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<th>Award Mechanism</th>
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<tr>
<td>Pilot Clinical Trial Award</td>
<td>Independent investigators at or above the level of Assistant Professor (or equivalent)</td>
<td>• Supports exploratory clinical trials of novel therapeutics to demonstrate feasibility and inform the design of more advanced trials in ALS. &lt;br&gt; • Must support a clinical trial and may not be used for preclinical research studies. &lt;br&gt; • Preliminary data are required. &lt;br&gt; • Applications investigating a therapeutic must include plans to generate biomarker data. Biomarkers may measure target engagement, pharmacodynamic effects, and/or be predictive/cohort selective. <strong>Clinical Care Tier:</strong> &lt;br&gt; • Applications not investigating a novel therapeutic, but proposing a clinical trial to optimize established ALS clinical care, may submit under the Clinical Care Tier. &lt;br&gt; • Types of efforts that will be supported include: &lt;br&gt; • Optimization of respiratory care strategies &lt;br&gt; • Improvements to approved devices and assistive technologies &lt;br&gt; • Specific symptom management strategies <strong>Pre-application submission is required; application submission is by invitation only.</strong></td>
<td>• The maximum allowable funding for the entire period of performance is <strong>$2,000,000</strong> for direct costs. &lt;br&gt; • <strong>Clinical Care Tier:</strong> &lt;br&gt; The maximum allowable funding for the entire period of performance is <strong>$1,000,000</strong> for direct costs. &lt;br&gt; • Indirect costs may be proposed in accordance with the institution’s negotiated rate agreement. &lt;br&gt; • The maximum period of performance is 3 years.</td>
<td>Pre-Application: (Preproposals): &lt;br&gt; April 29, 2022 &lt;br&gt; 5:00 p.m. Eastern time &lt;br&gt; Application: &lt;br&gt; July 28, 2022 &lt;br&gt; 11:59 p.m. Eastern Time</td>
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**Grants.gov Funding Opportunity Number:**  
W81XWH-22-ALSRP-PCTA
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| Clinical Biomarker Development Award    | Independent investigators at all academic levels (or equivalent)             | • Supports maximization of clinical ALS resources and biorepositories to better define subtypes, predict therapeutic response, or assess prognosis.  
• Emphasis is on the development of clinical biomarkers to enrich clinical trials in ALS. Biomarkers may measure target engagement, pharmacodynamic effects, and/or be predictive/cohorts-selective.  
• Data and resources sharing (biosamples/data sets/analyses) are important and scored criteria.  
• Types of efforts that will be supported include:  
  • Using patient-based resources to link biosamples to rigorous molecular data  
  • Collecting and analyzing biospecimens as a companion to an anticipated/ongoing clinical trial  
  • Correlating clinical trial-related data (e.g., biosample analyses, imaging, or epidemiological data) with clinical outcomes/ responses to therapies  
• Pre-application submission is required; application submission is by invitation only. | • The maximum allowable funding for the entire period of performance is $500,000 for direct costs.  
• Indirect costs may be proposed in accordance with the institution’s negotiated rate agreement.  
• The maximum period of performance is 2 years. | Pre-Application: (Preproposal):  
April 29, 2022  
5:00 p.m. Eastern time  
Application:  
July 28, 2022  
11:59 p.m. Eastern Time |

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| Therapeutic Development Award | Independent investigators at all academic levels (or equivalent) |  • Supports secondary preclinical validation and Investigational New Drug (IND)-enabling studies of therapeutics for ALS.  
  • Preliminary data are required, including strong rationale and efficacy data for the chosen therapeutic in at least one ALS-relevant model system.  
  • Biomarker development and/or characterization (if not already validated), in parallel to the main therapeutic effort, is a critical component of the Therapeutic Development Award.  
  • Pre-application submission is required; application submission is by invitation only. |  • The maximum allowable funding for the entire period of performance is $1,000,000 for direct costs.  
  • Indirect costs may be proposed in accordance with the institution’s negotiated rate agreement.  
  • The maximum period of performance is 3 years. | Pre-Application:  
  (Preproposal):  
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| Therapeutic Idea Award | Independent investigators at all academic levels (or equivalent) | Supports hypothesis-driven preclinical therapeutic development.  
  Projects focusing primarily on investigating ALS pathophysiology are outside the scope of this award mechanism.  
  Preliminary data are not required.  
  Early Career Investigators are encouraged to apply.  
  **Biomarker Option:** Applications that include development of biomarkers in parallel to the main therapeutic effort, and that meet criteria outlined in the Funding Opportunity Announcement, will qualify for a higher level of funding.  
  **Pre-application submission is required; application submission is by invitation only.** | The maximum allowable funding for the entire period of performance is $500,000 for direct costs.  
  **Biomarker Option:** The maximum allowable funding for the entire period of performance is $600,000 for direct costs.  
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