

Executive Summary

Prostate cancer is the most common cancer (aside from nonmelanoma skin cancer) and the second leading cause of cancer-related death in men in the United States. In 2002, an estimated 189,000 men were diagnosed with, and 30,200 died from, this disease. African American men are more likely than other racial and ethnic populations both to develop and to die from prostate cancer. While recent trends of stabilizing incidence and decreasing mortality rates are encouraging, prostate cancer remains a major health burden for American men and requires continued action.

In 1997, the National Cancer Institute (NCI) convened the Prostate Cancer Progress Review Group (PRG), a multidisciplinary committee of scientists, clinicians, and advocates, to help NCI define a national research agenda for prostate cancer. The Prostate Cancer PRG issued a 1998 report entitled *Defeating Prostate Cancer: Crucial Directions for Research*, which included priority research questions that should be addressed to advance prevention, detection, diagnosis, and treatment of prostate cancer. An internal NCI Prostate Cancer Working Group was recently convened to assess the research progress made since the release of this report. Besides producing the *Prostate Cancer Progress Report*, this working group contributed to the *NIH Prostate Cancer Research Plan FY 2003–FY 2008*.

The *NCI Prostate Cancer Progress Report* documents trends in the NCI prostate cancer research portfolio from 1998 to 2002. Multiple measures of progress are presented at varying levels of specificity, ranging from overall trends in NCI funding, projects, and resulting peer-reviewed publications, to more specific trends in the number of projects relevant to particular research priorities identified by the PRG. Recognizing the evolutionary nature of research, this progress report also relates priority research questions identified by the PRG to the objectives of the more recently released *NIH Prostate Cancer Research Plan FY 2003–FY 2008*.

Between 1998 and 2002, the NCI substantially expanded investments in prostate cancer research as evidenced by:

- ◆ tripling of prostate cancer funding from \$86.9 million in 1998 to \$278.4 million in 2002,
- ◆ approximate doubling of the number of relevant projects,
- ◆ more than doubling relevant individual training and career development awards,
- ◆ expanding ongoing and initiating new programs to sustain and advance both basic and clinical prostate cancer research,
- ◆ expanding the prostate Specialized Programs of Research Excellence (SPOREs) network from 3 to 11 sites, and
- ◆ expanding collaborative efforts and shared resources to improve the capacity to conduct prostate cancer clinical trials.

Work is under way to translate the discoveries generated by this expanded investment into new prostate cancer prevention, detection, diagnosis, and treatment interventions that will save lives. The following two pages summarize the NCI's investment by research category.

NCI's ability to capitalize on advances in prostate cancer research and care will require continued basic, translational, and clinical research support. This progress report, which documents the NCI's responses to the recommendations of the Prostate Cancer PRG, will help guide efficient and effective implementation of the NCI plans described in the *NIH Prostate Cancer Research Plan FY 2003–FY 2008*.

NCI's Prostate Cancer Research Investment Increased from \$86.9 Million in 1998 to \$278.4 Million in 2002

Biology

- ◆ Funding increased from \$15.2M to \$41.7M.
- ◆ Number of projects increased from 160 to 302.
- ◆ New initiatives included Age-Related Prostate Growth, Role of Hormones and Growth Factors in Prostate Cancer, and Molecular and Cellular Biology of Metastatic Tumor Cells.

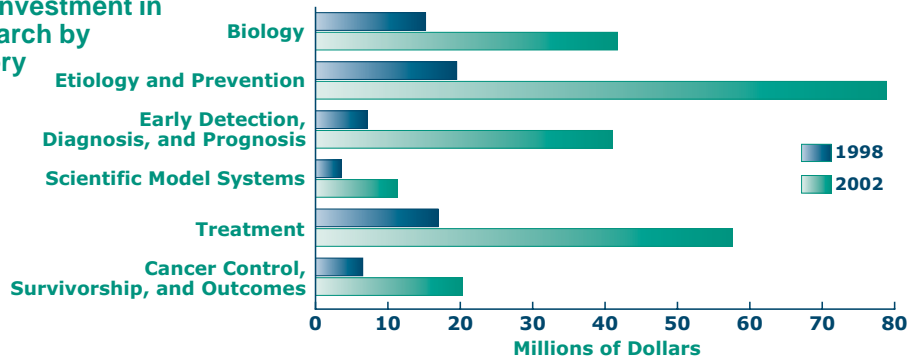
Etiology and Prevention

- ◆ Funding increased from \$19.5M to \$78.9M.
- ◆ Number of projects increased from 112 to 203.
- ◆ Ongoing clinical trials include the SELECT trial.
- ◆ New initiatives included NCI Cohort Consortium, RAPID, and the Small Grants Program for Cancer Epidemiology.

Early Detection, Diagnosis, and Prognosis

- ◆ Funding increased from \$7.1M to \$41.0M.
- ◆ Number of projects increased from 58 to 140.
- ◆ New initiatives included Clinical Proteomics Program, Director's Challenge, Early Detection Research Network, and Exploratory/Developmental Grants for Diagnostic Cancer Imaging.

