CDMRP

I. Overview

BEST BUSINESS PRACTICES

> "I will also ask for an appropriation of an extra $100 million to launch an intensive campaign to find a cure for cancer, and I will ask later for whatever additional funds can effectively be used. The time has come in America when the same kind of concentrated effort that split the atom and took man to the moon should be turned toward conquering this dread disease. Let us make a total national commitment to achieve this goal. America has long been the wealthiest nation in the world. Now it is time we became the healthiest nation in the world."
>
> **-President Richard M. Nixon, 1971, State of the Union address**

These 100 words were spoken by President Richard M. Nixon who declared a "War on Cancer" over 35 years ago. The 1971 National Cancer Act, which mandated substantial public investment into the U.S. cancer research enterprise, ushered in an era of scientific discovery and medical advances in cancer research. However, in 2007 it is estimated that 559,650 Americans will die from cancer, and approximately 1.445 million Americans will be newly diagnosed with cancer.[1] These staggering numbers and heightened public awareness about cancer and other diseases have influenced scientific policy and research. In response to these concerns and the national commitment to end the war on cancer, the U.S. Congress directed the Department of Defense (DOD) to manage intramural and extramural research programs that focus on specific diseases. Beginning in fiscal year 1992 (FY92), the U.S. Army Medical Research and Materiel Command (USAMRMC)[2] received a $25M (million) congressional appropriation for breast cancer research. The following year, Congress appropriated $210M to the DOD for extramural peer-reviewed breast cancer research. This was the beginning of the Congressionally Directed Medical Research Programs (CDMRP), a research directorate within the USAMRMC, which has been responsible for managing the breast cancer appropriation as well as other targeted appropriations totaling $4.36 billion (B) through FY07 for research on breast, prostate, and ovarian cancers; neurofibromatosis; military health; chronic myelogenous leukemia; tuberous sclerosis complex; autism spectrum disorder; post-traumatic stress disorder; traumatic brain injury; amyotrophic lateral sclerosis; and other health concerns (see Figure I-1, CDMRP Funding History).

[1] American Cancer Society, *Cancer Facts and Figures*, 2007.
[2] Known as the U.S. Army Medical Research and Development Command prior to 1995.

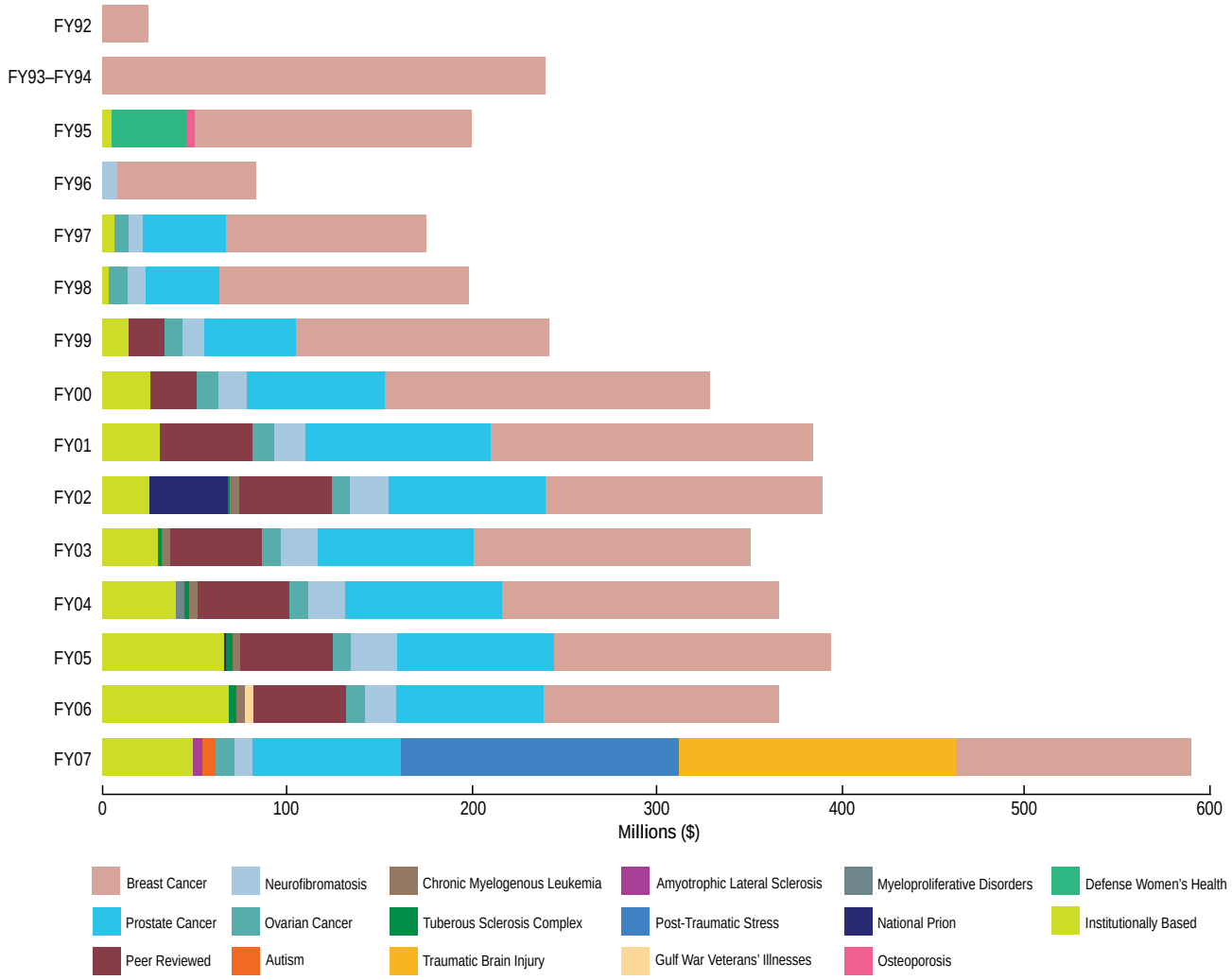


Figure I-1. CDMRP Funding History

Programs Managed by the CDMRP

Since its inception, the CDMRP has managed 81 separate research programs that are aimed at improving the health of all Americans. Congressional appropriations directed toward these 81 research programs total $4.36B. From FY92 through FY06, the CDMRP has managed 7,522 research grants, contracts, and cooperative agreements (Table I-1). Eleven of the programs managed by the CDMRP are considered primary programs because they either have received or have the potential to receive multiple appropriations and are characterized by standing Integration Panels (IPs) composed of expert scientists, clinicians, and consumer advocates. The other programs managed by the CDMRP are characterized by a one-time appropriation and/or are institutionally based research programs. Although the programs within the CDMRP share many common features, each program is unique and emphasizes the specific needs of its research and advocacy communities.

Table I-1. FY92–FY06 Awards Managed by the CDMRP

Program Fiscal Years	Grants Managed	Dollars Invested
Breast Cancer Research Program (FY92–FY06)	4,894	$1,687.4M
Prostate Cancer Research Program (FY97–FY06)	1,648	$638.7M
Neurofibromatosis Research Program (FY96–FY06)	198	$149.5M
Ovarian Cancer Research Program (FY97–FY06)	130	$88.0M
Peer Reviewed Medical Research Program (FY99–FY06)	247	$295.7M
Chronic Myelogenous Leukemia Research Program (FY02–FY06)	61	$19.3M
Tuberous Sclerosis Complex Research Program (FY02–FY06)	48	$11.9M
Gulf War Veterans Illnesses Research Program (FY07)	9	$4.5M
Other Programs (FY95–FY06)	287	$368.0M
TOTAL	7,522	$3,263.0M

The CDMRP utilizes a flexible and responsive 7-year management cycle that spans all phases of program execution, from the development of a vision through the completion of research grants (Figure I-2). All programs within the CDMRP exists because of yearly, individual congressional appropriations. These funds are not in the President's budget; Congress adds them annually to the DOD appropriation to fund new programs or to continue existing DOD programs. Because of the variability of the congressional appropriations, the CDMRP employs a flexible management cycle to maintain individuality of each program while also meeting the needs of Congress, the DOD, the research and advocacy communities, and the public at large. The effectiveness of the programs, the work of consumer advocates, and the need for additional, focused biomedical research have led to continuing appropriations for many of the programs managed by the CDMRP. Highlights of the CDMRP's 11 primary programs follow with additional details found in the corresponding program sections. Section XIII of this report contains information on the other programs managed by the CDMRP.

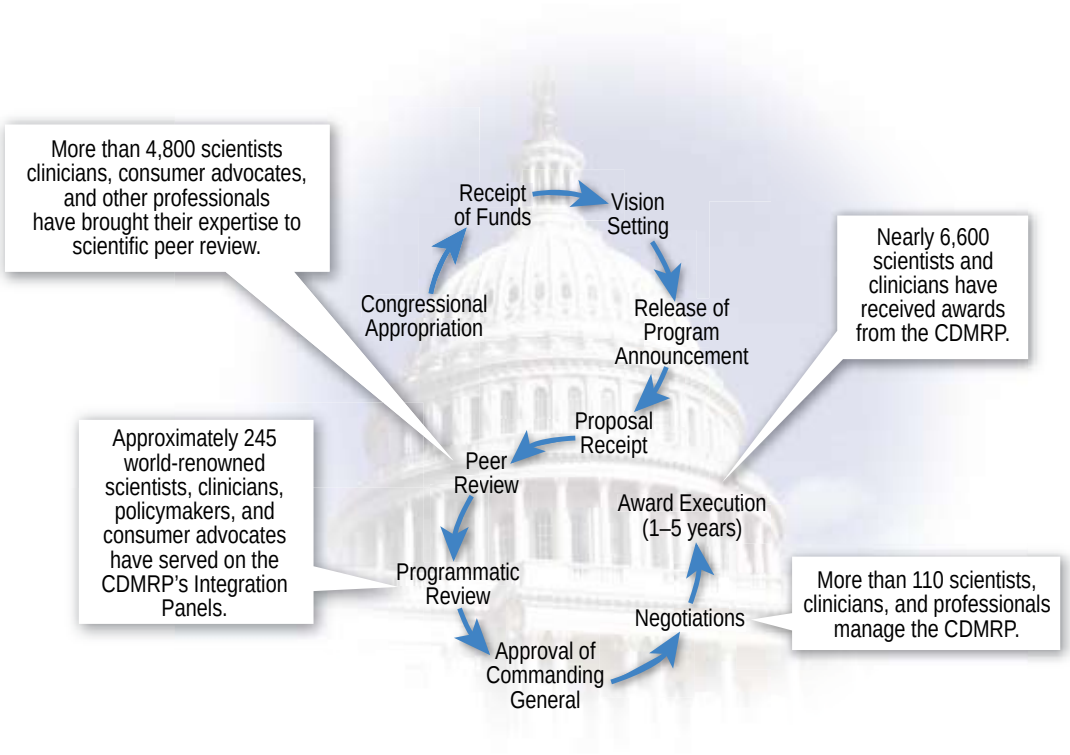


Figure I-2. CDMRP Flexible Execution and Management Cycle

Breast Cancer Research Program

The DOD Breast Cancer Research Program's (BCRP's) vision is to eradicate breast cancer. The BCRP was the first program managed by the CDMRP and is the second largest funder of extramural breast cancer research in the world. The BCRP has managed $2.1B in congressional appropriations from FY92 through FY07. In an effort to cure breast cancer, a wide-ranging and diversified research portfolio has been built spanning the prevention, detection, diagnosis, and treatment of breast cancer (Figure I-3). Awards made through this program support innovative ideas, the training of future generations of scientists and clinicians, necessary research resources, and translational research. Through FY06, the BCRP has received 31,426 proposals and has made 4,894 awards. The BCRP is described in further detail in Section II.

