

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MDL NO. 1430

MASTER FILE NO. 01-CV-10861-RGS

IN RE: LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

MEMORANDUM ACKNOWLEDGING RECEIPT AND REVIEW
OF MAZZONE AWARDS PROGRAMMATIC REPORT # 10

April 11, 2016

STEARNS, D.J.

On March 30, 2015, Dr. Myles A. Brown of the Dana-Farber/Harvard Cancer Center (DF/HCC), the principal investigator for the A. David Mazzone Research Awards Program (Program),¹ and co-principal investigator, Dr. Jonathan Simon, President of the Prostate Cancer Foundation (PCF), submitted the tenth in a series of Program Reports. This Report covers the period from July 1, 2015, to December 31, 2015.

¹ After dedicated service as the principal investigator for the Program, Dr. Philip Kantoff accepted a position as Chairman of the Department of Medicine at Memorial Sloan Kettering Cancer Center in New York City. Dr. Myles Brown is Dr. Kantoff's able successor. Dr. Brown has been actively involved with the Mazzone Program since its inception, both as an award recipient and a peer reviewer. Dr. Brown is a prominent leader in the field of breast and prostate cancer research. From 2002-2010, he served as Chief of the Division of Molecular and Cellular Oncology at the Dana-Farber Cancer Institute (DFCI), and currently is the Director of the Center for Functional Cancer Epigenetics at DFCI.

The Mazzone Awards Program, over its life, has supported the work of 146 investigators involved in forty-one separate prostate cancer and related research projects worldwide, as well as funding community outreach programs, career development for treatment specialists, and basic and advanced research training.² With the work of the Program coming to a close, Report #10 provides a cumulative summary of the Program's accomplishments. The court has appended the Report for the benefit of all of those who are interested in the achievements of this historical undertaking. The court expresses special appreciation for the stewardship of Dr. Kantoff, Dr. Brown, Dr. Simon, and Dr. Soule, and for the groundbreaking work of the many investigators whose accomplishments will be fully celebrated in the Fifth Annual Report of Scientific Progress and Accounting due on September 30, 2016.

SO ORDERED.

/s/ Hon. Richard G. Stearns
UNITED STATES DISTRICT JUDGE

² On August 6, 2010, this court awarded the surplus funds from the Lupron® Class Settlement Pool to Dana-Farber/Harvard Cancer Center (DF/HCC) and the Prostate Cancer Foundation (PCF) to be distributed according to the terms of the proposal submitted to the court on May 20, 2010, as modified and approved by the court. The Program issued four annual rounds of Requests for Applications from 2011-2014. As of 2015, the Program has awarded the funding available from the Settlement and has “graduated” its first class of grant recipients.

DF/HCC

DANA-FARBER / HARVARD CANCER CENTER

A. David Mazzone
Research Awards Program

Report #010

Programmatic Report Period: July 1, 2015 to December 31, 2015

Principal Investigator: Myles A. Brown, MD
Dana-Farber/Harvard Cancer Center

Co-Principal Investigator: Jonathan Simons, MD
Prostate Cancer Foundation

Respectfully Submitted to
U.S. District Court for the District of Massachusetts
Boston, Massachusetts

March 30, 2016

Beth Israel Deaconess Medical Center
Brigham and Women's Hospital
Boston Children's Hospital
Dana-Farber Cancer Institute
Harvard Medical School
Harvard School of Public Health
Massachusetts General Hospital



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A. David Mazzone Awards Program

Programmatic Report Period: July 1, 2015 to December 31, 2015

Introduction

The A. David Mazzone Awards Program is a grant awarded by the U.S. District Court for the District of Massachusetts (the Court) to Dana-Farber/Harvard Cancer Center (DF/HCC) in conjunction with the Prostate Cancer Foundation (PCF). Under the leadership of Dr. Phil Kantoff, succeeded by Dr. Myles Brown in 2015, the Mazzone Program supports collaborative and innovative cancer research, career development, community outreach, and training projects to address a range of research needs in prostate cancer and Lupron-treatable diseases. This report describes programmatic activities during the second half of calendar year 2015.

The Program was designed to issue a call for applications on an annual basis until the funding assigned to the various mechanisms was fully spent. To that end, the Program issued four rounds of requests for applications (RFAs) from 2011 to 2014 and distributed grants in accordance with the approved proposal. Appendix 1 in this report provides a financial summary of the funding distribution as approved by the Program's Scientific Advisory Board and the Massachusetts District Court.

