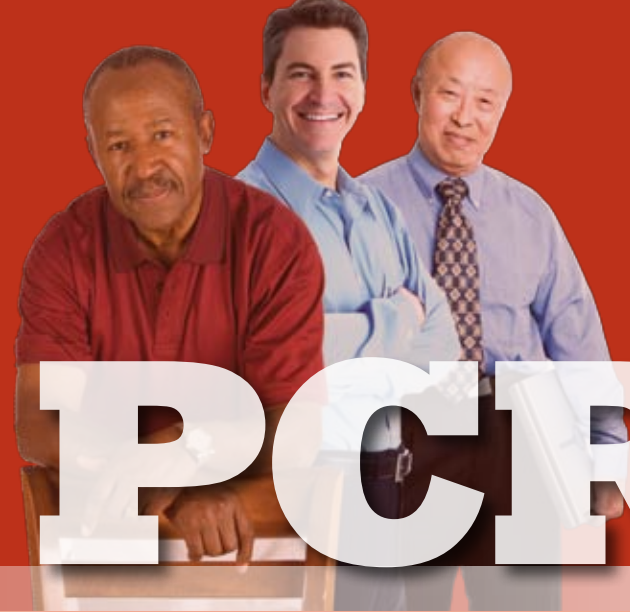


CDMRP
Department of Defense
Prostate Cancer Research Program

PCRP Perspectives

Volume 3, Number 1 – February 2011

In This Issue

page 1 IMPaCT 2011; Rapid Clinical Trials; Featured Opinion page 2 Rapid Clinical Trials, continued page 3 Spotlight; Program News; Calendar of Events
page 4 IMPaCT 2011, continued; Did You Know; Contact Information page 5 Spotlight, continued; Rapid Clinical Trials, continued
page 6 Summary of FY10 PCRP Award Recommendations; Grant Writing Tips; Opinion, continued

Featured Opinion

Howard R. Soule, Ph.D.

Executive Vice President, Discovery and Translation, and Chief Science Officer, Prostate Cancer Foundation
PCRP Integration Panel Member

This issue of PCRP Perspectives focuses on two of the most significant efforts of the DOD Prostate Cancer Research Program in reaching toward its vision of conquering prostate cancer: The Prostate Cancer Clinical Trials Consortium (PCCTC) and the Innovative Minds in Prostate Cancer Today (IMPaCT) conference.

The PCCTC, composed of 13 Centers of Excellence in genitourinary medical oncology, has pioneered the development of new treatments with a singular goal: speed the delivery of life-prolonging therapies to men with advanced prostate cancer.

In 1996, CaP CURE (now known as the Prostate Cancer Foundation, PCF) founded a consortium with six charter members: Memorial Sloan-Kettering Cancer Center (MSKCC), M. D. Anderson Cancer Center, University of Michigan, University of Wisconsin, Johns Hopkins University, and Dana-Farber Cancer Institute. In 1998, PCF added University of California, San Francisco. In 2005, the DOD PCRP awarded a grant that formed the PCCTC, with MSKCC, the Coordinating Center, functioning as the administrative hub. Additional

» continued, **SEE OPINION, PG. 6**

IMPaCT 2011: On the Road to Conquering Prostate Cancer

The Department of Defense (DOD) Prostate Cancer Research Program (PCRP) will hold its second Innovative Minds in Prostate Cancer Today (IMPaCT) meeting on March 9–12, 2011, in Orlando, Florida. Approximately 1,000 PCRP-funded investigators and consumer advocates have been invited to convene for a review of the program's progress toward its vision to conquer prostate cancer. The proceedings will feature awards granted in fiscal years 2006–2008 (FY06–FY08), along with selected awards from previous years and from FY09, and meeting participants will weigh the challenges and successes in prostate cancer research and discuss potential new breakthroughs just on the horizon.

This meeting, co-chaired by FY11 PCRP Integration Panel (IP) Chair, Dr. Natasha Kyprianou of the University of Kentucky and IP consumer advocate Mr. Westley Sholes of the California Prostate Cancer Coalition, will provide a broad overview of the latest advancements in prostate cancer

» continued, **SEE IMPaCT 2011, PG. 4**

The PCRP Facilitates Rapid Pace for Clinical Trials

The Prostate Cancer Clinical Trials Consortium (PCCTC), established in 2006 with joint support from the PCRP and the Prostate Cancer Foundation, facilitates the rapid movement of new therapies for prostate cancer through Phase I/II and Phase II clinical trials, and ultimately into clinical practice. Now encompassing 13 leading cancer centers across the country (**Figure 1**), the PCCTC has enrolled more than 2,400 patients in over 83 clinical trials (48 completed) during the past 5 years and has investigated in excess of 50 drugs, 8 of which have advanced to Phase III clinical trials.

