

BIOGRAPHICAL SKETCH

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NAME Michael A. Carducci		POSITION TITLE Professor of Oncology and Urology	
eRA COMMONS USER NAME mcarduc1			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Georgetown University, Washington, D.C.	A.B.	1983	American Studies
Wayne State University, Detroit, MI	M.D.	1988	Medicine
University of Colorado HSC, Denver, CO	Intern/Resident	1988-91	Medicine
University of Colorado HSC, Denver, CO	Chief Resident	1991-92	Medicine
Johns Hopkins University SOM, Baltimore, MD	Research Fellow	1992-95	Oncology

A. Personal Statement

As a translational researcher, I direct a laboratory program focused on the re-expression of epigenetically silenced genes in cancer cells *via* the use of small molecules targeting DNA methyltransferases and histone deacetylases and manage a portfolio of clinical trials targeted at introducing these and other small molecules into cancer treatment. Overall, my laboratory and clinical research focus is on the development and evaluation of new therapies for urologic cancers. I also lead the Johns Hopkins Kimmel Cancer Center Phase I program and am a member of the NCI Investigational Drug Steering Committee and GU Steering Committee. I will provide expertise in the development of theranostic agents in Research Component 1 and be responsible for identifying and recruiting patients for the PSMA clinical trial.

B. Positions and Honors

Professional Experience

1995-96	Instructor of Oncology and Urology, Johns Hopkins University School of Medicine
1996-01	Assistant Professor of Oncology and Urology, Johns Hopkins University
2001-07	Associate Professor of Oncology and Urology, Johns Hopkins University
2003	Chair, Prostate Cancer Subcommittee, Eastern Cooperative Oncology Group
2004	Co-Leader, Prostate Cancer Program, Kimmel Cancer Center at Johns Hopkins
2006	Co-Leader, Chemical Therapeutics Program, Kimmel Cancer Center at Johns Hopkins
2007	Professor of Oncology and Urology, Johns Hopkins University
2009	AEGON Professor in Prostate Cancer Research

Honors

1986	Alpha Omega Alpha
1988	M.D. with High Distinction, Wayne State University
1991	Housestaff Teaching Award, University of Colorado Health Sciences Center
1997	Osler Medicine Housestaff Teaching Award, Johns Hopkins University
2005	Director's Teaching Award for Clinical Science, Kimmel Cancer Center at Johns Hopkins
2007	Urology Excellence in Teaching Award, Brady Urological Institute, Johns Hopkins

C. Selected Peer-reviewed Publications (selected from 145 peer-reviewed publications)

Most relevant to the current application

1. Kachhap S, Faith D, Qian D, Shabbeer S, Galloway N, Pili R, Denmeade S, DeMarzo A, Carducci M. The N-myc Down Regulated Gene1 (NDRG1) is a Rab4a Effector Involved in Vesicular Recycling of E-cadherin. PLoS One 2007; Sep 5;2 (9): e844.
2. Carducci MA, Saad F, Abrahamsson P-A, Dearnaley DP, Schulman CC, North SA, Sleep DJ, Isaacson JD, Nelson JB. A phase 3 randomized controlled trial of the efficacy and safety of atrasentan in men with metastatic hormone-refractory prostate cancer. Cancer. 2007; 110:1959-1966.
3. Baselga J, Rothenberg ML, Tabernero J, Seoane J, Daly T, Cleverly A, Berry B, Rhoades SK, Ray CA, Fill J, Farrington DL, Wallace LA, Yingling JM, Lahn M, Arteaga C, Carducci M. TGF- β signaling related

markers in cancer patients with bone metastasis. *Biomarkers*. 2008;13:217-236. PMC Journal – In Process.