The Program established a national presence as a source of funding for prostate cancer research. Most importantly, the Program fostered an unprecedented effort for institutions to collaborate on inter-institutional Prostate Cancer research projects breaking down barriers to knowledge dissemination and collaboration. In the coming six months, the program will continue to actively monitor and evaluate the progress of funded projects in preparation for the fifth annual report of scientific progress and accounting, which is due to the Court by September 30, 2016.

At the end of its fifth year, the program supported a total of 146 investigators working on 41 projects at institutions across the United States. Appendix 2 provides a detailed list of Mazzone Awards Program Grantees for years 2011 to 2014. These projects include thirty five projects funded by DF/HCC through six award mechanisms and six projects funded through the PCF Mazzone Challenge Awards mechanism.

2015 Programmatic Activity

As of 2015, the Program had awarded all its funding opportunities and therefore, it did not issue a request of applications this year. The activity of the Program focused primarily on monitoring existing grantees and managing administrative processes related to the maintenance and closing of those existing awards.

As it is summarized in Appendix 1, "Funding Structure", the total funding approved by the Court was issued to grantees over the agreed-upon 4-year period. The table provides information on actual grants amounts for the award mechanisms authorized for DF/HCC and PCF. DF/HCC issued grants in the total amount of \$5,530,000 and PCF issued grants totaling \$5,000,000 as of 2014. The total amount funded and committed plus DF/HCC overhead assessment of 1,170,000, total the grant actual estimated funding of \$11,700,000. (see Table 2 Below for grants distribution as provided on the original grant application).

In accordance with the approved Funding Structure, the Court disbursed two payments of \$4,000,000 each in November 2010 and November 2012; Payments of \$2,000,000 and \$1,585,000 were issued in January 2015 and December 2015 respectively. At the time of the December 2015 payment, the Court reserved a final disbursement of approximately \$115,000 to be issued to DF/HCC upon satisfactory submission and approval of progress and accounting reports due to the Court by September 2016.

It is possible that some of the remaining active Mazzone funded projects will require a no-cost extension for the period of 2016 to 2017. In such case, the Program will continue to monitor those projects and will prepare and submit a final progress and accounting report in September 2017.

Table 2. Grant Awards Approved by the Court

Award Category	Amount	Number of Awards	Total Allocation
Career Development	100,000	6	600,000
Community Outreach	100,000	4	400,000
Disparities Research	100,000	5	500,000
High Impact Award (Original Number was 5)	500,000	4	2,000,000
Lupron-Treatable Diseases and Conditions	100,000	3	300,000
Project Development	100,000	9	900,000
Student Training	160,000	1	160,000
New (2012): High Impact Clinical Trials (1 reallocated from High Impact)	500,000	1	500,000
New (2012): Seed Funding - Community Outreach Proposal Development	10,000	1	10,000
Prostate Cancer Foundation Special Challenge Awards	1,000,000	5	5,000,000
Total Approved Allocation for All Mechanisms			10,370,000

Notes: in 2012, the Court authorized the DF/HCC contingent of the Mazzone Program to create a new award category for “High Impact Clinical Trials” by reallocating one of the five originally approved “High Impact Awards”. This new award was issued in 2013. A one-time seed funding grant was awarded to Dr. Glenn Bublely in 2012. The deliverable, which was received in a timely manner, was a reviewed and improved grant application from Dr. Bublely in 2012. Finally, in 2014, the Court approved allocation of funding for Disparities Research, Community Outreach, and Student Training for \$160,000 which had not been allocated in the original Program proposal above.

Program Progress and Reporting

As of July 2015, 2012 DF/HCC and PCF award recipients completed their no cost extension periods, 2013 grantees completed their second year and 2014 grantees completed their first year of research activities. Each award recipient produced the required annual scientific progress report and financial reports. Over the late fall of 2015, the Program continued to issue payments on active projects and continued to monitor program activity. The Program submitted to the Court the annual progress and accounting report in October 2015 for the period of activity ending in July 31, 2015. A copy of the Program reporting schedule to the Court is provided in Appendix 3.

Progress reports are reviewed by the Program’s Principal Investigator and as necessary distributed to the members of the SAB for additional review or approval. If investigators demonstrate adequate progress toward the goals of the project, recipient institutions are issued continued support and payments based on financial reports and invoices signed by fully authorized accounting officers at the recipient institutions. Annual progress and accounting

reports guidelines and requirements are stipulated to each grantee institution in grant contractual agreements at the time of issuing each grant.

