



## EXECUTIVE SUMMARY

**N**early 35 years ago, President Richard M. Nixon declared a “War on Cancer” and enacted bold legislation to mobilize the nation’s resources against these devastating diseases. The 1971 National Cancer Act, which authorized substantial public investment into the U.S. cancer research enterprise, ushered in an era of scientific discovery and medical advances that continue to have a significant impact on cancer prevention, treatment, and mortality. The Office of the Congressionally Directed Medical Research Programs (CDMRP), a research directorate within the U.S. Army Medical Research and Materiel Command (USAMRMC) at Fort Detrick, Maryland, plays a pivotal role in advancing the country’s cancer research agenda. The CDMRP proudly partners with Congress, the Department of Defense (DOD), consumer advocates, researchers, physicians, and the American public to develop and implement targeted funding programs that are enabling the nation to cure cancers and other diseases that exert a substantial toll on public health. Since its inception, the CDMRP has managed 54 programs totaling almost \$3.4 billion (B) in congressional appropriations and 6,193 awards in areas including breast, prostate, and ovarian cancers; chronic myelogenous leukemia; neurofibromatosis; tuberous sclerosis complex; and military health and readiness.



The CDMRP is a pioneer in exploring and mobilizing untapped research and science management opportunities, from creating award mechanisms that fulfill unique niches to developing innovative management execution processes, many of which are now being adopted by other funding agencies.

## HISTORY OF THE CDMRP

The CDMRP arose from a unique partnership among the public, Congress, and the military. The breast cancer consumer advocacy community, led by the National Breast Cancer Coalition (NBCC), launched a grassroots campaign in 1992 to raise public and government awareness of the need for increased funding for breast cancer research. As part of this campaign, the NBCC presented President Bill Clinton with a 2.6 million-signature petition for a comprehensive plan to eradicate breast cancer. Congress, in response to these efforts, appropriated \$25 million (M) in fiscal year 1992 (FY92) for breast cancer research. The DOD, specifically the USAMRMC, was selected as the steward of these funds because of its long history of medical research and its adaptable management structure. Congress subsequently increased the USAMRMC’s mandate in FY93 with a \$210M appropriation for extramural peer reviewed breast cancer research, leading to the creation of the CDMRP within the USAMRMC to manage the new Breast Cancer Research Program (BCRP).

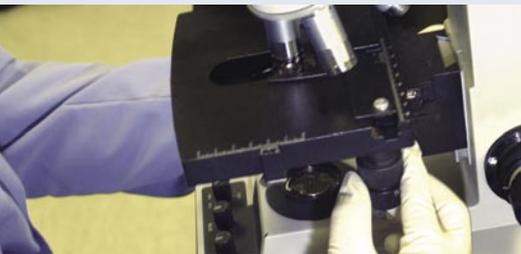
The USAMRMC operates outstanding medical research facilities in the United States and abroad that focus on medical research and technology relevant to national defense. Consequently, the Army, recognizing that breast cancer was outside its core expertise, solicited advice from the National Academy of Sciences Institute of Medicine (IOM) on how to manage the FY93 appropriation most effectively. The IOM



committee made two pivotal recommendations in its report to the USAMRMC<sup>1</sup>—(1) the development of an annual investment strategy to guide allocations and allow the program to respond to changing needs in breast cancer research and (2) the implementation of a two-tier review process in which both scientific merit and programmatic relevance would be addressed. These recommendations became cornerstones in the administration of the FY93 BCRP and were later adapted for most of the CDMRP's other targeted research programs.

## PROGRAM DEVELOPMENT, EXECUTION, AND MANAGEMENT

The CDMRP utilizes a flexible 7-year cycle that spans from the receipt of annual congressional appropriations through the completion of research grants. Once appropriations are received, each program's Integration Panel (IP)—an advisory board of leading scientists, clinicians, and consumers—develops an investment strategy for the upcoming year that meets the unique needs of the research field and encourages exploration of innovative, novel, and underinvestigated areas. Program announcements requesting research proposals through specific award mechanisms are subsequently prepared and released. Submissions received in response to each announcement are evaluated for both scientific merit and programmatic relevance in a two-tier process. Scientifically sound proposals that best meet the program's interests and goals are recommended to the Commanding General (CG), USAMRMC, for funding. Once the CG approves the funding recommendations, awards are made in the form of 1- to 5-year grants, contracts, or cooperative agreements and assigned to Grants Managers for monitoring of progress. At the end of the award period, grant files are closed out.