Key to the PCCTC's success is its efficient management by the Coordinating Center, under the leadership of Principal Investigator Howard Scher, M.D., and Director Jake Vinson, at Memorial Sloan-Kettering Cancer Center. The Coordinating Center serves as the central hub of the PCCTC, streamlining processes that would otherwise impede timely trial activation, con-

» continued, **SEE RAPID CLINICAL TRIALS, PG. 2**

VISION: Conquer prostate cancer.
MISSION: Fund research that will end death and suffering from prostate cancer.

» RAPID CLINICAL TRIALS, CONTINUED FROM PG. 1

duct, completion, and analysis. It boasts an organizational structure that facilitates seamless interaction between clinical sites, trial sponsors, internal and external advisory boards, and regulatory agencies. These stakeholders work together through the Coordinating Center to select only the most promising clinical development opportunities. Coordinating Center services include project management, protocol development, budgeting and contracting, regulatory document management, and database development, maintenance, and security.

The PCCTC has been able to accelerate the pace of clinical research, in part due to more informative trial designs, expedited trial activation, its broad range of scientific expertise and institutional resources, and the dynamic collaboration between clinical sites that fosters rapid accrual of patients to clinical trials. Trial activation is a complex, multistep process that ensures all legal and regulatory requirements have been satisfied prior to patient enrollment. Strikingly, the PCCTC has activated more than 85% of its trials in less than 1 year. As multiple successive and successful trials are necessary for a new therapy to be approved for patients by the U.S. Food and Drug Administration (FDA), the PCCTC's pace has the potential to bring new drugs into clinical practice several years earlier than without PCCTC involvement, some drugs having been brought to Phase III development in what is estimated to be half the time it might otherwise have taken.

Among the most promising agents the Consortium is focused on, abiraterone acetate exemplifies the rapid progress of agents to Phase III clinical trials under the direction of the PCCTC. Abiraterone blocks the synthesis of androgens in the testes, in the adrenal gland, and in prostate tumors through the inhibition of the enzyme CYP17 (**Figure 2**). The drug was introduced into the PCCTC in 2006 by Charles Ryan, M.D., of the University of California San Francisco, as a Phase I clinical trial in patients who had already received chemotherapy. Decreased androgen levels and other promising outcomes led to the initiation of three Phase II clinical trials in 2006 and 2007. These trials further demonstrated decreased prostate-specific antigen (PSA) levels in nearly 40% to 50% of patients, warranting further investigation. An international Phase III trial, also in patients who had already received chemotherapy, led by Dr. Scher and Dr. Johann de Bono of the Royal Marsden Hospital in London, was initiated by the PCCTC in June 2008

Figure 1. The PCCTC is represented by 13 leading cancer centers across the country.

and was recently completed. This trial demonstrated a significant survival benefit for abiraterone (14.8 months) compared to placebo (10.9 months) [1]. Additional trials are ongoing, including a Phase III study in patients who have not received chemotherapy and a Phase II study in patients who have been treated with ketoconazole.

Another agent whose development has been accelerated by the PCCTC is MDV3100, a second-generation anti-androgen. MDV3100 blocks androgens from binding to the androgen receptor (AR), thereby preventing AR from entering the nucleus of tumor cells, which in turn blocks the activation of key genes that may play a role in prostate cancer. The PCCTC initiated a Phase I dose escalation study of MDV3100 in July 2007 in men with castration-resistant prostate cancer (CRPC) and quickly expanded the trial into a Phase I/II study after early signs of antitumor activity. This trial was developed, conducted, and analyzed in less than 18 months, with 140 CRPC patients accrued from 5 clinical sites. Multiple positive outcomes were observed from this study in both pre- and post-chemotherapy settings, including tumor regression, decreased PSA levels, and no progression of bone metastases [2]. A Phase III trial in the post-chemotherapy setting was initiated in 2009 and has recently completed its accrual; another trial in the pre-chemotherapy setting was initiated in 2010.