In conclusion, DF/HCC and PCF are pleased with the ongoing progress of the Mazzone Award Program and are committed to ensuring that the program continues to support and foster innovative collaborative research in 2016.

Change in Principal Investigator

In the fall of 2015, Dana-Farber/Harvard Cancer Center requested and received approval from the Court to change the Principal Investigator of record for the Mazzone Awards Program. After providing a remarkable and dedicated service as principal investigator for the past five years, Dr. Kantoff relinquished leadership of the Program as part of his relocation to take a new position as Chairman of the Department of Medicine at Memorial Sloan Kettering Cancer Center in New York City.

Dr. Kantoff was replaced in the capacity as Principal Investigator by Dr. Myles Brown, Dana-Farber Cancer Institute. Dr. Brown has been an enthusiastic supporter of the Mazzone Program over the years. In several occasions, he served as peer reviewer and he himself had the honor of receiving a Mazzone Project Development award in 2011. Dr. Brown is intimately knowledgeable of the Mazzone program and a prominent contributor in the field of Breast and Prostate Cancer research. Following is a brief profile summary of Dr. Brown.

Myles A. Brown, MD

Director, Center for Functional Cancer Epigenetics
Professor of Medicine, Harvard Medical School

Dr. Brown obtained his undergraduate degree in Biology from Yale University and his M.D. from the Johns Hopkins University School of Medicine. He completed training in Internal Medicine at the Brigham and Women's Hospital while doing research with David Livingston at the Dana-Farber. He went on to complete training in Medical Oncology at the Dana-Farber and postdoctoral research with Phillip Sharp at MIT. Following the completion of his training he joined the faculty of the Dana-Farber and Harvard Medical School. From 2002-2010 he served as Chief of the Division of Molecular and Cellular Oncology at the Dana-Farber. In 2010 together with Shirley Liu he founded the Center for Functional Cancer Epigenetics at the Dana-Farber.

Dr. Brown's research laboratory focuses on elucidating the epigenetic factors underlying the action of steroid hormones. This work has important implications both for normal physiology and for the treatment of hormone dependent malignancies including breast and prostate cancer. He is recognized for three seminal discoveries. His lab opened the steroid receptor coregulator field, illuminated the dynamic nature of receptor and coregulator interaction with the genome and elucidated the importance of epigenetically determined distant cis-regulatory steroid receptor binding sites. His contributions have uniquely reformulated the understanding of steroid hormone action in normal physiology and in hormone-dependent cancer.

The overall aim of research in our laboratory is the elucidation of the factors underlying the hormonal responsiveness of human cancers. This work is focused primarily on the role of steroid hormone receptors and their coregulators. We are currently defining the programs of gene expression controlled by steroid hormones and their receptors in relevant cell types using a combination of approaches including gene expression profiling and "ChIP-chip." In addition we are testing the hypothesis that coregulators act as mediators of the differential activity of receptors bound by agonist and antagonist ligands. In addition we are asking whether alterations in coregulator function play a role in both resistance to endocrine therapy and in carcinogenesis. This work has focused primarily on the role of estrogen receptor and its coregulators in breast cancer and androgen receptor and its coregulators in prostate cancer.

Background:

Board Certification

Medical Oncology, 1989

Internal Medicine, 1986

Fellowship:

Massachusetts Institute of Technology, Cancer Biology, 1987-1990

Dana-Farber Cancer Institute, Medical Oncology, 1986-1989

Residency:

Brigham and Women's Hospital, Internal Medicine, 1982-1986

Medical School:

Johns Hopkins University School of Medicine, 1978-1982

Appendix 1: Mazzone Awards Program Funding Structure as of 2015

**A. David Mazzone Awards Program
Funding Structure Plan- Five Years (2010 - 2015)**

Revised by Juan Carlos Hincapie on December 23, 2015

Court Disbursement	Tranche 1 (2011-2013)	Tranche 2 (2012-2014)	Tranche 3 (2013-2015)	Tranche 4 (2015-2016)	Tranche 4 (2016-2017)	Total
Date Issued	Nov-10	Nov-12	Jan-15	Nov-15	Nov-16	
Expected Disbursement	4,000,000	4,000,000	2,000,000	1,585,000	115,000	11,700,000
IDC	400,000	400,000	200,000	158,500	11,500	1,170,000
PCF	1,800,000	1,800,000	1,200,000	200,000	0	5,000,000
DF/HCC	1,800,000	1,800,000	600,000	1,226,500	103,500	5,530,000

Estimated Awards Funding Distribution by DF/HCC for 2011 - 2015 Based on Original Grant Proposal Approved by the Court

The following table shows the expected funding distribution per the proposal approved by the Court and expected adjustments for distribution changes to award mechanisms.

