

FISCAL YEAR 2017  
LUPUS RESEARCH PROGRAM  
STAKEHOLDERS MEETING

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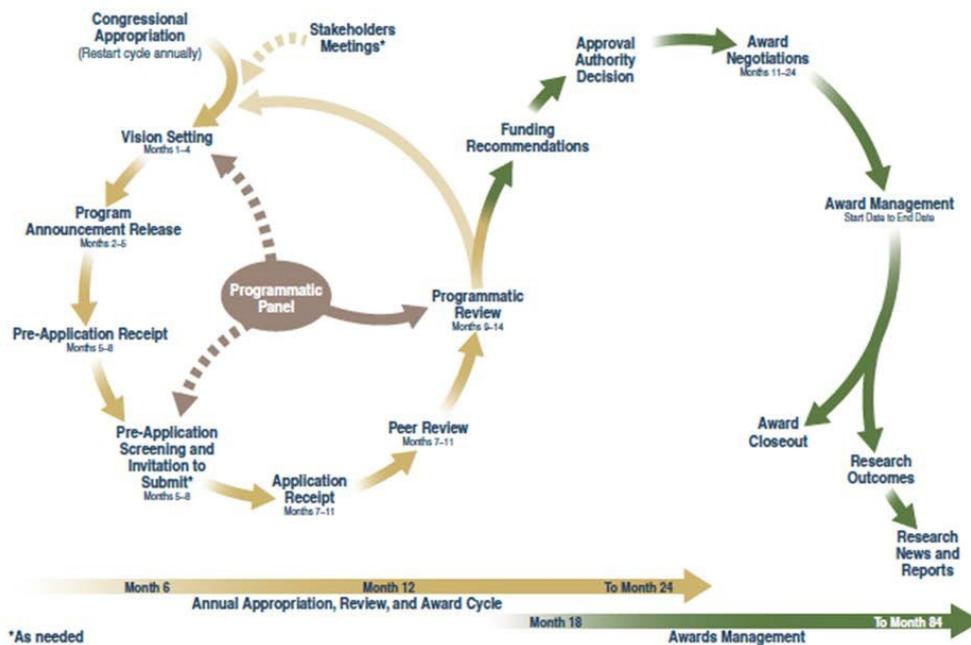
Summary

*Congressionally Directed Medical Research Programs –  
Lupus Research Program Stakeholders Meeting*

**Background**

The US Army Medical Research and Materiel Command (USAMRMC) is a major subordinate Command of the US Army Medical Command. The Congressionally Directed Medical Research Programs (CDMRP), a subordinate organization within the USAMRMC, is responsible for planning, coordinating, integrating, programming, budgeting, and executing biomedical research funding programs. The CDMRP’s flexible execution and management cycle includes the receipt of annual Congressional appropriations and core dollars; inaugural stakeholders meeting for each new program; vision setting meeting; release of full applications; full application receipt; two-tier review; recommendation of grants for funding; and oversight of research grants (Figure 1).

*Figure 1. The CDMRP Program Cycle*



The basic programmatic cycle for award recommendation is a two-tier system that is dependent on the annual vision setting meeting to guide the upcoming fiscal year investments strategy. During the first year of a program, a stakeholders meeting is held prior to the vision setting meeting. The purpose of the stakeholders meeting includes identifying critical issues facing lupus research and patient treatment, as well as acknowledging the underfunded areas of research and patient care in the field of lupus. Combined with vision setting, the stakeholders meeting reviews the current state of the science and proposes goals for the future of research and patient care to successfully treat lupus. The outcomes of the vision setting meeting set up the program cycle for the fiscal year. Products of the vision setting meeting include the vision and mission statements, the focus areas, and the program’s investment strategy, which will be translated into funding opportunities or program announcements.

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The CDMRP developed a two-tier model based upon recommendations from a 1993 Institute of Medicine (now called the National Academy of Medicine) report.<sup>1</sup> The recommended two-tier review procedure for research applications was composed of a scientific peer review and a separate programmatic review (Figure 1) to ensure that each program's research portfolio reflects not only the most meritorious science, but also the most programmatically relevant research.