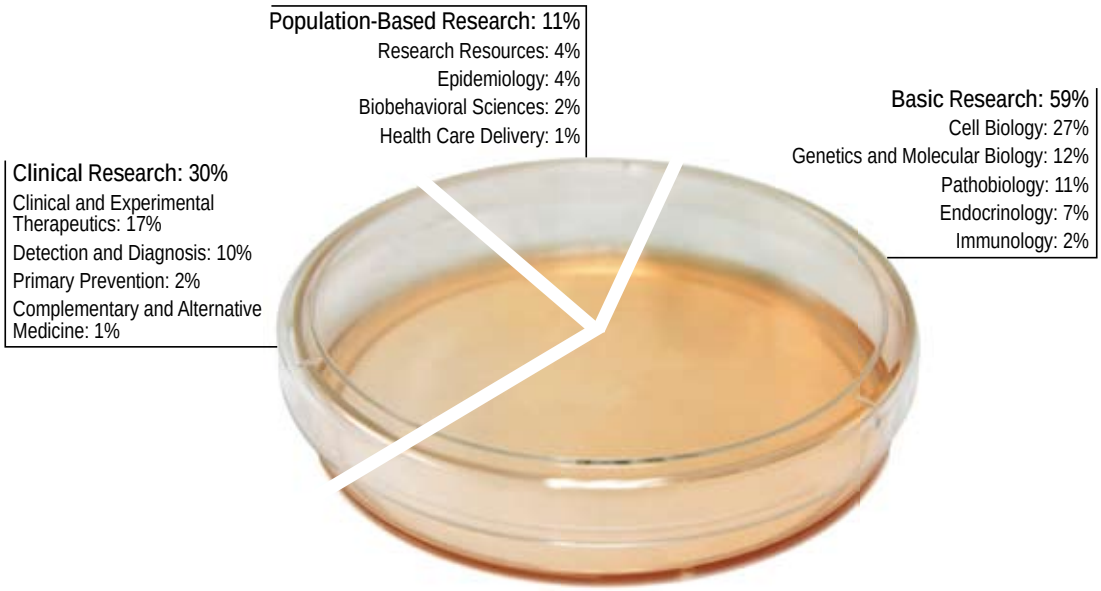


Figure I-3. FY92–FY06 BCRP Portfolio by Research Area

Prostate Cancer Research Program

The DOD Prostate Cancer Research Program's (PCRP's) vision is to conquer prostate cancer. As the second largest funder of extramural prostate cancer research in the United States, the PCRP has been responsible for the management of $810M in congressional appropriations for prostate cancer research through FY07. Throughout its history, the PCRP has been impacting the field of prostate cancer by strengthening translational research in prostate cancer and addressing the significant disparities in the incidence and mortality rates of prostate cancer that exist among different ethnic groups. The program's portfolio includes basic, clinical, and population-based research as depicted in Figure I-4. Through FY06, this program has received 7,383 proposals, resulting in 1,648 awards. More information about the PCRP is included in Section III.

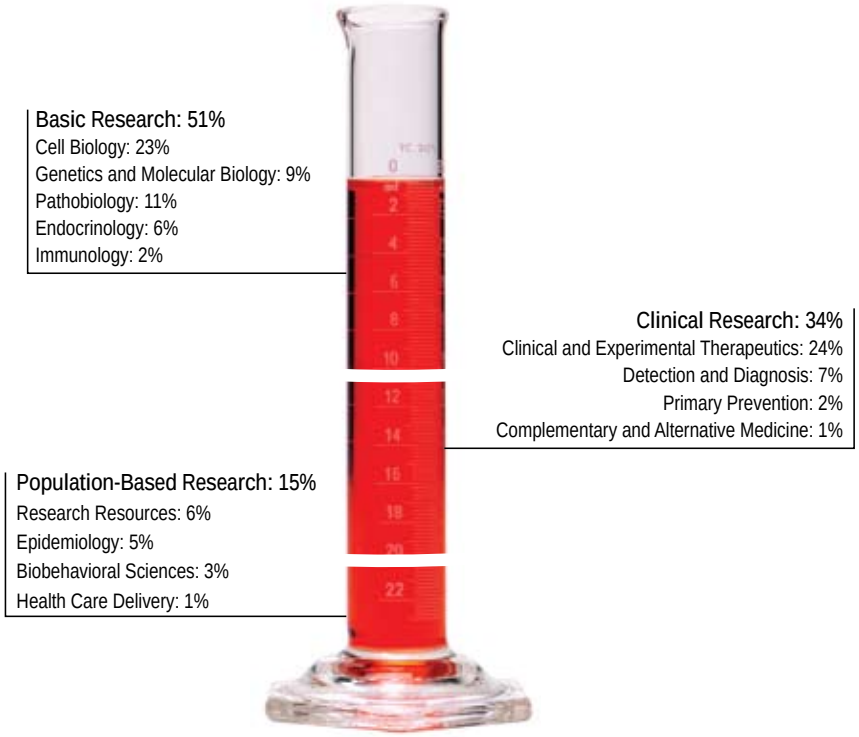


Figure I-4. FY97–FY06 PCRP Portfolio by Research Area

Neurofibromatosis Research Program

The DOD Neurofibromatosis Research Program's (NFRP's) vision is to decrease the clinical impact of neurofibromatosis (NF). The NFRP is the second-oldest program within the CDMRP and is considered a leader in NF research funding worldwide. Over 10-years strong, the NFRP has managed $182.3M in congressional appropriations from FY96 through FY07. The NFRP has supported a diversified portfolio aimed at improving and enhancing the quality of life of persons with NF and schwannomatosis (Figure I-5). Over the years, the program has placed emphasis on building collaborative connections throughout the NF community including support for large natural history studies and consortium awards. From FY96 through FY06, the NFRP received 705 proposals that have resulted in 198 awards. Additional features of the NFRP appear in Section IV.

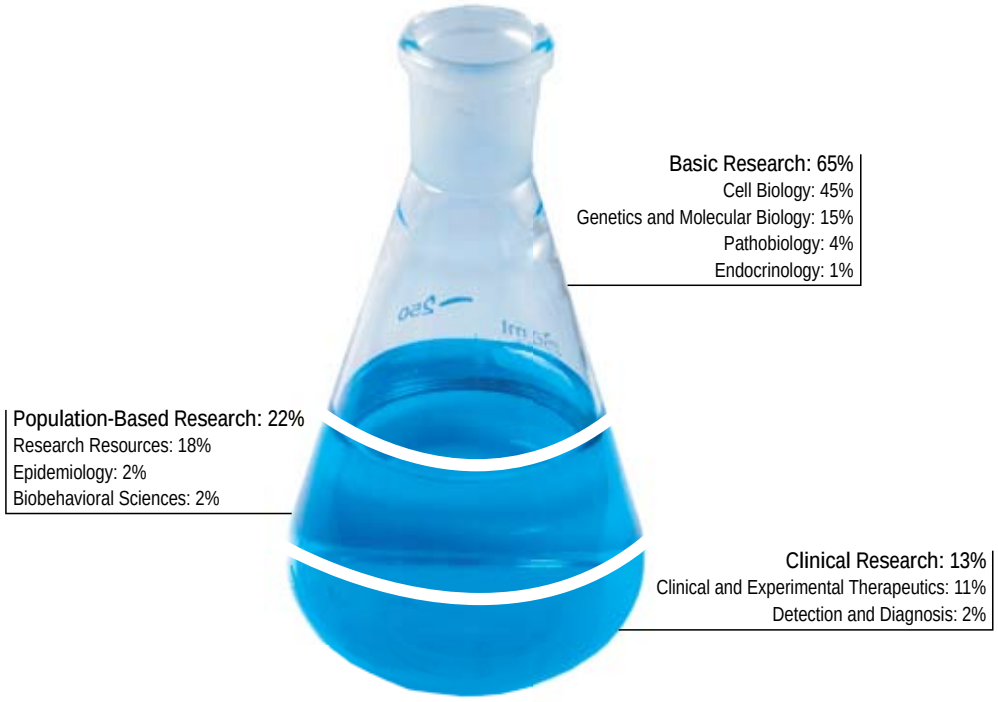


Figure I-5. FY96–FY06 NFRP Portfolio by Research Area

Ovarian Cancer Research Program

The DOD Ovarian Cancer Research Program's (OCRP's) vision is to eliminate ovarian cancer. Through 11 years of funding, the program is impacting progress in the field of ovarian cancer research. Appropriations for the FY97 through FY07 OCRP total $111.7M. Since the program's inception through FY06, 1,544 proposals have been received, leading to 130 awards. The program's emphasis has been far-reaching with a research portfolio encompassing basic, clinical, and research resources (Figure 1-6). Read more about the OCRP in Section V.

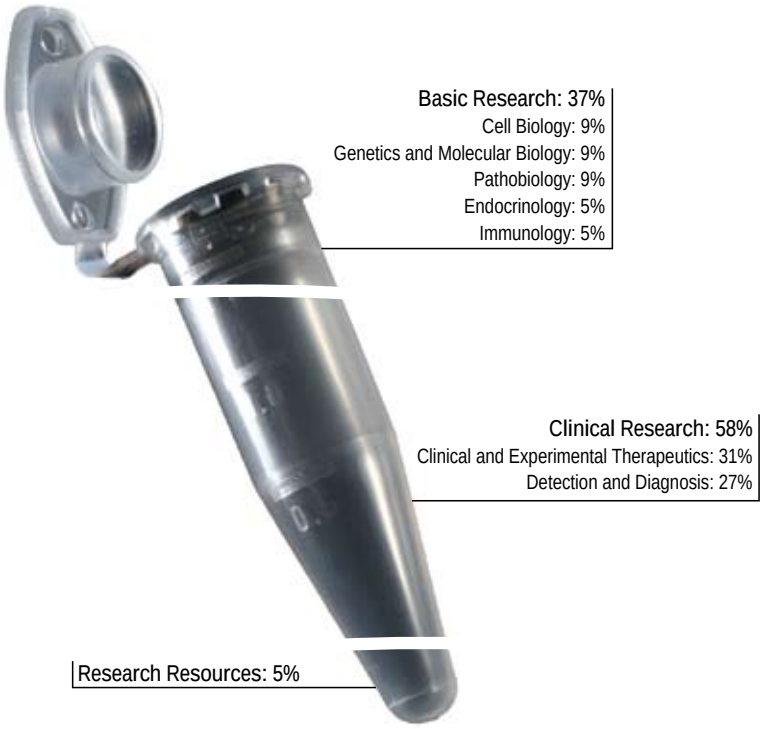


Figure I-6. FY97–FY06 OCRP Portfolio by Research Area

Peer Reviewed Medical Research Program

The DOD Peer Reviewed Medical Research Program's (PRMRP's) mission is to support research on issues with direct relevance to military health to include family members and veterans. A total of $344.5M has been managed by the PRMRP from FY99 through FY06. The portfolio of research developed by the program covers 247 medical research projects in more than 60 topic areas that have direct relevance to military health. Figure I-7 reflects the FY99 through FY06 PRMRP portfolio by research area. The PRMRP is described in greater detail in Section VI.

Figure I-7. FY99–FY06 PRMRP Portfolio by Research Area

Chronic Myelogenous Leukemia Research Program

The DOD Chronic Myelogenous Leukemia Research Program's (CMLRP's) vision is to eradicate chronic myelogenous leukemia (CML). The CMLRP was established in FY02 and has received annual congressional appropriations through FY06 totaling $22.05M for research in CML. A total of 61 awards have been made through FY06 bridging basic, clinical, and population-based research (Figure I-8). Additional details regarding the CMLRP can be found in Section VII.