## BREAST CANCER

Breast cancer, the most frequently diagnosed cancer among women, occurs in approximately one in eight women. The American Cancer Society estimated that more than 210,000<sup>a</sup> new cases of breast cancer would be diagnosed in the United States in 2005. Although almost 90% of these patients will survive more than 5 years, more than 40,000 women were expected to die from the disease in 2005.

The BCRP, the second largest funder of extramural breast cancer research in the world, has managed \$1.83B in appropriations since its inception in FY92, including \$150M in FY05. More than 4,200 grants have been awarded.

<sup>a</sup> American Cancer Society, *Cancer Facts and Figures, 2005*.

<sup>1</sup> 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*.



## PROSTATE CANCER

Prostate cancer is second only to lung cancer as a leading cause of cancer deaths in American men. Over 230,000 new cases and 30,000 deaths were expected in 2005.<sup>a</sup> Prostate cancer incidence and death rates are significantly higher in African American men than in white men for reasons that are not fully understood.

Congress appropriated \$85M to the FY05 PCRFP, for a total of \$650M from FY97 through FY05 for innovative peer-reviewed prostate cancer research. More than 1,200 grants have been awarded, including projects that address the significant disparities in prostate cancer incidence and mortality in the African American community.

<sup>a</sup> American Cancer Society, Cancer Facts and Figures, 2005.

## PROGRAM EVALUATION AND INFORMATION DISSEMINATION: IDENTIFYING AND SHARING OUR SUCCESSES

The continuation of the CDMRP is dependent upon annual congressional appropriations. The CDMRP, in turn, has an obligation to demonstrate adherence to congressional mandates, verify return on investment, and keep stakeholders—Congress, the DOD, and the public—apprised of achievements and ongoing activities. As such, a program evaluation division was established within the CDMRP to assess research relevance, productivity, and accomplishments, starting during the grants management period and continuing after award closeout. Information on our successes is disseminated on our website (<http://cdmrp.army.mil>), in annual reports, and at national conferences. The CDMRP also partners with scientific news outlets, research institutions, and consumer advocacy organizations to post information on their websites. The CDMRP's commitment to guarding the public trust and maintaining positive visibility with its stakeholders helps ensure continued support for our mission.



## THE CDMRP IN FISCAL YEAR 2004

The success of the CDMRP in addressing the needs of the scientific and consumer communities, combined with the dedicated efforts of advocacy groups, resulted in continuation of our programs in FY04. The FY04 CDMRP featured seven core programs, which are characterized by receipt of multiple appropriations and standing IPs:

- ◆ Breast Cancer Research Program (BCRP)
- ◆ Prostate Cancer Research Program (PCRFP)
- ◆ Neurofibromatosis Research Program (NFRP)
- ◆ Ovarian Cancer Research Program (OCRFP)
- ◆ Peer Reviewed Medical Research Program (PRMRP)
- ◆ Chronic Myelogenous Leukemia Research Program (CMLRP)
- ◆ Tuberous Sclerosis Complex Research Program (TSCRFP)



## THE VISION FOR THE FISCAL YEAR 2005 PROGRAMS

The CDMRP, by leveraging the resources and expertise of Congress, the DOD, consumer advocates, researchers, clinicians, and the public, continues to fulfill a unique niche in biomedical research. In FY05, Congress appropriated \$395.5M to the CDMRP to continue its investment in innovative research aimed at improving the health of all Americans. In accordance with the recommendations of the 1993 IOM panel, funding allocations and investment strategies have been adapted to most effectively address emerging needs and evolving priorities. In particular, many new award mechanisms have been added to support the development of novel therapies and the training of researchers and clinicians to carry out this work.

