US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS
FISCAL YEAR 2023 (FY23) AMYOTROPHIC LATERAL SCLEROSIS RESEARCH PROGRAM (ALSRP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY23 ALSRP called for applications in response to program announcements (PAs) for four award mechanisms released in February 2023:

- Clinical Biomarker Development Award (CBDA)
- Pilot Clinical Trial Award (PCTA)
- Therapeutic Development Award (TDA)
- Therapeutic Idea Award (TIA)

Pre-applications were received for these four PAs in April 2023 and screened in May 2023 for the PCTA and CBDA and in June for the TDA and TIA 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 2023 and peer reviewed in September 2023. Programmatic review was conducted in November 2023.

In response to the CBDA PA, 27 pre-applications were received and the Principal Investigators (PIs) of 19 of these were invited to submit a full application. Fifteen compliant applications were received and 5 (33.3%) were recommended for funding for a total of $5.7 million (M).

In response to the PCTA PA, 12 pre-applications were received and the PIs of 8 of these were invited to submit a full application. Six compliant applications were received and 3 (50.0%) were recommended for funding for a total of $6.1M.

In response to the TDA PA, 18 pre-applications were received and the PIs of 14 of these were invited to submit a full application. Eight compliant applications were received and 3 (37.5%) were recommended for funding for a total of $6.0M.

In response to the TIA PA, 87 pre-applications were received and the PIs of 53 of these were invited to submit a full application. Forty-seven compliant applications were received and 18 (38.3%) were recommended for funding for a total of $16.9M.

Submission and award data for the FY23 ALSRP are summarized in the table(s) below.

Table 1. Submission/Award Data for the FY23 ALSRP*

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Clinical Biomarker Development Award	27	19 (70.4%)	15	5 (33.3%)	$5,727,132.00
Pilot Clinical Trial Award	8	5 (62.5%)	4	2 (50.0%)	$4,613,057.00
Pilot Clinical Trial Award – Clinical Care Tier	4	3 (75%)	2	1 (50.0%)	$1,489,508.00
Therapeutic Development Award	18	14 (77.8%)	8	3(38.3%)	$6,027,637.00
Therapeutic Idea Award	72	43 (59.7%)	39	13 (33.3%)	$12,668,312.00
Therapeutic Idea Award – Biomarker Option	15	10 (66.7%)	8	5 (62.5%)	$4,184,954.00
Total	**144**	**94 (65.3%)**	**76**	**29 (38.2%)**	**$34,710,600.00**

*These data reflect funding recommendations only. Pending FY23 award negotiations, final numbers will be available after September 30, 2023.

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

CBDA, PCTA, TDA, and TIA applications were peer reviewed in September 2023 by six panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Peer review was conducted via teleconference for the CBDA by a single panel (13 scientists and 2 consumer reviewers), for the PCTA by a single panel (11 scientists and 1 consumer reviewer), for the TDA by a single panel (4 scientists and 2 consumer reviewers), and for the TIA by three panels (23 scientists and 6 consumer reviewers).

Each peer review panel included a Chair, an average of eight scientific reviewers, an average of 1.8 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 2023 by the FY23 Programmatic Panel that 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 CBDA were as follows: ratings and evaluations of the scientific peer review panels; relevance to the mission of the DHP and FY23 ALSRP as evidenced by the following: adherence to the intent of the award mechanism, program portfolio composition, and relative impact.

Programmatic review criteria published in the PA for the PCTA were as follows: ratings and evaluations of the scientific peer review panels; relevance to the mission of the DHP and FY23 ALSRP as evidenced by the following: adherence to the intent of the award mechanism, program portfolio composition, programmatic relevance, and relative clinical impact.

Programmatic review criteria published in the PA for the TDA were as follows: ratings and evaluations of the scientific peer review panels; relevance to the mission of the DHP and FY23 ALSRP as evidenced by the following: adherence to the intent of the award mechanism, relative impact, including transition potential, and program portfolio composition.

Programmatic review criteria published in the PA for the TIA were as follows: ratings and evaluations of the scientific peer review panels; relevance to the mission of the DHP and FY23 ALSRP as evidenced by the following: adherence to the intent of the award mechanism, relative innovation and impact, and program portfolio composition.

After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.