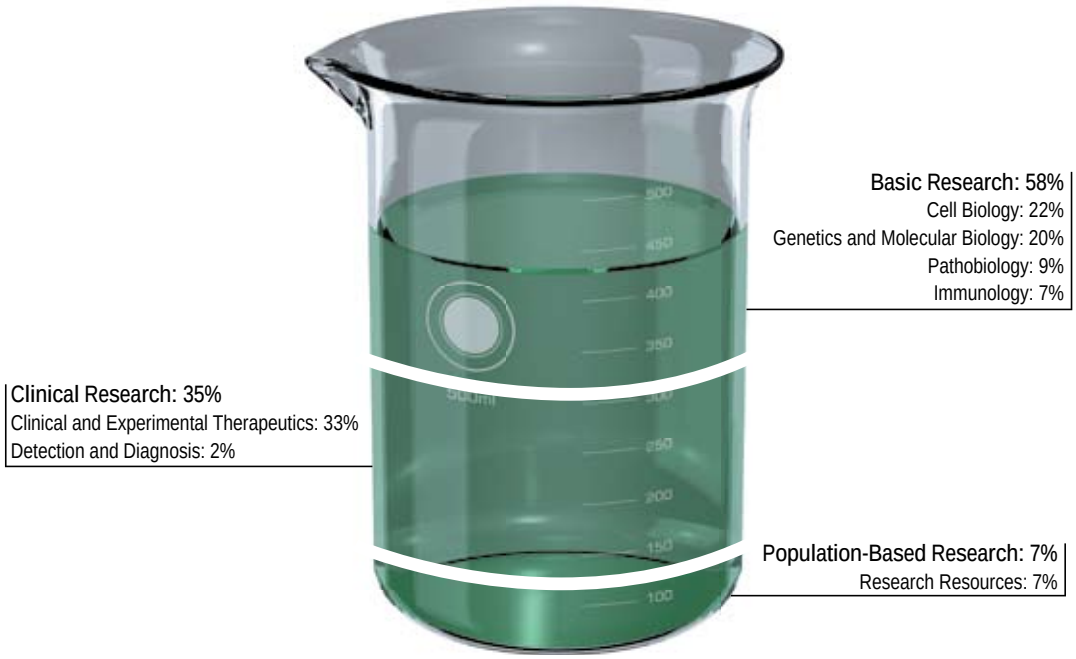


Figure I-8. FY02–FY06 CMLRP Portfolio by Research Area

Tuberous Sclerosis Complex Research Program

The DOD Tuberous Sclerosis Complex Research Program's (TSCRP's) vision is to lessen the impact of tuberous sclerosis complex (TSC). The TSCRP was established by a $1M appropriation in FY02 for TSC research and received annual congressional appropriations totaling $13.5M through FY06. A total of 48 awards have been made through FY06 in basic, clinical, and population-based research (Figure I-9). Projects funded by this program are advancing progress in TSC research and span the spectrum of groundbreaking concepts and ideas, natural history studies, and the development of clinical resources. Read more about the TSCRP in Section VIII.

Figure I-9. FY02–FY06 TSCRP Portfolio by Research Area

Gulf War Veterans' Illnesses Research Program

The DOD Gulf War Veterans' Illnesses Research Program's (GWVIRP's) vision is to identify beneficial treatments for 1991 Gulf War veterans who are affected by Gulf War illnesses. The GWVIRP was established by a $5M appropriation in FY06 for research on Gulf War Veterans' illnesses.

A total of nine awards were made across two award mechanisms. Projects funded by this program span basic, clinical, and population-based research and are impacting the health of our Gulf War veterans (Figure I-10). The GWVIRP is described in further detail in Section IX.

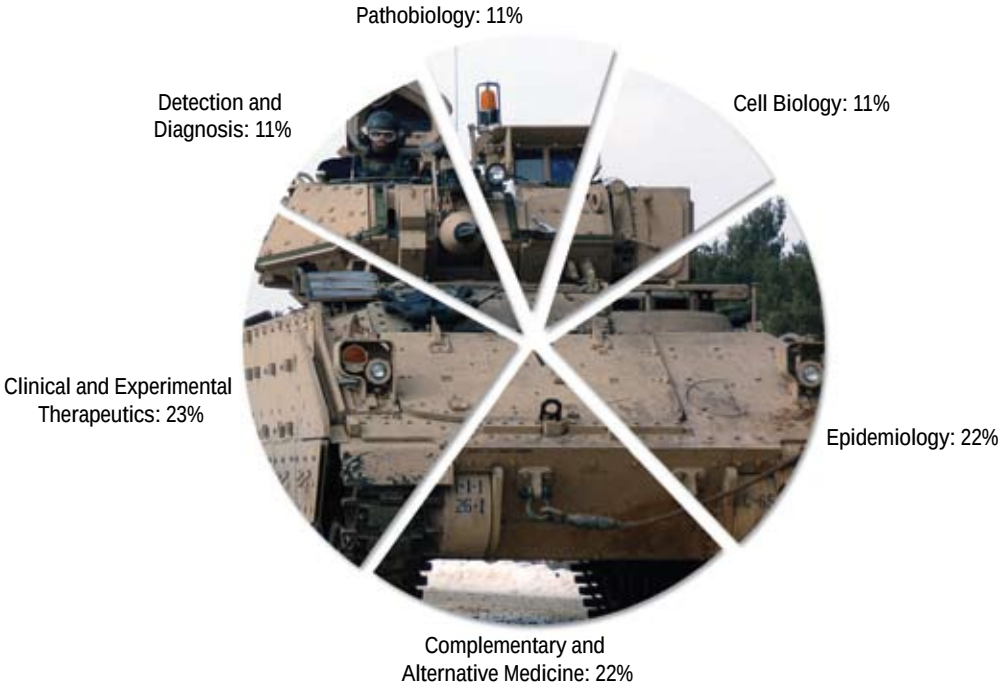


Figure I-10. FY06 GWVIRP Portfolio by Research Area

Autism Spectrum Disorder Research Program

The DOD Autism Spectrum Disorder Research Program's (ASDRP's) vision is to improve the lives of individuals with autism spectrum disorder now. The ASDRP is one of three primary programs new to the CDMRP in FY07. It was established by a $7.5M appropriation for research on autism spectrum disorder. The program is offering three award mechanisms to encourage innovative research that advances the understanding of autism spectrum disorder and leads to improved treatment outcomes. The projected FY07 investment strategy by award mechanism is depicted in Figure I-11. Additional information about this new program can be found in Section X.

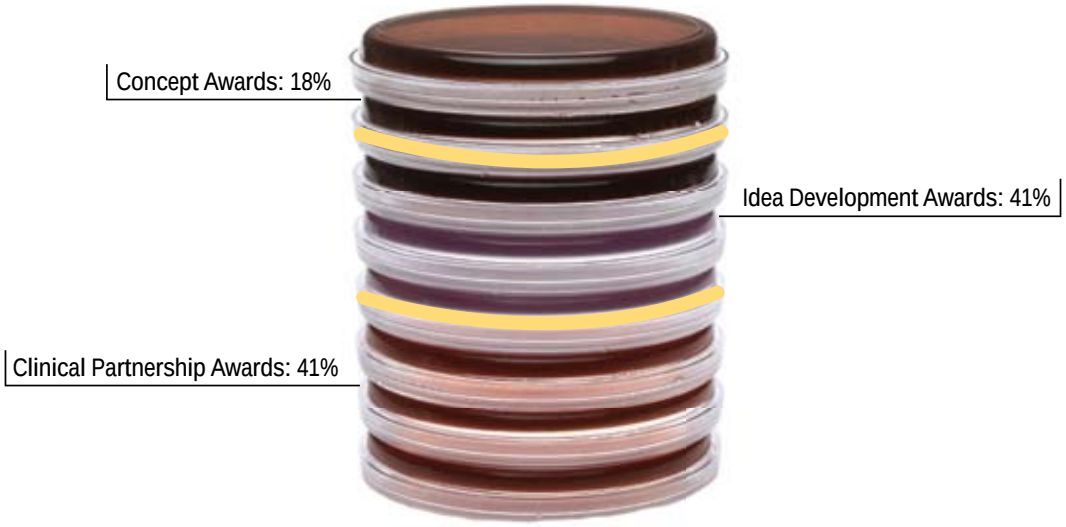


Figure I-11. Projected FY07 ASDRP Investment Strategy

Post-Traumatic Stress Disorder and Traumatic Brain Injury Research Program

The DOD Post-Traumatic Stress Disorder and Traumatic Brain Injury Research Program's (PTSD/TBIRP's) vision is to prevent, mitigate, and treat the effects of traumatic stress and traumatic brain injury on function, wellness, and overall quality of life for service members as well as their caregivers and families. The PTSD/TBIRP is one of three primary programs new to the CDMRP in FY07. It was established by congressional appropriations totaling $151M for research on post-traumatic stress and $150M for research on traumatic brain injury. The program is offering seven award mechanisms to establish, fund, and integrate both individual and multiagency research efforts that will lead to improved prevention, detection, diagnosis, and treatment of PTSD and TBI. Several research gaps were identified by the program, as depicted in Figure I-12. More details about this new program can be found in Section XI.

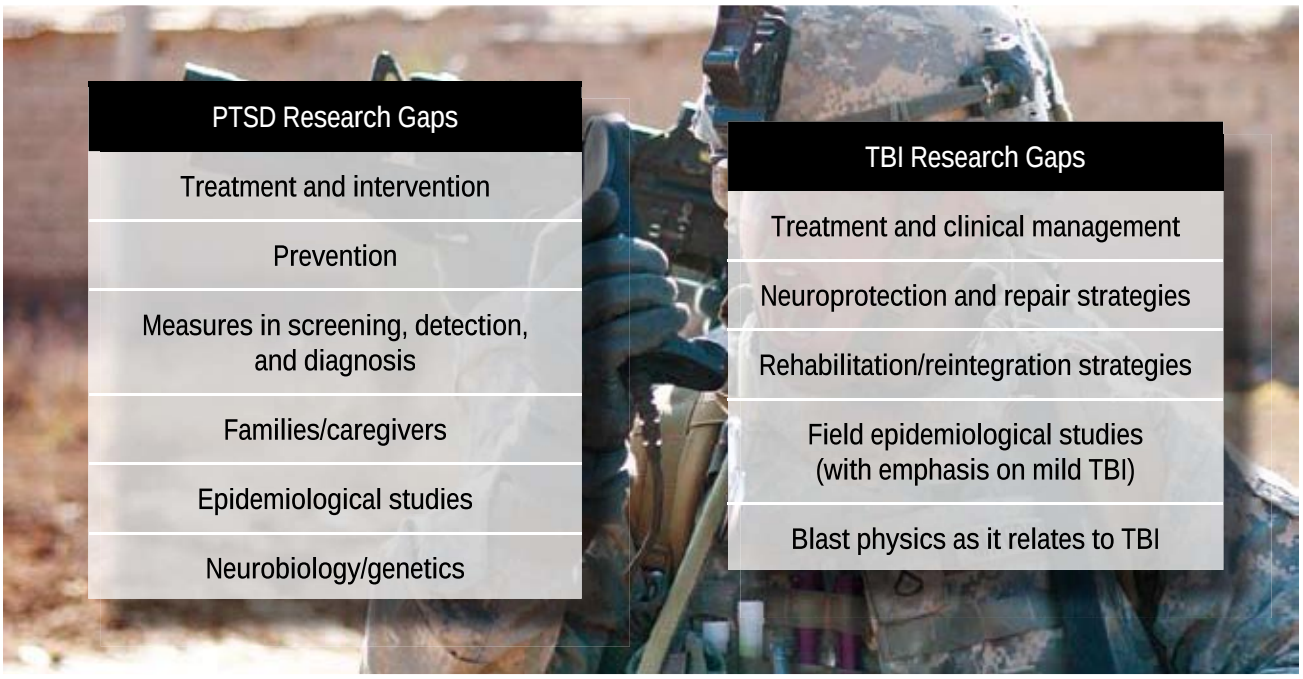
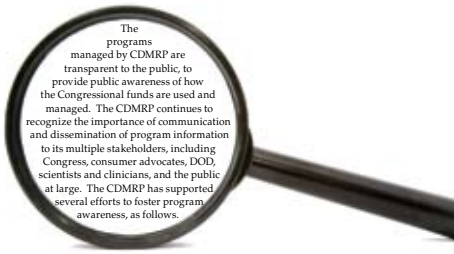


Figure I-12. Projected FY07 PTSD/TBIRP Research Gaps

Amyotrophic Lateral Sclerosis Research Program

The DOD redirected $5M to FY07 Army Research, Development, Test, and Evaluation funding for the CDMRP to initiate the Amyotrophic Lateral Sclerosis Research Program (ALSRP). The ALSRP is one of three primary programs new to the CDMRP in FY07. Similiar to the CDMRP's other primary programs, the ALSRP is being conducted according to the two-tier review model recommended by the National Academy of Sciences Institute of Medicine. The program is offering one award mechanism to expedite the pathway from bench science to clinical trials for new therapeutic approaches aimed at ALS. Read more about the ALSRP in Section XII.