4. Scher HI, Halabi S, Tannock IF, Morris MJ, Sternberg CN, Carducci MA, Eisenberger MA, Higano CS, Bubleby GJ, Dreicer R, Petrylak DP, Kantoff PW, Basch E, Kelly WK, Figg WD, Small EJ, Beer TM, Wilding G, Martin A, Hussain M. Design and endpoints of clinical trials for patients with progressive prostate cancer and castrate levels of testosterone: Recommendations of the Prostate Cancer Clinical Trials Working Group (PCWG2). *J Clin Oncol*, 2008; 26:1148-1159. PMC Journal – In Process.
5. Siu LL, Pili R, Duran I, Messersmith WA, Chen EX, Sullivan R, MacLean M, King S, Brown S, Reid GK, Li Z, Kalita AM, Laille EJ, Besterman JM, Martell RE, Carducci MA. A phase I study of MGCD0103 given as a three-times per week oral dose in patients with advanced solid tumors. *J Clin Oncol*, 2008; 26: 1940-1947. PMC Journal – In Process.
6. Nelson JB, Love W, Chin JL, Saad F, Schulman CC, Sleep DJ, Qian J, Steinberg J, Carducci M. Phase 3, randomized controlled trial of atrasentan in patients with nonmetastatic hormone refractory prostate cancer. *Cancer*, 2008; 113:2478-2487. PMC Journal – In Process.
7. Kortenhorst MSQ, Zahurak M, Shabbeer S, Kachhap S, Galloway N, Parmigiani G, Verheul HMW, Carducci MA. A multiple loop, double cube microarray design applied to prostate cancer cell lines with variable sensitivity to histone deacetylase inhibitors. *Clin Cancer Res*, 2008; 14:6886-6894. PMID2603330.
8. Liu W, Laitinen S, Khan S, Vihinen M, Kowalski J, Yu G, Chen L, Ewing CM, Eisenberger MA, Carducci MA, Nelson WG, Yegnasubramanian S, Luo J, Wang Y, Xu J, Isaacs WB, Visakorpi T, Bova GS. Copy number analysis indicates monoclonal origin of lethal metastatic prostate cancer. *Nat Med*, 2009; 15:559-565. PMID2839160.
9. Antonarakis ES, Heath EI, Walczak JR, Nelson WG, DeMarzo AM, Zahurak ML, Piantadosi S, Dannenberg AJ, Gurganus RT, Baker SD, Parnes HL, DeWeese TL, Partin AW, Carducci MA. A randomized, placebo controlled trial of neoadjuvant celecoxib in men with clinically localized prostate cancer: Evaluation of drug-specific biomarkers. *J Clin Oncol*, 2009; 27:4986-4993. Epub 2009 Aug 31. PMID2799055.
10. Lin J, Gilbert J, Rudek M, Zweibel J, Gore S, Jiemjit A, Zhao M, Baker S, Ambinder R, Herman J, Donehower R, Carducci MA. A phase I dose finding study of 5-azacytidine in combination with sodium phenylbutyrate in patients with refractory solid tumors. *Clin Cancer Res*, 2009; 15: 6241-6249. Epub 2009 Sep 29. PMID2845396.
11. Sharma P, Wisniewski A, Braga-Basaria M, Xu X, Yep M, Denmeade S, Dobs AS, Deweese T, Carducci M, Basaria S. Lack of an effect of high dose isoflavones in men with prostate cancer undergoing androgen deprivation therapy. *J Urol*. 2009; 18:2265-2273. Epub 2009 Sep 16. PMC Journal – In Process.
12. Armstrong AJ, Netto GJ, Rudek MA, Halabi S, Wood D, Creel P, Mundy K, Davis SL, Wang T, Albadine R, Schultz L, Partin A, Jimeno A, Fedor H, Febbo PG, George DJ, Gurganus R, DeMarzo AM, Carducci MA. A pharmacodynamic study of rapamycin in men with intermediate to high risk localized prostate cancer. A Department of Defense Prostate Cancer Clinical Trials Consortium Trial. *Clin Cancer Res*, 2010; 16:3057-3066. PMC Journal – In Process.
13. Kachhap SK, Rosmus N, Collis SJ, Kortenhorst MSQ, Wissing MD, Hedayati M, Shabbeer S, Mendonca J, Deangelis J, Marchionni L, Lin J, Hoti N, Nortier JWR, DeWeese TL, Hammers H. Carducci MA. Downregulation of homologous recombination DNA repair genes by HDAC inhibition in prostate cancer is mediated through the E2F1 transcription factor. *PLoSOne*, 2010;5 (6): e11208. PMID2887841.
14. Snyder CF, Frick KD, Blackford AL, Herbert RJ, Neville BA, Carducci MA, Earle CC. How does initial treatment choice affect short-term and long term costs for clinically localized prostate cancer? *Cancer*, 2010; Aug 23. PMC Journal – In Process.
15. Franke RM, Carducci MA, Rudek MA, Baker SD, Sparreboom A. Castration-dependent pharmacokinetics of docetaxel in patients with prostate cancer. *J Clin Oncol*. 2010 Sep 20. [Epub ahead of print] PMC Journal - In Process.

D. Research Support

Ongoing Research Support

2P50CA103175-06A2 (Bhujwalla)

NCI JHU ICMIC Program

09/22/11 - 07/31/16

This center grant funds an *in vivo* Cellular and Molecular Imaging Center at Johns Hopkins. The program consists of four research components, four developmental projects, one career development award and four resources.

NCI U01CA70095 (Carducci/Karp/Rudek) 09/22/95-02/28/13
Phase I Clinical Trials of New Anti-cancer Targeted Therapies
The major goal of this project is to evaluate new agents for advanced cancer.

NCI P50CA58236 (Nelson) 09/30/97-08/31/13
SPORE in Prostate Cancer Project #4 – Advancing Epigenetic Therapies in Prostate Cancer
The major goal of this project is to further determine the therapeutic potential of targeting HIF-1a and angiogenesis with novel combination strategies involving HDAC inhibitors for the treatment of PCA patients.