Award funding will run from August to July and it will be distributed to grant recipients based on a cost reimbursement method.

Program funding received November 2010 will support 75% of award payments for Round 1 from August 2011 to July 2012. Funding received in November 2012 will support final award payments (25%) for round 1 and 75% of Round 2 awards from August 2012 to July 2013. Funding received in November 2014 will support final award payments (25%) for Round 2 and new awards from August 2013 to July 2015 and additional allocation for 2014 - 2016.

Award Category	Number of Awards Approved	Total Funding Approved	Number of Awards funded 18% of total Proposals received for (2011-2013)	Total Funding Round 1 (75% of total award will fall in this period of time)	Number of Awards funded 22% of total Proposals received for (2012-2014)	Total Funding Round 2 (75% of awards plus 25% from Round 1)	Number of Awards funded 18% of total Proposals received for (2013-2015)	Total Funding Round 3 (100% of awards plus 25% from Round 2)	Special RFA 2014, 67% of total Proposals received for (2014-2016)	Total Funding Round 4 (100% of 2 final awards)	Grand Total Projected Direct Cost
Career Development	6	600,000	3	225,000	2	225,000	1	150,000			600,000
Community Outreach	4	400,000	0	0	1	75,000	1	125,000			200,000
Disparities Research	5	500,000	2	150,000	2	200,000	1	150,000			500,000
DR Additional Allocation 2014	2	140,000							2	140,000	140,000
High Impact Award	4	2,000,000	1	375,000	2	500,000	3	1,325,000			2,200,000
Lupron-treatable	3	300,000	1	75,000	2	175,000	0	50,000			300,000
Project Development	9	900,000	4	300,000	3	325,000	2	275,000			900,000
Student Training	8	160,000		12,793		17,013		130,194			160,000
ST Additional Allocation 2014	2	20,000								20,000	20,000
New Awards Approved in 2012											
High Impact Trials	1	500,000			0	0	1	500,000			500,000
Seed Fund Community Outreach	1	10,000			1	10,000		0			10,000
Total DF/HCC		5,530,000	11	1,137,793	12	1,527,013	9	2,705,194	2	160,000	5,530,000
DF/HCC Variance from Expected Total Disbursement: cted Total Disbursement:											0
PCF	5	5,000,000	2	2,000,000	2	2,000,000	1	500,000	1	500,000	5,000,000
Total Approved Direct Expense		10,530,000									
Indirect Cost Assessment		1,170,000									
Total Estimated in Grant Proposal		11,700,000									
Actual Projected Disbursement		11,700,000									

Notes:

In 2012, two one-time seed funding Community Outreach awards for \$10,000 each were approved. Only one seed project was funded in 2012

In 2012 one High Impact award was divided evenly between two projects.

In 2013, two out of four \$100K Community Outreach grants remained unfunded. \$200K was reallocated to fund a partial High Impact Project

In 2013, PCF funded one partial Mazzone Challenge Award. The remainder (\$500K) to be awarded through a 2014 RFA

In 2014, DF/HCC funded 2 additional Disparities Research Grants for \$140K total, plus \$20K additional Funding for Student training, PCF funded one partial Mazzone Challenge Award with the remainder (\$500K) from 2013