Best Business Practices: From Program Development through Science Management

The CDMRP's commitment to a cutting-edge environment can be attributed to five best business practices. These ingredients are simple but are keys to the growth and success of our organization. We employ these business practices in every program that we administer. While our business processes are fluid, we continually improve on them as programs and science evolve. Here is a look at our top five best business practices that facilitate our ability to find and fund the best research.

"Outside-the-Box" Thinking

Innovative and Rigorous Proposal Submission and Review Process

Unparalleled People and Partnerships

Highest Standards of Ethics—Good Stewards

Transparent and Open Communication

1 "Outside-the-Box" Thinking

From the outset, the CDMRP had a clear vision—to eradicate breast cancer. To bring the nation closer to this vision, the CDMRP recognized that breast cancer was outside its core expertise and therefore sought the advice of the top advisors to the nation on science, engineering, and medicine—the National Academy of Sciences (NAS)—to effectively manage the FY93 breast cancer appropriation. In response, the NAS Institute of Medicine (IOM) issued a report entitled *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*. The IOM committee made two pivotal recommendations in this report. First, the committee recommended an annual investment strategy to guide allocations of funds that best address the current needs in breast cancer research, as detailed on page I-19. Second, the committee recommended a two-tier review strategy consisting of scientific peer review and programmatic review (for more information about the review process, see Best Business Practice 2 on page I-24). Both of these recommendations have become cornerstones in the administration of the majority of programs managed by the CDMRP.

Agnes A. Day, Ph.D.
Howard University

"Cancer is like a 'million piece' jigsaw puzzle, with each piece representing a gene, a group of proteins, or a pathway that may be involved in its development and/or spread. Each cancer researcher seeks to connect, at most, a few 'pieces' of this puzzle to identify proteins and pathways which lead to cancer. Being a scientific reviewer for the DOD's CDMRP is similar to sneaking a peek at the picture on the box, that is, we get to see and hear about what other researchers are doing with their pieces and judging whether they have joined their pieces together to form a complete corner, or whether they have thought of a better or faster method for completing the puzzle. In the end, WE—the reviewers, the researchers, and the consumers—all win!"

Setting the Vision

The CDMRP seeks to find and fund the best research to eradicate diseases. Success in this venture is contingent on recruiting the most visionary scientists, clinicians, and consumer advocates to serve on each core program's IP. The IP is a collection of forward-thinking individuals who meet to deliberate the issues and concerns unique to the individual program, propose a vision to guide the investment strategies for the upcoming year, and eventually recommend a broad-based portfolio to cure disease (for more information on the IP's role on the review of research proposals, see Programmatic Review, page I-26).

Answering Unmet Needs: Developing an Investment Strategy

The expert opinion of IP members facilitates the development of an annual investment strategy to identify underfunded and underrepresented areas of research and to encourage research in those areas that are considered the most critical to patients, consumers, clinicians, and laboratory researchers. The annual investment strategy stems from the 1993 IOM recommendations[3] and provides a high degree of flexibility. It provides the framework and direction necessary to most effectively obligate each congressional appropriation while avoiding unnecessary duplication with other funding agencies. A critical component of the investment strategy is developing specific award mechanisms that capture the current needs of both the research and advocacy communities. Once an investment strategy is developed, a separate program announcement outlining the award mechanisms offered for each of the research programs managed by the CDMRP is developed and released each fiscal year. The CDMRP has utilized more than 35 different types of award mechanisms that fall predominantly into four categories: clinical research, innovative research, training and recruitment, and research resources as shown in Figures I-13–17. Some of these cutting-edge award mechanisms developed by the CDMRP have been emulated by other funding agencies.

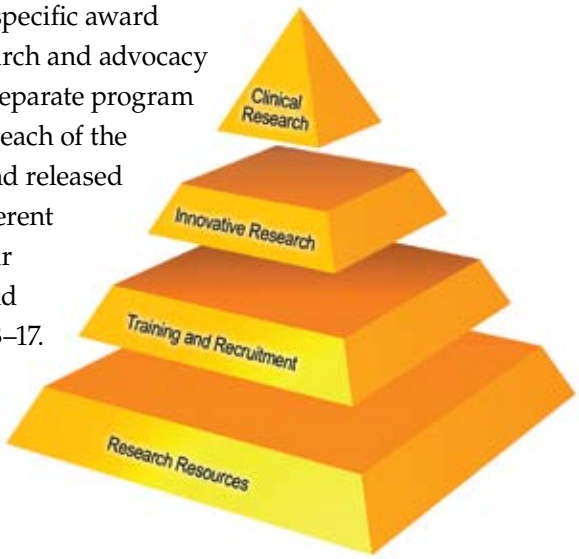


Figure I-13. CDMRP Funding Philosophy

[3] Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

Clinical Research

The CDMRP has supported the necessary research that will accelerate discoveries in basic science to the clinical setting. Basic science research typically begins in the laboratory where researchers may be studying cellular and molecular structures and events underlying biological processes. Typically, after extensive studies in animal and human cells, research then progresses to animal models. If this stage of research is successful, clinical testing can be conducted in humans after approval by the U.S. Food and Drug Administration. The CDMRP has supported several award mechanisms that promote the application of new knowledge and techniques to patient care as shown in Figure 1-14. Through FY06, the CDMRP has funded 122 clinical research awards.

Figure I-14. Examples of CDMRP Award Mechanisms That Emphasize Clinical Research

Innovative Research

In 1993, a recommendation was made to the USAMRMC by the IOM to "create an environment in which creative ideas and first-rate research can flourish and in which investigators are not afraid to gamble on risky but alluring ideas."[4] Today, the CDMRP's central philosophy is innovation. The CDMRP fills research gaps by funding high-risk, high-gain research that other agencies will not venture funding. Many of the award mechanisms offered by the CDMRP emphasize support for the exploration of revolutionary ideas and concepts that could ultimately "leap frog" scientific advances toward disease eradication (Figure I-15). While each mechanism has different award requirements, all share the common goal of advancing innovative ideas, creative solutions, and breakthrough technologies. Through FY06, the CDMRP has funded 4,082 innovative research awards.

Figure I-15. Examples of CDMRP Award Mechanisms That Emphasize Innovative Research

[4] Institute of Medicine, S*trategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

Training and Recruitment

The CDMRP has played a major role in training scientists at all points in their careers. In the 1993 IOM report, it was stated that the "best investment the program can make is to stimulate talented new investigators…."[5] The CDMRP's commitment to training the best and the brightest to eradicate human diseases is demonstrated by its portfolio of funded projects, nearly one-third of which focuses on training and recruitment (Figure I-16). The CDMRP has supported both new researchers in the field and established scientists interested in extending their expertise to the study of other diseases. A total of 2,049 training and recruitment awards have been made through FY06.

Figure I-16. Examples of CDMRP Award Mechanisms That Emphasize Training and Recruitment

[5] Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

Research Resources

In the 1993 IOM report, it was noted that "research in breast cancer is impeded by inadequate access to resources that are appropriate for sharing—including tumor samples, cell lines, animal models, DNA probes, follow-up data on women diagnosed with breast cancer, information about ongoing clinical trials, and economic data to evaluate the cost of care."[6] Based on this clear need in 1993 and the need for similar support identified in subsequent years, the CDMRP has funded 124 research resources awards through FY06 (Figure I-17). These awards are designed to provide researchers with support to (1) create or obtain materials and data from multiple sources that would otherwise be difficult to acquire or (2) establish and support centers or consortia that can provide a foundation for future research.

Figure I-17. Examples of CDMRP Award Mechanisms That Emphasize Research Resources

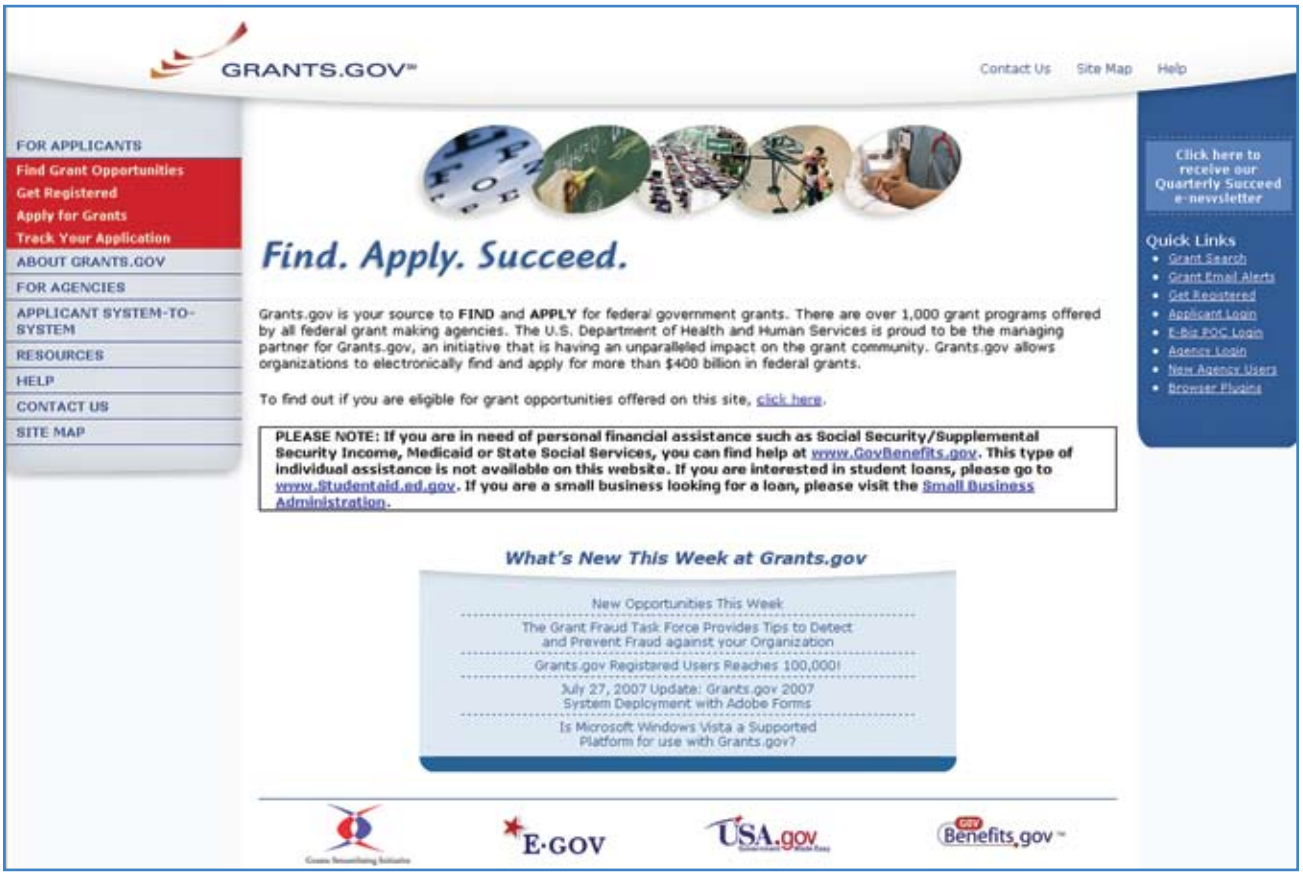
[6] Institute of Medicine, *Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*, The National Academies Press, 1993.

