US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC) CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP) FISCAL YEAR 2023 (FY23) LUNG CANCER RESEARCH PROGRAM (LCRP)

DESCRIPTION OF REVIEW PROCEDURES

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

- Idea Development Award (IDA)
- Translational Research Award (TRA)
- Patient-Centered Outcomes and Survivorship Award (PCOSA)

Pre-applications were received for the IDA and TRA PAs in May 2023. Letters of Intent (LOIs) were received for the PCOSA PA in July 2023.

Applications were received for the IDA and TRA PAs in August 2023 and peer reviewed in September 2023. Programmatic review was conducted in December 2023.

Applications were received for the PCOSA PA in August 2023 and peer reviewed in September 2023. Programmatic review was conducted in December 2023.

In response to the IDA PA, 214 pre-applications were received; 116 compliant applications were received, and 15 (12.9%) were recommended for funding for a total of \$12.42 million (M).

In response to the TRA PA, 76 pre-applications were received; 35 compliant applications were received, and 2 (5.7%) were recommended for funding for a total of \$2.86M.

In response to the PCOSA PA, 21 LOIs were received; 15 compliant applications were received, and 3 (20.0%) were recommended for funding for a total of \$2.83M.

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

Mechanism	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
IDA	116	15 (12.9%)	\$12.42M
TRA	35	2 (5.7%)	\$2.86M
PCOSA	15	3 (20.0%)	\$2.83M
Totals	166	20 (10.8%)	\$18.11M

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

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

Table 2. FY23 LCRP Application Data by Area of Emphasis 1**

Area of Emphasis	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Biology and Etiology: Understand the molecular mechanisms of initiation and progression to lung cancer.	20	1 (5.0%)	\$0.86M
Biology and Etiology: Understand contributors to lung cancer development other than tobacco.	4	1 (25.0%)	\$0.89M
Prevention: Identify innovative strategies for prevention of the occurrence of lung cancer(s) or subsequent primaries.	0	0 (0.0%)	\$0.00M
Prevention: Identify innovative strategies for the prevention of recurrence or metastases from lung cancer.	10	1 (10.0%)	\$0.78M
Detection, Diagnosis, and Surveillance: Improve approaches to screening and early detection of lung cancer.	11	0 (0.0%)	\$0.00M
Detection, Diagnosis, and Surveillance: Identify strategies for prompt detection and/or characterization of progressive disease.	9	1 (11.0%)	\$0.85M
Treatment and Prognosis: Identify innovative strategies for the treatment of lung cancer, including overcoming resistance.	81	10 (12.3%)	\$9.22M
Treatment and Prognosis: Develop or optimize biomarkers to assist with therapeutic decision-making.	5	0 (0.0%)	\$0.00M
Treatment and Prognosis: Enhance the treatment and understanding of brain metastases in lung cancer.	7	1 (14.3%)	\$0.93M
Health Outcomes and Survivorship: Identify and understand the long-term and cumulative effects of lung cancer and its treatment(s) with respect to the impact of comorbidities on patient care and also, more broadly, in respect to their effects on patients and their quality of life including, but not	15	4 (26.7%)	\$3.65M

Area of Emphasis	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
limited to, physiological,			
psychosocial, cognitive, and			
financial effects.			
Disparities: Advance equity and			
reduce lung cancer disparities	4	1 (25 00/)	\$0.93M
among underserved and	4	1 (25.0%)	\$0.95W
underrepresented populations.			
Totals	166	20 (12.0%)	\$18.11M

^{**}The Area of Emphasis was selected by the applicant at the time of submission.

Table 3. FY23 LCRP Application Data by Area of Emphasis 2***

Area of Emphasis	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Biology and Etiology: Understand the molecular mechanisms of initiation and progression to lung cancer.	18	2 (11.1%)	\$1.74M
Biology and Etiology: Understand contributors to lung cancer development other than tobacco.	2	0 (0.0%)	\$0.00M
Prevention: Identify innovative strategies for prevention of the occurrence of lung cancer(s) or subsequent primaries.	4	1 (25.0%)	\$0.87M
Prevention: Identify innovative strategies for the prevention of recurrence or metastases from lung cancer.	9	3 (33.3%)	\$3.10M
Detection, Diagnosis, and Surveillance: Improve approaches to screening and early detection of lung cancer.	1	0 (0.0%)	\$0.00M
Detection, Diagnosis, and Surveillance: Identify strategies for prompt detection and/or characterization of progressive disease.	9	0 (0.0%)	\$0.00M
Treatment and Prognosis: Identify innovative strategies for the treatment of lung cancer, including overcoming resistance.	24	0 (0.0%)	\$0.00M

Area of Emphasis	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
Treatment and Prognosis: Develop or optimize biomarkers to assist with therapeutic decision-making.	28	5 (17.9%)	\$4.58M
Treatment and Prognosis: Enhance the treatment and understanding of brain metastases in lung cancer.	0	0 (0.0%)	\$0.00M
Health Outcomes and Survivorship: Identify and understand the long-term and cumulative effects of lung cancer and its treatment(s) with respect to the impact of comorbidities on patient care and also, more broadly, in respect to their effects on patients and their quality of life including, but not limited to, physiological, psychosocial, cognitive, and financial effects.	2	0 (0.0%)	\$0.00M
Disparities: Advance equity and reduce lung cancer disparities among underserved and underrepresented populations.	8	2 (25.0%)	\$1.97M
Not selected. Totals ***The Arms of French size and a stable that the selection of the se	61 166	7 20 (12.0%)	\$5.85M \$18.11M

^{***}The Area of Emphasis was selected by the applicant at the time of submission. The applicant was only required to choose one Area of Emphasis and had the option of choosing a second. This table reports the second Area of Emphasis chosen by the applicant if provided.

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

IDA, TRA, and PCOSA applications were peer reviewed in September 2023 by nine 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 the panel members then rated the applications confidentially.

Application Scoring

Evaluation Criteria Scores: The 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 December 2023 by the FY23 Programmatic Panel, which is comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in lung cancer. 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. The programmatic review criteria published in the PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance;

adherence to the intent of the award mechanism; program portfolio composition; and relative impact, innovation, and relevance to military health. After programmatic review, the applications recommended for funding were sent to the Commanding General, USAMRDC, for approval.