Appendix 2: Mazzone Awards Program Grantees, 2011 – 2014

Mazzone Awards Program -- Prostate Cancer Foundation Projects Funded as of 2014

2011 Prostate Cancer Foundation	2012 Prostate Cancer Foundation	2013 Prostate Cancer Foundation	2014 Prostate Cancer Foundation
<p><i>Imaging Biomarkers of Treatment Response Using NaF PET/CT Imaging: a Prostate Cancer Clinical Trials Consortium (PCCTC) Effort</i> PI: <u>Glenn Liu, MD</u> (UW Carbone Cancer Center) Collaborators: <u>Michael Morris, MD</u> (Memorial Sloan-Kettering Cancer Center); <u>William Dahut, MD</u> (National Cancer Institute); <u>Steven Larson, MD</u> (Memorial Sloan-Kettering Cancer Center); <u>Peter Choyke, MD</u> (National Cancer Institute); <u>Robert Jeraj, PhD</u>, (UW Carbone Cancer Center)</p>	<p><i>Promoter-Driven Molecular Radiotherapy for Prostate Cancer</i> PI: <u>Martin Pomper, MD, PhD</u> (Johns Hopkins Medicine) Collaborators: <u>George Sgouros, PhD</u> (Johns Hopkins Medicine); <u>Paul Fisher, PhD</u> (Virginia Commonwealth University).</p>	<p><i>Synergistic Immune and lipid Metabolism Targeting for Metastatic Prostate Cancer Therapy</i> PI: <u>Jennifer Wu, PhD</u>, (Medical University of South Carolina) Collaborators: <u>James S Norris, PhD</u> (Medical University of South Carolina); <u>Michael Lilly, MD</u> (Medical University of South Carolina); <u>Xiang Liu, MD, PhD</u> (Medical University of South Carolina); <u>Ali Goshayan, MD</u> (Medical University of South Carolina); <u>Richard Drake, PhD</u> (Medical University of South Carolina); <u>Ann-Marie Broome, PhD</u> (Medical University of South Carolina); <u>Elizabeth Garrett-Mayer, PhD</u> (Medical University of South Carolina).</p>	<p><i>T Cell Receptor Gene Therapy for Treatment of Lethal Prostate Cancer</i> PI: <u>David Baltimore, Ph.D.</u> (California Institute of Technology) Collaborators: <u>Owen N. Witte, M.D.</u> (University of California, Los Angeles); <u>Lili Yang, Ph.D.</u> (University of California, Los Angeles); <u>Michael T. Bethune, Ph.D.</u> (California Institute of Technology)</p>
<p><i>Induction of Synthetic Lethality with Epigenetic therapy (ISLET) for Systemic Treatment of Prostate Cancer</i> PI: <u>William G. Nelson, MD, PhD</u> (Johns Hopkins Medicine) Collaborators: <u>Srinivasan Yegnasubramanian, MD, PhD</u> (Johns Hopkins Medicine); <u>Jun O. Liu, PhD</u>, (Johns Hopkins Medicine); <u>Stephen B. Baylin, MD</u> (Johns Hopkins Medicine); <u>Michael A. Carducci, MD</u> (Johns Hopkins Medicine); <u>Martin J. Aryee, PhD</u> (Johns Hopkins Medicine)</p>	<p><i>Targeting the p160 Steroid Receptor Coactivators (SRCs) as a Novel Approach for the Treatment of Castration-Resistant Prostate Cancer</i> PI: <u>Bert O'Malley, MD</u> (Baylor College of Medicine) Collaborators: <u>Nancy Weigel, PhD</u>; <u>Ming-Jer Tsai, PhD</u>; <u>Francesco DeMayo, PhD</u>; <u>Michael Ittman, MD, PhD</u>; <u>Nicholas Mitsiades, MD, PhD</u>; <u>Sean McGuire, MD, PhD</u>, (Baylor College of Medicine)</p>		

Mazzone Awards Program -- Dana-Farber/Harvard Cancer Center Projects Funded as of 2014

2011 High Impact	2012 High Impact	2013 High Impact
<p><i>Functional Annotation of Prostate Cancer Risk Loci Discovered through Genome Wide Association Studies</i> PI: Matthew Freedman, MD (DFCI) Collaborator: Gerhard Coetzee, PhD (USC/Norris Cancer Center - Keck School of Medicine).</p>	<p><i>Molecular Characterization Of Gleason 3 Tumors That Progress To Gleason 4</i> PI: Steven Balk, (Beth Israel Deaconess Medical Center) Collaborator: Wei Li (Baylor College of Medicine).</p>	<p><i>Co-targeting AR and ERG to treat advanced prostate cancer</i> PI: Karen Knudsen, PhD (Thomas Jefferson University). Collaborators: Felix Feng, MD (University of Michigan); Myles Brown, MD (Dana-Farber Cancer Institute).</p>
	<p><i>Defining the spectrum of resistance to androgen ablation therapy in prostate cancer</i> PI: Levi Garraway (Dana-Farber Cancer Institute) Collaborators: William Hahn (Dana-Farber Cancer Institute), Mark Rubin (Weill Cornell Medical College).</p>	<p><i>Genome-wide analysis of response to androgen deprivation therapy</i> PI: Mark Pomerantz, MD (Dana-Farber Cancer Institute) Collaborators: Matthew Freedman, MD (Dana-Farber Cancer Institute); Christopher Sweeney, MBBS (Dana-Farber Cancer Institute); Manish Kohli, MBBS (Mayo Clinic); Svitlana Tyekucheva, PhD (Dana-Farber Cancer Institute).</p>
		<p><i>Targeting Androgen Receptor Pathway-Independent Prostate Cancer (APIPC)</i> PI: Peter Nelson, MD (Fred Hutchinson Cancer Research Center). Collaborators: Marc Vidal, PhD (Dana Farber Cancer Institute); Muneesh Tewari, MD, PhD (Fred Hutchinson Cancer Research Center).</p>