The PCCTC has seen six additional agents advance to Phase III clinical trials, including dasatinib, an Src family tyrosine kinase inhibitor; ipilimumab, a human monoclonal antibody that binds to CTLA-4 (a molecule on T cells that plays a role in regulating the immune response); IMC-A12 (cixutumumab), a human monoclonal antibody against the IGF-1 receptor; sunitinib, another tyrosine kinase inhibitor; TAK-700, an inhibitor of androgen synthesis; and tasquinimod, an inhibitor of angiogenesis.

The PCCTC continues to test new and exciting drugs for therapeutic benefit. The small molecule XL184, a promising agent for patients with metastatic CRPC, is particularly exciting because it targets multiple receptor tyrosine kinases rather than targeting the androgen axis directly, as many of the current prostate cancer agents in clinical testing do. Targets of specific interest are those involved in angiogenesis, such as

» continued, **SEE RAPID CLINICAL TRIALS, PG. 5**

In This Issue

page 1 IMPaCT 2011; Rapid Clinical Trials; Featured Opinion page 2 Rapid Clinical Trials, continued page 3 Spotlight; Program News; Calendar of Events
page 4 IMPaCT 2011, continued; Did You Know; Contact Information page 5 Spotlight, continued; Rapid Clinical Trials, continued
page 6 Summary of FY10 PCRP Award Recommendations; Grant Writing Tips; Opinion, continued

Spotlight

Finding Hope and Encouragement in the Search for a Cure

James Kiefert, Ed.D.
Us TOO International
PCRP Integration Panel Member

In 1989, at age 50, I was diagnosed with prostate cancer. I had a PSA level of 39 and was told the disease had spread to my seminal vesicles. Following surgery and 35 sessions of external beam radiation, my PSA levels continued to rise, and I was given 1-3 years to live and little time to get my life in order. That was 21 years and 3 months ago.

Feeling very much alone and in need of hope and encouragement, I searched for, and found, a support group composed of other men with advanced prostate cancer. Through this group I learned how these other men managed their disease and continued to have a good quality of life. This led me to start a new support group closer to home through Us TOO International, which I came to realize was the only organization whose sole purpose was to provide education and support to men and their families dealing with prostate cancer. Us TOO International showed me how to be an advocate for individuals and how to inform state and national decision makers who fund medical research and support public awareness.

With the perspective of a consumer with advanced prostate cancer, I have maintained roles as a support group leader for 17 years, a patient representative to the FDA, and an active participant in the PCRP. I was also on the Board of Directors for Us TOO International, serving as chairman for 4 years; this type of service provided me with the opportunity to interact with support group leaders from across the country. Meeting face-to-face with men newly diagnosed and those dealing with the most advanced form of late-stage prostate cancer, I see their fear when they are told they have the "big C." Their first reaction is that "people die from cancer." Unfortunately, I have spoken at too many memorial services for men who have died from the disease.

My participation in the PCRP provides me with hope and encouragement because it is an organization bold enough to maintain a vision to "conquer prostate cancer" and a mission to fund research that will "eliminate death and suffering from prostate cancer." Consumers too often see only the present and short-term future, and this is why I am proud and honored to participate in the PCRP, as it sets its sights on the elimination of a disease that is predicted to kill 32,050[1] men annually. With the aging baby boomer population, these numbers will continue to rise unless we find a way to "conquer" this menacing disease.

» continued, **SEE SPOTLIGHT, PG. 5**

[1] *Cancer Facts and Figures 2010, American Cancer Society*

Program News

- Scientific peer review and programmatic review for applications to the Fiscal Year 2010 (FY10) PCRP were completed by October 2010. A total of 161 applications were recommended for funding.
- Dr. Natasha Kyprianou, James F. Hardymon Chair in Urology Research, Professor of Urology, Molecular Biochemistry, Pathology and Toxicology, University of Kentucky Medical Center, assumed the chairmanship of the PCRP Integration Panel at the FY11 Vision Setting Meeting in November 2010.
- The PCRP Integration Panel outlined 12 award mechanisms for FY11, with Program Announcements to be released in March 2011 pending congressional appropriations. Brief details for the anticipated funding opportunities are provided at http://cdmrp.army.mil/pcrp/.
- The 2011 IMPaCT meeting will be held on March 9–12 in Orlando, Florida.
- Representatives from the CDMRP will present information on the PCRP and other CDMRP programs on April 4, 2011, at the AACR Annual Meeting in Orlando, Florida. PCRP Integration Panel member Dr. James Kiefert of Us TOO International will be a featured speaker.