2 Innovative and Rigorous Proposal Submission and Review Process

The CDMRP has administered appropriated funds for congressionally directed medical research since 1992. Beginning in 1992, the CDMRP managed one program in which 72 hard copy proposals were received and 26 awards were made compared to FY06, when the CDMRP managed 44 programs, received 5,671 electronic proposals, and made 586 awards. In response to this tremendous growth, the CDMRP has remained on the cutting edge of science administration through its proposal submission and review process as detailed in the following paragraphs.

Electronic Proposal Submission

In 2002, President Bush began a push for improved public access to government services through "E-Government Initiatives." One of these initiatives is "Grants.gov," a common portal for all grant applications submitted to the federal government. Although the CDMRP has been receiving electronic submissions through eReceipt since 2002, in 2007 it joined the National Institutes of Health, National Science Foundation, and more than 20 other government agencies in using the Grants.gov site for electronic submission of grant proposals. This unified site provides applicants with easy access to standardized forms, eligibility information, funding levels, and help with the application process. In 2007, the CDMRP had approximately $550M available for research from a pool of over $400B available from Grants.gov.



Two-Tier Review Process

Critical to the success of the CDMRP is the two-tier review process that was derived from 1993 IOM recommendations. Although the two tiers of review are fundamentally different, they are complementary. The goal of the two-tier review process is to develop funding recommendations that balance the most meritorious science across many disciplines and offer the highest promise to fulfill the programmatic goals set forth by each program. Scientifically sound proposals that most effectively address the unique focus and goals of the program are then recommended to the Commanding General, USAMRMC, for funding. Additional details about the full funding and review process can be found on the CDMRP website at http://cdmrp.army.mil/fundingprocess.htm.

Peer Review

Peer review is a criteria-based process where proposals are evaluated based on their scientific and technical merit. This review is performed by an external scientific peer review contractor. Proposals are evaluated by scientific discipline, specialty area, or award mechanism by both scientific and consumer peer reviewers. A two-part scoring procedure is used. Proposals are assigned an overall global priority score as well as individual evaluation criteria scores.

- Evaluation of scientific merit
- Criteria-based evaluation
- Proposals evaluated by scientific discipline, specialty area, or award mechanism

Programmatic Review

After proposals have been scientifically peer reviewed, they are programmatically reviewed by members of the program's IP. Programmatic review is a comparison-based process in which submissions from multiple research areas compete in a common pool. Programmatic review balances the potential outcomes and risks of scientifically meritorious applications. A typical set of criteria used by members of the IP to make funding recommendations includes: ratings and evaluations of the scientific and consumer peer reviewers, programmatic relevance, relative innovation, program portfolio balance, research targeting special populations, and adherence to the intent of the award mechanism.

- Evaluation of programmatic relevance
- Comparison-based evaluation
- Proposals evaluated across multiple disciplines

Inquiry Review Panel

The Inquiry Review Panel (IRP) was established by the CDMRP to enable grant applicants to address queries and complaints regarding the scientific peer review or programmatic review of their proposals. IRP appeals must be based on the occurrence of factual or procedural errors that occur at receipt, peer review, or programmatic review. While only 1 percent of all funding decisions was appealed across all programs from FY99 to FY05, this process is an integral part of our business practices.

3 Unparalleled People and Partnerships

The CDMRP believes that through the best people and effective collaborations and partnerships, diseases will be cured. Public, private, government, and military partnerships occur in all aspects of the programs and are central to the success of the CDMRP. These effective partnerships are leading closer to cures for many diseases and are facilitating the CDMRP's ability to effectively address critical health issues. Some of the most significant partnerships shaping the CDMRP are discussed on the following pages.

Consumer Advocates and the CDMRP

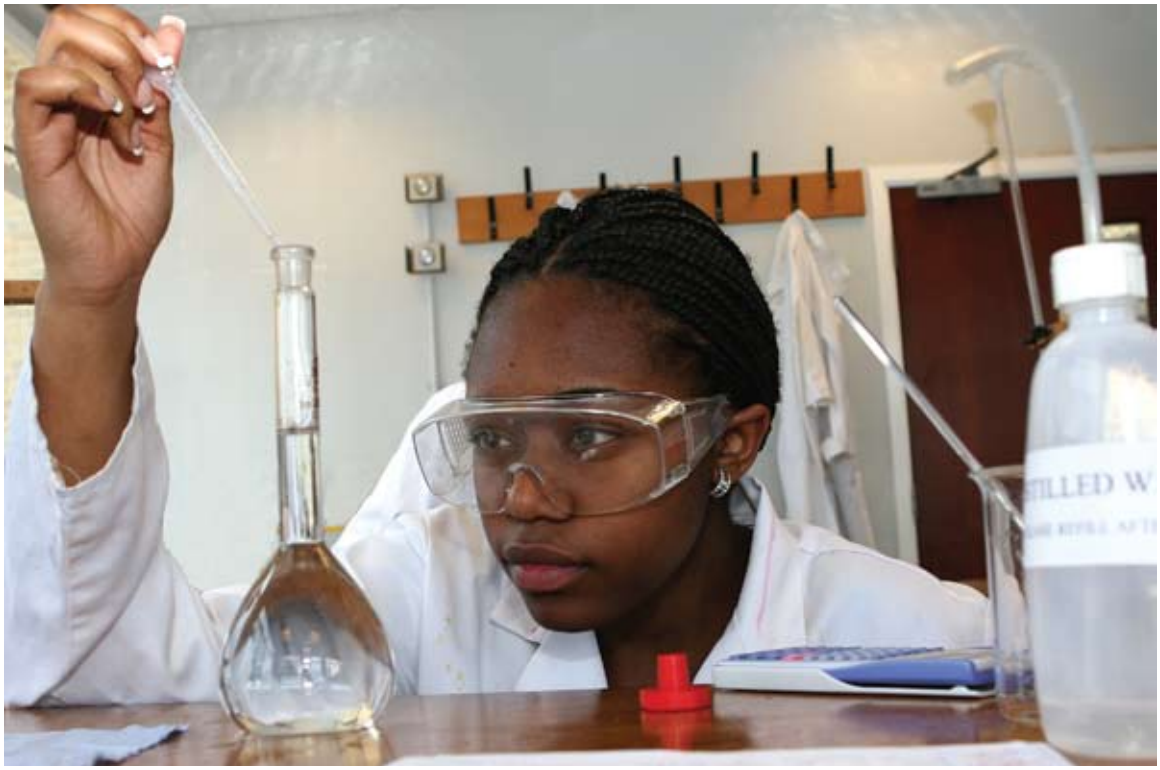
The unique voices and experiences of survivors and their families have played a pivotal role in the establishment and growth of the CDMRP. The relentless work of thousands of advocates has resulted in $4.3B in appropriations for targeted diseases through FY07. Today, the CDMRP is a recognized leader in integrating consumers in virtually all aspects of program execution. Consumers for most of the primary programs are survivors of the respective diseases and representatives of consumer advocacy organizations. The value of consumer involvement is derived from each individual's firsthand experience with the disease. This adds a perspective, passion, and a sense of urgency that ensure that the human dimension is incorporated in the program policy, investment strategy, and research focus. For instance, approximately 40 consumers have served as IP members from 1993 to the present while others have been active participants in executing some research projects. More than 1,000 consumers have served on scientific peer review panels since 1995. Finally, consumers have had opportunities to learn about the scientific advances by attending multidisciplinary meetings held by the CDMRP, such as the BCRP's Era of Hope meetings and the PCRP's inaugural Innovative Minds in Prostate Cancer Today meeting. For more information on consumer involvement and serving as a consumer reviewer in the first tier of review (peer review), see the consumer involvement pages on the CDMRP website (http://cdmrp.army.mil).

The Scientific Community and the CDMRP

The scientific community is essential in assisting the CDMRP in shaping the future of health care. The fulfillment of program goals requires cooperation and communication across multiple scientific and clinical disciplines. To date, more than 4,800 scientists and clinicians have provided the necessary subject matter expertise on peer review panels. Approximately 245 world-renowned basic scientists, clinicians, and policymakers have participated in vision setting and programmatic review as IP members, and more than 215 scientists have served as ad hoc programmatic reviewers. More than 110 scientists, clinicians, and professionals currently are involved in all phases of program execution and science management of the CDMRP. Collectively, these scientists have assisted the CDMRP in funding more than 6,600 researchers in an effort to tackle the complex causes of disease and translate this knowledge to improved disease prevention, patient survival, and quality of life.

Working with Minority and Underserved Populations

In 1998, the CDMRP established the Minority and Underserved Populations Program to enhance its ability to address significant disparities that exist in the incidence, morbidity, and mortality among different ethnic groups for many of the diseases for which the CDMRP provides support. The mission of the Minority and Underserved Populations Program is to enhance the CDMRP's efforts in this area by creating new award mechanisms, reaching out to underserved, understudied, and underrepresented communities through improved communication, and partnering with other agencies. In total, the CDMRP has made 104 health disparity and Historically Black Colleges and Universities/ Minority Institutions (HBCU/MI) partnership awards totaling $44M.



International Cancer Research Partners: One Voice, One Vision

In 2000, the CDMRP joined with the National Cancer Institute (NCI) and the National Cancer Research Institute (NCRI) of the United Kingdom to form the International Cancer Research (ICR) Partners in an effort to maximize the benefits of the global investment in cancer research. Today, the ICR Partners includes 50 cancer funding organizations from the United States, Canada, and throughout the United Kingdom that have come together to classify their respective research portfolios using a common coding scheme (called the Common Scientific Outline or CSO). The mission of the ICR Partners is to enhance the impact of research to benefit all individuals affected by cancer through global collaboration and strategic coordination of research.

As a first step in achieving their mission, the ICR Partners developed a relational database of cancer research supported by its members called the ICR Portfolio (ICRP). The ICRP allows users to find information about actively funded research in one central, searchable database. Researchers can use the site to identify scientists doing similar work, as well as contacts for multidisciplinary research and collaborations. Moreover, the ICRP is useful to cancer funding organizations and government/policy officials to enhance their awareness of the research funded by the ICR Partners—either to gauge the state of cancer science or set directions for future research efforts.

As a second step in achieving their mission, the ICR Partners are actively engaged in an initial strategic analysis of their joint and respective research portfolios. This work has necessitated the development of common terminology, search features, and currency conversions in addition to the already-established coding platform using the CSO. In addition, the Partners are developing plans for future joint primary analyses using new measures and outcomes as benchmarks. Finally, the Partners are currently involved in dialogues with other interested cancer research funding organizations in the United States, Europe, and elsewhere to join the partnership, making it even more globally strategic in its efforts.