		2013 High Impact Clinical Trials
		<p><i>Clinical Trials Assessing Mechanisms Mediating Sensitivity and Resistance to Enzalutamide</i></p> <p>PI: <u>Mary-Ellen Taplin, MD</u> (Dana Farber Cancer Center).</p> <p>Collaborators: <u>Bruce Montgomery, MD</u> (University of Washington); <u>Elahe Mostaghel, MD, PhD</u> (Fred Hutchinson Cancer Research Center); <u>Xin Yuan, MD, DSc</u> (Beth Israel Deaconess Medical Center); <u>Steven Balk, MD, PhD</u> (Beth Israel Deaconess Medical Center); <u>Glenn Bublely, MD</u> (Beth Israel Deaconess Medical Center); <u>Mark Pomerantz, MD</u> (Dana Farber Cancer Center); <u>Colm Morrissey, PhD</u> (University of Washington).</p>

2011 Project Development	2012 Project Development	2013 Project Development
<p><i>Epigenetic Reprogramming of AR Function in CRPC</i> PI: Myles Brown, MD. (Dana-Farber Cancer Institute).</p>	<p><i>Castration-Resistant Luminal Cells in the Prostate</i> PI: Zhe Li (BWH) Collaborator: Stuart Orkin (Children’s Hospital Boston).</p>	<p><i>Developing Novel Targeted Therapies for Advanced Prostate Cancer</i> PI: Karen Cichowski, PhD (Brigham and Women's Hospital).</p>
<p><i>Pharmacological validation of Etk/BMX as a target for the treatment of prostate cancer</i> PI: Nathanael Gray, PhD. (Dana-Farber Cancer Institute) Collaborator: Steven Balk, MD, PhD (Beth Israel Deaconess Medical Center).</p>	<p><i>Developing a Blood-based Metabolomic Signature of Gleason Score</i> PI: Massimo Loda (DFCI) Collaborators: Kathryn Penney (Brigham and Women's Hospital), Svitlana Tyekucheva (Harvard School of Public Health).</p>	<p><i>Targeting the Co-Activator Site on the Androgen Receptor</i> PI: Gregory Verdine, BS, PhD (Harvard University – Chemistry Department) Collaborator: Levi Garraway, MD (Dana-Farber Cancer Institute).</p>
<p><i>Cancer Stem Cells Targeting in Castration Resistant Prostate Cancer</i> PI: Pier Paolo Pandolfi, MD., PhD (Beth Israel Deaconess Medical Center).</p>	<p><i>Nanoplatfoms for Localized Chemo Radiation Therapy for Prostate Cancer</i> PI: Robert Cormack (DFCI) Collaborators: Anthony D’Amico (Dana-Farber Cancer Institute), Alec Kimmelman (Dana-Farber Cancer Institute), Mike Makrigiorgos (Dana-Farber Cancer Institute), Srinivas Sridhar (Northeastern University).</p>	
<p><i>DNase-seq for Cost-effective Identification of Functional Mutations in Prostate Cancers</i> PI: Xiaole Shirley Liu, PhD (Dana-Farber Cancer Institute) Collaborators: Myles Brown, MD (Dana-Farber Cancer Institute) Levi Garraway, MD, PhD (Dana-Farber Cancer Institute) Soumya Raychaudhuri, MD, PhD (Harvard Medical School).</p>		