The scientific peer review is conducted by an external panel that consists of scientists, clinicians, military members and consumers, which is recruited specifically for each peer review session and, therefore, is not a standing panel. The peer review process includes evaluation of applications based on the criteria delineated in the program announcements. Each application is judged on its own scientific and technical merit with respect to the described criteria. The second tier of review, programmatic review, includes discussions by experts in the programmatic field. The programmatic panel is a group of scientists, clinicians, consumers, and members of the military who assess the applications based on the scientific peer review ratings and summaries, portfolio balance, and programmatic intent. Scientifically sound applications that best meet the program's interests and goals are recommended for funding by the programmatic panel. Once approval is received by the decision making authority, awards are made in the form of 1- to 4-year grants.

Lupus research was first funded by the CDMRP beginning in Fiscal Year 2005 (FY05) under the Peer Reviewed Medical Research Program (PRMRP). From FY05 through FY16, the PRMRP invested over \$20 million (M) in lupus research. In FY17, Congress directed \$5M to lupus research in the Department of Defense (DoD) appropriation, thus establishing the Lupus Research Program (LRP). The LRP's purpose in holding an inaugural stakeholders meeting was to gain an understanding of the current landscape in lupus research and patient care and to build a program that can fill knowledge gaps in lupus.

### **Meeting Purpose and Objectives**

A stakeholders meeting for the FY17 LRP was held on 23 August 2017. Participants were asked to share their perspective on the current state of lupus as it pertains to research, patient care, and the needs of the lupus community. Stakeholders were asked to speak to the most important research topics and goals for lupus and to describe any current lupus research funding initiatives. The input of the stakeholders was used by the programmatic panel to determine the vision and mission of the LRP.

### **Stakeholder Participants**

- Representatives from consumer organizations, academia, and government institutions that have an interest in lupus research.

### **Key Activities**

- Presentations from representatives of the Lupus Foundation of America (LFA), Lupus Research Alliance (LRA), Lupus and Allied Diseases Association, Inc. (LADA), Molly's

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<sup>1</sup>Institute of Medicine Committee to Advise the Department of Defense on its Fiscal Year 1993 Breast Cancer Program. 1993. *Strategies for Managing the Breast Cancer Program: A Report to the U.S. Army Medical Research and Development Command*. National Academy Press 1-58. Washington, DC.

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Fund Fighting Lupus, and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

- Discussion of current major issues and gaps in the field of lupus research.

**Outcomes**

- A summary of recommended research areas where the CDMRP LRP should focus their funding efforts.

