sharing plan.

- **For validation studies**, describe the strategies for maximizing reproducibility, including standard operating procedures for missing data, documentation, etc.
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5. Description of Drug Discovery Team and Resources

- Describe the investigative team, showing that the required expertise and resources are in place to complete the study objectives.
 - Discuss the inclusion of any consultants with digital biomarker or clinical expertise in neurodegenerative disease that were involved in the design of the proposed studies or the development of the commercialization plan.
 - Where internal expertise is not available, include a description of external partners (e.g. consultants, contract research organizations) that will help to execute the research. (Please provide competitive quotes from more than one vendor where possible. Quotes should be uploaded in the Supplemental Materials packet).
 - Where applicable (and required for validation studies), identify any potential commercial partners and indicate whether you have initiated conversations with these companies.
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6. Intellectual Property (IP)

- Provide information on existing IP and stage of prosecution. If no IP currently exists, describe the projected plan to generate IP; note if you expect this project to generate new IP.
 - Indicate any freedom to operate issues.
 - Include a brief discussion on future directions and eventual path towards commercialization.
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7. Other Support

- List other financial support, awarded and pending.
- Include grant title, principal investigator, percent effort of investigator, granting agency, amount, and projected funding period.
- Indicate any overlap between the aims or investigator effort from other funding with the proposed work.

8. References

B. STUDY POPULATION QUESTIONNAIRE

Complete and submit the [Study Population Questionnaire form \(.doc\)](#).

C. BUDGET AND JUSTIFICATION

Complete the [budget template \(.doc\)](#) and provide a brief justification for each line item. Please review permissible costs [here](#).

D. BIOGRAPHICAL INFORMATION

Include a biosketch for each of the key personnel involved in the project. Existing [NIH biosketch forms](#) or other formats are accepted.

Alzheimer's Drug Discovery
Foundation



A GuideStar-
Rated Charity

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