"Advancing Prostate Cancer and Germ Cell Tumour Knowledge with Clinical and Translational Research"

A thesis submitted for
the Degree of

Doctor of Health Sciences

in the
Faculty of Health and Medical Sciences

of
The University of Adelaide

by
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Dedication

I dedicate this thesis to my dear wife, Rosie, who shared the most precious of commodities, time, and provided endless support that allowed me to pursue the research endeavours underpinning this thesis. I would also like to acknowledge the value of education and learning instilled in me by my parents (Mary and Michael Sweeney) and siblings (Anne, David, Julie and Paul) which provided the essential guidance and support to foster my early academic inclinations.

Introduction

Being a medical oncologist provides unique insights into the limitations encountered when treating patients with cancer but also provides the opportunities to identify possible strategies to decrease the burden of cancer. However, to develop new interventions requires rigorous multi-disciplinary research. In this thesis by publication, the details of six research themes are presented which have stemmed from observations derived from caring for patients with prostate cancer and germ cell tumours. This body of work emanated from the inspiration I gained from the patients fighting cancer and clinicians providing compassionate care. It became abundantly clear during my training that research spanning laboratory-based discovery science to clinical research to epidemiological studies have lead to advances for some but not all patients. Moreover, it was apparent that team-science was critical to harness all the expertise needed to make these advances. To that end, since commencing my clinical and laboratory research training as an advanced trainee in Medical Oncology in 1997, I have been a part of, and later, lead research teams on the quest to improve the outcomes of patients with cancer.

More specifically, I have devoted approximately 60% of my time to clinical care delivery for patients with cancer which included caring for patients on phase 1 to phase 3 clinical trials. The other 40% of my time was devoted to research and teaching activities which included designing, conducting and reporting on the results of investigator initiated clinical trials, building clinical data registries and biorepositories which have generated novel clinical, pathological and genomic findings. I have also lead multiple bench-top translational laboratory research projects. For the latter, I had my own laboratory at Indiana University while at Dana-Farber Cancer Institute I funded and supervised post-doctoral researchers in the laboratories of collaborators. My leadership skills and collaborative spirit have been critical in bringing the teams together to perform the research in both the clinic and the laboratory.

In brief, research led by me has resulted in new insights into cancer biology as well as improved therapies and prognostic stratifications of patients with prostate and testicular cancer. This work has been funded by national peer-reviewed funding bodies (NIH, DOD, and foundation grants). The most notable completed investigator-sponsored phase 3 clinical trials led by me include two trials that have led to improvements in prostate cancer care (CHAARTED and ENZAMET) and were both published in the New England Journal of Medicine. My work has also led to unique insights regarding germ cell tumours including clinical outcomes and biological findings. Detailed in the body of this thesis are the key elements of the six research themes which highlight the major contributions from my research. The summaries detail: (i) the clinical context guiding the research contribution, (ii) the key collaborators, mentors and mentees that enabled the research and (iii) the reprints of key publications that serve as exemplars of the research findings. The six research themes are:

1. Conduct of investigator sponsored clinical trials leading to improvements in prostate cancer therapy.
2. Conduct of biomarker analysis leading to improved understanding of prostate cancer clinical outcomes.
3. Evaluation of intermediate clinical endpoints in prostate cancer as robust surrogates of overall survival
4. Leadership of randomized phase 3 industry sponsored clinical trials that have informed prostate cancer biology and prostate cancer care.
5. Development of a nuclear factor kappa B inhibitor from bench to bedside.
6. Clinical and translational research providing unique insights into germ cell tumour clinical outcomes and biology.

Statement Supporting Application for Awarding the Degree of Doctor of Health Science

As a graduate of Medicine (MBBS) from The University of Adelaide in 1993, it is with great honour and enthusiasm that I assumed the role as Director of the South Australian Immunogenomics Cancer Institute (SAiGENCI) at the University of Adelaide on December 5, 2022. Prior to my return to the University of Adelaide I had spent more than 25-years in the USA as a clinician researcher with a focus on cancer clinical trials and translational cancer research. My research has focused on cancer biomarkers and drug development with a special interest in testis and prostate cancer. My application for the award of Degree of Doctor of Health Science from the University of Adelaide is based on my research accomplishments, which is detailed below.

After completing medical school in 1992, I then undertook a rotating internship in medicine and surgery at the Royal Adelaide Hospital and then moved to the USA and completed a residency in Internal Medicine at the Gundersen Lutheran Medical Center, La Crosse WI (USA) and became board certified by the American Board of Internal Medicine in 1997. I then completed a Fellowship in Hematology-Oncology at Indiana University Hospital and was board certified in Medical Oncology by the American Board of Internal Medicine in 2000.

After my clinical training, I was appointed Assistant Professor of Medicine in 2000 and then promoted to Associate Professor of Medicine at Indiana University in 2006. My “job-mix” during this time was 60% clinical and 40% research as I provided clinical care as a medical oncologist while also pursuing an academic cancer research career. I returned to The University of Adelaide in 2008 as Professor in the Faculty of Health Sciences and as a Medical Oncologist and Director of Clinical Trials at the Royal Adelaide Hospital. I returned to the USA in 2009 as an Associate Professor (2010-18) and then promoted to Full Professor of Medicine in 2018 at the Harvard Medical School. While at Harvard Medical School I continued to have the privilege of providing care to patients with cancer as a Medical Oncologist at the Dana-Farber Cancer Institute in Boston, Massachusetts. My time commitments continued to be approximately 60% clinical care and 40% research.

In addition, I was Associate Member of the Broad Institute in Boston and am still an active member of the American Society of Clinical Oncology, the Eastern Co-Operative Oncology Group and the American Association for Cancer Research and Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). I have also served as Chairman of the Hoosier Oncology Group from 2005-2007 and while at Dana-Farber Cancer Institute received the 2014 George Canellos Award for Excellence in Clinical Investigation and Patient Care and in 2012 the Ellen and Stephen Fine Outstanding Teaching in Cancer Medicine Award. In 2020, Professor Ian Davis and I were awarded the Australian Clinical Trials Alliance Research Clinical Trial of the Year Award for the leadership of the ENZAMET trial. Furthermore, the ICECaP international collaboration, under my leadership as Principal Investigator has led identification and use of a new intermediate clinical endpoint for adjuvant prostate cancer trials that has been accepted by regulatory agencies in USA and Europe (icecap.movember.com). In 2021, the ICECaP effort was awarded Statistical Partnerships Among Academe, Industry, and Government (SPAIG) Award (joint awardee with ICECaP biostatisticians) by the American Statistical Association Research. Upon my departure from Dana-Farber Cancer Institute, recognition of my work was realized by an endowment that was raised in 2023 for the *Christopher J. Sweeney, MBBS, Seminar in Prostate Cancer* (Harvard Medical School and Dana-Farber Cancer Institute).

Statement Detailing Past or Current Affiliation with University of Adelaide

In 1987, I commenced medical school at University of Adelaide and completed the course work in 1992 and had the degree of MBBS conferred in May 1993.

When I was working at the Royal Adelaide Hospital in 2008 and 2009, I had an academic appointment as a Full Professor at the University of Adelaide.

On December 5, 2022, I commenced a full-time position at University of Adelaide as Director of the South Australian Immunogenomics Cancer Institute (SAiGENCI) and appointed as Professor of Medicine. I was appointed after an international search.

In addition to the duties as Director of SAiGENCI, I will continue my clinical trial cancer research as well as the biomarker and drug development projects in SAiGENCI at The University of Adelaide.

Statement Declaring None of the Work Has Formed Part or All of an Award for Another Degree

None of the work detailed in this thesis has formed part or all of an award for another degree. My honorary *Masters of Arts* degree from Harvard University is awarded to all Full Professors at Harvard University who have not had an undergraduate or a post graduate degree from Harvard University.

Bibliometrics and Patents

As of April 2023, my research efforts have resulted in 29,087 lifetime citations and a h-Index of 83 with an i10-index of 302. As detailed in my List of Publications, my research has resulted in more than 309 peer-reviewed publications [246 original peer-reviewed publications, 63 peer-reviewed publications in the forms of reviews, editorials, consensus statements] plus 28 other non-peer reviewed scientific or medical publications. Notably I have been the first or senior author on papers published in high-ranking journals such as the *New England Journal of Medicine*, *Lancet, Lancet Oncology, Nature* and *Nature Medicine, Journal of Clinical Oncology* and *Annals of Oncology.* The upward trajectory of my output is realized by noting in the last 5-years my the number of citations of my work has increased by 12,442 and h-index 25 points. Specifically, my annual citations were: 1941 in 2017; 3691 in 2022 and 1300 by April 30, 2023 annualised to 3900.

In addition, as detailed in Report of Technological and Other Scientific Innovations in full curriculum vitae, this work has supported 4 successful patent applications.

Summary of Grant Funding

My research efforts have been enabled by more than $10 million AUD in national peer reviewed grant funding from National Institutes of Health (USA), Department of Defence (USA) and Prostate Cancer Foundation (USA) as Principal Investigator (i.e. CI-A). In addition, I have designed and conducted investigator-sponsored clinical trials which have been supported by more than $100 million AUD from pharmaceutical companies. The most notable recent efforts initiated by me include the phase 3 trials of ENZAMET, ENZARAD and DASL-HiCaP have had the research and funds co-ordinated by ANZUP and University of Sydney. I would also like to clarify that most of my clinical trial work has been investigator-sponsored which has required me to generate the idea, raise the funds and report the results. I have also led and been on steering committees of large phase 3 industry sponsored trials. (Please see complete curriculum vitae below for full details)

Summary of Teaching and Mentoring

In my academic positions, I have taught in in two different settings:

1) Peer-to-Peer Teaching at the local, regional, national and international levels.
2) Mentoring junior faculty, clinical trainees, PhD candidates and post-doctoral researchers.

Peer-to-Peer Teaching at the local, national and international level: I have an extensive history of teaching peers as evidenced by both organizing and participating in Continuing Medical Education (CME) courses and delivering more than 200 invited lectures at local, regional national and international meetings. I have been a discussant of oral abstracts, chaired scientific and education sessions at ASCO as well as served on the ASCO Program and Education Committees for the ASCO Annual General Meeting and the annual ASCO Genitourinary Oncology meeting.

Mentoring junior faculty, clinical fellows and residents, PhD candidates and post-doctoral researchers: I have been an effective teacher at an individual level by mentoring trainees and junior faculty by integrating them into my research program and having them obtain research skills and gain experience with writing manuscripts as first author which ultimately support their academic careers. The trainees directly mentored by me include 9 clinical trainees from USA, UK, France, Italy, Australia, as well as 2 PhD candidates, 7 post-doctoral researchers and 9 junior faculty. (Please see complete curriculum vitae below for full details).

Research Theme 1: Conduct of investigator sponsored clinical trials leading to improvements in prostate cancer therapy.