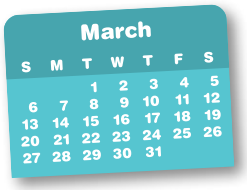
Calendar of Events

FEBRUARY

17–19: Genitourinary Cancers Symposium: An Evidence-based Multidisciplinary Approach, Orlando, FL. Sponsor: ASCO/ASTRO/SUO

24–27: Targeting PI3K/mTOR Signaling in Cancer, San Francisco, CA. Sponsor: AACR

Feb. 27–Mar. 2: AACR-National Cancer Institute Conference on Systems Biology: Confronting the Complexity of Cancer San Diego, CA. Sponsor: AACR



MARCH

3–6: Stem Cells, Development, and Cancer, Vancouver, British Columbia, Canada. Sponsor: AACR

9–12: Innovative Minds in Prostate Cancer Today (IMPaCT), Orlando, FL. Sponsor: DOD PCRP

APRIL

2–6: AACR 102nd Annual Meeting, Orlando, FL. Sponsor: AACR

MAY

14–19: American Urological Association (AUA) Annual Meeting, Washington, DC. Sponsor: AUA

In This Issue

page 1 IMPaCT 2011; Rapid Clinical Trials; Featured Opinion page 2 Rapid Clinical Trials, continued page 3 Spotlight; Program News; Calendar of Events
page 4 IMPaCT 2011, continued; Did You Know; Contact Information page 5 Spotlight, continued; Rapid Clinical Trials, continued
page 6 Summary of FY10 PCRP Award Recommendations; Grant Writing Tips; Opinion, continued

» IMPaCT 2011, CONTINUED FROM PG. 1

research and highlight the important contributions made by PCRP-funded investigators. Educational sessions led by experts will offer in-depth coverage of topics, such as prostate cancer screening, treatment options of localized disease, and quality of life in late-stage disease among others. Evening receptions will focus on bringing prostate cancer scientists, clinicians, and advocates together to share ideas, identify promising and innovative avenues for exploration, and forge new collaborations to pursue potentially groundbreaking research.

Keynote addresses by leading investigators will kick off the meeting's scientific discussions on the first evening. Nobel Laureate Dr. Phillip Sharp of the Massachusetts Institute of Technology will discuss the role of current research in expanding our understanding of cell biology and in developing new concepts for therapies against cancer and other diseases. Dr. Mark Litwin of the University of California Los Angeles and creator and director of California's state-funded free prostate cancer care program, will talk about his work through this program and how the health services research conducted through it has moved laboratory science from its typically insular domain out into the community.

Other distinguished presenters include Dr. Arul Chinnaiyan of the University of Michigan, Dr. Jim Mohler of Roswell Park Cancer Institute, Dr. Howard Scher of Memorial Sloan-Kettering Cancer Center, Dr. John Isaacs of the Johns Hopkins University, Dr. Michael Rosenfeld of the University of California San Diego, Dr. Rick Kittles of the University of Chicago, and IP Chair Emeritus Dr. Donald Tindall of the Mayo Clinic, among the hundreds of exceptional researchers presenting their latest advancements against prostate cancer. Several consumer advocates will also speak at the IMPaCT meeting, including IP members Mr. Virgil Simons of The Prostate Net and Mr. James Kiefert of Us TOO, International, and founder and president of the Prostate Health Education Network, Mr. Thomas Farrington, among others. Also addressing meeting participants is Florida State Senator Anthony C. "Tony" Hill, Sr.

The PCRP was established by Congress in 1997 to promote innovative research focused on eradicating prostate cancer and has received more than $1 billion in appropriations since then to facilitate this goal through the awarding of research funds using a two-tier peer reviewed process. Over the course of the past 13 years, the PCRP has funded more than 1,800 investigators with more than 2,300 awards through more than 20 different award mechanisms, representing efforts in basic, population-based, translational, and clinical research, including clinical trials.

