

# CONTINUING DISCOVERY

Research **Centered**



Patient **Focused**



Donor **Empowered**



Results **Driven**



The Promise of 2011







# FASTER. FURTHER. BETTER.

The Prostate Cancer Foundation (PCF) is committed to results-driven research.

In 2010, more progress was achieved in prostate cancer research than in the previous decade. Yet, we believe 2011 holds even greater promise if we can direct needed resources to strategic programs.

Empowered by the generosity of our donors and the innovative thinking of our supported researchers worldwide, we stand ready to build upon a rich foundation of scientific discovery and deliver better diagnostics and treatments for patients and their families.

## PCF's 2010 Impact by the Numbers

<b>1</b> MISSION	 <b>2 bills</b>	<b>3</b> FDA APPROVALS	<b>8</b> PHASE III TRIALS	<b>1 in 6</b> men will be diagnosed with prostate cancer during their lifetimes
<b>24</b> clonal types of prostate cancer found in the clinic	<b>28</b> new drugs in Phase I/II entered trials thanks to PCF's Clinical Trials Consortium	<b>59</b> PCF YOUNG INVESTIGATORS	<b>69</b> NEW MEDICINES TESTED 2005-2010 VIA DoD-PCF PARTNERSHIP	 <b>112</b> Home Runs
<b>100</b> PERCENT BOARD PARTICIPATION & GIVING	<b>9,690</b> A 1300% Increase in Facebook Followers	<b>2,334</b> patients treated through PCa Clinical Trials Consortium 2005-2010	 <b>16.4</b> minutes pass between each prostate cancer death domestically	<b>217,730</b> men diagnosed with prostate cancer in 2010
<b>5</b> million dollars invested in PCF Proactive Surveillance Consortium	 <b>45.6</b> million dollars committed to PCF research projects	<b>435</b> MILLION DOLLARS RAISED FOR PCa RESEARCH 1993-2010	<b>1.1</b> billion dollars in DoD research funding through PCF advocacy	<b>10</b> BILLION DOLLARS LEVERAGED FOR GLOBAL RESEARCH ENTERPRISE

# THE PROMISE OF 2011

## A Roadmap for Continued Discovery and Advances

The Prostate Cancer Foundation's high-risk, high-impact-to-patients research funding strategy yielded the highest return on our 17-year biomedical research investment in 2010. For men battling the most advanced cases of prostate cancer, there were three new therapies approved by the FDA: Provenge (sipuleucel-T, Dendreon)—the world's first immunotherapy for prostate cancer, Jevtana (cabazitaxel, Sanofi-Aventis), and Xgeva (denosumab, Amgen). An additional 28 new prostate cancer drugs entered Phase I/II clinical trials and 8 new Phase III drug trials commenced. The year was doubly unprecedented in the prolific rate of new discoveries we saw in clinics and laboratories we fund across the world. Whether PCF scientists were isolating a single stem cell of origin for human prostate cancer, mapping entire prostate cancer genomes, or identifying 24 unique types of human prostate cancer, the knowledge we gained has been game-changing and paves the way for the promise of 2011.



While discussing the progress made in prostate cancer research in 2010, one patient recently said, "I currently have a sixty percent chance that my disease will recur. Knowing the incredible advances that have recently been made, and what is coming through the discovery pipeline, I am confident there will be new treatments and new technologies ready for me and my doctors if or when we need them. This is a tremendous source of hope and encouragement for me and my family."

This is why PCF exists.

For a growing number of families, being a cancer patient today isn't what it once was. We can better manage cancers. Some can even be cured. The Prostate Cancer Foundation, with our supporters and scientists, remains committed to accelerating the world's most promising cancer research, focusing on a day when we will cure more and overtreat less.

Given the rapid progress of scientific discovery and the achievements of the past year, the coming year promises to be another milestone for prostate cancer. But, with current economic realities, strategy and discipline are crucial elements for moving forward. What are the most promising areas of research?

Which projects will deliver the greatest rewards? And, what additional resources, including human capital, are required?

PCF and our team of global experts have considered these questions and identified five areas of exceptional opportunity for the next decade.

## Accelerating New Drug Approvals

The development of a new medicine takes an average of 10 to 15 years, with relatively few drugs surviving the clinical trials process. This can make drug and biotech companies risk-averse to supporting certain drugs for specific indications.

What's worse, during the 1990s, advanced prostate cancer

was considered a "death knell indication" for which drugs could not be made commercially viable with FDA-approvable endpoints. However, recent FDA approval for several new drugs, buoyed by advances in identifying new targets and treatment science research, is changing that thinking.

With more new medicines in the pipeline, PCF is working to support research that can help us better understand patient responses to new medications and to create remissions that last longer than three to nine months in patients. Further, reducing the time from preclinical to early-phase clinical trials in less than five years is imperative.

