FDA Office of Orphan Products Development (OOPD)

Systematic Review of Clinical Outcome Assessments for Communication Brain-Computer Interface Devices in Amyotrophic Lateral Sclerosis

Application Instructions and Helpful Hints

OOPD has posted general instructions and helpful hints for applying for natural history grants and clinical trial grants which provide more details to help navigate the application process. **Specific items of importance or those regarding this RFA explicitly are noted below.**

Application Due Date:

The application submission deadline for this Request for Application (RFA) is **May 24, 2023** by 11:59 PM Eastern Time. **Late applications will not be accepted.**

Helpful Hints:

- Applicants should review the following prior to application submission:
  - RFA-FD-23-030
  - How to Apply - Application Guide for Grants & Funding
- All applications must be submitted electronically through Grants.gov

Pre-Application Registrations:

Helpful Hints: **Required registrations for System for Award Management (SAM), eRA Commons, and Grants.gov can take 6 weeks or more,** so applicants are encouraged to begin this process as outlined in the RFA well before the application submission date.

General Application Instructions:

- Applicants should refer to the **SF424 (R&R) Application Guide** posted by NIH for detailed instructions on completing the SF424 (R&R) forms.

SF424 (R&R) "APPLICATION FOR FEDERAL ASSISTANCE" (Pages 1-2):

- Only "New" applications will be accepted.
- The title field is limited to 200 characters, including the spaces between words and punctuation. Use abbreviations as needed to ensure that the title is descriptive.
- Total Federal Funds Requested: Enter total (direct and indirect) federal funds requested from OOPD for the entire project period for a maximum of 2 years of support.

SF424 "RESEARCH & RELATED Other Project Information": Budget: FDA's Orphan Products Clinical Trial Grants Program uses the Research & Related Budget Component. The duration of the project period is anticipated to be up to one year for the UH2 Phase, and up to one additional year for the UH3 Phase. Application budgets should not exceed total costs of (direct and indirect costs) for year 1 (UH2 Phase) of $200,000 and year 2 (UH3 Phase) of $300,000.

Helpful Hint: Applicants must provide a detailed budget for each requested year and attach a budget

justification. Failure to include a well justified budget is a frequent weakness of grant applications.

SF424 "PHS 398 Research Plan": Research Strategy: This section is limited to 30 pages. FDA does not follow the order/headings that are included in the NIH's 424 R&R Application Guide. **The following sections should be included under the Research Strategy section (see RFA for additional details on each scoring criteria):**

1. Rationale
2. Study Design/Approach
3. Investigator(s)
4. Infrastructure and Resources
5. Ability to Advance the Current Field

Helpful Hint: When addressing the Research Strategy portion of the grant proposal, applicants should first describe the UH2 Phase (Literature Review and Key Opinion Leader (KOL) Interviews) and then the UH3 Phase (Patient and Caregiver Interviews) with a clear demarcation between them. (It is not necessary to repeat background information or details of methods in the UH3 portion that were provided in the UH2 portion).

Helpful Hint: The Study Design/Approach section of the Research Strategy should include clearly specified, well-defined milestones and timelines for assessing progress in both the UH2 and UH3 phases, as well as for progressing from the UH2 to UH3 Phase.

Letters of support - The following should be included (see RFA for additional details):

1. Study Sites and Key Personnel
2. Intellectual Property (if applicable)

Appendix - The following should be included (see RFA for additional details):

1. Protocols and Interview Guides: Draft protocols for each phase as described in the Research Strategy section. Draft interview guides/scripts should also be included with the protocol.
2. Informed Consents: Consent forms, assent forms, and any other information given to a participant must be provided and must comply with all elements of Human Subject Research per 21 CFR 50.25.

Helpful Hint: Missing study protocols and informed consent/assent documents are a frequent weakness noted by panel reviewers of OOPD's grant applications.

Useful Links:

- **FDA Office of Orphan Products Development**
- **FDA Orphan Products Grants Program**
- **FDA Rare Neurodegenerative Disease Grant Program**
- **Grants Forms Library**
- **Grants.gov Applicant FAQs**
- **Grants.gov Submitting Your Application**
- **Grants 101**
- **FDA Clinical Outcome Assessments (COAs) in Medical Device Decision-Making**
- **FDA Patient Preference Information (PPI) in Medical Device Decision-Making**
- **FDA Center for Devices and Radiological Health Patient Engagement**
- **Factors to Consider When Making Benefit-Risk Determinations in Medical Device**

Premarket Approval and De Novo Classifications: Guidance for Industry and Food and Drug Administration Staff

- **Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations: Guidance for Industry and Food and Drug Administration Staff**