During my medical oncology fellowship and first years as a junior faculty I was mentored by compassionate and skilled clinicians, clinical trialists and statisticians at Indiana University and as part of the Genitourinary Oncology subcommittee of the NCI sponsored Eastern Co-operative Oncology Group (ECOG). This provided the requisite training and experience in design and conduct of investigator-initiated trials and writing up the results of completed trials as first or senior author (examples in list of publications: original research publications #2,10,27,28,30). Based on this documented proficiency, I was given the responsibility and honour of writing and being the principal investigator of the NCI sponsored ECOG, *E3805: CHAARTED trial – Chemohormonal Therapy Versus Androgen Ablation Randomized Trial In Extensive Disease Prostate Cancer*. The hypothesis of this study was that given docetaxel was proven to modestly improve the survival of men with castration resistant disease, it would be more effective when given with men with metastatic hormone sensitive disease at the time of starting their testosterone suppression therapy. This 790-patient randomized phase 3 study was the first to document the major improvement in overall survival of patients when docetaxel (a chemotherapy) was given with androgen deprivation therapy (ADT) in the form of testosterone suppression. Given the major improvement in overall survival, it was selected as part of the main plenary session (namely one of the top 4 abstracts out of more than 2,000 accepted abstracts) at the American Society of Oncology meeting in 2014. The results were published in the *New England Journal of Medicine* in 2015:

- **Sweeney C,** Chen Y-H, Carducci MA, Liu, G, Jarrard, D, Eisenberger, M, Wong, Y, Hahn, N, Kohli, M, Vogelzang, N, Cooney, M, Dreicer, R, Picus, J, Shevrin, D, Hussain, M, Garcia, J, DiPaola. R: Chemohormonal Therapy in Metastatic Hormone-Sensitive Prostate Cancer. *N Engl J Med.* 2015 Aug 20;373(8):737-46 (see accompanying reprint).

At the time of study design in 2004, with the help of the GU ECOG subcommittee and reviewing published literature, I lead the team which also prospectively defined patients based on the number and sites of metastatic lesions who we projected would have a worse prognosis with ADT alone and designated the group as “high volume”. The patients were stratified by low and high-volume disease as we also anticipated the high-volume group would get more benefit from docetaxel than patients with low volume disease. The number of events was too low at the first follow-up to confirm whether the benefit was more pronounced in patients with high-volume disease. When enough events had occurred, I mentored a junior faculty member in analysing and reporting the results which documented for the first time that patients with high-volume metastatic hormone sensitive disease have a more pronounced benefit from docetaxel in 2018. This finding was confirmed by an individualized patient data meta-analysis by the STOPCaP working group (manuscript accepted in May 2023 for publication in *Lancet Oncology*).

- Kyriakopoulos CE., Chen Y, Carducci MA, Liu G, Jarrard DF, Hahn N, Shevrin DH, Dreicer R, Hussain M, Eisenberger M, Kohli M, Plimack ER, Vogelzang, NJ, Picus J, Cooney MM, Garcia JA, DiPaola RS, **Sweeney CJ.** Chemohormonal Therapy in Metastatic Hormone-Sensitive; Prostate Cancer: Long-Term Survival Analysis of the Randomized Phase III E3805 CHAARTED Trial. *J Clin Oncol*. 2018 Apr 10;36(11):1080-1087.

In 2012, the potent androgen receptor inhibitor, enzalutamide, was shown to prolong the overall survival of men with castration resistant prostate cancer after they had received docetaxel. With this knowledge, I again instigated a trial to see if an agent with documented activity in metastatic castration resistant prostate cancer (enzalutamide) would be more active in metastatic hormone sensitive prostate cancer. I leveraged my track-record and networks emanating from successful completion of the CHAARTED trial and commenced discussions in 2013 with the medical leadership of Astellas for the conduct of an investigator-sponsored trial. After informal discussions, it was decided to conduct an investigator-initiated trial with the support of a co-operative group based in Australia. Ultimately, with the support of ANZUP and University of Sydney’s NHMRC Clinical Trials Centre, the ENZAMET trial was designed and conducted. Professor Ian Davis from Monash University and ANZUP Chair was study co-chair with me and Professor Andrew Martin from University of Sydney’s NHMRC Clinical Trials Center was the study biostatistician. In addition, I was able to use my international network to engage Cancer Trials Ireland, Canadian Cancer Trials Group and Dana-Farber Cancer Institute in USA to support the trial. The study was activated in 2014 and on account of a pronounced treatment effect an overall survival benefit was seen at the first interim analysis, *the ENZAMET trial* was selected as part of the main plenary session in 2019 (again one of the top 4 abstracts out of more than 2,000 accepted abstracts) at the American Society of Oncology meeting in 2014. In brief, the results showed patients with metastatic hormone sensitive prostate cancer treated also have a major prolongation in the overall survival when enzalutamide is added to testosterone suppression. The results were concurrently published in the *New England Journal of Medicine* with the study co-chair, Professor Davis as first author and I was senior author.

- Davis ID, Martin AJ, Stockler MR, Begbie S, Chi KN, Chowdhury S, Coskinas X, Frydenberg M, Hague WE, Horvath LG, Joshua AM, Lawrence NJ, Marx G, McCaffrey J, McDermott R, McJannett M, North SA, Parnis F, Parulekar W, Pook DW, Reaume MN, Sandhu SK, Tan A, Tan TH, Thomson A, Tu E, Vera-Badillo F, Williams SG, Yip S, Zhang AY, Zielinski RR, **Sweeney CJ;** ENZAMET Trial Investigators and the Australian and New Zealand Urogenital and Prostate Cancer Trials Group. *N Engl J Med*. 2019 Jul 381:121-131 (see accompanying reprint).

On account of reporting at the interim analysis, more follow-up was required to get more granular survival data for all the subgroups. With foresight, one of the patient stratifications of ENZAMET also included high and low volume disease aligned with the CHAARTED trial and the case report forms captured whether patients presented with metastatic disease at first diagnosis of prostate cancer (synchronous) or relapsed after initially being found to have disease apparently localized to the prostate cancer (metachronous). Moreover, given the CHAARTED findings of docetaxel prolonging the overall survival of some men with metastatic hormone sensitive prostate cancer when added to testosterone suppression and the fact ENZAMET was an investigator sponsored trial, we were able to incorporate a stratification by planned docetaxel use. Consequently, ENZAMET is the only study to report the outcomes of adding enzalutamide for patients with synchronous high and low volume disease and metachronous high and low volume disease as well as report their outcomes with and without docetaxel. In short, ENZAMET confirmed the benefit of adding enzalutamide to docetaxel in men with synchronous metastatic hormone sensitive disease as was observed in the PEACE-1 trial with adding abiraterone to docetaxel and in the ARASENS trial with adding darolutamide to docetaxel. However, no studies have been conducted randomizing patients to testosterone suppression plus potent androgen receptor inhibition with and without docetaxel. The ENZAMET design, however, allows a review of the patients accrued contemporaneously with and without docetaxel with the longest follow-up. In short, the data indicates men with more indolent disease such as metachronous low volume do not appear to benefit from adding docetaxel to testosterone suppression plus enzalutamide. In contrast, patients with the poorest prognosis, especially synchronous high-volume disease, appear to benefit from adding docetaxel to testosterone suppression plus enzalutamide.

- **Sweeney CJ**, Martin AJ, Stockler MR, Begbie S, Cheung L, Chi KN, Chowdhury S, Frydenberg M, Horvath LG, Joshua AM, Lawrence NJ, Marx G, McCaffrey J, McDermott R, McJannett M, North SA, Parnis F, Parulekar W, Pook DW, Reaume MN, Sandhu SK, Tan A, Tan TH, Thomson A, Vera-Badillo F, Williams SG, Winter D, Yip S, Zhang AY, Zielinski RR, Davis ID; ENZAMET trial investigators and Australian and New Zealand Urogenital and Prostate Cancer Trials Group. Testosterone suppression plus enzalutamide versus testosterone suppression plus standard antiandrogen therapy for metastatic hormone-sensitive prostate cancer (ENZAMET): an international, open-label, randomised, phase 3 trial. *Lancet Oncol*. 2023 Apr; 24(4):323-334. PMID: 36990608

Two other global phase 3 prostate cancer trials also instigated by me are aimed at improving the outcomes of men with high-risk localized or locally advanced prostate cancer where the standard of care is 2-years of testosterone suppression plus radiation.

- Enzalutamide and Androgen Deprivation Therapy With Radiation Therapy for High Risk, Clinically Localised, Prostate Cancer (ENZARAD); NCT02446444 ENZARAD (800 patients accrued). Study Co-Chairs: Radiation Oncology Scott Williams, Peter MacCallum Cancer Centre and Paul Nguyen, Dana-Farber Cancer Institute; Medical Oncology: **Christopher Sweeney,** University of Adelaide and Ian Davis, Monash University.
- Darolutamide Augments Standard Therapy for Localised Very High-Risk Cancer of the Prostate (DASL-HiCaP); NCT04136353 (more than 1,000 of 1,100 accrued by May 2023). Study Co-Chairs **Christopher Sweeney**; Tamim Niazi, McGill University, Montreal Quebec.

Both trials emanated from the same collaborative global framework that underpinned the success of the ENZAMET trial and are also being conducted with the support of ANZUP and University of Sydney's NHMRC Clinical Trials Centre. The ENZARAD trial is funded and run in collaboration with Astellas and will define whether adding enzalutamide to testosterone suppression plus primary prostate radiation decreases the rate of relapse and death of men with higher and very high-risk prostate localized and locally advanced prostate cancer. Cancer Trials Ireland, Canadian Cancer Trials Group and Dana-Farber Cancer Institute have been key co-operative group partners in this study. The DASL-HiCaP trial is funded and run in collaboration with Bayer and will define whether adding darolutamide to testosterone suppression plus primary prostate or post-operative salvage radiation decreases the rate of relapse and death of men with high and very high-risk prostate localized and locally advanced prostate cancer. Cancer Trials Ireland, Canadian Cancer Trials Group and Prostate Cancer Clinical Trials Group in the USA are the key co-operative group partners.

Following pages are PDF reprints of manuscripts relevant to Research Theme 1

LIBRARY NOTE:

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Sweeney C, Chen Y-H, Carducci MA, Liu, G, Jarrard, D, Eisenberger, M, Wong, Y, Hahn, N, Kohli, M, Vogelzang, N, Cooney, M, Dreicer, R, Picus, J, Shevrin, D, Hussain, M, Garcia, J, DiPaola. R: *Chemohormonal Therapy in Metastatic Hormone-Sensitive Prostate Cancer*. N Engl J Med. 2015 Aug 20;373(8):737-46

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Davis ID, Martin AJ, Stockler MR, Begbie S, Chi KN, Chowdhury S, Coskinas X, Frydenberg M, Hague WE, Horvath LG, Joshua AM, Lawrence NJ, Marx G, McCaffrey J, McDermott R, McJannett M, North SA, Parnis F, Parulekar W, Pook DW, Reaume MN, Sandhu SK, Tan A,Tan TH, Thomson A, Tu E, Vera-Badillo F, Williams SG, Yip S, Zhang AY, Zielinski RR, Sweeney CJ, *Enzalutamide with Standard First-Line Therapy in Metastatic Prostate Cancer*. N Engl J Med. 2019 Jul 381:121-131

Research Theme 2: Conduct of biomarker analysis leading to improved understanding of prostate cancer clinical outcomes.

At the time of designing the CHAARTED trial in 2004, it was clear there were no biomarkers to define the prognosis and/or explain the biology associated with a shorter versus longer survival of men treated with testosterone suppression alone. With this in mind, I wrote the consent form for CHAARTED to allow collection and analysis of tumour, circulating blood proteins and sex steroids as well as germline DNA specimens and blood for RNA and protein and exome profiling and successfully applied for funding to collect and store the samples. This has culminated in development of a clinically annotated biorepository to perform numerous correlative studies. With funding from an NCI R01 grant (R01CA208254, CI-A Sweeney) my team has completed the assays of circulating proteins of inflammation, metabolism and bone turnover from 550 men and reporting the correlations with clinical outcomes (see research publication #208; other papers in preparation May 2023). With funding from another NCI R01 grant, (R01CA238020, CI-A Sweeney) the team has also defined the prostate cancer gene expression and exome profiles in the patients' primary tumours. In short, this clinically annotated biorepository is creating new knowledge that is starting to identify factors associated with a poor response to ADT and benefit from early docetaxel. Prior to these new findings being translated into routine clinical care we will be required to demonstrate reproducibility in an independent trial. To that end, the ENZAMET team has collected and stored samples in a manner aligned with the CHAARTED trial as well harmonized the clinical data across both trials to determine which findings from CHAARTED can be reproduced in ENZAMET. The ENZAMET samples are being sent for analysis in 2023. The following two projects are examples related to this theme.

