

CONGRESSIONALLY DIRECTED
MEDICAL RESEARCH PROGRAMS:
PARTNERING FOR A CURE

Executive Summary



Congressionally Directed Medical Research Programs: A History Rooted in Partnerships

In 1970, the American people expressed an urgent desire to find a cure for cancer, the second leading cause of death in the United States. During the 1971 State of the Union address, President Nixon responded by stating his intent to request a \$100 million (M) appropriation to launch an intensive national campaign to find a cure for cancer. On December 23, 1971, President Nixon followed through with this promise when he signed the National Cancer Act into law and declared a national “War on Cancer.” This declaration initiated ongoing partnerships among the U.S. Government, the American public, and the scientific community to cure cancer.

Similarly, the origins of the Office of the Congressionally Directed Medical Research Programs (CDMRP) can be traced back to public concerns over cancer and its toll on the American public. In 1992, the breast cancer advocacy community launched a grassroots effort to raise public awareness on the need for increased funding for breast cancer research. In response, Congress appropriated \$25M in fiscal year 1992 (FY92) for breast cancer research. This appropriation was placed under the stewardship of the U.S. Army Medical Research and Materiel Command (USAMRMC) because of its long history of medical research and its adaptable management structure. In FY93, Congress appropriated \$210M to the USAMRMC for extramural peer-reviewed breast cancer research. Because of the increased appropriation and mandate for peer-reviewed research, the CDMRP was created within the USAMRMC to manage the new Breast Cancer Research Program (BCRP). Thus, the CDMRP arose from unique partnerships among the American public, Congress, and the U.S. Army.

Partnering for Effective Program Development, Execution, and Management Strategies

Recognizing that breast cancer was outside of its core expertise, the U.S. Army initiated a partnership with the scientific community by soliciting advice from the National Academy of Sciences Institute of Medicine (IOM) on how to effectively manage the BCRP. In its report to the USAMRMC,¹ the IOM made two pivotal recommendations: (1) Develop an annual investment strategy to guide allocations and allow the program to respond to changing needs in breast cancer research and (2) implement a two-tiered review process in which both scientific merit and programmatic relevance are addressed. These recommendations became cornerstones in the administration of the FY93 BCRP and have been adopted by the other targeted research programs that were subsequently mandated by Congress and managed by the CDMRP.

In keeping with the IOM recommendations, the CDMRP convenes an advisory board, called an Integration Panel, for each of its primary programs. The Integration Panel, composed of leading scientists, clinicians, and consumer advocates, is a key partner in the fight against disease. The Integration Panel establishes a vision and investment strategy for the upcoming year. Once an investment strategy is developed, proposals are solicited in response to specific program announcements. Each submission is evaluated for scientific and technical merit by scientific peer review panels that are organized by scientific discipline, specialty area, or award mechanism. Proposals are then reviewed by the Integration Panel (the advisory board that recommended the initial investment strategy) for programmatic relevance, as recommended by the IOM. Scientifically sound proposals that best meet the goals and interests of that program are recommended to the Commanding General, USAMRMC, for funding.

¹ 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.

Partnering to Assess Program Outcomes

Awards are made in the form of 1- to 5-year grants, contracts, or cooperative agreements. Each award is assigned to a CDMRP Grants Manager, a doctoral-level scientist or clinician, for monitoring progress. Because there is a certain level of unpredictability in research, particularly novel research, the Grants Manager works closely with individual investigators to monitor each project, ensuring that the vision of the project and ultimately program remains true. In addition, in an effort to demonstrate adherence to congressional mandates and show accountability to the American public, the CDMRP established a program evaluation division to specifically assess research relevance, productivity, and accomplishments. Combined with the activities of the grants managers, these efforts have collectively enabled CDMRP to evaluate program operations and outcomes.

Additionally, in 2000, CDMRP partnered with the National Cancer Institute to form the International Cancer Research (ICR) partners. Today, the ICR partnership includes 8 U.S.- and 18 U.K.-based cancer funding organizations that have come together to classify their respective cancer research portfolios using a common coding scheme called the Common Scientific Outline. Through this collaborative partnership, the ICR Partners developed a relational database of cancer research supported by member organizations called the International Cancer Research Portfolio (ICRP). The ICRP is available to the public (www.cancerportfolio.org) and enables users to browse, search, and/or sort research portfolios by many data fields including type of cancer, funding organization, and research area. Researchers can use the ICRP to identify scientists doing similar work or to identify contacts for multidisciplinary research and collaborations. In addition, the ICRP can be used by cancer funding organizations and government/policy officials to gauge the state of cancer science or set directions for future research efforts.