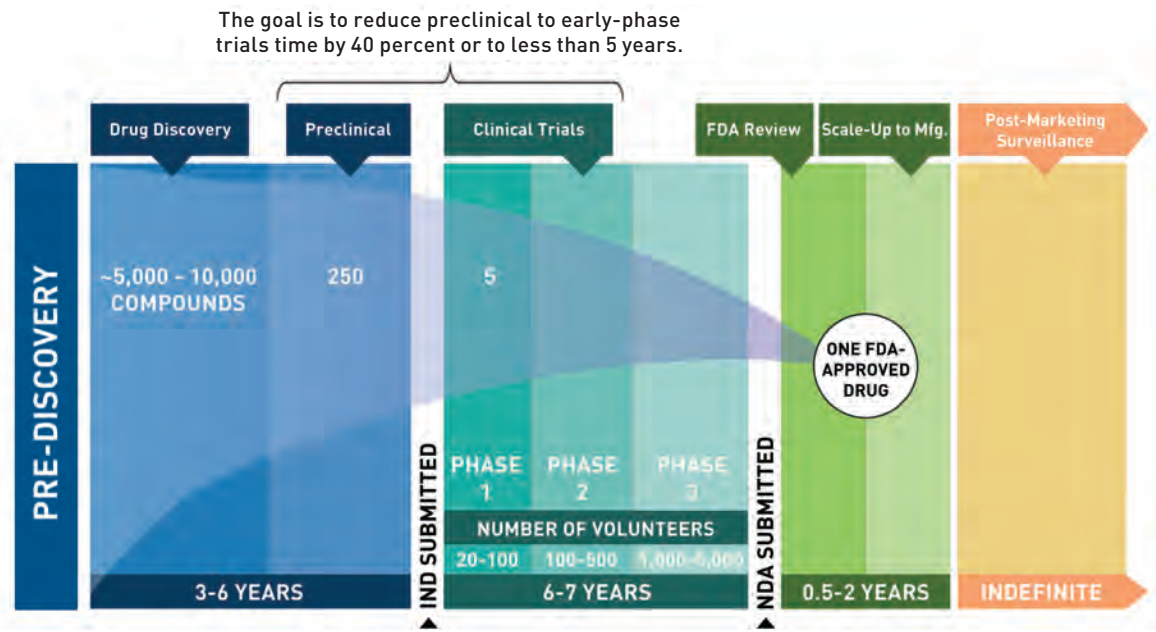
With a proven ability to accelerate clinical trials and move new treatments to patient in less time by the Prostate Cancer Clinical Trials Consortium (PCCTC), funded jointly by PCF and the U.S. Department of Defense, PCF is working to expand the clinical trials consortium both within the U.S. and around the world.

**Continuing to support PCF's activities in accelerating new drug approvals requires an additional \$5 million in 2011 and 2012.**

## Prescribing Research and Transforming the Clinic

The PCCTC is one of our most important tools for moving new, targeted therapies from microscope to market. Its network of 13 clinical sites across the U.S. provides a scale and depth of data that could not be realized by any one institution.

As the cost of clinical research continues to rise more rapidly than inflation, more new drug targets for prostate



Sources: Drug Discovery and Development: Understanding the R&D Process, [www.innovation.org](http://www.innovation.org); CBO, *Research and Development in the Pharmaceutical Industry*, 2006.

cancer are emerging from basic science programs housed at academic institutions. Thus, there is an urgent need to close the gap between academic and clinical research programs.

Chris Logothetis, MD, a researcher long associated with PCF, is noted for saying “we can prescribe research because it works if you want to live longer.”

Abiraterone, currently under FDA review, is a new drug for patients with advanced disease who become resistant to androgen (testosterone) deprivation therapy. Its story is an important study of how the development of a new drug can be accelerated through unique academic, clinical and corporate collaboration.

With the goal of closing the gap between basic science and clinical research, PCF is focused on accelerating treatment

science research for eight new drugs being tested in Phase I-III trials. Included in this effort is a promising new drug, XL184, that has been shown to drastically reduce bone metastases in prostate cancer patients.

Another impressive example of treatment science research is the approval of targeted nanoparticles. PCF-supported researcher, Bob Langer, MD (David H. Koch-PCF-MIT-Harvard Nanotherapeutics Challenge Award recipient), recently introduced a PLGA biodegradable nanoparticle into their first patient a full year ahead of their already ambitious schedule.

Enabling the success of more projects like these will move us closer to eliminating death and suffering from prostate cancer and ultimately curing more patients.