After getting approval for use of the primary prostate cancer specimens from the CHAARTED trial and a collaboration with Decipher (now Veracyte) to perform whole transcriptome RNA profiling and an NCI R01 grant to fund the analysis, Dr. Hamid, under my mentorship as an Australian research fellow working at DFCI, lead the authorship of this paper. In essence, multiple locked gene classifiers were assessed. Notably patients with the luminal B gene expression profile, initially defined for breast cancer using the PAM50 classifier, treated with testosterone suppression alone had a poor overall survival and had the most benefit with addition of docetaxel. In contrast patients with the basal gene expression profile had a much better survival with testosterone suppression alone compared with their luminal B counterparts and had no benefit with addition of docetaxel. Also, patients with low volume disease which derived less benefit from docetaxel and had a major benefit from adding enzalutamide to testosterone suppression have a gene signature indicating higher androgen receptor activity. These particular findings will be specifically looked at in the ENZAMET and STAMPEDE trials to see if the benefit with docetaxel (with or without enzalutamide) is associated with the luminal B profile and if men with a high AR-A score can be spared treatment with docetaxel.

- Hamid AA, Huang HC, Wang V, Chen YH, Feng F, Den R, Attard G, Van Allen EM, Tran PT, Spratt DE, Dittamore R, Davicioni E, Liu G, DiPaola R, Carducci MA, **Sweeney CJ.** Transcriptional profiling of primary prostate tumor in metastatic hormone-sensitive prostate cancer and association with clinical outcomes: correlative analysis of the E3805 CHAARTED trial. Ann Oncol 2021 Sep;32(9):1157-1166 (see accompanying reprint).

At DFCI, Dr. Hamid also curated the clinical and genomic data of men with prostate cancer treated at Dana-Farber Cancer Institute who had had tumours subjected to exome profiling. Based on preclinical data documenting the more aggressive *in vitro* and *in vivo* features of prostate cancers with loss of function 2 or 3 tumour suppressors, we proposed patients with tumours with two or three mutations associated with loss of function in TP53, PTEN, and RB1 would have worse clinical outcomes. This paper documented for the first time the dose effect of poorer outcomes for men with localized, metastatic hormone sensitive prostate cancer or metastatic castration resistant prostate cancer who have loss of function mutations in zero vs 1 versus 2 of these tumour suppressors. These finding supported the application to the NCI to use specimens from the CHAARTED trial as well as the NCI R01CA238020. The whole exome sequencing data from the CHAARTED study has been completed and the analyses are ongoing in May 2023. Funding is in place to assess for reproducibility of findings and samples are collected and being prepared for exome analyses in late 2023 from patients' tumour from the ENZAMET trial.

- Hamid AA, Gray KP, Shaw G, MacConaill LE, Evan C, Bernard B, Loda M, Corcoran NM, Van Allen EM, Choudhury AD, **Sweeney CJ.** Compound Genomic Alterations of TP53, PTEN, and RB1 Tumor Suppressors in Localized and Metastatic Prostate Cancer. Eur Urol. 2019 Jul;76(1):89-97

Following pages are PDF reprints of manuscripts relevant to Research Theme 2

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

ORIGINAL ARTICLE

Transcriptional profiling of primary prostate tumor in metastatic hormone-sensitive prostate cancer and association with clinical outcomes: correlative analysis of the E3805 CHAARTED trial☆

A. A. Hamid[1,2], H.-C. Huang[3], V. Wang[4], Y.-H. Chen[4], F. Feng[5], R. Den[6], G. Attard[7], E. M. Van Allen[1], P. T. Tran[8], D. E. Spratt[9], R. Dittamore[3], E. Davicioni[3], G. Liu[10], R. DiPaola[11], M. A. Carducci[8] & C. J. Sweeney[1*]

[1]Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, USA; [2]University of Melbourne, Melbourne, Australia; [3]Decipher Biosciences, San Diego; [4]Department of Data Science, Dana-Farber Cancer Institute, Boston; [5]Helen Diller Family Comprehensive Cancer Center, University of California San Francisco, San Francisco; [6]Department of Radiation Oncology, Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, USA; [7]University College London Cancer Institute, London, UK; [8]Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore; [9]Department of Radiation Oncology, University of Michigan, Ann Arbor; [10]University of Wisconsin Carbone Cancer Center, Madison; [11]University of Kentucky Medical Center, Lexington, USA

Available online 12 June 2021

Background: The phase III CHAARTED trial established upfront androgen-deprivation therapy (ADT) plus docetaxel (D) as a standard for metastatic hormone-sensitive prostate cancer (mHSPC) based on meaningful improvement in overall survival (OS). Biological prognostic markers of outcomes and predictors of chemotherapy benefit are undefined.

Patients and methods: Whole transcriptomic profiling was performed on primary PC tissue obtained from patients enrolled in CHAARTED prior to systemic therapy. We adopted an *a priori* analytical plan to test defined RNA signatures and their associations with HSPC clinical phenotypes and outcomes. Multivariable analyses (MVAs) were adjusted for age, Eastern Cooperative Oncology Group status, *de novo* metastasis presentation, volume of disease, and treatment arm. The primary endpoint was OS; the secondary endpoint was time to castration-resistant PC.

Results: The analytic cohort of 160 patients demonstrated marked differences in transcriptional profile compared with localized PC, with a predominance of luminal B (50%) and basal (48%) subtypes, lower androgen receptor activity (AR-A), and high Decipher risk disease. Luminal B subtype was associated with poorer prognosis on ADT alone but benefited significantly from ADT + D [OS: hazard ratio (HR) 0.45; $P = 0.007$], in contrast to basal subtype which showed no OS benefit (HR 0.85; $P = 0.58$), even in those with high-volume disease. Higher Decipher risk and lower AR-A were significantly associated with poorer OS in MVA. In addition, higher Decipher risk showed greater improvements in OS with ADT + D (HR 0.41; $P = 0.015$).

Conclusion: This study demonstrates the utility of transcriptomic subtyping to guide prognostication in mHSPC and potential selection of patients for chemohormonal therapy, and provides proof of concept for the possibility of biomarker-guided selection of established combination therapies in mHSPC.

Key words: metastatic prostate cancer, docetaxel, Decipher, gene expression profiling, biomarker

INTRODUCTION

Most men with metastatic hormone-sensitive prostate cancer (mHSPC) respond to testosterone suppression, commonly referred to as androgen-deprivation therapy (ADT), achieved by medical or surgical castration; however, the durability of response and time to castration resistance are variable. The treatment paradigm of mHSPC has changed rapidly in the last 7 years, with improvements in overall survival (OS) demonstrated first by concurrent use of cytotoxic chemotherapy [docetaxel (D)][1-3] and agents targeting the androgen receptor (AR) axis by inhibition of extragonadal androgen synthesis (abiraterone acetate)[4,5] or direct AR antagonism (enzalutamide; apalutamide),[6,7] with a backbone of ADT. The phase III randomized CHAARTED study was the first trial to demonstrate a marked improvement in time to castration-resistant PC (ttCRPC) and OS with ADT + D versus ADT alone.[1] Subgroup analyses have suggested that the OS benefit from chemohormonal therapy is consistently evident in patients who present with high-volume metastatic disease.[2,8]

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E-mail: Christopher_Sweeney@dfci.harvard.edu (C.J. Sweeney).

☆Note: This study was presented in part at the Oral Abstract Session, *American Society of Clinical Oncology Genitourinary Cancer Symposium*, San Francisco, February 2020.

Currently, there are no validated molecular biomarkers to personalize treatment in mHSPC to guide which men should receive ADT + D or AR-targeted therapy, resulting in a critical unmet need. Biomarker-informed prediction of chemohormonal therapy benefit may offer greater precision than clinical factors such as disease volume. Metastatic PC is associated with increased, but nonetheless modest, DNA mutational burden and the majority of primary tumors do not harbor genomic alterations associated with selective sensitivity to available treatments.[9,10] By contrast, discrete transcriptomic subgroups of PC have been identified as prognostic for a greater risk of metastatic relapse from localized HSPC, namely, intrinsic luminal—basal subtype using the PAM50 classifier (luminal A, luminal B and basal subgroups), the Decipher genomic classifier (GC), and AR activity (AR-A; classified as average versus lower).[11-13] In localized HSPC, luminal B subtype is associated with higher AR-A score and poorer prognosis. Patients with lower AR-A tumors may have an attenuated response to ADT alone in the adjuvant setting. Prior work by our group using gene expression-based models of drug sensitivity (derived from analyses of diverse cancer cell lines) showed that luminal and high AR activity (AR-A) subtypes are predicted to have greater sensitivity to taxane chemotherapy, compared with basal and low AR-A subtypes.[13]

These classifiers represent unique biological profiles of HSPC. Their clinical utility in the context of (chemo)hormonal therapy for metastatic disease remains unknown. We, therefore, leveraged primary PC samples from patients enrolled in the CHAARTED trial and sought to define the transcriptional landscape of mHSPC and the impact of these signatures on outcomes with ADT alone as a prognostic biomarker, and with the addition of docetaxel as a potential predictive biomarker.

METHODS

Trial and correlative study design

The primary objective of the CHAARTED trial was to determine whether docetaxel would improve OS in men with mHSPC commencing ADT. The clinical trial was designed by the Eastern Cooperative Oncology Group-ACRIN Cancer Research Group (ECOG-ACRIN). Sanofi provided docetaxel for study conduct and grant support for pilot correlative studies but had no role in protocol design, data analysis, or preparation of the current manuscript. Decipher Biosciences completed gene expression profiling as in-kind support and aided in data interpretation. This correlative substudy followed a National Clinical Trials Network (NCTN)-approved ancillary project analysis plan, with exploratory components as noted. Patients consented to use of their samples and Institutional Review Board (Dana-Farber Cancer Institute) approval was obtained.

Patients, RNA processing, and microarray profiling

The ECOG-ACRIN biobank retrieved available formalin-fixed, paraffin-embedded (FFPE) biopsy and radical prostatectomy samples from patients enrolled in the CHAARTED trial. Deidentified specimens were sent to Decipher Biosciences (San Diego, CA) for central pathology review. The highest grade tumor focus was identified and underwent RNA extraction after macrodissection by a genitourinary pathologist. At least 0.5 mm^2 of tumor with at least $\geq$60% tumor cellularity was required for the assay. RNA was extracted using the RNeasy FFPE kit (Qiagen, Germantown, MD), converted into cDNA and amplified using the Ovation FFPE kit (TECAN Genomics, Redwood City, CA) and hybridized to the Human Exon 1.0 ST oligonucleotide microarray (Thermo Fisher, Carlsbad, CA), as previously described,[14] in a Clinical Laboratory Improvement Amendments-certified laboratory facility (Decipher Biosciences, San Diego, CA). Quality control was performed using Affymetrix Power Tools, and normalization was performed using the single-channel array normalization (SCAN) algorithm. A total of 198 of 790 patients (25%) had banked FFPE tumor blocks available for profiling. Among the 190 samples with sufficient tumor available for RNA profiling, 160 samples (84%) passed quality control for downstream analysis.

Correlative study design

The NCTN prespecified analysis plan included Decipher GC score and AR-A. With the emergence of data regarding luminal—basal subtyping as a prognostic biomarker in localized PC[12] and as a potential predictive marker of taxane benefit from *in silico* modeling,[15] we expanded our *a priori* analysis plan to include this classifier as a third putative biomarker.