## SCIENTIFIC OUTCOMES AND ADVANCES

The CDMRP originated from an unprecedented partnership of the American public, Congress, and the DOD that remains vital to ongoing initiatives. The CDMRP also continues to forge collaborations with the scientific and consumer communities and other funding agencies. As described in the following sections, these relationships provide the critical support and resources—human, managerial, and scientific—that are key to our continued progress toward disease eradication.



## NEUROFIBROMATOSIS

Neurofibromatosis (NF) encompasses three distinct genetic disorders—NF1, NF2, and schwannomatosis—that are characterized by the development of nervous system tumors. Non-nervous tissues such as the bones and blood vessels may also be affected. NF affects individuals of both sexes and all races and ethnic groups throughout the world.

NF1, the most common of the disorders, occurs in approximately 1 in 2,600<sup>a</sup> to 1 in 4,000 births worldwide, whereas NF2 and schwannomatosis each affect 1 in 40,000 individuals.<sup>b,c</sup>

The NFRP, the second oldest CDMRP core program, was established in FY96 with an \$8M appropriation and has managed \$155.3M, including an unprecedented \$25M appropriation received in FY05. From FY96 through FY04, 140 awards have been made.

<sup>a</sup> Lammert M, Friedman JM, Kluwe L, et al. 2005. Prevalence of neurofibromatosis 1 in German children at elementary school enrollment. *Arch Dermatol* 141:71.

<sup>b</sup> Report on Neurofibromatosis, Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Neurological Disorders and Stroke, 2003.

<sup>c</sup> The Children's Tumor Foundation, <http://www.ctf.org>.



## OVARIAN CANCER

An estimated 22,220 new cases of ovarian cancer were expected in 2005. Ovarian cancer, which is often not diagnosed until its advanced stages, causes more deaths than any other cancer of the female reproductive system (over 16,000 deaths were anticipated in 2005).<sup>a</sup>

The OCRP has received \$91.7M in appropriations from FY97 through FY05, including \$10M in FY05. The OCRP has supported a total of 92 awards, including 12 grants in FY04 in the areas of cancer etiology/tumor biology, pre-clinical development of targeted therapies, and imaging.

<sup>a</sup> American Cancer Society, Cancer Facts and Figures, 2005.

### *Leveraging Funding to Cure Disease*

The CDMRP received \$3B in congressional appropriations and funded 6,193 research awards from FY92 through FY04. The CDMRP's philosophy is to fund innovative ideas and concepts that have the potential to revolutionize the landscape of science. The success of the CDMRP's programs and the demonstration of responsible stewardship of funds have led to widespread support by the American public, vigorous consumer advocacy efforts on behalf of CDMRP initiatives, and ultimately the continued allocation of funds from Congress.

## PEER REVIEWED MEDICAL RESEARCH

Members of our armed forces are exposed to health risks that are not normally encountered by the public, including hearing loss, lung injury, and infectious diseases. The PRMRP supports biomedical research with direct relevance to military health and readiness.

The PRMRP was established in FY99 with a \$19.5M appropriation and has managed \$294.5M from FY99 through FY05. A total of 29 proposals were funded from the \$50M FY04 appropriation.

### *Leveraging People to Cure Disease*

The CDMRP maintains strong and dynamic partnerships with people of diverse backgrounds, all of whom are essential to realizing the vision of eradicating disease. The CDMRP is an innovator in integrating the voices of consumers—disease survivors and, for the NFRP and TSCR, their family members—in virtually all aspects of program execution, serving as a model for other funding agencies. Approximately 900 consumers have served as peer reviewers and IP members, and many others have aided in patient recruitment, public education, and advising researchers. The CDMRP also values the guidance of the renowned research scientists and clinicians who participate in peer and programmatic review. Moreover, the CDMRP's training and research awards serve to both recruit new investigators and keep established scientists



engaged in the battle against human disease. Additionally, dedicated DOD and contract professionals provide valuable scientific and managerial services in support of the CDMRP's mission.