A unique and important feature of the PCRP has always been the strong partnership between scientists, clinicians, and prostate cancer survivors and advocates, all of whom play an integral role in the execution of the program. Since its inception, more than 1,600 scientists and clinicians and 331 consumer advocates have participated in the peer and programmatic review processes. Together these individuals have changed the landscape of biomedical research and energized the research community in conducting potentially high-risk research with the promise of transformative advancements toward the elimination of death and suffering from prostate cancer.

"The PCRP is an amazing force in helping the scientific community to focus on critical issues in prostate cancer. At this IMPaCT meeting, participants will be exposed not merely to small incremental steps in dissecting molecular pathways, but to the entire landscape of basic, translational, and clinical research discoveries built on innovative ideas from investigators supported by the PCRP."

Natasha Kyprianou, Ph.D., James F. Hardymon Chair in Urology Research, Professor of Urology, Molecular Biochemistry, Pathology and Toxicology, University of Kentucky Medical Center
FY11 PCRP Integration Panel Chair and IMPaCT Meeting Co-Chair

"The 2011 IMPaCT meeting honors the research accomplishments by the outstanding and dedicated scientists and clinicians funded by the PCRP, as well as the consumer advocates who work to support the vision of the PCRP. The meeting provides all stakeholders an opportunity to recharge their commitment to carry on the fight for a cure for prostate cancer."

Westley Sholes, M.P.A., California Prostate Cancer Coalition
PCRP Integration Panel Member and IMPaCT Meeting Co-Chair

Did You Know...

- More than 2 million U.S. men are survivors of prostate cancer.
- Men diagnosed with local or regional prostate cancer at time of diagnosis have a 100% 5-year survival rate; however, men diagnosed with distant prostate cancer at time of diagnosis have a 31% 5-year survival rate. The PCRP has made developing more effective therapies for advanced prostate cancer one of its top priorities in funding research.
- The PCRP consumer advocates who have participated in the review meetings over the past 3 years represent 42 different prostate cancer advocacy organizations.
- There are two PCRP-supported prostate cancer biorepositories from which prostate cancer researchers can request data and biological samples for scientific investigations. These are the North Carolina-Louisiana Prostate Cancer Project (PCaP) (http://www.ncla-pcap.org/) and the Prostate Cancer Biorepository Network (www.prostatebiorepository.org).

Prostate Cancer Research Program

For more information:
http://cdmrp.army.mil/pcrp/default

General Questions:
Phone: (301) 619-7071

Proposal Requirements:
Phone: (301) 619-7079
E-mail: cdmrp.pa@amedd.army.mil

Consumer Involvement:
Phone: 301-619-7071
E-mail: cdmrpconsumers@amedd.army.mil

In This Issue

page 1 IMPaCT 2011; Rapid Clinical Trials; Featured Opinion page 2 Rapid Clinical Trials, continued page 3 Spotlight; Program News; Calendar of Events
page 4 IMPaCT 2011, continued; Did You Know; Contact Information page 5 Spotlight, continued; Rapid Clinical Trials, continued
page 6 Summary of FY10 PCRP Award Recommendations; Grant Writing Tips; Opinion, continued

» SPOTLIGHT, CONTINUED FROM PG. 3

Having participated as a consumer reviewer alongside the experienced scientists and clinicians in the PCRP application review process, I have been respectfully treated as an equal partner. The views and opinions of consumers are encouraged and appreciated since we can provide a perspective and an urgency that enables these researchers to focus on the best approaches in biomedical research—approaches that will ultimately benefit prostate cancer patients and their families. As a member of the PCRP Integration Panel, I have witnessed firsthand the depth of forethought shown by the panel members as they carefully deliberate to ensure that current challenges in prostate cancer research are addressed by the PCRP investment strategy. This passionate yet thoughtful discussion reflects the type of professionalism and values maintained by IP members. Considering this, I must say it is both a privilege and an honor to participate in the PCRP.

The efforts of the PCRP are yielding results. I am fortunate enough to have been invited to the 2011 IMPaCT conference where I look forward to hearing about how the PCRP supports novel concepts, advances promising agents to clinical trial, and fosters multi-institutional collaborations like the Prostate Cancer Clinical Trials Consortium and the North Carolina-Louisiana Prostate Cancer Project. Until 2010, only one drug approved by the FDA for advanced prostate cancer offered survival benefit. This past year, two new drugs with survival benefit were approved. Recently, the PCCTC has moved eight new therapies into Phase III clinical trials. I see the progress of these trials moving toward application approval. Similarly, findings from the landmark Prostate Cancer Project will give us insights into factors associated with prostate cancer health disparity. These are just some of the results of the PCRP's investment that we can all be proud of. I anticipate we will learn more about breakthroughs in treatment and new discoveries for translation in prostate cancer. The message I convey to other consumers is one of hope and encouragement, as some of the best and brightest researchers are working zealously to conquer death and suffering from prostate cancer. Of all the medicines available to cancer patients, one of the greatest we can provide is HOPE.