Transcriptomic signatures

PAM50 subtyping consists of three PC-relevant subtypes (luminal A, luminal B, and basal-like). Previously developed cut points were used to call subtypes, based on the 50-gene messenger RNA signature developed in breast cancer,[16] with the exclusion of the Her2-enriched subtype. True Decipher scores (continuous scale of 0-1) were generated based on 22 transcripts as previously described.[14] Categorical GC results are presented by quartile based on the analytic cohort of 160 samples; given that the middle two quartiles have comparable prognoses, the two quartiles are grouped to form three groups: [0, 0.568], (0.568, 0.835], (0.835, 1]. The commercial cut points of the GC were not used as they were optimized in localized PC. The AR-A score comprises nine canonical AR transcriptional target genes (*KLK3, KLK2, FKBP5, STEAP1, STEAP2, PPAP2A, RAB3B, ACSL3,* and *NKX3-1*). The AR-A model was used with the previously locked cut point (score of 11) to define lower versus average AR-A.[13]

Endpoints

The primary endpoint of CHAARTED and this ancillary study was OS, defined as the time from randomization to death from any cause. Secondary endpoints included ttCRPC, defined as the time from randomization to prostate-specific antigen (PSA) and/or clinical progression (excluding death

as an endpoint), with a testosterone level of <50 ng/dL or documentation of gonadal suppression at progression. As the primary analyses, biomarkers were assessed for the ability to independently associate with ttCRPC and OS in the full analytic cohort. Subsequently, the biomarkers were assessed within the ADT arm and the ADT + D arm, to determine whether a differential treatment effect with the addition of docetaxel existed by transcriptomic subgroup.

Statistical analysis

OS and ttCRPC were estimated by the Kaplan–Meier method and the log-rank test was used for comparison, in keeping with the original trial analysis plan. The prognostic ability of biomarker subgroups on OS and ttCRPC was assessed across the analytic cohort using Cox univariable (UVA) and multivariable analyses (MVA) with Firth's penalized method.[17] Covariables in the MVA models were age, ECOG performance status (PS), prior local therapy, volume of disease (as defined by the CHAARTED trial[1]), and treatment arm. In the trial cohort, all patients who did not receive prior local therapy presented with *de novo* metastatic disease, and all patients who received prior local therapy presented with recurrent (metachronous) metastatic disease. Multiple testing adjusted (MT-adj) results using Bonferroni correction for three signatures were performed within each endpoint for the primary analyses. This ancillary study was not powered to detect a treatment–biomarker interaction and was designed as a training set for related mHSPC trials.[3,6] We estimated <30% power to identify a treatment–biomarker interaction on OS with the current sample size when postulating a hazard ratio (HR) of no smaller than 0.6 with a two-sided alpha of 0.05, and thus interaction tests were not performed. Treatment effect in each biomarker subset was illustrated by Cox biomarker-subset UVAs, with HRs and 95% confidence intervals (CIs). Statistical analyses were performed using R, version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria). All statistical tests were two-sided and a P value <0.05 was deemed statistically significant.

RESULTS

Biopsy and cohort characteristics

The treatment arms of the final analytic cohort (76 in the ADT arm, 84 in the ADT + D arm; Supplementary Figure S1, available at https://doi.org/10.1016/j.annonc.2021.06.003) were balanced with respect to clinical prognostic variables such as age, ECOG PS, volume of disease, and receipt of prior local therapy (Supplementary Table S1, available at https://doi.org/10.1016/j.annonc.2021.06.003). The median follow-up was 4 years. A significant OS improvement favoring ADT + D was observed in the analytic cohort [median OS 53.9 versus 32.4 months; HR 0.58, 95% CI 0.38-0.87; $P = 0.009$]. Compared with the trial cohort, there was a higher proportion of patients with poor prognostic features including *de novo* metastatic (88% versus 73%) and high-volume (78% versus 65%) disease (Supplementary Table S2, available at https://doi.org/10.1016/j.annonc.2021.06.003).

Landscape of transcriptomic subtypes in primary prostate cancer specimens of patients with mHSPC

The relative frequencies of transcriptomic subtypes were discovered to differ from the frequencies reported in non-mHSPC, consistent with enrichment in mHSPC of transcriptional profiles associated with a higher risk of metastatic progression. The distribution of luminal–basal subtypes in mHSPC were as follows: basal 50%, luminal B 48%, and luminal A 2%, compared with 34%, 33% and 33%, respectively, in localized PC,[12] and 65%, 30% and 5%, respectively, in nonmetastatic CRPC (nmCRPC).[18] The median GC score was 0.72, and 71% was Decipher high risk compared with 0.37 and 16.5%, respectively, in localized PC.[11] About 42% of patients with mHSPC had lower AR-A compared with 58% in nmCRPC,[18] but only 10% in localized PC.[13] All three transcriptomic biomarkers were well-balanced by treatment arm (Supplementary Table S3, available at https://doi.org/10.1016/j.annonc.2021.06.003). Samples with higher Decipher scores tended to have higher luminal B scores, although these interbiomarker correlations were relatively weak, indicating no substantial overlap between subtypes. Furthermore, strong correlation between biomarker scores and volume of disease was not observed, with the exception of AR-A where high-volume disease was significantly associated with lower AR-A scores (median AR-A in low versus high volume: 12 versus 11; $P = 0.042$; Figure 1); 48.6% and 18.4% of low- and high-volume subgroups had AR-A scores in the highest quartile, respectively. AR-A did not correlate strongly with luminal B nor Decipher scores.

Clinical outcomes of patients by luminal–basal (PAM50) subtype

Only three patients (2%) were classified with luminal A disease and all were alive at their last follow-up. Greater than 50% of patients in luminal B and basal groups had died. There were no significant differences between luminal B or basal groups in the overall cohort with respect to OS or ttCRPC in UVA or MVA (OS: $P = 0.298$, MT-adj $P = 0.894$; ttCRPC: $P = 0.399$, MT-adj $P > 0.99$; Table 1 and Supplementary Figure S2A, available at https://doi.org/10.1016/j.annonc.2021.06.003).

Survival in the ADT alone arm and the relative treatment effect of docetaxel differed by luminal–basal subtype. Consistent with a prior report in the localized PC setting,[12] luminal B subtype was associated with poorer OS on ADT alone versus basal subtype (median OS: 29.8 versus 47.1 months; HR 1.75, 95% CI 0.99-3.10; $P = 0.052$; Figure 2A). We then tested the OS benefit associated with the addition of docetaxel split by transcriptomic subtype. Patients with basal disease showed no evidence of a significant OS benefit from docetaxel

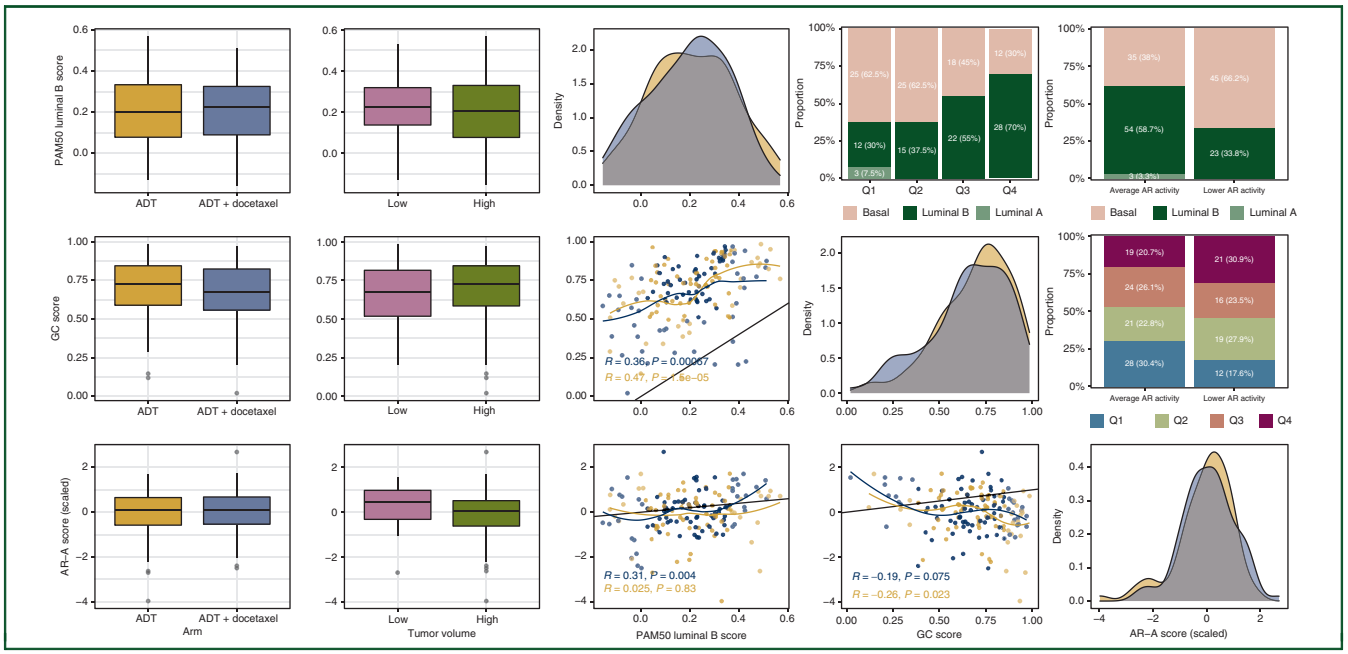

Figure 1. Pairs plot of transcriptomic signatures by treatment arm and volume of disease.
Orange denotes the androgen-deprivation therapy (ADT) arm; blue denotes the ADT plus docetaxel arm. Axes represent the range of the respective biomarker scores; box and whisker plots represent the median, interquartile range, and range of biomarkers scores within a given subgroup (left two columns). Scatterplots and density plots represent continuous interbiomarker correlations and distributions, respectively, with correlation (R) denoting Pearson's coefficient with corresponding *P* value. Bar graphs represent categorical interbiomarker distributions with subtypes defined as described in study methodology.
AR-A, androgen receptor activity; GC, Genomic classifier (Decipher); Q1, lowest quartile; Q2-3, middle quartiles; Q4, highest quartile.

(median OS: 47.1 versus 49.2 months; HR 0.85, 95% CI 0.47-1.54; $P = 0.584$; Figures 3 and 4A), even in the subgroup of patient with high-volume disease. In the luminal B subgroup, there was an improvement in OS with docetaxel (median OS: 29.8 versus 52.1 months; HR 0.45, 95% CI 0.25-0.81; $P = 0.007$), suggesting a potential treatment—biomarker interaction. No substantial differences in receipt of OS-improving therapies upon disease progression were noted when comparing luminal B and basal subtypes (Supplementary Table S4, available at https://doi.org/10.1016/j.annonc.2021.06.003). No differential treatment benefit by subtype was observed with respect to ttCRPC (Figure 4B and Supplementary Figures S3A and S4A, available at https://doi.org/10.1016/j.annonc.2021.06.003).

Clinical outcomes of patients by Decipher score (GC)

In the overall cohort, GC significantly stratified both ttCRPC and OS, with Q1, Q2-3, and Q4 cut-off subgroups showing 3-year OS rates of 77%, 60%, and 31%, respectively (Supplementary Figure S2B, available at https://doi.org/10.1016/j.annonc.2021.06.003). On MVA, continuous GC scores were independently associated with OS (HR 1.21, 95% CI 1.08-1.36 per 0.1-unit increase; $P < 0.001$, MT-adj $P = 0.002$) and ttCRPC (HR 1.17, 95% CI 1.07-1.29; $P <$

Table 1. Multivariable analysis of OS and time to CRPC.