**Supporting PCF’s continued activities in forwarding treatment science research requires an additional \$20 million in 2011 and 2012.**

## **Controlling Cancer through Progression Biomarkers**

Biomarkers are a crucial tool for controlling prostate cancer. They are biological molecules found in blood, other body fluids, or tissues that provide a measure of a normal or abnormal process related to prostate cancer. Our rapidly-expanding understanding of biomarkers provides a dynamic and powerful approach to understanding the spectrum of prostate disease.

Advanced biomarkers offer applications for epidemiology and accelerating randomized clinical trials and have roles in diagnosing the disease, predicting outcomes and measuring patient response to treatments. Thus, developing better biomarkers will have a significant impact on improving patient treatment, outcomes and overall quality of life.



Circulating tumor cells (CTCs) are an excellent example of new biomarkers. Scientists using fluidic micro devices are now able to capture one cancer cell out of five to ten billion red blood cells. Being able to quantify and analyze CTCs provides the necessary tools for identifying the specific type of prostate cancer (genomic subtype) as well as measuring disease progression and patient response to specific treatments. In clinical trials, researchers are utilizing CTCs to establish new endpoints for evaluating drug efficacy. PCF supported early CTC technology development for prostate cancer with an initial \$2.25 million investment. At the start of 2011, a division of Johnson & Johnson made a \$30 million commitment to develop the next generation of CTC capture devices for several types of cancer.

Another promising area is the development of imaging biomarkers that can be used in prostate cancer drug development. However, qualification of an imaging biomarker must follow the roadmap for all biomarkers as outlined by the FDA.

Validating analytical methods for imaging is complex, as there are numerous confounding factors that can influence a scan depending on the imaging modality. Clinical qualification of imaging biomarkers will involve developing comprehensive imaging metrics, defining their analytic precision, and then undergoing clinical qualification. Biomarker qualification criteria mandate both high responsiveness and high reproducibility (low uncertainty), which in imaging is defined by a high signal-to-noise ratio. In every clinical study, a biomarker must be tested for a specific context of use, such as its use as a response indicator or as an outcome predictor. The final step of clinical qualification is assessing the predictive power of the imaging biomarker, which is the association between the biomarker measurement and clinical outcome.

**Advancing new biomarker development for controlling cancer requires an additional \$10 million in 2011 and 2012.**

## Advancing Genomic Science

Prostate cancer is an extraordinarily complex disease with at least 24 known molecular types, and all prostate cancers begin in our DNA. The recent completion of the Prostate Cancer Whole Genome Sequencing Project opens the door to a new era of prostate cancer science and discovery. The landmark project, led by Levi Garraway, MD, from the Dana-Farber Cancer Institute and teams of scientists from 17 other leading research centers, catalogued thousands of protein-encoding genes in lethal prostate cancer human genomes.

The benefits of this project are immense in terms of improving patient outcomes and quality of life, as well as ultimately reducing the economic burden of cancer.

Applying data from the genome sequencing project will move us closer to being able to discern between highly aggressive, life-threatening prostate cancers and indolent varieties that do not pose a threat to patients, and treating each individual with a specific plan and new therapies that are appropriate for their level of cancer.

PCF has identified the following needs for advancing genomic science:

- A large-scale, high-throughput multi-institutional effort to sequence and characterize genetic and epigenetic changes associated with the development of prostate cancer in approximately 1,000 patients
- Identifying and using molecular clonotypes of prostate cancer to stratify patients for clinical trials
- Mapping genomic changes to specific pathways for identifying potential new drug targets
- Developing a library of shared genomic data for basic and clinical researchers to accelerate additional discovery

- Developing next generation analytical tools and mathematical models for utilizing large and varied sets of information
- Provide new tools for managing clinical trials and patient specimen acquisition