2011 Lupron-Treatable Diseases and Conditions	2012 Lupron-Treatable Diseases and Conditions	
<p><i>Cancer and Endometriosis</i> PI: <u>Stacey Missmer, ScD</u> (Brigham and Women's Hospital) Collaborators: <u>Rulla Tamimi, ScD</u> (Brigham and Women's Hospital); <u>Jiali Han, PhD</u> (Brigham and Women's Hospital).</p>	<p><i>Targeting estrogen-dependent mechanisms in lymphangi leiomyomatosis (LAM)</i> PI: <u>Elizabeth Henske, MD</u> (Brigham and Women's Hospital) Collaborator: <u>Jane Yu, PhD</u> (Brigham and Women's Hospital).</p>	
	<p><i>Pre-clinical in vivo studies investigating the efficacy of mTOR inhibitors for uterine fibroids</i> <u>Aaron Styer, PhD</u> Replaced: <u>Jose Teixeira, PhD</u> (Massachusetts General Hospital) Collaborator: <u>Bradley Quade, MD</u> (Brigham and Women's Hospital).</p>	

2011 Disparities Research	2012 Disparities Research	2013 Disparities Research	2014 Disparities Research
<p><i>Enhancing Usability of the Personal Patient Profile-Prostate (P3P) for Black and Hispanic Men</i> PI: Donna Berry, PhD, RN (Dana-Farber Cancer Institute) Collaborators: Julia Hayes, MD (Dana-Farber Cancer Institute) Martin Sanda, MD (Beth Israel Deaconess Medical Center) Seth Wolpin, PhD, MPH, RN (University of Washington).</p>	<p><i>Estimating The Prostate Cancer Burden Attributed To Lifestyle And Genetic Factors Among African-American And White Men</i> PI: Lorelei Mucci (Harvard School of Public Health) Collaborators: Edward Giovannucci (Harvard School of Public Health), Massimo Loda (Dana-Farber Cancer Institute), Lisa Signorello (Vanderbilt University).</p>	<p><i>Chronic stress and racial disparities in prostate cancer</i> PI: Lisa Signorello, ScD (Harvard School of Public Health). Collaborators: Jennifer Rider, ScD (Harvard School of Public Health); Sebastien Haneuse, PhD (Harvard School of Public Health); Unnur Valdimarsdottir, PhD (University of Iceland).</p>	<p><i>Do Baseline Prostate Specific Antigen (PSA) Levels Predict Advanced Prostate Cancer in African-American Men?</i> PI: Mark Preston, MD, MPH (BWH) Collaborator: Lorelei Mucci, ScD (HSPH)</p>
<p><i>Understanding Racial Differences in Prostate Cancer Mortality</i> PI: Nancy Keating, MD, MPH (Harvard Medical School) Collaborators: Glen Taksler, PhD (New York University) David Cutler PhD (Harvard University School of Economics).</p>	<p><i>Factors Influencing Willingness To Participate In Biobanking Among Black Men With And At-Risk For Prostate Cancer</i> PI: Karen Emmons (Dana-Farber Cancer Institute) Collaborators: Laura Hayman (University of Massachusetts Boston), J Jacques Carter (Beth Israel Deaconess Medical Center, Aymen Elfiky (Dana-Farber Cancer Institute), Christopher Lathan (Dana-Farber Cancer Institute).</p>		<p><i>Whole genome sequencing based identification of clinically relevant genomic aberrations specific to prostate cancer cases in African Americans</i> PI: Zoltan Szallasi, MD (BCH) Co-PI: Matthew Freedman, MD (DFCI) Collaborator: Mark Pomerantz, MD (DFCI)</p>

2011 Community Outreach	2012 Community Outreach	2013 Community Outreach
	<p><i>Engaging African American Faith Communities in Prostate Cancer Education</i> PI: Jennifer D. Allen, DSc, MPH, RN (Dana-Farber Cancer Institute) Collaborator: Donna Berry (Dana-Farber Cancer Institute).</p> <hr/> <p><i>Seed funding grant (\$10K) for proposal development for: Enhancing the effectiveness, mission and outreach of an ongoing community prostate cancer support group</i> PI: Glenn Bublely, MD (Beth Israel Deaconess Medical Center)</p>	<p><i>Shared Medical Appointments: An Innovative Approach to Prostate Cancer Survivorship Care</i> PI: Larissa Nekhlyudov, MD, MPH (Harvard Vanguard Medical Associates). Collaborators: Ann Partridge, MD, MPH (Dana-Farber Cancer Institute); Wilmer Roberts, MD, PhD (Harvard Vanguard Medical Associates); Michael Pistiner, MD, MMSc (Harvard Vanguard Medical Associates); Aymen Elfiky, MD, MPH (Dana-Farber Cancer Institute); Christopher Recklitis, PhD, MPH (Dana-Farber Cancer Institute); Sarah Reed, MPH,MSW (Dana-Farber Cancer Institute).</p>