The ICRP Partners are as follows: NCI, CDMRP, American Cancer Society, California Breast Cancer Research Program, Oncology Nursing Society, Prostate Cancer Foundation, Susan G. Komen for the Cure, Canadian Cancer Research Alliance, which includes 23 Canada-based funding organizations, and the NCRI, which includes 20 U.K.-based funding organizations (http://www.cancerportfolio.org/).

Gynecological Cancer Foundation Allied Support Group

The CDMRP is a member of the Gynecological Cancer Foundation Allied Support Group, a group composed of 7 major ovarian cancer funders and 18 advocacy organizations to facilitate synergy among organizations that share goals of prevention and early detection of gynecological cancers. This group meets annually to initiate collaborations pertaining to ovarian cancer education, advocacy, and research. Additional information about the support group can be accessed at http://www.thegcf.org/about/allied.htm.

GCF Gynecologic Cancer Foundation

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Gynecologic Cancer Foundation's Allied Support Group

In 1998, the Gynecologic Cancer Foundation (GCF) created an Allied Support Group consisting of newly created national ovarian cancer advocacy organizations to promote open dialogue and collaboration among the advocacy groups. The GCF agreed at that time to host semiannual meetings and to serve as the "administrator" of the Allied Support Group. Over the ensuing few years, the Allied Support Group expanded its membership to include other gynecologic cancer related advocacy and research organizations. As currently constituted, the group represents most national and some international organizations that have interest in women's gynecologic cancer health.

In addition to meeting semiannually to review the activities of their individual organizations, members of the Allied Support Group have collaborated on a variety of special educational, advocacy and research projects. A partial list of these projects follows:

- Educational presentation/slide kits for medical professionals and lay public
- Ovarian National Resource List
- Ovarian Cancer Product Guide
- Ovarian Cancer Survivor's Course
- WCN/WCN Wall of Hope/Survivor Section/Calendar of Events
- Newspaper supplements
- News/magazine articles
- Research grants (GCF has received funding from various allied support group members to support research grants)
- Speakers at each member's conferences
- Educational materials
- Exhibiting at member's conferences
- Government relations/congressional receptions

Further recognizing the importance of the Allied Support Group, in 2002 the GCF appointed Ronald Alvarez, MD, a member of the GCF Executive Committee, to a newly established position of Advocacy Chair. In this role, he serves as the liaison between SGO/GCF and the Allied Support Group members. He chairs the Allied Support Group meetings.

Mission Statement

At the February 2003 Allied Support Group meeting there was initial discussion among the members regarding a mission statement, operational issues, and special areas of emphasis. It was decided to have a session during the September 2003 meeting with Dr. Saralyn Mark of the Office of Women's Health acting as a facilitator to further discuss these areas in anticipation of creating general guidelines/policies manual for the group. The proposals below were approved at the March 2004 meeting and are listed below.

Multidisciplinary Meetings

Era of Hope

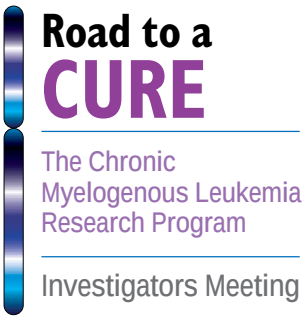
The BCRP has sponsored four major international scientific meetings, called the Era of Hope, to provide a forum for thousands of scientists, clinicians, health care providers, and consumers to communicate ideas and promising new directions in breast cancer research. These meetings are recognized as premier breast cancer conferences in the United States. They provide unprecedented opportunities for disseminating program information and developing future collaborations. The next Era of Hope meeting is planned for June 2008 in Baltimore, Maryland.

IMPaCT

The PCRP hosted its first meeting in September 2007 during National Prostate Cancer Awareness Month called "IMPaCT: Innovative Minds in Prostate Cancer Today." The intent of the meeting was to promote the exchange of ideas and explore innovative avenues of research that will advance the prostate cancer field in a forum highlighting PCRP-supported studies. The IMPaCT meeting recognized the program's successes in funding innovative and high-impact research, addressing health disparities, and training the next generation of prostate cancer researchers. More information about this inaugural meeting can be found in Section III, page 28.

Military Health Research Forum

The PRMRP has sponsored two Military Health Research Forums to provide a means for investigators funded by the program to present their research findings, products, and technologies and to develop future collaborations related to military health research. In addition, the forums emphasized ways for investigators to expedite the transition from research to field-usable products



Road to a Cure—The CML Investigators Meeting

The CMLRP sponsored its first research meeting in December 2006 called the "Road to a Cure" to facilitate dissemination of research accomplishments, communication, and the development of future collaborations. The meeting provided a means for funded investigators and consumer advocates to share ideas and promising directions in CML research.

Collaborative Research Mechanisms

The CDMRP has supported several different award mechanisms that foster strong partnerships and collaborations in the scientific community. Since 1997, $220M has been invested across the programs to establish 132 Consortia, Centers, and Program Projects. In addition, 104 awards totaling $44M were awarded to HBCU/MI under different mechanisms that support collaboration (Figure I-18). Combined, these award opportunities are enabling research communities to pool and leverage their resources and knowledge to move one step closer to disease eradication.

Figure I-18. Examples of CDMRP Award Mechanisms That Support Collaborative Research

Small Business Innovation Research/Small Business Technology Transfer

The CDMRP has participated in the DOD Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) programs to leverage research and product development not typically supported by the CDMRP. The SBIR/STTR programs are designed to harness the innovative talents of U.S. small businesses for our country's military and economic strength. The SBIR/STTR programs provide seed money for small businesses to use in the development of innovative products and technologies that the government can potentially use and that the small business can commercialize outside of the programs. Through September 2007, the SBIR/STTR programs have supported over $18M in technology development for early detection of breast, prostate, and ovarian cancers as well as other health concerns.

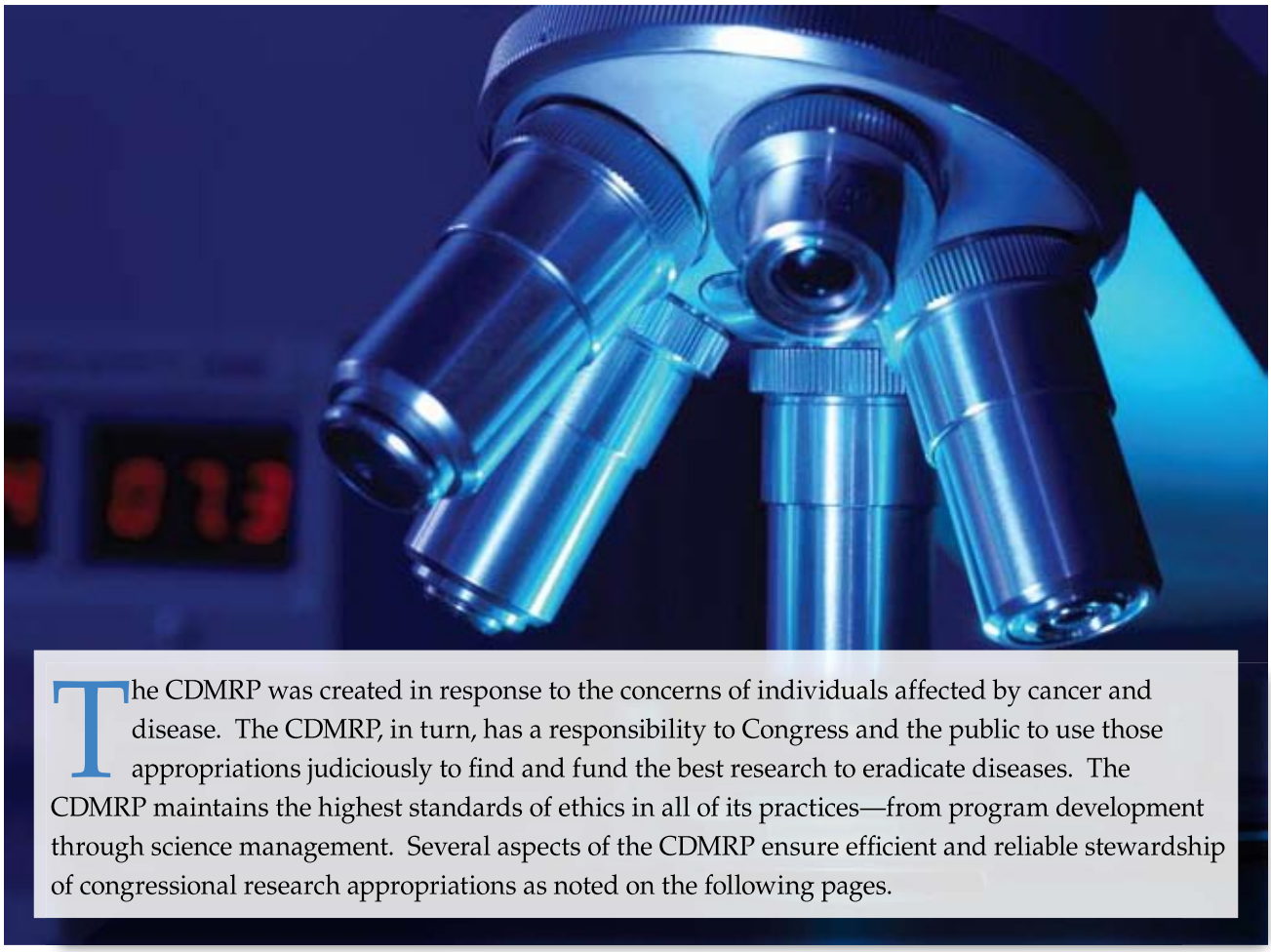
The promising and exciting projects supported by the SBIR/STTR program are leading us closer to new products and technologies that have the potential to revolutionize disease prevention, management, and treatment. For example, several SBIR/STTR-supported projects have the potential to impact the detection of prostate cancer. One project is supporting the development of a diagnostic assay based on autoantibodies, a natural product of an immune response against self-antigens. Since these autoantibodies develop at an early stage of cancer progression and are absent in noncancerous conditions, they may be useful not only for the early detection of prostate cancer but for monitoring disease progression. Other cutting-edge projects supported by the SBIR/STTR program focus on pharmacological modulators of angiogenesis, the formation of new blood vessels. For instance, one project is evaluating a novel, natural inhibitor of RSK (a kinase that is an important drug target for cancer) that is isolated from the bark of Forsteronia refracta. RSK appears to reduce the mobility of endothelial cells and may prove to be important in regulating tumor-induced angiogenesis. In addition to cancer, the SBIR/STTR program has also supported research and development in military health-related disciplines such as the development of new therapeutics for wound healing as well as ante-mortem detection assays for prion-related diseases such as "mad cow disease." Although early detection and diagnosis of prion infectious material in both the food and blood supply are critical to preventing the transmission of this disease, there is no ante-mortem detection or diagnostic assay for any of the prion diseases. Through the SBIR/STTR programs, the CDMRP has funded the development of reagents and assays for the detection and diagnosis of prion disease. One project is optimizing a misfolded protein diagnostic assay that uses conformationally active peptides that undergo a conformational change when exposed to the infectious protein in the human form of prion disease, Creutzfeldt-Jacob disease. Two other projects have taken different approaches in developing cervid cell culture models that propagate prions and the assays for ante-mortem detection of chronic wasting disease, the prion disease found in deer and elk.