MMSG-08-011-01-CPPB (Snyder) 01/01/08-12/31/12
American Cancer Society
Using Patient-Reported Outcomes Assessment to Improve the Quality Care
The main goal of this project is to develop an independent science in PRO's.

XRP6976J/3503 (Carducci) 03/28/08-03/27/14
Sanofi-Aventis Group
A Phase III Study of Leuprolide +/- Docetaxel for Asymptomatic Prostate Cancer Subjects with a Rising PSA Following Local Therapy
The goal of this project is to gather additional information about the effectiveness and safety of Leuprolide +/- Docetaxel and to evaluate the overall benefit-risk relationship of the drug.

DOD W81XWH-09-1-0149 (Carducci) 04/01/09-03/31/13
Prostate Cancer Clinical Trials Consortium-Johns Hopkins Kimmel Cancer Center Site
The major goal of this project is to discover and develop new prostate cancer treatments.

20080016 (Carducci) 06/27/09-06/26/13
Amgen, Inc.
A Phase 1 First-in-Human Study Evaluating the Safety, Tolerability, PK and PD of AMG 900 in Adult Subjects with Advanced Solid Tumors
The main goal of this project is to test the new agent for safety and tolerability.

A4061046 (Carducci) 05/12/09-05/11/13
Pfizer Inc.
Randomized, Double-Blind Phase II Study of Axitinib (AG-013736) with or without Dose Titration in Patients with Metastatic Renal Cell Carcinoma
The main goal of this study is to determine the safety and efficacy of axitinib in metastatic renal cell carcinoma.

G-202-001 (Carducci) 12/17/09-12/16/14
Genspera, Inc
An Open-Label, Single-Arm, Dose-Escalation Phase 1 Study of G202 in Patients with Advanced Solid Tumors
The main goal of this study is determining the safety/tolerability of G202 in patients with advanced solid tumors

90041228 (Carducci) 03/01/10-02/28/15
Kinex Pharmaceuticals
Phase II Study Evaluating the Safety, Efficacy and PK of KX2-391 in Patients with Bone-Metastatic CRPC Who Have Not Received Prior Chemotherapy
The main goal of this study is to determine the safety, tolerability, and efficacy and PK of KX2-391 in Patients with Bone-Metastatic CRPC Who Have Not Received Prior Chemotherapy.

D4320C00015 (Carducci) 02/28/08-08/27/13
AstraZeneca LP

A Phase III, Randomized, Placebo-controlled, Double-blind Study of Once-daily Orally Administered ZD4054 10 mg in Non-metastatic HRPC Patients

The goal of this clinical trial is to gather additional information about the effectiveness and safety of ZD4054 and to evaluate the overall benefit-risk relationship of the drug.

Completed Projects Within Last Three Years

NCI P30CA006973-44 (Nelson) 05/07/97-04/30/11

Regional Oncology Research Center

This project funds the CORE Grant for the Johns Hopkins Oncology Center. Specific effort involves directing the scientific and operational aspects of the Analytical Pharmacology Core which includes pharmacological trial design, sample handling, analytical method development, validation, and implementation, data interpretation and Pharmacokinetic and Pharmacodynamic modeling.

R21CA134805 (Snyder) 08/15/09-07/31/11

NIH

Feasibility and Value of a Website for Assessing Patient-Reported Outcomes

The overall goal of this project is to pilot-test the prototype website to assess its use, usefulness, and acceptability to clinicians and patients.

GUP-0515-2 (Carducci) 12/17/08-12/16/11

PomWonderful, LLC.

A Randomized Placebo-Controlled, Pre-Surgical Study of the Effects of Pomegranate Pills in Men with Prostate Cancer Prior to Radical Prostatectomy

The main goal of this clinical trial is to measure the effects of daily consumption of two POMX pomegranate pills compared to placebo on prostatic oxidative damage-8-hydroxydeoxyguanosine (8OhdG) levels when given orally for up to four weeks to men with adenocarcinoma of prostate prior to undergoing radical prostatectomy as primary therapy for localized prostate cancer.

NCI P50CA88843 (Sukumar) 09/30/00-11/30/11

SPORE in Breast Cancer

The main goal of this grant is to support a translational breast cancer research program of four research projects and three cores.

C11981/1047/ON/US (Carducci) 06/29/07-07/01/10

Cephalon, Inc.

An Open-Label Study to Determine the Maximum Tolerated Oral Dose of the Kinase Inhibitor CEP-11981 in Patients with Advanced Cancer

The main goal of this clinical study is to assess the safety and tolerability of the antiangiogenesis agent CEP-11981 in patients with solid tumors.

90034107 (Carducci) 04/10/08-04/09/10

Agensys

A Phase 1, Open-label, Multi-center, Dose Escalation Study of the Safety and Pharmacokinetics of AGS-16M18 in Advanced Renal Cell Carcinoma

The main goal of this trial is to assess the antitumor activity of the novel monoclonal antibody AGS-16M18 in kidney cancer.