2011 Career Development	2012 Career Development	2013 Career Development
<p><i>Probing androgen receptor signaling in circulating tumor cells in prostate cancer</i> PI: David Miyamoto, MD, PhD (Massachusetts General Hospital) Collaborator: Daniel Haber, MD, PhD (Massachusetts General Hospital).</p>	<p><i>Within-Person Molecular Differences in Primary Versus Metastatic Prostate Cancer</i> PI: Julie Kasperzyk (Brigham and Women’s Hospital) Collaborators: Steven Balk (Beth Israel Deaconess Medical Center), Giovanni Parmigiani (Harvard School of Public Health, Meir Stampfer (Brigham and Women’s Hospital).</p>	<p><i>Impact on Prognosis of Inter- and Intratumor Heterogeneity In Prostate Cancer</i> PI: Jennifer Sinnott, PhD Collaborators: Lorelei Mucci, ScD (Harvard School of Public Health), Giovanni Parmigiani, PhD (Dana-Farber Cancer Institute), Massimo Loda, MD (Dana-Farber Cancer Institute); Kathryn Penney, ScD (Brigham and Women's Hospital).</p>
<p><i>Prostate cancer genetic variants, molecular alterations and mRNA expression</i> PI: Kathryn Penney, ScD, BA (Brigham and Women’s Hospital) Collaborator: Massimo Loda, MD (Brigham and Women’s Hospital).</p>	<p><i>Inflammation and Tissue Microenvironment As Predictors Of Prostate Cancer Risk, Mortality And Therapy Response Among Men With An Initially Benign TURP</i> PI: Jennifer Rider (Harvard School of Public Health) Collaborators: Lorelei Mucci (Harvard School of Public Health), Giovanni Parmigiani (Dana-Farber Cancer Institute), Christopher Sweeney (Dana-Farber Cancer Institute), Michelangelo Fiorentino (Harvard School of Public Health), Ove Andren (University of Orebro)</p>	
<p><i>Phosphorus and calcium intake, tumor microenvironment and prostate cancer progression</i> PI: Kathryn Wilson, Sc.D. (Harvard School of Public Health) Collaborators: Lorelei Mucci, MPH, ScD (Brigham and Women’s Hospital), Edward Giovannucci, MD, ScD (Harvard School of Public Health), Michelangelo Fiorentino, MD, PhD (Harvard School of Public Health).</p>		

Appendix 3: Program Reporting Schedule

A. David Mazzone Awards Program Reporting Schedule

Awards Program Timeframes

Overall program start and end date October 1, 2010 through September 30th, 2017 (seven years)
 Overall program reporting period October 1, 2010 through September 30th, 2017 (seven years)
 All program grants issued between July 1, 2011 and July 1, 2015 (five years)

Reporting Period	Report Number	Report due by	Notes
October 1, 2010- June 30, 2011	One	July 31, 2011	This report will describe programmatic progress
July 1, 2011 - December 31, 2011	Two	March 31, 2012	This report and all subsequent March reports will describe programmatic progress
July 1, 2011 - June 30, 2012 <i>annual report</i>	Three	September 30, 2012	This report and all subsequent September reports will report on annual research progress and accounting for all grants
July 1, 2012 - December 31, 2012	Four	March 30, 2013	Programmatic report
July 1, 2012 - June 30, 2013 <i>annual report</i>	Five	September 30, 2013	Research progress and accounting for all grants
July 1, 2013 - December 31, 2013	Six	March 30, 2014	Programmatic report
July 1, 2013 - June 30, 2014 <i>annual report</i>	Seven	September 30, 2014	Research progress and accounting for all grants
July 1, 2014 - December 31, 2014	Eight	March 30, 2015	Programmatic report
July 1, 2014 - June 30, 2015 <i>annual report</i>	Nine	September 30, 2015	Research progress and accounting for all grants
July 1, 2015** - December 31, 2015	Ten	March 30, 2016	Programmatic report
July 1, 2015** - June 30, 2016 <i>annual report</i>	Eleven	September 30, 2016	Research progress and accounting for all grants
July 1, 2016 - December 31, 2016	Twelve	March 30, 2017	Programmatic report
July 1, 2016 - September 30, 2017 <i>final annual report</i>	Thirteen	December 31, 2017	Final reports on extended grants and final reconciliation reports

** Last scheduled 2 year grants issued by July 31, 2015, for closure by June 30, 2017