Growth of NCI's Investment in Extramural Research by Scientific Category



Scientific Model Systems

- ◆ Funding increased from \$3.6M to \$11.3M.
- ◆ Number of projects increased from 40 to 99.
- ◆ New initiatives included Mouse Models of Human Cancers Consortium, Cancer Therapy-Related Use of Genetically Engineered Mice, and Competing Supplements for Organotypic Models of Cancer.

Treatment

- ◆ Funding increased from \$16.9M to \$57.6M.
- ◆ Number of projects increased from 143 to 277.
- ◆ Ongoing clinical trials include the PIVOT study and the Phase III Study of Docetaxel and Estramustine versus Mitoxantrone and Prednisone (SWOG 9916).
- ◆ New initiatives included Quick-Trials for Novel Cancer Therapies, Program for Assessment of Clinical Cancer Tests, and National Cooperative Drug Discovery Groups.

Cancer Control, Survivorship, and Outcomes

- ◆ Funding increased from \$6.5M to \$20.3M.
- ◆ Number of projects increased from 24 to 48.
- ◆ Ongoing clinical trials include the PLCO and PCOS studies.
- ◆ New initiatives included Special Populations Networks, Cancer Research Network, Cancer Interventions and Surveillance Modeling Network, Health Communications in Cancer Control, and Cancer Outcomes Measurement Working Group.

Examples of Progress Resulting from NCI's Prostate Cancer Research Investment

Biology

- ◆ Recent advances include identifying molecular mechanisms of cancer initiation, progression, and metastasis; new models of the development of androgen-independent cancers; and growth factor contributions to cancer progression.
- ◆ Future investment is needed in new technologies (e.g., proteomics and bioinformatics) and new model systems to advance the study of molecular mechanisms of normal prostate development and cancer progression and the role of tumor microenvironment and macroenvironment.

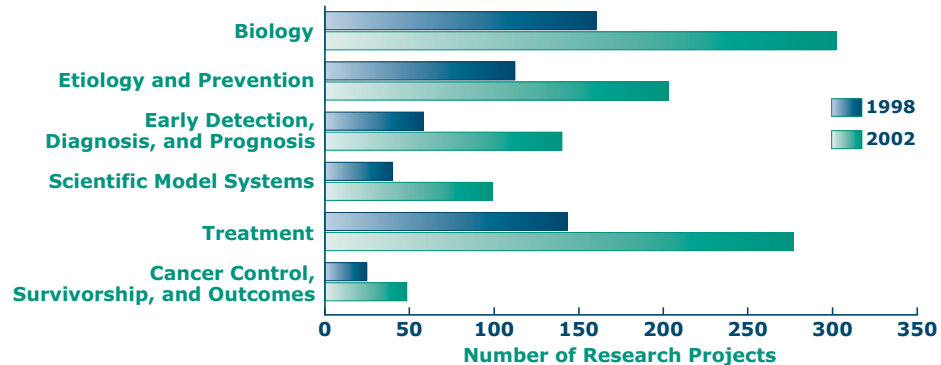
Etiology and Prevention

- ◆ Recent advances include finasteride as a chemopreventive agent, diet/nutrient intake and reducing cancer risk, gene–environment associations, and identification of biological factors of cancer.
- ◆ Future investment is needed in rapidly initiating and completing prevention trials, refining etiological components of cancer, and validating lifestyle and chemical preventive measures.

Early Detection, Diagnosis, and Prognosis

- ◆ Recent advances include biomarker identification, imaging device enhancement, and molecular profiling analyses.
- ◆ Future investment is needed in validating and including new biomarkers in trials, further enhancement of noninvasive devices, and better characterization of tumors for predicting clinical behavior.

Growth of NCI's Relevant Prostate Cancer Research by Scientific Category



Scientific Model Systems

- ◆ Recent advances include use of the TRAMP mouse model and variants, xenograft mouse models, and metastatic mouse models using gene knockouts.
- ◆ Future investment is needed in models covering the natural progression of prostate cancer and evaluating the similarities and differences between models and human disease.

Treatment

- ◆ Recent advances in clinical care include hormone therapy as adjuvant with external beam radiation therapy, interstitial brachytherapy for selected patients with localized disease, and zoledronic acid for prevention and treatment of bone metastatic disease.
- ◆ Recent advances in research include new chemotherapeutics development and evaluation and surrogate biomarkers in clinical trials.
- ◆ Future investment is needed in enhanced capacity in the clinical trials infrastructure, enhanced translational research, and identification and validation of new targets and new interventions.

Cancer Control, Survivorship, and Outcomes

- ◆ Recent advances include identifying causes of racial disparities, understanding patient-focused outcomes, and treatment-related complications.
- ◆ Future investment is needed in quality-of-life assessments, enhanced surveillance, evaluation of screening and treatment intervention outcomes, biobehavioral research, and dissemination practices.