Model	Variable	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value
		PAM50 luminal B—basal B		AR-A score		GC score	
OS	Genomic signature	1.25 (0.82-1.91)	0.298	0.91 (0.84-0.99)	0.024	1.21 (1.08-1.36)	<0.001
	ADT + docetaxel versus ADT	0.63 (0.42-0.95)	0.027	0.59 (0.39-0.89)	0.012	0.59 (0.39-0.89)	0.011
	Age	1.00 (0.98-1.02)	0.929	1.00 (0.98-1.03)	0.902	1.00 (0.98-1.02)	0.844
	ECOG 1-2 versus 0	1.77 (1.15-2.70)	0.010	1.73 (1.13-2.63)	0.013	1.65 (1.06-2.51)	0.025
	Prior local treatment versus none	1.20 (0.60-2.19)	0.580	1.37 (0.68-2.50)	0.354	1.40 (0.70-2.55)	0.319
	Tumor volume high versus low	1.82 (1.05-3.39)	0.032	1.82 (1.06-3.36)	0.030	2.01 (1.16-3.73)	0.012
ttCRPC	Genomic signature	1.18 (0.81-1.72)	0.399	0.93 (0.86-1.00)	0.049	1.17 (1.07-1.29)	<0.001
	ADT + docetaxel versus ADT	0.48 (0.33-0.69)	<0.001	0.46 (0.32-0.67)	<0.001	0.47 (0.32-0.68)	<0.001
	Age	0.98 (0.96-1.00)	0.133	0.99 (0.97-1.01)	0.173	0.98 (0.96-1.00)	0.108
	ECOG 1-2 versus 0	1.51 (1.00-2.24)	0.049	1.43 (0.95-2.12)	0.083	1.47 (0.98-2.18)	0.062
	Prior local treatment versus none	0.90 (0.47-1.60)	0.737	0.96 (0.50-1.70)	0.899	1.06 (0.55-1.88)	0.853
	Tumor volume high versus low	2.41 (1.47-4.18)	<0.001	2.44 (1.49-4.21)	<0.001	2.65 (1.61-4.60)	<0.001

Hazard ratios of luminal—basal classifier are reported for luminal B subtype versus basal subtype (as reference). HRs of GC score are reported per 0.1-unit increase. HRs of AR-A score are reported per 1-unit increase.
ADT, androgen-deprivation therapy; AR-A, androgen receptor activity; CI, confidence interval; ECOG, Eastern Cooperative Oncology Group (performance status); GC, Genomic classifier (Decipher); OS, overall survival; ttCRPC, time to castration resistant prostate cancer.

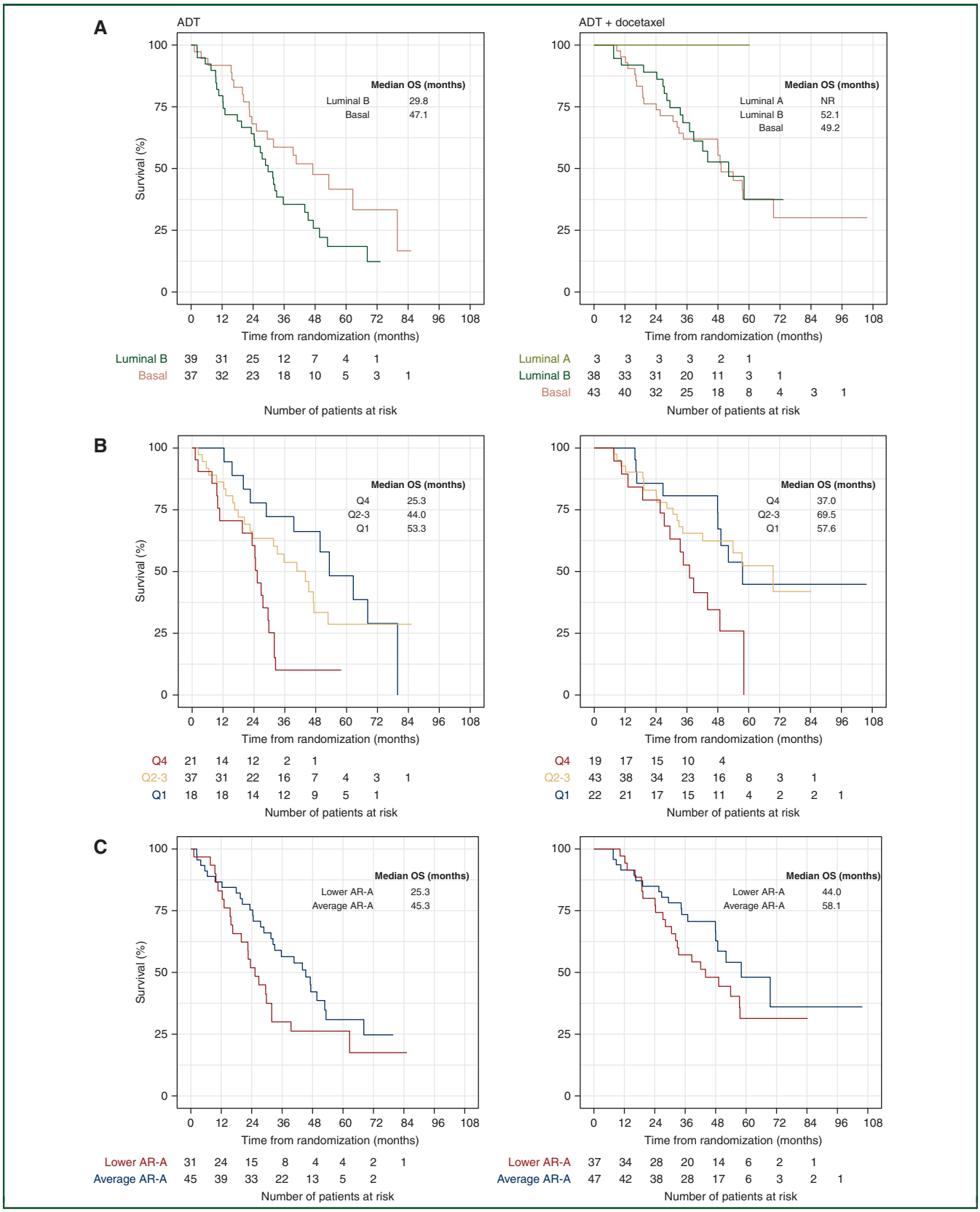

Figure 2. Kaplan-Meier estimates of overall survival (OS) in treatment arms by transcriptomic signatures.
(A) Luminal—basal subtype, (B) genomic classifier (GC; Decipher) subgroup, and (C) androgen receptor activity (AR-A) subtype.
Q1, lowest quartile; Q2-3, middle quartiles; Q4, highest quartile. ADT, androgen-deprivation therapy.

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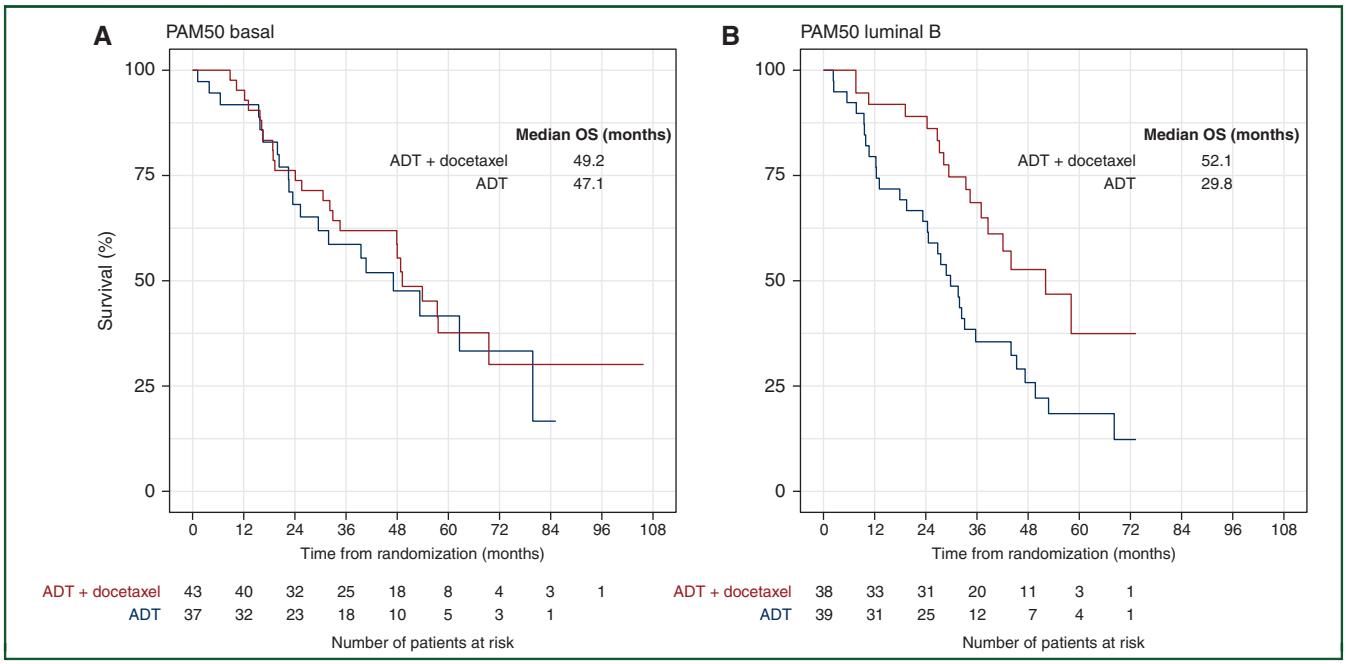

Figure 3. Kaplan-Meier estimates of overall survival (OS) by treatment arm within luminal–basal subtypes.
(A) Basal subtype and (B) luminal B subtype.
ADT, androgen-deprivation therapy.

0.001, MT-adj $P = 0.002$; Table 1). Similar results were seen when GC was analyzed categorically (not shown). The effect of docetaxel on OS was observed across all GC groups; however, the relative benefit of chemohormonal therapy varied by GC group was significant with higher GC (higher risk) disease (Q1: HR 0.72, 95% CI 0.29-1.73; Q2-3: HR 0.57, 95% CI 0.30-1.05; and Q4: HR 0.41, 95% CI 0.19-0.84; Figure 4A). This can be represented as an absolute benefit in OS for addition of docetaxel to ADT for men with tumors in GC Q1 versus GC Q4 of 9% versus 25% at 3 years, respectively (Supplementary Figure S5, available at https://doi.org/10.1016/j.annonc.2021.06.003).

Clinical outcomes of patients by AR activity (AR-A)

The transcriptional signature of AR-A was prognostic. Lower AR-A exhibited both shorter ttCRPC and OS; in the overall cohort, 3-year OS was 45% versus 65% and 1-year CRPC-free survival was 47% versus 58% in lower compared with average AR-A subtypes, respectively (Supplementary Figure S2C, available at https://doi.org/10.1016/j.annonc.2021.06.003). As a continuous variable, a 1-unit increase in AR-A score had a multivariable HR of 0.91 and 0.93 for OS and ttCRPC ($P = 0.024$ and 0.049; MT-adj $P = 0.072$ and 0.147), respectively (Table 1).

Consistent with prior studies in localized PC, lower AR-A was associated with rapid development of CRPC compared with average AR-A patients treated with ADT alone; the 6-month CRPC-free rates were 40.7% versus 73.0%, respectively [Supplementary Figures S3C and S4C (left panel), available at https://doi.org/10.1016/j.annonc.2021.06.003]. By contrast, there was no association with AR-A and differential benefit from chemohormonal therapy in decreasing the rate of castration resistance or death. A similar magnitude of survival benefit from the addition of docetaxel was seen in both lower AR-A (HR 0.56, 95% CI 0.31-0.98; $P = 0.042$) and average AR-A (HR 0.55, 95% CI 0.30-0.99; $P = 0.048$) subgroups (Figure 4A and Supplementary Figure S6, available at https://doi.org/10.1016/j.annonc.2021.06.003).