Partnering with Communities to Cure Disease

The vision of the CDMRP is to find and fund the best research to eradicate diseases and support the warfighter for the benefit of the American public. Toward that end, the CDMRP strives to foster collaborations that facilitate research advancements and lead to significant progress against targeted diseases. While individual partnerships are crucial to the management and execution of the CDMRP, partnerships between the CDMRP and other organizations and communities allow for the pooling of resources and facilitate the exchange of ideas and knowledge, thereby reducing redundancy.



Scientific Community

Through the combined efforts of the consumer advocacy and research communities, the CDMRP has forged new territory in the execution and management of biomedical research. Research scientists and clinicians sit side-by-side to determine the direction of research funded by our various programs, evaluate its scientific merit, and assess its relevance to programmatic goals. In addition, scientists funded by the CDMRP are encouraged to work together, often as teams, despite geographic distance and differing areas of expertise, to address crucial problems from varying perspectives.



Consumer Advocates

The unique perspective of disease survivors was also recognized as being essential to the success of the CDMRP. To date, the relentless work of thousands of consumer advocates has resulted in approximately \$3.8 billion in congressional appropriations to the CDMRP for targeted disease research. In addition, the CDMRP pioneered the integration of consumer advocates—disease survivors who represent consumer advocacy organizations and their constituents—into every aspect of program execution. Consumer advocates are members of each program’s Integration Panel, thereby participating in the development of the annual investment strategy and the review of submissions for programmatic relevance. In addition, consumer advocates have been participating in scientific peer review for the CDMRP since 1995. Furthermore, consumer advocates have the opportunity to participate in CDMRP-funded research projects and multidisciplinary meetings held by the CDMRP to learn about scientific advances supported by these programs. Partnering with consumer advocates brings a unique perspective and sense of urgency to each of CDMRP’s programs that ensures each program remains focused on its goal—to eradicate disease.



Fostering Partnerships through Multidisciplinary Meetings

The CDMRP has sponsored several multidisciplinary meetings that provide funded investigators the opportunity to disseminate research findings and develop collaborations to further their research efforts.

- ❖ To date, the BCRP has hosted four Era of Hope meetings, which are major international conferences that showcase BCRP-funded research and provide scientists, consumer advocates, and health care providers with an opportunity to communicate ideas and identify promising new directions in breast cancer research.
- ❖ The Peer Reviewed Medical Research Program (PRMRP) has sponsored two Military Health Research Forums to further research related to military health by emphasizing ways to expedite the transition from research to, field-usable products and/or methodology.
- ❖ In December 2006, the Chronic Myelogenous Leukemia Research Program (CMLRP) will host Road to a Cure—The CML Investigators Meeting to provide a forum for investigators and consumer advocates to communicate and develop collaborations.
- ❖ The Prostate Cancer Research Program (PCRP) is planning its first multidisciplinary conference called “IMPACT: Innovative Minds in Prostate Cancer Today,” which will be held in September 2007. The goal of this meeting is to promote the exchange of ideas and explore innovative research that will advance prostate cancer research while highlighting PCRP-funded studies.

Partnering for Continued Success: The CDMRP in FY05 and FY06

The continued success of the CDMRP in addressing the needs of the scientific and consumer communities, combined with the dedicated efforts of consumer advocacy groups resulted in the continuation of seven primary programs in FY05. CDMRP primary programs are characterized by the receipt of multiple appropriations and standing Integration Panels. For FY05, the primary programs included:

- ❖ Breast Cancer Research Program
- ❖ Prostate Cancer Research Program
- ❖ Neurofibromatosis Research Program (NFRP)
- ❖ Ovarian Cancer Research Program (OCRP)
- ❖ Peer Reviewed Medical Research Program
- ❖ Chronic Myelogenous Leukemia Research Program
- ❖ Tuberous Sclerosis Complex Research Program (TSCR)

In addition, Congress appropriated a total of \$293.1M in FY06 toward these primary programs to continue the mission of promoting innovative research, recognizing untapped opportunities, creating partnerships, and guarding the public trust. Each of the FY06 programs has developed an investment strategy and adjusted its interests to reflect the latest innovations in appropriate fields of research. In particular, many award mechanisms are being offered to encourage collaboration between differing areas of scientific expertise and bring investigators together in a team-oriented approach to research.

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 212,000² new cases of breast cancer would be diagnosed in the United States in 2006. 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 2006.

The BCRP, the second largest funder of extramural breast cancer research in the world, has managed \$1.96B in appropriations since its inception in FY92, including \$127.5M in FY06. More than 4,600 grants have been awarded.