» RAPID CLINICAL TRIALS, CONTINUED FROM PG. 2

MET and vascular endothelial growth factor, which are highly expressed in prostate cancer bone metastases. Early results have demonstrated notable reduction of bone metastases. Preparations are under way by the PCCTC for a Phase II clinical trial in men with metastatic CRPC.

The PCCTC has also launched an initiative to incorporate biomarkers in its clinical protocols to fulfill the critical, unmet need in prostate cancer drug development for reliable indicators of clinical benefit. Since prostate cancer is heterogeneous both clinically and molecularly, patient response to any individual drug is likely to be variable, requiring a more personalized treatment approach based on biomarkers. Following the Oncology Biomarker Qualification Initiative road map of the FDA, NCI/NIH, and the Centers for Medicare and Medicaid Services, the PCCTC has tasked itself with the validation and qualification of potential biomarkers including bone scans and other imaging modalities, drug-specific molecular assays, and circulating tumor cells. Crucially, the availability of a broader spectrum of biomarkers for use as intermediate or surrogate endpoints for clinical trials should allow researchers to more quickly assess the usefulness of investigational drugs and, ultimately, expedite FDA approval for those that are effective.

The Consortium's successful acceleration and streamlining of the clinical trial process is a tribute to the collaborative nature and intellectual synergy of its members coupled with the willingness of study participants to contribute to prostate cancer research. The PCCTC will continue to make a significant impact on the lives of prostate cancer patients through its rigorous evaluation of novel treatment strategies. To learn more about the PCCTC and its ongoing clinical trials, visit www.pcctc.org.

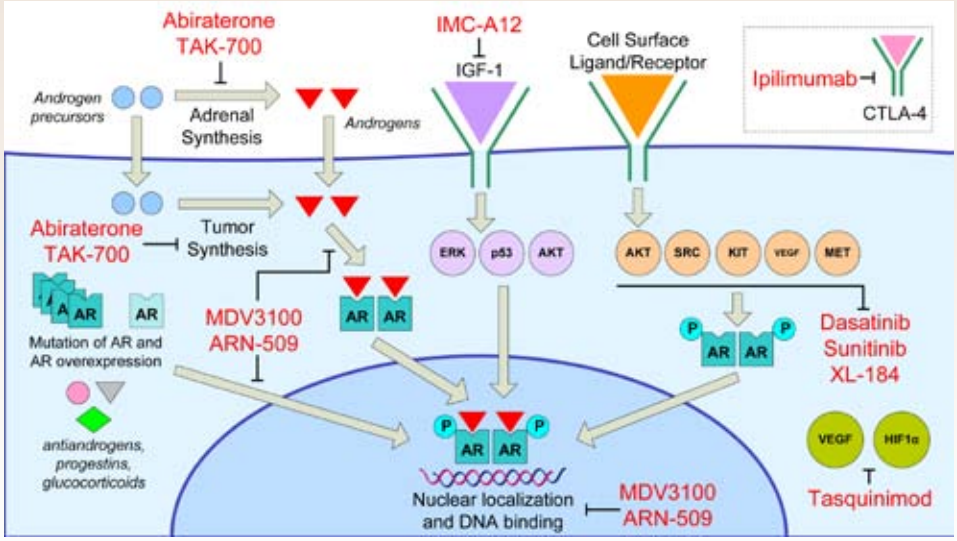


Figure 2. Drugs currently being tested in Phase III clinical trials by the PCCTC target many different pathways.

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In This Issue

page 1 IMPaCT 2011; Rapid Clinical Trials; Featured Opinion page 2 Rapid Clinical Trials, continued page 3 Spotlight; Program News; Calendar of Events
page 4 IMPaCT 2011, continued; Did You Know; Contact Information page 5 Spotlight, continued; Rapid Clinical Trials, continued
page 6 Summary of FY10 PCRP Award Recommendations; Grant Writing Tips; Opinion, continued

Summary of FY10 PCRP Award Recommendations

The PCRP Integration Panel makes recommendations for funding awards. Fiscal year 2010 (FY10) awards recommended for funding are currently in negotiations.

