

**US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)  
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)  
FISCAL YEAR 2021 (FY21) AMYOTROPHIC LATERAL SCLEROSIS  
RESEARCH PROGRAM (ALSRP)**

**DESCRIPTION OF REVIEW PROCEDURES**

The programmatic strategy implemented by the FY21 ALSRP called for applications in response to program announcements (PAs) for four award mechanisms released in February 2021:

- Therapeutic/Biomarker Pilot Trial Award
- Therapeutic Development Award
- Clinical Development Award
- Therapeutic Idea Award

Pre-applications were received for these four PAs in April 2021 and screened in May 2021 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PAs.

Applications were received for these four PAs in July 2021 and peer reviewed in September 2021. Programmatic review was conducted in November 2021.

In response to the Therapeutic/Biomarker Pilot Trial Award PA, Five pre-applications were received and the Principal Investigators (PIs) of four of these were invited to submit a full application. Four compliant applications were received and two (50%) were recommended for funding for a total of \$6.6 million (M).

In response to the Therapeutic Development Award PA, 14 pre-applications were received and the PIs of 11 of these were invited to submit a full application. Ten compliant applications were received and six (60%) were recommended for funding for a total of \$7.4M.

In response to the Clinical Development Award PA, 21 pre-applications were received and the PIs of 18 of these were invited to submit a full application. Sixteen compliant applications were received and nine (56%) were recommended for funding for a total of \$6.3M.

In response to the Therapeutic Idea Award PA, 89 pre-applications were received and the PIs of 63 of these were invited to submit a full application. Sixty compliant applications were received and 23 (38%) were recommended for funding for a total of \$16.2M.

Submission and award data for the FY21 ALSRP are summarized in the table below.

**Table 1. Submission/Award Data for the FY21 ALSRP\***

<b>Mechanism</b>	<b>Pre-Applications Received</b>	<b>Pre-Applications Invited (%)</b>	<b>Compliant Applications Received</b>	<b>Applications Recommended for Funding (%)</b>	<b>Total Funds</b>
Therapeutic/Biomarker Pilot Trial Award	5	4 (80%)	4	2 (50%)	\$6.6M
Therapeutic Development Award	14	11 (79%)	10	6 (60%)	\$7.4M
Clinical Development Award	21	18 (86%)	16	9 (56%)	\$6.3M
Therapeutic Idea Award	89	63 (71%)	60	23 (38%)	16.2M
<b>Total</b>	<b>129</b>	<b>96 (74%)</b>	<b>90</b>	<b>40 (44%)</b>	<b>\$36.5M</b>

\*These data reflect funding recommendations only. Pending FY21 award negotiations, final numbers will be available after September 30, 2022.

## **THE TWO-TIER REVIEW SYSTEM**

The USAMRDC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) (now called the National Academy of Medicine) of the National Academy of Sciences report, *Strategies for Managing the Breast Cancer Research Program: A Report to the Army Medical Research and Development Command*. The IOM report recommended a two-tier review process and concluded that the best course would be to establish a peer review system that reflects not only the traditional strengths of existing peer review systems, but also is tailored to accommodate program goals. The Command has adhered to this proven approach for evaluating competitive applications. An application must be favorably reviewed by both levels of the two-tier review system to be funded.

### **THE FIRST TIER—Scientific Peer Review**

Therapeutic/Biomarker Pilot Trial Award, Therapeutic Development Award, Clinical Development Award, and Therapeutic Idea Award applications were peer reviewed in September 2021 by six panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Each peer review panel included a Chair, scientific reviewers, consumer reviewers, and a nonvoting Scientific Review Officer. The primary responsibility of the panelists was to review the technical merit of each application based upon the evaluation criteria specified in the relevant PA.

### **Individual Peer Review Panels**

The Chair for each panel presided over the deliberations. Applications were discussed individually. The Chair called upon the assigned reviewers for an assessment of the merits of each application using the evaluation criteria published in the appropriate PA. Following a panel

discussion, the Chair summarized the strengths and weaknesses of each application, and panel members then rated the applications confidentially.

## **Application Scoring**

*Evaluation Criteria Scores:* Panel members were asked to rate each peer review evaluation criterion as published in the appropriate PA. A scale of 1 to 10 was used, with 1 representing the lowest merit and 10 the highest merit, using whole numbers only. The main reasons for obtaining the criteria ratings were to (1) place emphasis on the published evaluation criteria and provide guidance to reviewers in determining an appropriate overall score, and (2) provide the applicant, the Programmatic Panel, and the Command with an informed measure of the quality regarding the strengths and weaknesses of each application. The evaluation criteria scores were not averaged or mathematically manipulated in any manner to connect them to the global or percentile scores.

*Overall Score:* To obtain an overall score, a range of 1.0 to 5.0 was used (1.0 representing the highest merit and 5.0 the lowest merit). Reviewer scoring was permitted in 0.1 increments. Panel member scores were averaged and rounded to arrive at a two-digit number (1.2, 1.9, 2.7, etc.). The following adjectival equivalents were used to guide reviewers: Outstanding (1.0–1.5), Excellent (1.6–2.0), Good (2.1–2.5), Fair (2.6–3.5), and Deficient (3.6–5.0).

*Summary Statements:* The Scientific Review Officer on each panel was responsible for preparing a Summary Statement reporting the results of the peer review for each application. The Summary Statements included the evaluation criteria and overall scores, peer reviewers' written comments, and the essence of panel discussions. This document was used to report the peer review results to the Programmatic Panel. It is the policy of the USAMRDC to make Summary Statements available to each applicant when the review process has been completed.

## **THE SECOND TIER—Programmatic Review**

Programmatic review was conducted in November 2021 by the FY21 Programmatic Panel, which was comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in ALS. Programmatic review is a comparison-based process that considers scientific evaluations across all disciplines and specialty areas. Programmatic Panel members do not automatically recommend funding applications that were highly rated in the technical merit review process; rather, they carefully scrutinize applications to allocate the limited funds available to support each of the award mechanisms as wisely as possible.

Programmatic review criteria published in the PA for the Therapeutic/Biomarker Pilot Trial Award were as follows: Ratings and evaluations of the scientific peer review panels; adherence to the intent of the award mechanism; relative clinical impact; and program portfolio composition.

Programmatic review criteria published in the PA for the Therapeutic Development Award were as follows: Ratings and evaluations of the scientific peer review panels; adherence to the intent

of the award mechanism; relative impact including translational potential; and program portfolio composition.

Programmatic review criteria published in the PA for the Clinical Development Award were as follows: Ratings and evaluations of the scientific peer review panels; adherence to the intent of the award mechanism; program portfolio composition; and relative impact.

Programmatic review criteria published in the PA for the Therapeutic Idea Award were as follows: Ratings and evaluations of the scientific peer review panels; adherence to the intent of the award mechanism; relative innovation and impact; and program portfolio composition.

After programmatic review, the Commanding General, USAMRDC, approved funding for the applications recommended during programmatic review.