DISCUSSION

In this study, we demonstrate that comprehensive gene expression profiling of primary prostate tumors obtained prior to ADT in men with mHSPC has the potential to prognosticate outcomes on ADT alone and predict benefit from chemohormonal therapy. To our knowledge, this is the first published study of whole transcriptome profiling of mHSPC using primary PC specimens and is also the only report linked to clinical outcomes on ADT and chemohormonal therapy from a randomized clinical trial. Furthermore, we have uniquely described the landscape of key transcriptomic PC subtypes as biomarkers in mHSPC.

Much of our knowledge on the molecular landscape of PC lies at the clinical bookends of disease: on one end, localized tumors, which may be associated with later development of mHSPC, and on the other, metastatic CRPC, which is associated with lethal outcomes. Both exhibit transcriptional heterogeneity among tumors of the same disease stage.[19-21] The former, however, has proven the most active area for the development of expression-based biomarkers to stratify prognosis independent of traditional predictors such as stage, PSA, and Gleason grade. Some tools have undergone incorporation in prospective clinical

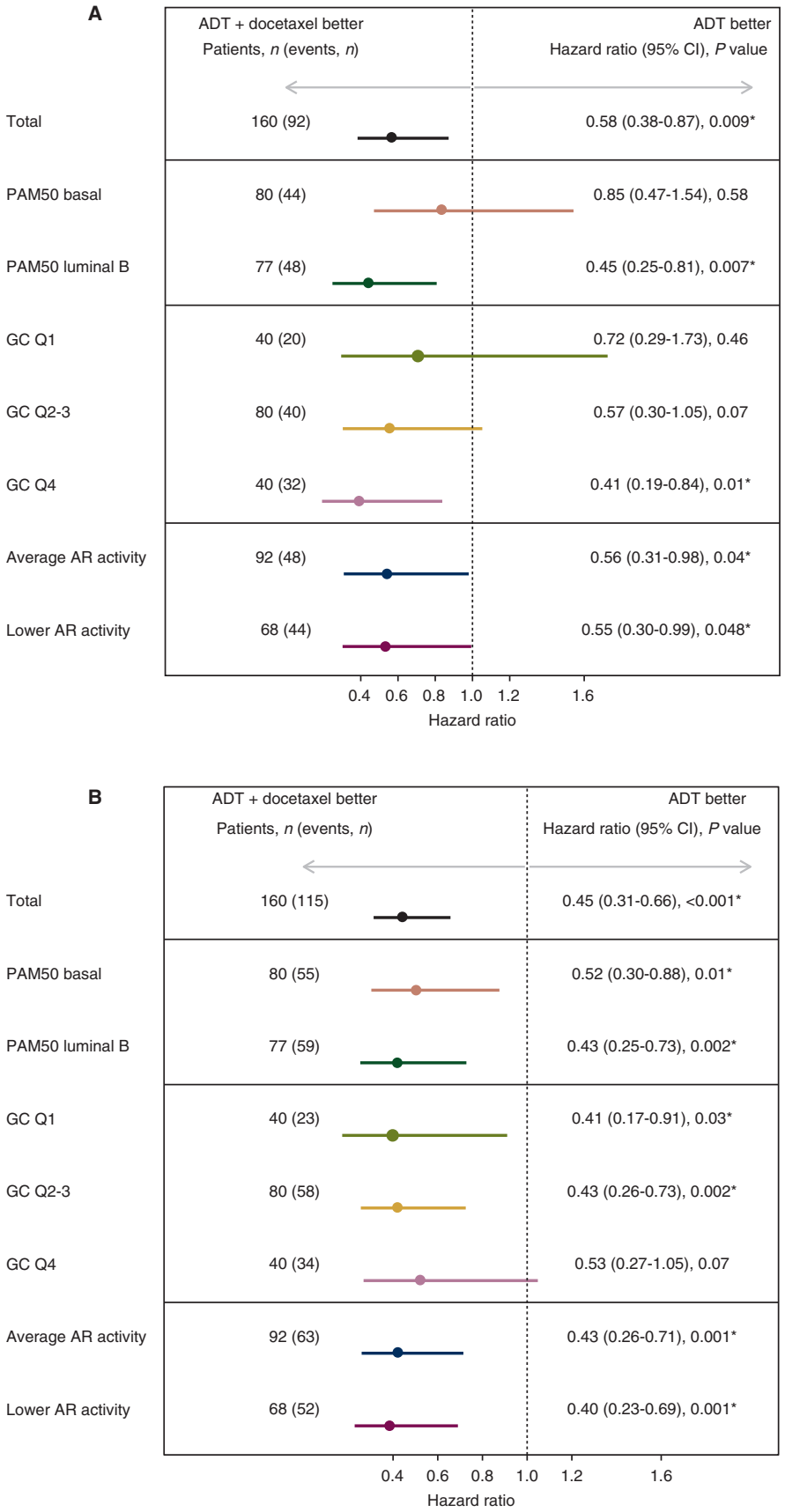

Figure 4. Forest plot of overall survival (OS) and time to castration-resistant prostate cancer (CRPC) by transcriptomic subgroups.
(A) OS; (B) time to CRPC. Univariable hazard ratios and 95% confidence intervals (95% CIs) of treatment arms are represented. *Denotes *P* value <0.05. AR-A, androgen receptor activity; GC, Genomic classifier (Decipher); Q1, lowest quartile; Q2-3, middle quartiles; Q4, highest quartile.

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trials, mirroring the development of gene expression classifiers in other tumor types, most notably breast cancer.

The clinical impact of molecular alterations in mHSPC remains largely undefined despite significant advances in therapy. Limited data of the mutational profile of mHSPC reveal recurrent aberrations in *AR*, *PTEN*, *TP53*, *RB1*, *BRCA2*, and *SPOP*, with frequencies that lie intermediately between localized PC and metastatic CRPC.[9,10,22] Our study has shed first light on the mHSPC transcriptome, with specific focus on subtyping tied to clinical outcomes. We observed a marked difference in the distribution of luminal—basal subtypes compared with localized PC,[12] with very few luminal A tumors and an increasing predominance of AR-low, basal, and GC-high subtypes akin to a previous report in CRPC.[18] Similarly, >40% of tumors had low AR-A compared with 10% in independent cohorts of localized PC.[13] These findings suggest that diverse transcriptional programs in primary tumors of mHSPC, whether related to intrinsic cell subtype or AR signaling, are closer in spectrum to primary tumors from patients with CRPC and are dominated by subtypes associated with aggressive biology and poorer prognosis. Our study cohort predominantly comprised patients with high volume and *de novo* metastatic disease, allowing a unique opportunity to correlate biological (RNA) features with aggressive, lethal PC and study treatment effects that may be pronounced in a poor-prognostic cohort. Even in the setting of profiling only a single focus of primary tumor, transcriptomic subtypes still held clear prognostic value despite known genomic heterogeneity between primary tumors and metastases.[23,24] Whether more indolent mHSPC evidenced by relapsing with low-volume disease years after a prostatectomy or radiation for apparently localized disease has similar features remains an area of active investigation, so too is the transcriptional reprogramming that may occur during evolution from a localized tumor to hormone-naïve metastasis.

We found that luminal B subtype was associated with poorer survival on ADT alone, consistent with previous reports in localized PC, but this lies in contrast to pan-cancer analyses, which generally associated basal disease with shorter OS, with the analysis being agnostic to the type of therapy.[12,25] However, luminal B subtype in another hormone-dependent cancer, early breast cancer, also portends poorer long-term outcomes similar to our findings.[26] It remains challenging to extrapolate clinical and biological features of luminal—basal subtype between cancers. However, luminal B tumors highly express proliferative markers in breast cancer[27] and PC[12] which may in part account for poorer survival on ADT alone for mHSPC. Similarly, GC score, which includes proliferation and cell cycle genes, had an association with prognosis. The association of low AR-A with poorer prognosis (independent of disease volume) parallels similar findings in localized PC and suggests AR-independent drivers. In metastatic CRPC, low AR-A subgroup is associated with early enzalutamide resistance and lineage plasticity;[28] however, our data indicate that a low AR-A subtype does not abrogate significant clinical benefit associated with early chemotherapy.

The observation that luminal B subtype (and not basal subtype) retained OS benefit from docetaxel may have two possible explanations. First, and more simplistically, poor-prognostic disease profiles may preferentially benefit from early treatment intensification with docetaxel as reflected by the greater magnitude of benefit from chemohormonal therapy seen in patients with *de novo* high-volume presentation and the GC Q4 (highest) subgroup. Second, unique biological features of luminal B versus basal mHSPC may govern response to docetaxel. Preclinical drug response models suggest that luminal B PC is associated with increased taxane sensitivity versus basal subtype; however, the reasons for this remain unclear. Nonetheless, an initial report from the randomized phase III TITAN trial in mHSPC of ADT versus ADT plus apalutamide (an AR inhibitor shown to improve OS in this setting) demonstrated a greater benefit in radiographic progression-free survival from combination therapy in basal, compared with luminal subtype.[29] Together, these findings raise the first possibility in mHSPC of precision decision making regarding docetaxel versus novel AR inhibition driven by gene expression classification, specifically luminal—basal subtype.

In comparison to OS, docetaxel was associated with improved ttCRPC across all transcriptomic subtypes including luminal B and basal. It is possible that the luminal—basal lineage may predict the effectiveness of subsequent therapies after upfront docetaxel, as we did not observe differences in receipt of life-prolonging therapies that could account for OS differences after progression to mCRPC. It may be that luminal B tumors undergo transcriptional plasticity with upfront treatment intensification, with a shift to a more sensitive phenotype for sequential mCRPC therapies. In addition, PSA-based endpoints may not be the most reliable marker for therapy resistance in the mHSPC setting, as intrinsic expression of *KLK3* which encodes PSA is lower in basal tumors[13] and 'harder' endpoints of radiographic progression-free survival and OS may represent the cumulative effect of the biological differences better than PSA alone.

Our study has some limitations. First, the study has a smaller sample size due to the availability of specimens and represents a subset of the trial cohort, although we observed a clear treatment effect in the analytic cohort which was consistent with the overall cohort. The sample size reduces the power to detect potentially significant treatment—biomarker interactions. Second, the possibility of significant heterogeneity between primary prostate and metastatic tumors is noted, yet the former represents the most frequent site of tumor biopsy at diagnosis of mHSPC and hence is clinically relevant. The use of validated classifiers such as Decipher risk remains unoptimized for clinical translation in mHSPC; however, GC score estimation has provided valuable biological insight and clearly holds prognostic value. The clinical impact of PAM50 and AR-A classifiers that we observed in CHAARTED requires validation. In short, this cohort provides a robust basis to support our approach of testing the utility of transcriptomic classifiers in independent randomized phase III trials of ADT and ADT +

D (STAMPEDE; ENZAMET) employing the Decipher Biosciences microarray platform. These efforts remain critical to meet a threshold of evidence to support translation in the clinical setting as potential prognostic and predictive tools employing an available clinical-grade assay with strong potential for generalizability. Our planned parallel effort to perform RNA profiling of specimens from trials of novel AR-targeted therapy in mHSPC and compare findings with those from chemohormonal therapy trials may well inform the selection of optimal combination treatment when analyzed collectively.

In conclusion, gene expression profiling of mHSPC in the CHAARTED trial reveals a distinct transcriptional landscape with profiles that serve as potential prognostic biomarkers for survival outcomes on ADT as well as profiles that provide predictive information regarding survival benefit from upfront chemohormonal therapy. These findings hold the promise of ushering in an era of improved prognostication and greater precision in selecting therapy for mHSPC.