### *Leveraging Science Management to Cure Disease*

Since its inception, the CDMRP employs a flexible management strategy that allows for rapid adaptation to fulfill unique niches and address the evolving needs of the biomedical research community. In particular, the CDMRP has been a leader in the development of innovative award mechanisms to recruit and train new investigators, foster collaborative research networks, and support the exploration of novel ideas that have the potential to revolutionize disease prevention and treatment. The CDMRP also is a pioneer in the use of electronic technology for all phases of the grant life cycle, including proposal submission, peer and programmatic review, funding notification, management of funded awards, and grant closeout. Notably, the Electronic Grants System, launched in FY02, allows for real-time electronic management of proposals and has virtually eliminated the paperwork associated with grant administration. A tribute to the success of the CDMRP's innovations in science management is that these enhancements are now being adopted by other funding organizations.

## **CHRONIC MYELOGENOUS LEUKEMIA**

Chronic Myelogenous Leukemia (CML) is characterized by overgrowth of granulocytes, a specific type of white blood cell; its cause is unknown. Approximately 4,600 new cases of CML were anticipated in 2005, resulting in about 850 deaths.<sup>a</sup> CML is primarily an adult disease; only 2% of patients are children.

The CMLRP began in FY02 with an appropriation of \$5M and was continued with yearly appropriations of \$4.25M in FY03, FY04, and FY05. Eight awards were supported in FY04.

<sup>a</sup> American Cancer Society, <http://www.cancer.org/>.



### *Leveraging Ideas to Cure Disease*

The CDMRP, in keeping with the recommendations from the 1993 IOM panel, seeks to foster a research environment in which “investigators are not afraid to gamble on risky but alluring ideas.” Accordingly, the CDMRP funds revolutionary studies that other granting agencies generally do not support but that may ultimately lead to significant advances in disease prevention or treatment. Each of the award mechanisms that promote innovative research has different requirements that focus attention on novel approaches, concepts, or technologies.



## TUBEROUS SCLEROSIS COMPLEX

Tuberous sclerosis complex (TSC) is a genetic disorder characterized by seizures, behavioral problems, kidney disease, and the development of tumors on vital organs. Two thirds of the cases are caused by spontaneous mutations in either the *TSC1* or *TSC2* gene. TSC affects nearly 1 million people worldwide, including approximately 50,000 in the United States.<sup>a</sup>

The TSCRP was established in FY02 with a \$1M appropriation and has managed \$9.2M in appropriations through FY05. A total of 13 awards were supported in FY04.

<sup>a</sup> Tuberous Sclerosis Alliance, <http://www.tsalliance.org>.

### *Leveraging Collaborations to Cure Disease*

The CDMRP is dedicated to fostering the development of collaborative teams of investigators and consumers with diverse expertise to address critical questions in biomedical research. A total of \$172.7M has been invested across programs to create 46 Consortia, Centers of Excellence, and Program Projects that enable the scientific community to advance research in ways that cannot be accomplished by individual investigators. The CDMRP is particularly interested in promoting the participation of investigators of varying backgrounds in multidisciplinary teams. To achieve this aim, the BCRP, OCRP, and PCRP have offered award mechanisms that support the formation of partnerships between faculty investigators at Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) and established researchers at other institutions. At the managerial level, the CDMRP has also formed international collaborations with other granting organizations to pool resources and facilitate the exchange of ideas and knowledge. Additionally, to facilitate dissemination of research findings, communication, and the development of future collaborations, the CDMRP also funds research conferences, notably the biannual Era of Hope breast cancer symposia.

### *Leveraging Technology for Product Development to Cure Disease*

The CDMRP has developed a diverse portfolio of basic, translational, and clinical research totaling 6,193 awards and almost \$3.4B in appropriations. We have already begun to see a return on our investment, including approximately 11,680 publications and 130 patents/licensures (including applications). The CDMRP also has implemented a product assessment initiative to identify tangible research outcomes that may lead to clinical and public health application. Retrospective analysis of our portfolio across all programs through FY02 identified 11,812 potential products from 4,841 awards. Prospective analysis of grants awarded since FY02 is ongoing.





## LOOKING AHEAD

Finding solutions to today's most devastating health problems remains a significant challenge. In 2006, the CDMRP will continue to leverage the considerable expertise and resources of its partners—public, private, government, and military—in support of the ambitious goal of eradicating disease. Together, we will win this battle.