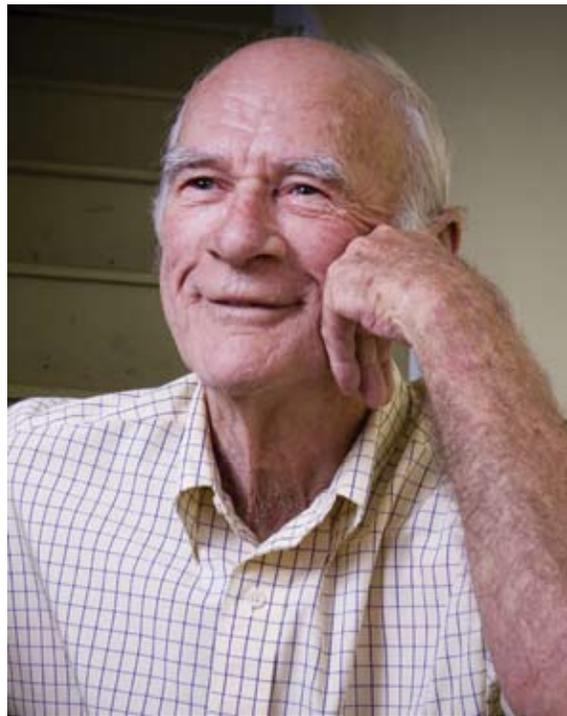


² American Cancer Society, *Cancer Facts and Figures*, 2006.

PROSTATE CANCER

Prostate cancer is second only to lung cancer as a leading cause of cancer deaths in American men. More than 234,000 new cases and 27,000 deaths were expected in 2006.³ 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 \$80M to the FY06 PCRP, for a total of \$730M from FY97 through FY06 for peer-reviewed prostate cancer research. More than 1,400 grants have been awarded, including projects that address the significant disparities in prostate cancer incidence and mortality in the African American community.



³ American Cancer Society, *Cancer Facts and Figures*, 2006.

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. Together, NF1 and NF2 affect more than 100,000 Americans.

The NFRP, the second oldest CDMRP primary program, was established in FY96 with an \$8M appropriation and has managed \$172.3M, including a \$17M appropriation received in FY06. From FY96 through FY05, 181 awards have been made.



OVARIAN CANCER

An estimated 20,180 new cases of ovarian cancer were expected in 2006. Ovarian cancer, which is often not diagnosed until its advanced stages, causes more deaths than any other cancer of the female reproductive system (more than 15,000 deaths were anticipated in 2006).⁴

The OCRP has received \$101.7M in appropriations from FY97 through FY06, including \$10M in FY06. The OCRP has supported a total of 108 awards, including 16 grants in FY05 in the areas of cancer etiology/tumor biology, preclinical development of targeted therapies, and early detection/diagnosis of ovarian cancer.



⁴ American Cancer Society, *Cancer Facts and Figures*, 2006.

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 \$344.5M from FY99 through FY06 including \$50M in FY06. A total of 40 awards were supported by the \$50M FY05 appropriation.



CHRONIC MYELOGENOUS LEUKEMIA

Chronic myelogenous leukemia (CML) is characterized by the overgrowth of granulocytes, a specific type of white blood cell; its cause is unknown. Approximately 4,500 new cases of CML were anticipated in 2006, resulting in about 900 deaths.⁵ 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 through FY05 and \$4.3M in FY06. A total of 11 awards were supported in FY05.



⁵ American Cancer Society, <http://www.cancer.org/>.

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 to 2 million people worldwide, including as many as 25,000 to 40,000 in the United States.⁶

The TSCRP was established in FY02 with a \$1M appropriation and has managed \$13.5M in appropriations through FY06 including \$4.3M in FY06. A total of 15 awards were supported in FY05.

⁶ National Institute of Neurological Disorders and Stroke Tuberous Sclerosis Fact Sheet.



Partnering to Win the War on Cancer

Since 1971 and President Nixon's declaration of a "War on Cancer," many advances have been made in the detection, prevention, and treatment of this disease. A diagnosis of cancer once was the virtual equivalent of a death sentence. However, since the mid-1990s, the cancer death rate has been decreasing steadily. Today, nearly half of all cancer patients can expect to live for 5 or more years after the diagnosis of cancer. However, cancer remains the second leading cause of death in the United States, signifying that there is much work to be done. Through the continuation of these critical partnerships, the CDMRP aims to contribute significantly to the eradication of this disease. Together, we will find a cure.