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DISCLOSURE

A.A.H reports consulting fees from Merck Sharp & Dohme. H-C.H., R.D. and E.D. are employees of Decipher Biosciences. F.F. reports receiving fees for serving as a consultant from Janssen during the conduct of the study, Celgene, Blue Earth Diagnostics, Astellas, Myovant, Roivant, Genentech, and Bayer; being a co-founder having stock options in PFS Genomics; and having stock options and serving on the scientific advisory board of SerImmune Stock outside the submitted work. G.A. reports personal fees, research support and travel support from Janssen during the conduct of the study; personal fees and/or travel support from Astellas, Pfizer, Millennium Pharmaceuticals, Ipsen, Ventana, Veridex, Novartis, Abbott Laboratories, ESSA Pharmaceuticals, Bayer Healthcare Pharmaceuticals, Takeda and Sanofi-Aventis and research funding from AstraZeneca, Innocrin Pharma and Arno Therapeutics outside the submitted work; in addition, G.A.'s former employer, The Institute of Cancer Research (ICR), receives royalty income from abiraterone acetate and GA receives a share of this income through ICR's Rewards to Discoverers scheme. E.M.V.A reports advisory/consulting role: Tango Therapeutics, Genome Medical, Invitae, Enara Bio, Janssen, Manifold Bio, Monte Rosa; research support: Novartis, BMS; equity: Tango Therapeutics, Genome Medical, Syapse, Enara Bio, Manifold Bio, Microsoft, Monte Rosa; travel reimbursement: Roche/Genentech; patents: Institutional patents filed on chromatin mutations and immunotherapy response, and methods for clinical interpretation. P.T.T. reported receiving grants from RefleXion Medical, the Prostate Cancer Foundation, and Movember Foundation; personal fees from Noxopharm, Janssen-Taris Biomedical, Myovant, AstraZeneca, and RefleXion; grants from Astellas and Bayer Healthcare; and owning patent No. 9114158 (with royalties from Natsar Pharmaceuticals) outside the submitted work. D.E.S reports personal fees: Janssen, AstraZeneca, Bayer, Boston Scientific, and Blue Earth; funding: Janssen. G.L. is a co-founder and chief medical officer of AIQ Solutions (Madison, WI). M.A.A. reports past consultation for Pfizer, Astellas, and Exelixis, and current research funding from Arcus, Pfizer, and Merck. C.J.S. report consulting or advisory role: Sanofi, Janssen, Astellas Pharma, Bayer, Genentech, Pfizer, Lilly; research funding: Janssen Biotech (Inst), Astellas Pharma (Inst), Sanofi (Inst), Bayer (Inst), Sotio (Inst), Dendreon (Inst); patents, royalties, other intellectual property: Pathenolide (Indiana University): dimethylaminoparthenolide (Leuchemix); Exelixis: Abiraterone plus cabozantinib combination; stock or other ownership: Leuchemix.

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Research Theme 3: Evaluation of intermediate clinical endpoints in prostate cancer as robust surrogates of overall survival

It became abundantly clear to me during the design and conduct of the trials for patients with metastatic hormone sensitive prostate cancer and localized high risk and locally advanced prostate cancer presented in Research Theme 1, that the long time for read-outs from phase 3 trials in these settings has been a major impediment for the conduct of studies in these earlier and potentially more curable and/or treatment responsive settings. As such the evaluation of new therapies has predominantly been conducted in the more expedient castration resistant setting. To make clinical trial conduct in the earlier settings more viable, I spear-headed the Intermediate Clinical Endpoints of Cancer of the Prostate (ICECaP) initiative. This was implemented with the aid of a Prostate Cancer Foundation Challenge Award which helped create the global multi-disciplinary working group and the biostatistics coordinating centre at Dana-Farber Cancer Institute in 2015 as well as the collation of an individual patient data repository from 43 trials with data from 38,950 unique patients who have undergone therapy for clinically localized prostate cancer In the accompanying list of publications, "other peer-reviewed publication" #27 from 2015 is the citation for the "white paper" in the Journal of the National Cancer Institute documenting the rationale and process for defining intermediate clinical endpoints as surrogates for overall survival in adjuvant prostate cancer trials which. This was lead by me on behalf of the ICECaP working group. In 2020 the effort was also adopted by Movember as a key research collaborative to support (icecap.movember.com).

The first major output from this initiative was the documentation of metastasis-free survival (MFS) as a robust surrogate for overall survival in the following publication:

- Xie W, Regan MM, Buyse M, Halabi S, Kantoff PW, Sartor O, Soule H, Clarke NW, Collette L, Dignam JJ, Fizazi K, Paruleker W, Sandler HM, Sydes MR, Tombal B, Williams SG, **Sweeney C.** Metastasis Free Survival is a Strong Surrogate of Overall Survival in Localized Prostate Cancer J Clin Oncol. 2017 Sep 20;35(27):3097-3104 (see accompanying reprint).

This work was done in consultation with the FDA and has resulted in regulatory agencies such as the FDA in the USA and EMA in Europe accepting MFS as a primary endpoint to document the clinical benefit to support possible approval of a new therapy for adjuvant therapy for prostate cancer. Consequently, multiple industry sponsored and co-operative groups studies (including ENZARAD and DASL-HiCaP referenced in research theme 1) have designed studies with MFS as an endpoint to enable more expeditious read-outs of new therapies that may decrease deaths from prostate cancer. This work was awarded the 2021 Statistical Partnerships Among Academe, Industry, and Government (SPAIG) Award (joint awardee with ICECaP biostatisticians): American Statistical Association Research

The ICECaP database of 43 trials with data from 38,950 unique patients is now being mined under my leadership with collaborators from around the globe to define prognostic variables to guide prostate cancer therapy and clinical trial design. This includes "negative" publications such as:

- Xie W, Regan MM, Buyse M, Halabi S, Kantoff PW, Sartor O, Soule H, Berry D, Clarke N, Collette L, De Abreu Lourenco R, Dignam J, Eisenberger M, James N; Fizazi K, Gillessen S, Loriot Y, Mottet N, Parulekar W, Sandler H, Spratt D, Sydes MR, Tombal B, Williams S, **Sweeney CJ**, on behalf of the ICECaP Working Group; Event-Free Survival, a PSA-Based Composite Endpoint, is Not a Surrogate for Overall Survival in Men with Localized Prostate Cancer Treated with Radiation; J. Clin Oncol 2020 Sep 10;38(26):3032-3041

In brief, this paper documents that while a PSA relapse (as the main component of the Event-free survival endpoint, EFS) is prognostic and associated with a greater risk of dying of prostate cancer its correlation with overall survival at the trial was not strong enough to be able to replace MFS an earlier intermediate clinical endpoint.

In 2015, I also helped start the process and am on the steering committee for collecting and analyzing individual patient data from the metastatic hormone sensitive clinical trials as part of the STOPCaP effort [http://www.stopcapm1.org/] which is based at University of College London and Medical Research Council in the UK. In addition to performing the analyses for assessing potential clinical endpoints for surrogacy, the team is performing secondary analyses to get greater granularity on which therapies are most appropriate for given subgroups. Moreover, this collaboration is also collating all the clinico-genomic data being done as part of the many active adjuvant and metastatic hormone sensitive prostate cancer trials to define biomarkers associated with clinical outcomes in both localized and metastatic hormone sensitive prostate cancer (icecap.movember.com).

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Xie W, Regan MM, Buyse M, Halabi S, Kantoff PW, Sartor O, Soule H, Clarke NW, Collette L, Dignam JJ, Fizazi K, Paruleker W, Sandler HM, Sydes MR, Tombal B, Williams SG, Sweeney C. *Metastasis Free Survival is a Strong Surrogate of Overall Survival in Localized Prostate Cancer.* J Clin Oncol. 2017 Sep 20;35(27):3097-31041166

Research Theme 4: Leadership of randomized phase 3 industry sponsored clinical trials that have informed prostate cancer biology and prostate cancer care.

From the details provided for Research Themes 1, 2 and 3, it is clear most of my research efforts have been focused on investigator-sponsored earlier stage prostate cancer trials. However, I have also strategically devoted some of my time to being a part of the leadership team / steering committee for industry-sponsored trials in metastatic castration resistant prostate cancer. The following two publications are examples of this work.

- **Sweeney C,** Bracarda S, Sternberg CN, Chi KN, Olmos D, Sandhu S, Massard C, Matsubara N, Alekseev B, Parnis F, Atduev V, Buchschacher GL Jr, Gafanov R, Corrales L, Borre M, Stroyakovskiy D, Alves GV, Bournakis E, Puente J, Harle-Yge; ML, Gallo J, Chen G, Hanover J, Wongchenko MJ, Garcia J, de Bono JS. Ipatasertib plus abiraterone and prednisolone in metastatic castration-resistant prostate cancer (IPATential150): a multicentre, randomised, double-blind, phase 3 trial. *Lancet.* 2021 Jul 10; 398 (10295): 131-142 (see accompanying reprint).

At the time of inception of this trial, there had been many efforts to target mTOR and PI3Kinase with no notable success. These are two cancer promoting proteins which also lead to activation of AKT The IPATential phase 3 study was the first to document the clinical activity of an AKT inhibitor, ipatasertib in patients with tumors with loss of PTEN as measured by immunohistochemistry (IHC). PTEN is a tumour suppressor which controls AKT activation. The primary endpoint of this study was radiographic progression-free survival (rPFS) and revealed patients with castration resistant prostate cancer and loss of PTEN by IHC treated with the hormonal therapy abiraterone plus ipatasertib had longer rPFS than patients treated with abiraterone. I was given the honour to be a part of the steering committee based on my expertise in prostate cancer trials, biomarker analyses and preclinical work. In turn, I was involved in the design and conduct and was first author of the paper and represented the clinical trialists, statisticians, the biomarker team and the medical team at Roche. However, with longer follow-up the delay in progression was not associated with an overall survival benefit when patients were assessed for loss of PTEN by IHC (presented at ASCO 2021 annual meeting). As a member of the steering committee we had also planned an exploratory biomarker analysis to look at the outcomes of patients with next generation sequencing with one or more of AKTmutation, PIK3CA mutation and/or PTEN alteration. Patients with this exome profile were found to have a clinically meaningful improvement in rPFS and overall survival. Given the latter is from a secondary analysis it cannot support approval of the drug for routine use. However, I am commencing efforts to make use of this data for the design of metastatic hormone sensitive trials.

- Powles T, Yuen KC, Gillessen S, Kadel EE 3rd, Rathkopf D, Matsubara N, Drake CG, Fizazi K, Piulats JM, Wysocki PJ, Buchschacher GL Jr, Alekseev B, Mellado B, Karaszewska B, Doss JF, Rasuo G, Datye A, Mariathasan S, Williams P, **Sweeney CJ.** Atezolizumab with enzalutamide versus enzalutamide alone in metastatic castration-resistant prostate cancer: a randomized phase 3 trial. *Nat Med.* 2022 Jan;28(1):144-153. (see accompanying reprint).

In 2016, major benefits had been seen with immunotherapy with checkpoint inhibition in many cancers and many patients with castration resistant prostate cancer were treated with PD1 or PDL1 inhibitors despite no clear evidence of benefit. I was even quoted in the New York Times as stating that patients with prostate cancer should only be offered these therapies as part of a trial or in presence of a predictive biomarker indicative of a reasonable chance of benefit.

