FDARFIOOPD10262022

TITLE: RFI: A Clinical Outcomes Study for Brain-Computer Interface Communication Devices in Patients Living with ALS.

OPDIV: FDA, Office of the Commissioner, Office of Clinical Programs and Policies, Office of Orphan Product Development

This Request for Information (RFI) is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of FDA. The Government does not intend to award a contract on the basis of responses, nor otherwise pay for the preparation of any information submitted for FDA's use of such information. Acknowledgement of receipt of responses will not be made, nor will respondents be notified of FDA's evaluation of the information received. However, should such a requirement materialize, no basis for claims against the Government shall arise as a result of a response to this RFI or the Government's use of such information as either part of the evaluation process or for the development of specifications of a subsequent requirement.

BACKGROUND

On December 23, 2021, the President signed into law the "Accelerating Access to Critical Therapies for ALS Act." (ACT for ALS).[1] Section 5 establishes FDA's Rare Neurodegenerative Disease Grant Program. Grants or contracts may be awarded to public and private entities to cover the costs of research and development of interventions intended to prevent, diagnose, mitigate, treat, or cure, amyotrophic lateral sclerosis and other rare neurodegenerative diseases in adults and children. Such costs include, for example, those incurred with respect to development and critical evaluation of tools, methods, and processes to increase efficiency and productivity of medical product development.

Brain-computer interfaces and brain-machine interfaces, also known as BCIs or BMIs respectively, are potentially important technology in improving a patient's ability to communicate with others. These devices consist of hardware and software that communicate with the brain. The BCI hardware component captures brain signals, while the software component analyzes the signals and converts them into commands that control an external device, such as a computer or wheelchair. The ability to communicate with loved ones, caregivers, and providers, as well as the ability to interact independently with the environment may be lost as ALS progresses. Thus, FDA is keenly interested in BCIs because they may be able to fulfill this unmet need.

The assessment of benefit for BCI devices meant to enable communication may be challenging. The FDA is interested in patient-centered assessments with evidence of validity and reliability that are fit-for-purpose for regulatory review. The assessment of communication in ALS patients with dysarthria has often focused on outcomes that are secondary to the ability to communicate, such as quality of life or depression. Direct assessments of communication effectiveness may provide a better evaluation of treatment via BCI devices. However, existing measures of communication ability and effectiveness may not be fit-for-purpose for use in clinical studies evaluating the effectiveness of BCI devices to improve communication in patients living with

[1] P.L. 117-79 (accessed at https://www.congress.gov/117/plaws/publ79/PLAW-117publ79.pdf).

ALS. During product review, FDA desires to ensure that appropriate and meaningful clinical outcome assessments (COAs) are used. Such COA measures will assist FDA and device manufacturers not only to assess the effectiveness of such BCI devices, but may also inform medical device development and modification, and guide clinicians in patient care in the future.

To this end, FDA may desire to conduct a review of available COAs and interviews of patients and caregivers as well as healthcare providers related to outcomes important to them with the goal of identifying where gaps may exist and where further development of COAs may be warranted. In anticipation of a future need to conduct a systematic review and evaluation of available assessments of communication ability and effectiveness for use with patients with ALS, the Government is publishing this RFI to obtain information from organizations with the appropriate technical capabilities.

PURPOSE AND OBJECTIVES

The overarching objective of this RFI is to obtain declarations of technical capabilities and various information, data, and materials from qualified business concerns.

The specific project objective is to conduct a BCI-focused systematic literature review and patient and caregiver interviews in the populations of interest and publish one or more peer reviewed manuscripts to ensure broad access to a detailed description of methods and results, including the underlying data.

For advice and transparency, FDA anticipates that such a study should include a Patient Consulting Committee comprised of patients, patient-advocates, and/or caregivers. Furthermore, patients, patient-advocates, and/or caregivers should represent a diverse group with regard to sex, race, ethnicity, age, educational level, and geographical diversity.

This qualitative research study should follow all applicable laws, and regulations, and consider recommendations in relevant FDA Guidances. These include but are not limited to:

- Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation;[2]
- Guidance for Industry and Food and Drug Administration Staff; Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications;[3] and
- Patient Engagement in the Design and Conduct of Medical Device Clinical Studies: Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders.[4]

The study should also abide by all applicable laws and regulations regarding human subject protection, privacy, and data security.

---

[2] *Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation* (January 2022) (accessed at https://www.fda.gov/media/141565/download)

[3] *Guidance for Industry and Food and Drug Administration Staff; Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications* (Aug 2019) (accessed at https://www.fda.gov/media/99769/download).

[4] *Patient Engagement in the Design and Conduct of Medical Device Clinical Studies: Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders* (Jan 26, 2022) (accessed at https://www.fda.gov/media/130917/download).

INFORMATION SOUGHT

Responses to this RFI shall address the following:

1. A description of technical capabilities to perform a systematic review and qualitative study in patients living with ALS and their caregivers as well as their healthcare providers;
2. Potential study design;
3. Protocol development, considering:
    a. The population of interest is patients living with ALS patients and their caregivers; and
    b. Potential methodology
4. Recruitment strategy; and
5. Human subject protection and privacy requirements.

Any response to this RFI provided should be well documented including prior experience with the federal government.

All respondents are asked to indicate the type and size of your business organization, e.g., Large Business, Small Business, Veteran-owned Small Business, Service-Disabled Veteran-Owned Small Business, Hubzone Small Business, Small Disadvantaged Business, Women-Owned Business, 8(a), Historically Black College or University/Minority Institution (HBCU/MI), educational institution, profit/non-profit hospital, or other nonprofit organization. Interested parties capable of furnishing the information requested above may submit capability statements via email in Word, PowerPoint, or PDF format. Responses shall be limited to 10-12 pages.

After responses to this RFI are received, the Government may subsequently post a Request for Proposals in FY 2023 to obtain contract services for a BCI-focused systematic review and qualitative study in patients living with ALS and their caregivers, as well as their healthcare providers. Parties desiring to compete for such contract must have signed-up and registered for a free SAM.gov account in advance. Please allow adequate time for SAM account registration.

Responses to this RFI must be received not later than **2:00 PM EST**, **December 5, 2022.** Capability statements will not be returned and will not be accepted after the due date.

Documentation should be emailed to: Howard S. Yablon at howard.yablon@fda.hhs.gov

Disclaimer and Important Notes. This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed. Information provided will be used to assess tradeoffs and alternatives available for the potential requirement and may lead to the development of a solicitation. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted.

Any solicitation resulting from the analysis of information obtained will be announced to the public in Federal Business Opportunities in accordance with the FAR Part 5. However,

responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality. No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).