Research Awards

Exploration–Hypothesis Development 27 Awards

Health Disparity Research 5 Awards

Impact 3 Awards

Idea Development 52 Awards

Laboratory-Clinical Transition 3 Awards

Population-Based Research 2 Awards

Synergistic Idea Development 13 Awards

Training/Recruitment Awards

Health Disparity Training 6 Awards

Physician Research Training 6 Awards

Prostate Cancer Training 44 Awards

Total of 161 Awards Recommended

» OPINION, CONTINUED FROM PG. 1

study sites include Cancer Center of New Jersey, Wayne State University, University of Chicago, Oregon Health and Sciences University, and University of Washington.

Funding from PCF and the DOD PCRP is explicitly directed to clinical trial infrastructure costs—nurses, clinical fellows, data managers, database costs, etc. The funding stream results in an ever-ready team of experts that rapidly plan and execute highly translational, science-driven, Phase I and II clinical investigations. Since the fourth quarter of 2005, the PCCTC has activated over 83 clinical trials while accruing approximately 2,400 patients. By any standard, this is a heroic achievement.

In 2006, the PCCTC team began studying abiraterone, a new medication for advanced prostate cancer. A series of four Phase II clinical trials was orchestrated through PCCTC and its corporate sponsor, Cougar Biotechnology (now owned by Johnson & Johnson). By mid-2008, a multinational Phase III clinical trial was launched, and in December 2010, the successful Phase III data were reported to the U.S. Food and Drug Administration. As approval for abiraterone is anticipated by mid-2011, this unprecedented progress for prostate cancer patients would not have been realized as quickly in the absence of the PCCTC.

The progress of the PCCTC will be highlighted along with other exciting PCRP-funded prostate cancer research at the upcoming IMPaCT conference in March 2011. This one-of-a-kind gathering is focused exclusively on solving the problems of prostate cancer. Bringing together nearly 1,000 prostate cancer researchers and consumer advocates to present, discuss, and foster the breadth and depth of new knowledge derived from the nontraditional, innovation-based, PCRP approach to funding research, this critical conference will infuse the prostate cancer community with new energy and cogent ideas to redouble its efforts in battling the disease.

Grant Writing Tips

- Prior to preparing your PCRP application, read the entire Program Announcement. Although an award mechanism may be offered on an annual basis, significant changes may be made from year to year based on the program priorities and focus for that fiscal year.
- When a collaborator is included in your project, describe the expertise of the collaborator and identify the experiments and/or areas of the project where the collaborator's participation will be crucial to the success of the project.
- It is important to submit your application early to avoid potential problems such as missing the application deadline.
- Trainees applying for funding should include among their Mentors/Collaborators at least one or more individuals who are well established in the prostate cancer field as demonstrated through publication and funding records.
- For award mechanisms that require a Statistical Plan and Preliminary Data, be sure to include and clearly describe a strong statistical plan that includes sufficient patient populations and/or samples to obtain statistical power and preliminary data that best support the proposed research.
- For the Preproposal Narrative, provide a strong and clearly described rationale. Your objectives should be cohesive in supporting the overall project and the potential impact of the work, whether near term, far term, or both and should be clearly and realistically described.

Watch for more tips in the next issue!

Visit the PCRP Webpage for Up-to-Date Program Information

The DOD Prostate Cancer Research Program (PCRP) supports innovative ideas and technologies to accelerate our vision to conquer prostate cancer through individual, multidisciplinary, and collaborative research. These efforts are focused toward basic research discoveries and translating discoveries into clinical practice to improve the quality of care and life of men with prostate cancer. For more information on PCRP initiatives, highlights of funded research, and consumer profiles, please visit the PCRP webpage at

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In This Issue

page 1 IMPaCT 2011; Rapid Clinical Trials; Featured Opinion
page 2 Rapid Clinical Trials, continued
page 3 Spotlight; Program News; Calendar of Events
page 4 IMPaCT 2011, continued; Did You Know; Contact Information
page 5 Spotlight, continued; Rapid Clinical Trials, continued
page 6 Summary of FY10 PCRP Award Recommendations; Grant Writing Tips; Opinion, continued