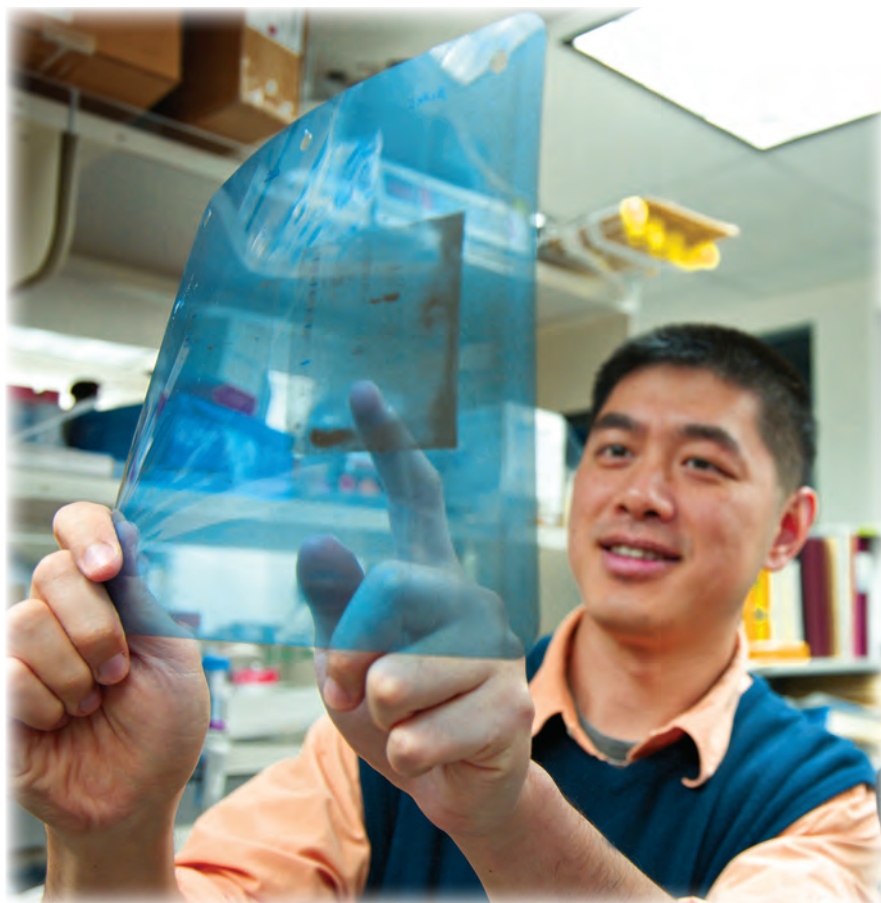
The knowledge gained through a genomic research program of this proportion will not only benefit prostate cancer research and patients, but the entire biomedical research enterprise, providing a crucial platform for making advances against other life-threatening human cancers and diseases.

**Continuing to support PCF's activities in prostate cancer genomics requires an additional \$20 million in 2011 and 2012.**

### **Fast Forwarding a Universal Prostate Cancer Code (UPCC)**

Advances in genomics are enabling us to more rapidly identify new drug targets and potential new therapeutics to address them. What's more, by integrating genomic information into the diagnostic and treatment process, each patient will be matched with personalized, predictive and optimal treatments, fast-forwarding our goal of delivering personalized cures—delivering just the right treatment plan—for every patient who is diagnosed.

Achieving this goal will require a massive Manhattan Project-style effort to identify the best means of screening patients molecularly for cancer-causing DNA gene fusions. With this data, physicians will be able to place patients on available therapies and enroll them in clinical trials with drugs that specifically target the causal pathway of their cancer.



A “barcode” approach to prostate cancer treatment will include a variety of data points specific to each individual patient and will deliver personal cures for every patient that is diagnosed.

This research effort will enlist the innovative thinking of our cohort of 60 past and present Young Investigators, the talent of some of the world's leading scientists whose careers have focused on various aspects of prostate cancer, and the collaboration of numerous institutions.

**Supporting PCF's goal of fast-forwarding the reality of a Universal Prostate Cancer Code requires an additional \$10 million in 2011 and 2012.**

## Investing in Human Capital



In 2010, PCF-funded Young Investigators forwarded their innovative programs. Among their accomplishments: Felix Feng, MD, at the University of Michigan began matching the most effective treatments to the recently-identified 24 unique types of prostate cancer; Himisha Beltran, MD, of the Weill Cornell Medical College commenced genetic analysis of neuroendocrine prostate cancer—the most lethal variety—to help inform better treatments for patients; Jay Shendure, MD, PhD, at the University of Washington developed new genetic biotechnologies that enable sequencing of very small amounts of DNA. This is necessary for generating genomic information for personalized treatments. PCF currently funds a total of 51 Young Investigators and is targeting 20 new grants for 2011.

**Reaching the PCF goal of investing in human capital by awarding 20 new Young Investigator grants requires an additional \$4.5 million in funding.**

## 2011: No Better Time than Now

It's true. In light of the achievements made over the past year, and progress within grasp in the coming years, there is no time more reassuring to be faced with a prostate cancer diagnosis. New diagnostics, prognostics, disease pathways and targeted treatments are all within our grasp. Thus, it is our moral imperative to do everything we can to continue the momentum provided by our recent discoveries and build upon the rich scientific base we have established.

Through the continued generosity of our donors and the innovative talents of world-class scientists, we will soon be able to cure more and overtreat less. We will, within our lifetime, end death and suffering as a result of prostate cancer.



# 2010 DONOR ROLL

The support of our generous donors makes all that we do at PCF possible. This honor roll acknowledges actual gifts of \$5,000 or more, exclusive of pledges, made to PCF during calendar year 2010. We thank you, our friends and supporters, for making 2010 the best year ever in the history of PCF.

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