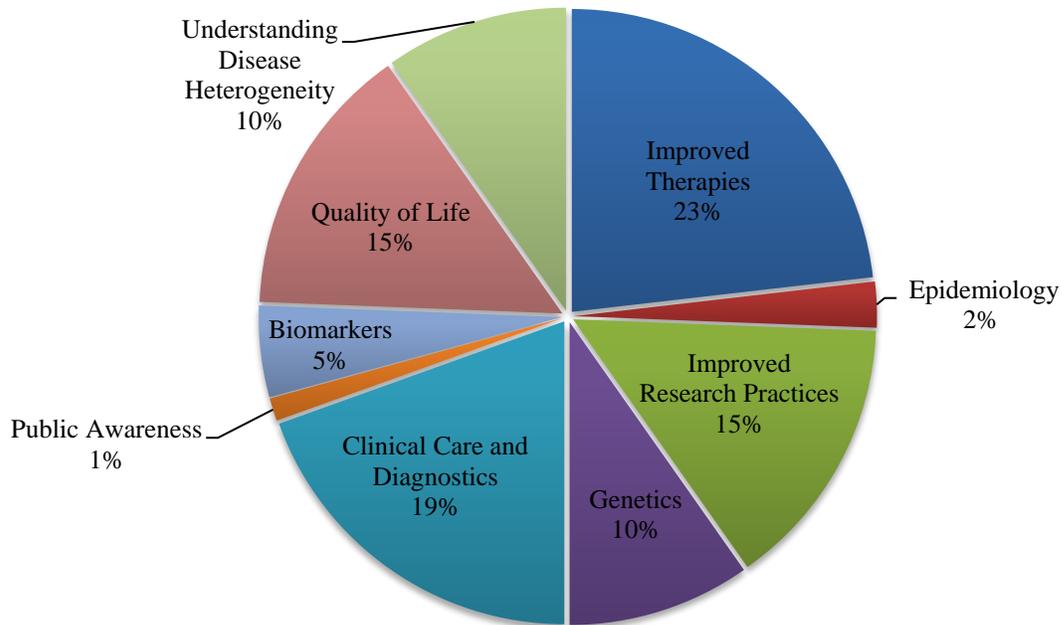
**Pre-Meeting Activities**

The LRP sent out a survey to representatives from four major lupus consumer organizations and all members of the LRP programmatic panel. Respondents were asked to identify the top five issues and/or gaps that are critical to lupus research and to identify the ways in which they could be addressed effectively by the CDMRP. The respondents were also asked to identify the types of research that would best address each problem. The respondents were asked to consider the following questions as they identified their issues and/or gaps.

1. What knowledge gaps, if filled, would have a significant impact on lupus patient care?
2. What significant issues in lupus research impede the goal of a cure?
3. What research gaps exist in Quality of Life issues for lupus?
4. What do you believe should be the goals of research in lupus over the next 5 years?
5. What do you believe should be the goals of patient care in lupus over the next 5 years?

The results of the survey were assigned to overarching categories and summarized for presentation at the stakeholders meeting (Figure 2). There was a 77% survey response rate.

***Figure 2. Gaps/Issues in Lupus Research***



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The survey responses were classified into the following categories: biomarkers, clinical care and diagnostics, epidemiology, genetics, improved research practices, improved therapies, public awareness, quality of life, and disease heterogeneity. Improving current therapies was the issue identified most frequently by the respondents.

**Stakeholders Meeting**

The list of individuals that attended the stakeholder’s meeting is presented below.

**Participants at the FY17 LRP Stakeholders Meeting**

Ms. Carole Andrew*	Lupus Research Alliance
Ms. Kathleen Arntsen	Lupus and Allied Diseases Association
Ms. Cindy Coney*	Lupus Foundation of America
Mr. Kenneth Farber	Lupus Research Alliance
Dr. Gary Gilkeson*	Medical University of South Carolina
Dr. Robert Kimberly*	The University of Alabama at Birmingham School of Medicine
Dr. Timothy Niewold*	New York University
Ms. Sandra Raymond	Lupus Foundation of America
Ms. Kelli Roseta	Molly’s Fund Fighting Lupus
Dr. Susana Serrate-Sztein*	National Institute of Arthritis and Musculoskeletal and Skin Diseases
Dr. Mark Jay Shlomchik*	University of Pittsburgh
Dr. Earl Silverman*	The Hospital for Sick Children
Dr. George Tsokos*	Beth Israel Deaconess Medical Center

**Stakeholder Presentations and General Discussion**

The following individuals gave oral presentations during the first half of the stakeholders meeting:

*Ms. Sandra Raymond – LFA*

*Mr. Kenneth Farber - LRA*

*Ms. Kathleen Arntsen - LADA*

*Ms. Kelli Roseta - Molly’s Fund Fighting Lupus*

*Dr. Susana Serrate-Sztein – NIAMS*

Listed below are key areas in lupus research that are being investigated by the major lupus stakeholder organizations:

- Improving education of the public and medical professionals about lupus
- Improving recruitment and efficiency for clinical trials
- Developing target pathways for new therapies

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\*Member of the LRP Programmatic Panel

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- Pediatric lupus
- Identifying predictive biomarkers
- Improving lupus patient quality of life
- Increasing engagement with partners who can accelerate development of treatments for lupus

After the presentations, an open discussion was held with all participants. During this time, the stakeholders provided their perspective on critical issues in lupus research to the programmatic panel. The stakeholders asked the LRP programmatic panel members to consider the following during their Vision Setting meeting as they identify focus areas for the program:

- Validating predictive biomarkers
- Identifying the underlying mechanisms of lupus
- Patient outcome-focused projects that improve clinical trials or diagnostics
- Projects that have a clear impact on patient quality of life
- Understanding disease heterogeneity
- Ability to correctly subset patients
- Epidemiological studies
- Etiology studies focused on why lupus impacts women disproportionately
- Follow-on studies to biomarker survey studies including functional genomic and gene-environment interaction studies
- Improved diagnostics and treatments
- Need for increased homogeneity in clinical trials
- Need to attract new researchers to the field of lupus
- Identifying environmental factors involved in lupus
- Need for new genetic testing and therapies
- Development of treatments targeting symptom relief