Breast Cancer Research Semipostal Program

The Breast Cancer Stamp, a 55-cent semipostal stamp, is the first semipostal stamp in our nation's history. The Breast Cancer Stamp was introduced by Public Law 105-41, which resulted from the work of breast cancer advocates who raised the national public interest in breast cancer research. Net revenues from the Breast Cancer Stamp are used to support breast cancer research at both the DOD BCRP and the National Institutes of Health. Since the stamp was first offered for sale in 1998, the DOD BCRP has received 30% of the sales of the stamp revenue totaling $16,387,657.27. Through FY06 these monies have been used to fully fund 34 BCRP Idea Awards and partially fund 2 other Idea Awards. Beginning in FY07, the stamp funds began supporting the Synergistic Idea Awards. To date, 1 Synergistic Idea Award has been fully funded and 2 others have been partially funded with revenue from the Breast Cancer Stamp. Idea Awards support highly innovative, high-risk/high-reward breast cancer research that ultimately could lead to critical discoveries or major advancements that will accelerate the eradication of breast cancer. Synergistic Idea Awards add collaboration to the Idea Award mechanism to promote synergy to accelerate the research effort. Portfolio analysis of the research areas funded by the DOD Breast Cancer Research Semipostal Program demonstrated a wide scope of areas covering basic, translational, and behavioral sciences.

The DOD carefully invests the income from the Breast Cancer Stamp in the best science from among the nation's most innovative, qualified scientists and clinicians. Highlights of research supported by the Breast Cancer Stamp and the complete investment strategy can be found in Appendix C.

4 Highest Standards of Ethics—Good Stewards



The CDMRP was created in response to the concerns of individuals affected by cancer and disease. The CDMRP, in turn, has a responsibility to Congress and the public to use those appropriations judiciously to find and fund the best research to eradicate diseases. The CDMRP maintains the highest standards of ethics in all of its practices—from program development through science management. Several aspects of the CDMRP ensure efficient and reliable stewardship of congressional research appropriations as noted on the following pages.

Maintaining Low Management Costs

Funding is maximized by keeping management costs as low as possible. For example, in FY06 the average management costs for CDMRP core programs was 6.7 percent. These significant savings in management costs enabled the greatest amount of funds to be directed to research.

Employing an Effective Grants Management Process

CDMRP awards are made in the form of grants, contracts, or cooperative agreements, and the research is executed over 1 to 5 years, depending on the type of award mechanism. With 7,522 awards made through FY06 and with approximately 500 to 600 new grants being processed each year, the negotiation and management of these grants, contracts, and/or cooperative agreements are a major focus of the CDMRP. As such, the CDMRP ensures fiscal responsibility through cost containment and clear cost-benefit analyses. Also important are ongoing efforts to make certain that the research supported by the American public is monitored thoroughly for technical progress and compliance with animal and human use regulations.

Grants Negotiations

Funding is maximized through effective grant negotiations. A detailed analysis of each budget is performed to realize cost savings. Cost-sharing is pursued when possible. As grants are negotiated, overlap of research funded by other grants or other funding agencies is verified to ensure that research funds and efforts are not duplicated.

Grants Management Team

The research management infrastructure involves a proactive grants management team to facilitate success of the research. Each CDMRP award is assigned to a Grants Manager for the life of that grant, ensuring a broad knowledge of each grant, continuity among all parties involved in the award, and the most comprehensive assistance possible to the Principal Investigator. All Principal Investigators are required to submit annual progress reports, which are carefully reviewed and feedback is provided to investigators. The annual reporting requirement ensures that the research plan is consistent with the statement of work. The progress of large grants and consortia is also monitored by site visits and reverse site visits.

Electronic Grants System

To assist with the grants management process, the CDMRP developed a state-of-the-art database called the Electronic Grants System (EGS) in FY02 to enable real-time electronic management of CDMRP proposals from proposal receipt to award closeout. EGS is an internal, customized, and integrated business system that securely allows multiple users within the USAMRMC to input data, download reports, and manage daily administrative tasks associated with grants. The implementation of EGS has allowed the CDMRP to virtually eliminate the paper processing of grants, which not only saves time and money but also increases the accuracy of the grant management processes.

Continual Evaluation of Our Programs and Processes

CDMRP programs are highly visible research programs that address health issues of high public priority. The inherent urgency of these programs creates a substantial requirement for evaluating and reporting program outcomes as Congress, DOD, scientists, consumer advocates, and the public anxiously await results of CDMRP-supported research. Thus, the CDMRP established a program evaluation division to ensure that it is finding and funding the best research to eradicate diseases. Monthly meetings of the Program Evaluation Steering Committee (PESC) are held to design and monitor progress on evaluation projects that assess research relevance, productivity, and accomplishments. Subcommittees are then formed to pursue specific program evaluation projects. Final reports are delivered to the PESC once a project has been completed. In addition, evaluation projects of interest to the public have been presented at national and international meetings and/or posted on the CDMRP website.

Born out of a program evaluation initiative, the CDMRP developed a detailed taxonomy system for identifying and tracking the progression of research products, that are defined as research outcomes, which may lead to a clinical or public health application (including research resources). Information on CDMRP-funded research products are housed in a products database that follows the research outcomes from every grant awarded by the CDMRP since 1993. This database identifies the research and clinical products that arise directly from our funded grants and tracks the contributions of the CDMRP to their discovery, development, and translation into the clinic. The CDMRP portfolio of products by type and phase are illustrated in Figures I-19 and I-20, respectively.

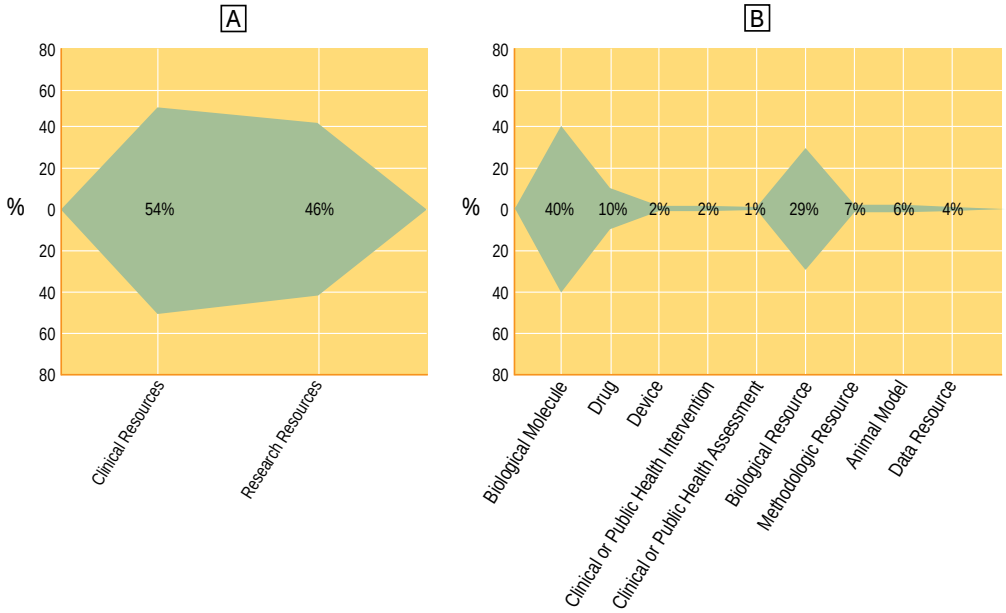


Figure I-19. Percentage of CDMRP-Funded Products by (A) Major Classification and (B) Specific Type

Each award funded by the CDMRP is monitored annually for progress. During each review, the CDMRP's product taxonomy system is used to identify research products and track them through their various stages of development. This taxonomy system classifies each product as being either a clinical resource or a research resource and further identifies each product as one of the following types:

Clinical Resources

- Biological Molecule—human molecular substance (e.g., a gene, protein, or hormone)
- Clinical or Public Health Assessment—potential or proven biological procedure (e.g., biomarker assay or risk assessment)
- Clinical or Public Health Intervention—potential or tested medical or behavioral procedure (e.g., surgical technique or diet modification program)
- Device—an instrument, equipment, or other apparatus used for medical purposes (e.g., a digital mammography machine)
- Drug—a natural or synthetic compound not of human origin (e.g., taxol)

Research Resources

- Animal Model—a nonhuman animal system that mimics specific biological processes (e.g., a mouse model)
- Biological Resource—biological material used for research purposes (e.g., a cell line or antibody)
- Data Resource—a database or other collection of information used for research (e.g., database of medical records or a collection of digital mammography images)
- Methodological Resource—a process or procedure used for research (e.g., informatics techniques or statistical models)

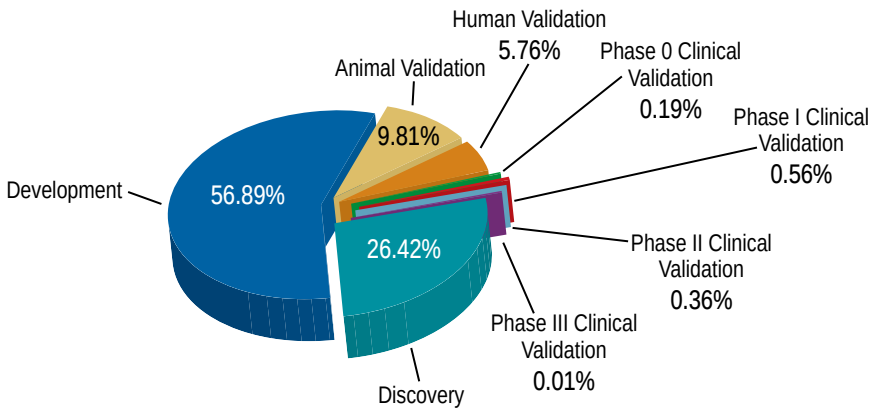
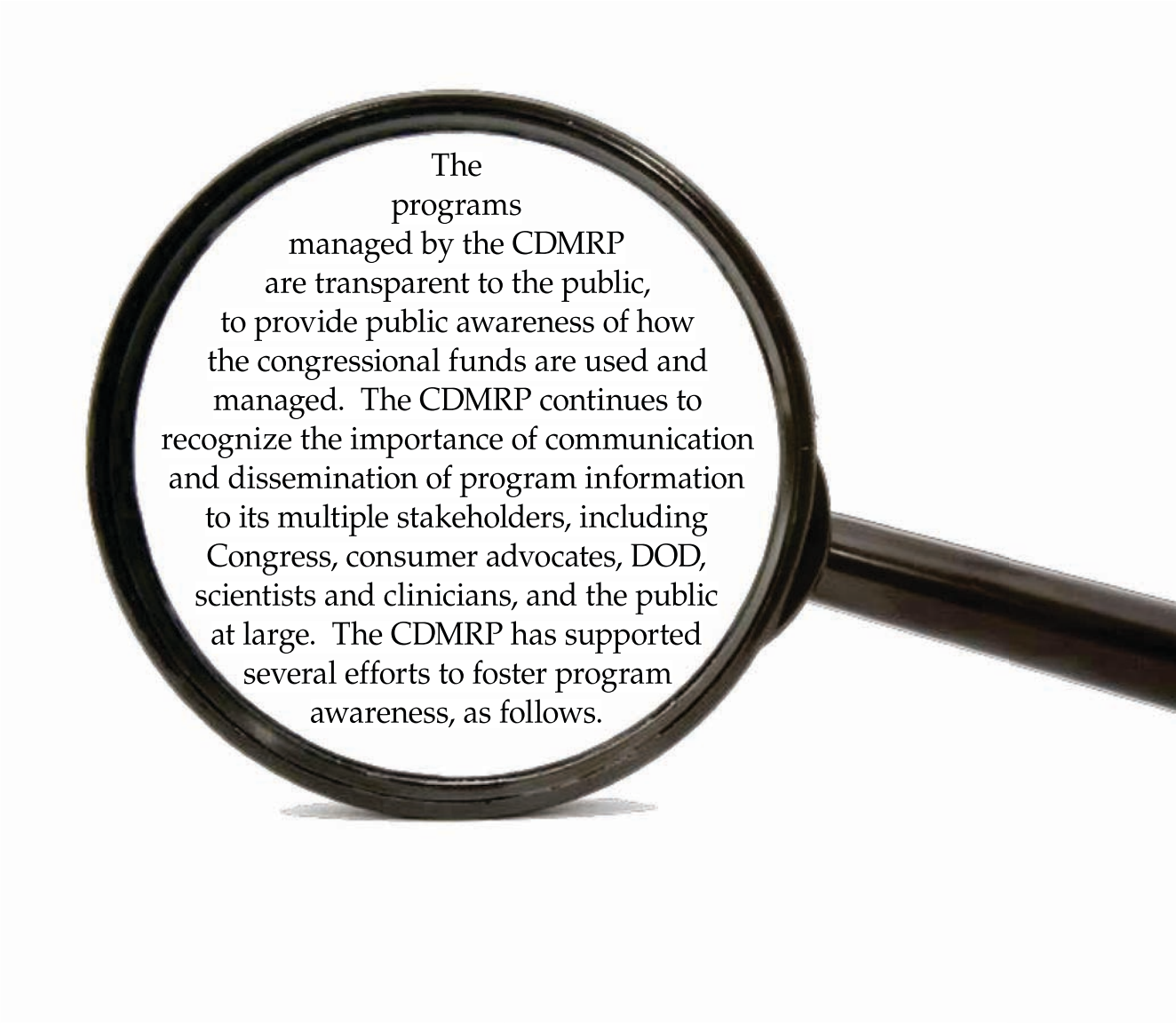


