

**US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND (USAMRMC)  
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)  
FISCAL YEAR 2016 (FY16) BREAST CANCER RESEARCH PROGRAM (BCRP)**

**DESCRIPTION OF REVIEW PROCEDURES**

The programmatic strategy implemented by the FY16 BCRP called for applications in response to the Breakthrough Award Levels 3 and 4 program announcement (PA) released in July 2016 and the Breakthrough Award Levels 1 and 2 PA released in August 2016.

Applications for the Breakthrough Award Levels 1 and 2 PA were received in November 2016 and peer reviewed in January 2017. Programmatic review was conducted in March 2017.

In response to the Breakthrough Award Levels 1 and 2 PA, 437 compliant applications were received and 19 (4.3%) were recommended for funding for a total of \$20.4 million (M)

Pre-applications for the Breakthrough Award Levels 3 and 4 PA were received in September 2016 and screened in October 2016 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PA. Invited applications were received for this PA in December 2016 and peer reviewed in January 2017. Programmatic review was conducted in March 2017.

In response to the Breakthrough Award Levels 3 and 4 PA, 64 pre-applications were received for Funding Level 3. The Principal Investigators (PIs) of 23 Funding Level 3 pre-applications were invited to submit a full application. Twenty-two compliant Funding Level 3 applications were received, and 3 (13.6%) were recommended for funding for a total of \$17.6M.

In response to the Breakthrough Award Levels 3 and 4 PA, 8 pre-applications were received for Funding Level 4. The PIs of two Funding Level 4 pre-applications were invited to submit a full application. Two compliant Funding Level 4 applications were received, and none were recommended for invitation to Stage 2 programmatic review (oral presentations).

Submission and award data for the FY16 BCRP Breakthrough Award Levels 1 and 2 and Breakthrough Award Levels 3 and 4 are summarized in Table 1 below.

**Table 1. Submission/Award Data for the FY16 BCRP by Mechanism\***

| <b>Mechanism</b>                                    | <b>Compliant Applications Received</b> | <b>Applications Recommended for Funding (%)</b> | <b>Total Funds</b>  |
|---|--|---|---------------------|
| Breakthrough Award - Level 1                        | 186                                    | 6 (3.2%)  | \$3,598,138         |
| Breakthrough Award - Level 1 - Partnering PI Option | 70                                     | 2 (2.9%)  | \$1,926,000         |
| Breakthrough Award - Level 2                        | 110                                    | 6 (5.5%)  | \$7,015,965         |
| Breakthrough Award - Level 2 - Partnering PI Option | 71                                     | 5 (7.0%)  | \$7,886,313         |
| Breakthrough Award Level 3                          | 22                                     | 3 (13.6%)                                       | \$17,647,098        |
| Breakthrough Award Level 4                          | 2                                      | 0 (0.0%)  | 0                   |
| <b>Total</b>  | <b>461</b>                             | <b>22 (4.8%)</b>                                | <b>\$38,073,514</b> |

\*These data reflect funding recommendations only. Pending FY16 award negotiations, final numbers will be available after September 30, 2017.

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

The USAMRMC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) 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**

Breakthrough Award Levels 1 and 2 and Breakthrough Award Levels 3 and 4 applications were peer reviewed in January 2017 by thirteen 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 (SRO). The panel reviewing Breakthrough Award Levels 3 and 4 applications also included biostatisticians. The primary responsibility of the panelists was to review the technical merit of each application based upon the evaluation criteria specified in the relevant PAs.

## **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 PAs. 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 PAs. 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 SRO 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 applicants' abstracts, 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 USAMRMC 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 March 2017 by the FY16 Programmatic Panel (Funding Levels 1 through 4) and ad hoc members (Funding Level 1 and 2 only). The reviewers were a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in breast 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.

Programmatic review criteria published in the Breakthrough Award Levels 1 and 2 and Breakthrough Award Levels 3 and 4 PAs were as follows: ratings and evaluations of the

scientific peer review panels; adherence to the intent of the award mechanism; program portfolio composition; relative impact; and relative innovation (Level 1 only). For Stage 2 (Funding Level 4 oral presentations) - Understanding of barriers to overcome in the overarching challenge selected/identified; articulation of a realistic vision for transitioning the results of the project into a near-term clinical impact for individuals with, or at risk for, breast cancer; and capability to lead efforts to transform and revolutionize the clinical management and/or prevention of breast cancer. After programmatic review, the Commanding General, USAMRMC, and the Director of the Defense Health Agency, Research, Development and Acquisition Directorate approved funding for the applications recommended during programmatic review.