

**US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2023 (FY23) MULTIPLE SCLEROSIS RESEARCH PROGRAM (MSRP)**

DESCRIPTION OF REVIEW PROCEDURES

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

- Clinical Trial Award (CTA)
- Early Investigator Research Award (EIRA)
- Exploration - Hypothesis Development Award (EHDA)
- Investigator-Initiated Research Award (IIRA)

Pre-applications were received for the CTA, EHDA, and IIRA PAs in June 2023 and screened in July 2023 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. Letters of Intent (LOI) were received for the EIRA in July 2023.

Applications were received for these four PAs in October 2023 and peer reviewed in December 2023. Programmatic review was conducted in February 2024.

In response to the Clinical Trial Award PA, 36 pre-applications were received and the Principal Investigators (PIs) of 23 of these were invited to submit a full application. Nineteen compliant applications were received and two (10.53%) were recommended for funding for a total of \$3.64 million (M).

In response to the Early Investigator Research Award PA, 24 pre-applications (letters of intent) were received. Twenty compliant applications were received and eight (40.00%) were recommended for funding for a total of \$2.53M.

In response to the Exploration – Hypothesis Development Award PA, 73 pre-applications were received and the PIs of 46 of these were invited to submit a full application. Thirty-nine compliant applications were received and 11 (28.20%) were recommended for funding for a total of \$2.75M.

In response to the Investigator-Initiated Research Award PA, 94 pre-applications were received and the PIs of 60 of these were invited to submit a full application. Fifty-one compliant applications were received and nine (17.65%) were recommended for funding for a total of \$8.55M.

Submission and award data for the FY23 MSRP are summarized in the tables below.

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

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Clinical Trial Award	36	23 (63.89%)	19	2 (10.53%)	\$3.64M
Early Investigator Research Award**	24	NA	20	8 (40.00%)	\$2.53M
Exploration - Hypothesis Development Award	73	46 (63.01%)	39	11 (28.20%)	\$2.75M
Investigator-Initiated Research Award	94	60 (63.83%)	51	9 (17.65%)	\$8.55M
Total	227	129 (56.83%)	129	30 (23.26%)	\$17.47M

*These data reflect funding recommendations only. Pending FY23 award negotiations, final numbers will be available after September 30, 2024.

**Pre-applications in the form of LOI invitations were not applicable (NA).

Table 2. Submission/Award Data for the FY23 MSRP*

Topic Area	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Central Nervous System Regenerative Potential in Demyelinating Conditions	53	12 (22.6%)	\$7.56M
Correlates of Disease Activity and Progression in MS	20	6 (30%)	\$2.70M
Factors Contributing to or Associated with MS Etiology, Prodrome, Onset, and Disease Course	25	7 (28%)	\$2.03M
Biology and Measurement of MS Symptoms	12	3 (25%)	\$1.54M
Promoting Repair, Neuroprotection, and Remyelination in MS	9	0 (0%)	\$0.0M
Treatment of MS Symptoms	10	2 (20%)	\$3.64M
Total	129	30 (23.26%)	\$17.47M

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

Clinical Trial Award, Early Investigator Research Award, Exploration – Hypothesis Development Award, and Investigator Initiated Research Award applications were peer reviewed in December 2023 by nine panels of researchers, clinicians, and consumer advocates based on the evaluation criteria specified in the PAs.

Peer review was conducted via videoconference. Each peer review panel included a Chair, an average of seven scientific reviewers, an average of two 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 February 2024 by the FY23 Programmatic Panel, comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in multiple sclerosis. 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 PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance; relative impact; program portfolio composition; and adherence to the intent of the award mechanism. After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.