Figure I-20. Phase(s) of Product Development Supported by the CDMRP

The CDMRP's product taxonomy system not only identifies products according to their type but also captures the phase(s) of development supported by the CDMRP—from initial discovery through Phase III clinical validation. As such, the CDMRP may support multiple phases of development for each product. For example, if a drug is developed, then tested in cell lines and animal models, it would be identified as being in Discovery, Development, and Animal Validation. The various phases of development and their definitions are as follows:

- Discovery—initial design, identification, and/or synthesis of a product
- Development—product development and/or testing in in vitro systems (e.g., cell lines or in vitro assays) to determine product characteristics
- Animal Validation—assessing product characteristics in nonhuman animal models
- Human Validation—preclinical assessment of product characteristics in human biological substances (e.g., human tissue samples, human primary cell lines, or human bodily fluids)
- Phase 0 Clinical Validation—preliminary assessment of a product in human subjects. Phase 0 trials are typically exploratory trials with no therapeutic or diagnostic intent that use very small numbers (<10) of subjects (e.g., screening studies or microdose studies)
- Phase I Clinical Validation—assessment of administration characteristics (e.g., route of administration, dosing frequency, device settings and tolerances, drug metabolism, and acute side effects) or the equivalent in a small number of healthy volunteers (between 10 and 80)
- Phase II Clinical Validation—assessment of product safety, preliminary efficacy, and trial methods, or their equivalent. Phase II trials usually focus on a specific type of cancer, involve more participants (100–300), and involve those who have the disease or condition that the product seeks to address
- Phase III Clinical Validation—assessment of product efficacy and side effects in comparison to a standard treatment or approach, or the equivalent. Phase III trials typically involve large numbers of participants having the disease or condition (1,000–3,000) and randomization to study groups

5 Transparent and Open Communication



http://cdmrp.army.mil

The CDMRP website disseminates up-to-date program information to the public and the research community. Annually, approximately 9,800 visits are made to the homepage along with more than 20,900 total visits to the overall website. Features of the website include:

- Research Programs—new and historical information on individual programs managed by the CDMRP
- Funding Opportunities—calls to the scientific and clinical communities to submit proposals under individual award mechanisms offered by research programs
- Consumer Involvement—information on consumer involvement in scientific peer review
- Search Awards—search engines for posted awards that search by various criteria (including research program, fiscal year, Principal Investigator, institution, research topic, award mechanism, and clinical trial); the award amount, an abstract, and resulting publications are provided for each award
- Annual Reports—archives of CDMRP Annual Reports
- What's New—the most recent CDMRP happenings, including CDMRP-supported meetings, scientific accomplishments achieved by CDMRP-funded investigators, and press releases
- New and Archived Documents—documents about recent CDMRP happenings including press releases, fact sheets, annual reports, and program award books
- About Us—summary information about the CDMRP, our program cycle, funding history and process, and staff with links to Fort Detrick and the USAMRMC Commanding General
- Related Links—links to other sites

CDMRP Webpage Factoids

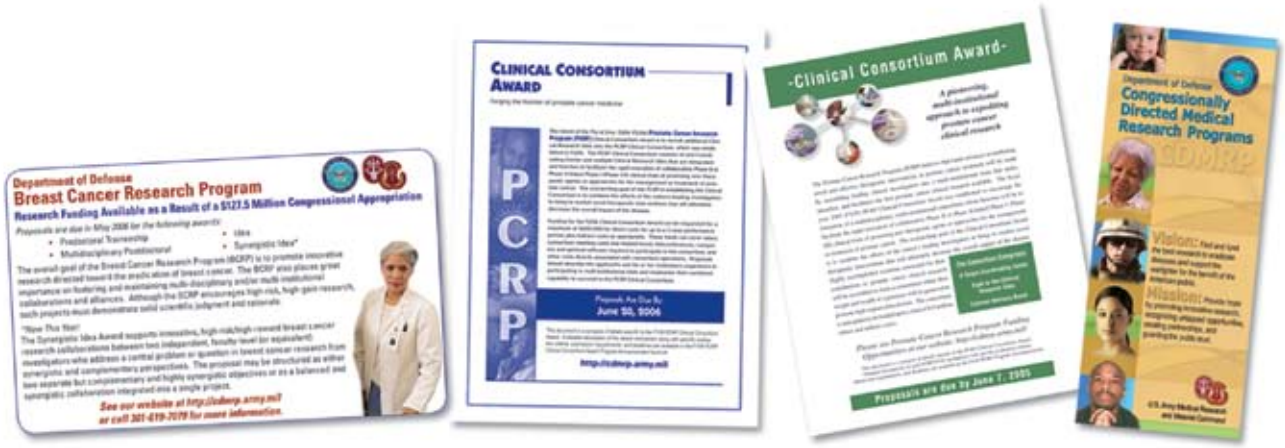
A sampling of some of the new postings that occurred this year:

- 30 Research Highlights
- 8 Consumer Highlights
- 25 News Items
- 15 Press Releases
- 10 Consumer Profiles

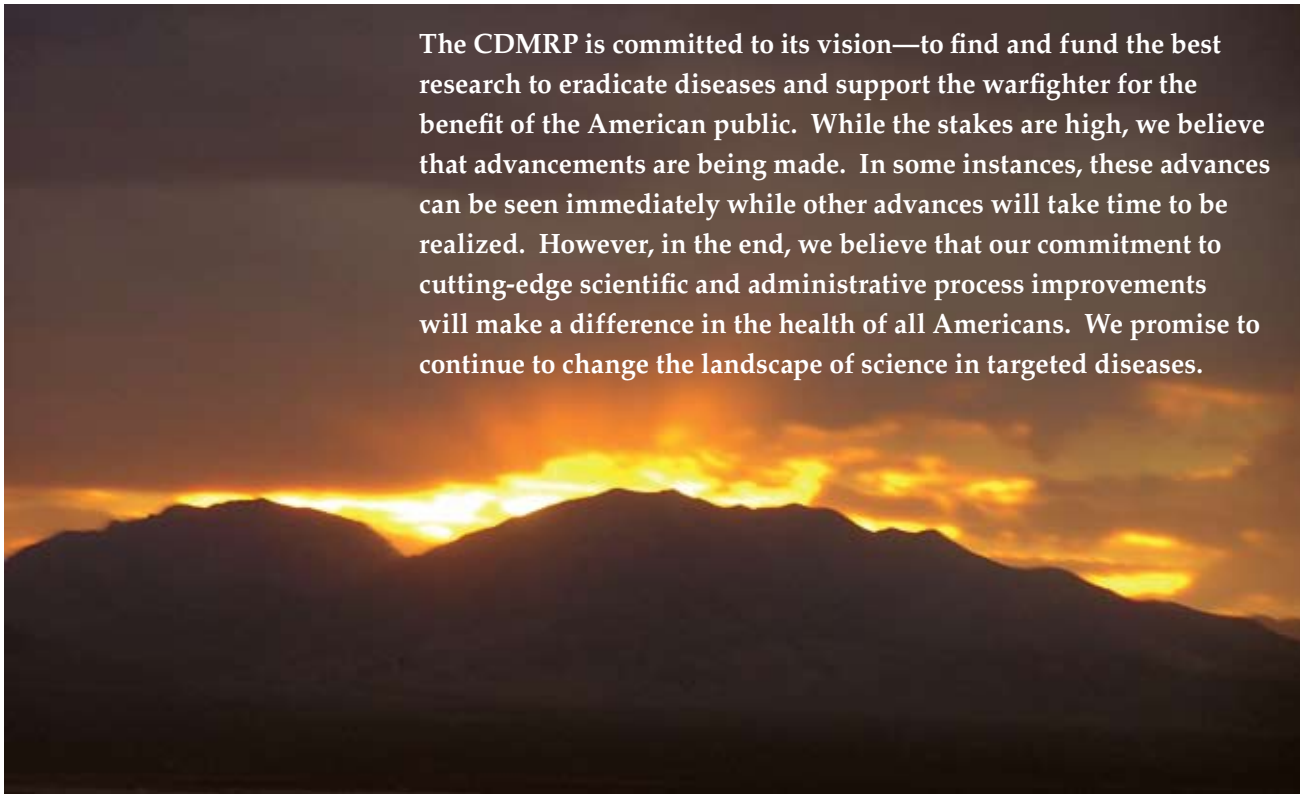
Funding Opportunities and Award Information

Programs within the CDMRP prepare and issue program announcements that provide details on individual award mechanisms, the application process, and requirements for submitting proposals. The following publicity efforts are directed toward alerting the scientific research community when new program announcements are released and propagating the word on funded awards:

- Posting program announcements on Grants.gov and the CDMRP website
- Posting award information on the CDMRP website
- Notifying websites that specialize in biomedical grant notification
- Alerting more than 800 research administrators of upcoming award opportunities with pre-announcements and release date announcements
- Notifying more than 50 professional associations, 160 Veterans Affairs and military research laboratories, 6 federal agencies, and more than 250 consumer advocacy organizations of upcoming funding opportunities
- Advertising both in broadly focused professional journals and on federal business websites
- Utilizing targeted e-mails and advertising for specific award mechanisms and outreach
- Sending 27,000 e-mails to prior applicants, scientific peer reviewers, and individuals who have requested that their names be placed on the CDMRP notification list
- Sending press releases to cancer research news outlets
- Distributing CDMRP electronic news items to more than 250 consumer advocacy groups
- Exhibiting the CDMRP display at national scientific meetings



On the Horizon



The CDMRP is committed to its vision—to find and fund the best research to eradicate diseases and support the warfighter for the benefit of the American public. While the stakes are high, we believe that advancements are being made. In some instances, these advances can be seen immediately while other advances will take time to be realized. However, in the end, we believe that our commitment to cutting-edge scientific and administrative process improvements will make a difference in the health of all Americans. We promise to continue to change the landscape of science in targeted diseases.