- https://www.nytimes.com/2018/04/26/health/doctors-cancer-immunotherapy.html

To that end, as co-Principal Investigator and member of the steering with the Roche medical team, clinical trialists, statisticians and the biomarker team we designed the Imbassador250 phase 3 trial of Atezolizumab with enzalutamide versus enzalutamide alone in metastatic castration-resistant prostate cancer to expeditiously determine if there is benefit. In 2020, I presented the results of the negative trial as an oral presentation at the Annual Meeting of the American Association for Cancer Research. In 2022, the results were published in *Nature Medicine* with me as senior author with the key biomarker work indicating some benefit in patients with high PD-L1 or CD8 expression and established immune gene signatures. However, it was noted the expected biology associated with response to immune checkpoint inhibitors is present in some patients' prostate cancer tumours but the rate is too low to lead to a benefit in unselected patients, It was concluded patients should only be treated awith PDL1 inhibitor with a well-defined biomarker. Work is still needed to properly define the biomarker associated with benefit.

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Sweeney C, Bracarda S, Sternberg CN, Chi KN, Olmos D, Sandhu S, Massard C, Matsubara N, Alekseev B, Parnis F, Atduev V, Buchschacher GL Jr, Gafanov R, Corrales L, Borre M, Stroyakovskiy D, Alves GV, Bournakis E, Puente J, Harle-Yge; ML, Gallo J, Chen G, Hanover J, Wongchenko MJ, Garcia J, de Bono JS. *Ipatasertib plus abiraterone and prednisolone in metastatic castration-resistant prostate cancer (IPATential150): a multicentre, randomised, double-blind, phase 3 trial*. Lancet. 2021 Jul 10; 398 (10295): 131-142

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Research Theme 5: Development of a nuclear factor kappa B inhibitor from bench to bedside.

In an effort to develop better cancer therapies, I have also made use of my clinical and pharmacology training as well as my leadership skills to bring a team together to develop a drug, dimethyl-aminoparthenolide (DMAPT). This drug has the unique ability to both inhibit the cancer promoting attributes of nuclear factor kappa B and generate cytotoxic oxidative stress in cancer cells. This research theme emanated from my initial interest in cyclooxygenase-2 and cancer (original research publications #5, 15) while a medical oncology trainee. This exposed me to the science of inflammation and cancer and work being done by my basic science collaborator at Indiana University, Dr. Harikrishna Nakshatri who was at the forefront of nuclear factor kappa B research in breast cancer. Given, nuclear factor kappa B was a major regulator of many inflammatory genes which promote cancer, I turned my attention to nuclear factor kappa B and prostate cancer. With the aid of a Department of Defense grant (New Investigator Award/DAMD17-02-1-1-0072) as CI-A with Dr. Nakshatri as CI-B, I initially performed the preclinical work with the aid of post-doctoral researchers in prostate cancer with parthenolide and validated nuclear factor kappa B as a target in prostate and other cancers and the ability to be inhibited by parthenolode (research publications #25, 29, 35, 44). Drs. Nakshatri and I were awarded a patent for parthenolide in cancer (6,890,946). I then designed and lead a trial which showed parthenolide was not able to be detected in the blood when taken as part of the nutraceutical "*Feverfew*" made from the plant Tanacetum Parthenium (original research publications #22).

Having also documented the poor oral bioavailability and limited in vivo activity of parthenolide, I developed a collaboration with a medicinal chemist (Dr. Peter Crooks) and molecular biologist (Dr. Craig Jordan) at the University of Kentucky who developed the orally bioavailable amino-derivative, DMAPT. With the aid of data generated by my laboratory team documenting DMAPT preclinical activity in prostate cancer and other cancers (research publications #54, 64) a second patent was filed by the University of Kentucky team and we co-founded a company, Leuchemix. I was successful in getting initial support from the NCI Rapid Access to Intervention Development (RAID) program (Awards 2004 and 2005; Sweeney CI-A) and which supplemented private investments for our team to complete the IND enabling studies and conduct a phase 1 trial of DMAPT in hematological malignancies in Europe. In 2023, work was ongoing with a new formulation at University of Adelaide to further improve the pharmaceutical properties to maximize the chance of successful cancer clinical trials.

The specific scientific discoveries made by the teams lead by me have shown DMAPT has both single agent activity in prostate, bladder and non-small cell lung cancer and the ability to substantially augment the relevant standard therapies for each disease. This body of work has also shown DMAPT can limit the toxicity of radiation to normal cells and enhance radiation efficacy (original research publications 156, 175). This work has been funded by national USA peer-reviewed grants from DOD (Idea Award/W81XWH-06-1-0225, CI-A Sweeney) and NCI (1R03CA156048-01 CI-A). An example of one recent publication is:

- Morel KL, Hamid AA, Clohessy JG, Pandell N, Ellis L, **Sweeney CJ.** NF-kappaB Blockade with Oral Administration of Dimethylaminoparthenolide (DMAPT), Delays Prostate Cancer Resistance to Androgen Receptor (AR) Inhibition and Inhibits AR Variants. Mol Cancer Res 2021 Jul;19(7):1137-1145 (see accompanying reprint).

In a quest to also define a key regulator of nuclear factor kappa B promoting lethal prostate cancer, I lead a team that utilized a systems biology approach that has identified tristetraprolin as a key regulator nuclear factor kappa (original research publications below and patent: US 2020/0041515 A1). This work was enabled by a DOD grant (Impact Award: PC101749 – CIA-A Sweeney) and a multi-disciplinary team science approach with bioinformaticians, epidemiologist, clinicians and basic scientists and is detailed in the attached publication and the BioRxiv on-line paper (manuscript under review May 2023):

- Gerke T, Beltran H, Wang X, Lee GM, Sboner A, Karnes RJ, Klein EA, Davicioni E, Yousefi K, Ross AE, Börnigen D, Huttenhower C, Mucci LA, Trock BJ, **Sweeney CJ.** Low Tristetraprolin Expression Is Associated with Lethal Prostate Cancer. Cancer Epidemiol Biomarkers Prev. 2019 Mar;28(3):584-590. (see accompanying reprint).
- Morel KL, Hamid AA , Falcón BG, Singh, JN, Burkhart DL, Kim K Kim J, Plummer JT You S, **Sweeney CJ*,** Leigh Ellis L* Loss of tristetraprolin activates NF-κB induced phenotypic plasticity and primes transition to lethal prostate cancer https://www.biorxiv.org/content/10.1101/2022.08.05.500896v1

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Research Theme 6: Clinical and translational research providing unique insights into germ cell tumor clinical outcomes and biology.

As a medical oncology trainee, I had the incredible opportunity to work with and learn from the world leaders in the field of germ cell tumour (GCT) clinical care. This in turn lead to me gaining unique subject matter expertise and a longstanding interest in the clinical care and biology of GCT. Specifically, I have lead multiple research projects which have led to novel discoveries regarding GCT clinical outcomes and biological features. The original research publications 83, 96, 144, 154 and the listed publication below are examples of projects lead by me utilizing data-bases I developed at Indiana University and later a Dana-Farber Cancer Institute to aid the conduct epidemiological and clinicopathological studies. Moreover, original research publications #210 and #211 highlight the contributions the DFCI data-base made to a global effort to refine the international prognostic classification of this relative rare and for most patients curable disease.

- **Sweeney CJ,** Hermans BP, Foster RS, Donohue JP, Einhorn LH Results and outcome of retroperitoneal lymph node dissection for clinical stage I embryonal carcinoma predominant testis cancer. J. Clin Oncology; 2000; 15: 358-62
- Lago-Hernandez CA, Feldman H, O'Donnell E, Mahal BA, Perez V, Howard S, Rosenthal M, Cheng SC, Nguyen PL, Beard C, D'Amico AV, **Sweeney CJ.** A refined risk stratification scheme for clinical stage 1 NSGCT based on evaluation of both embryonal predominance and lymphovascular invasion. Ann Oncol. 2015 Jul;26(7):1396-401
- Markt SC^, **Lago-Hernandez CA^, Miller RE, Mahal B, Bernard B, Albiges L, Frazier L, Beard C, Wright A, **Sweeney CJ.** Insurance Status and Disparities in Disease Presentation, Treatment and Outcomes in Men with Germ Cell Tumors, Cancer 2016 Oct 15;122(20):3127-35.

Moreover, all the years of developing a deep understanding of GCTs and collecting clinical data and pathological specimens laid the foundation for the scientific findings detailed in this Nature paper. This paper is yet another example of a team-science project with contributions from clinicians, bioinformaticians and basic scientists. The key new biological insight was defining the unique somatic feature that GCTs have highly recurrent chromosome arm level amplifications and reciprocal deletions (reciprocal loss of heterozygosity) variations that are significantly enriched in GCTs compared to 19 other cancer types.

- Taylor-Weiner A, Zack T, O'Donnell E, Bernard B, Guerriero J, Reddy A, Han GC, Aldubayan S, Mansour AA, Schumacher S, Litchfield K, Turnbull C, Gabriel S, Beroukhim R, Getz G, Carter SL, Hirsch M, Letai A, **Sweeney CJ*,** Van Allen EM*. Genomic origin and evolution of curable and lethal germ cell tumors. Nature. Dec 1, 2016, [*co-senior authors]. (see accompanying reprint).

This GCR collaboration with Dr. Van Allen at DFCI was ongoing in 2023 and supported by an NCI R01 grant with (R01CA222574, Van Allen CI-A, Sweeney CI-B). The ongoing project was also utilizing machine learning of the H&E slides of the tumours and epigenetic profiling of tumours the to gain insights into drivers of metastatic disease and the rare instances of resistance to chemotherapy.

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Complete Curriculum Vitae

Date Prepared: May 2023

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Education:

1993	MBBS (Bachelor of Medicine, Bachelor of Surgery)	Medicine	University of Adelaide, Adelaide, SA, Australia
2018	Masters of Arts (MA) (Honorary)	Arts	Harvard University, Cambridge, MA, USA

Postdoctoral Training

1/1993-12/1993	Internship	Medicine and Surgery	Royal Adelaide Hospital, Adelaide, South Australia (SA)
1/1994-5/1994	Physician Trainee	Internal Medicine	Royal Adelaide Hospital
7/1994-6/1997	Resident	Internal Medicine	Gundersen Lutheran Medical Center, La Crosse, WI
7/1997-12/2000	Fellow	Hematology-Oncology	Indiana University (IU) Indianapolis, IN

Faculty Academic Appointments

1/2001-6/2006	Assistant Professor	Medicine	IU
7/2007-11/2007	Associate Professor	Internal Medicine	IU
1/2008-8/2009	Professor	Faculty of Health Sciences	University of Adelaide
9/2009-11/2022	Visiting Professor (non-voting)	Faculty of Health Sciences	University of Adelaide
2/2010 – 9/2010	Lecturer in Medicine (Provisional appointment pending formal appointment)	Medicine	Harvard Medical School (HMS), Boston, MA
10/2010 -5/2018	Associate Professor	Medicine	HMS
06/2013-	Honorary Associate	National Health and Medical Research Council Clinical Trials Centre	Sydney Medical School Sydney, Australia
10/2017-	Associate Member	Broad Institute	Massachusetts of Technology (MIT) and Harvard, Cambridge, MA

5/2018-11/2022	Professor	Medicine	HMS
12/2022 -	Director	Medicine	South Australian Immunogenomics Cancer Institute, University of Adelaide

Appointments at Hospitals/Affiliated Institutions

Past

12/2000 -11/2007	Medical Oncologist	Medicine/ Hematology-Oncology	IU Hospital, VA Roudebush Medical Center, Indianapolis, IN Wishard Hospital, Indianapolis, IN
1/2008 -8/2009	Consultant Physician	Medical Oncology	Royal Adelaide Hospital Lyell McEwin Hospital, Elizabeth Vale, South Australia Adelaide, South Australia
9/2009 -3/2012	Staff Physician	Medical Oncology	Dana-Farber Cancer Institute (DFCI), Boston, MA
4/2012 -9/2017	Senior Physician	Medical Oncology	DFCI
1/2010 – 11/2022	Associate Physician	Department of Medicine, Medical Oncology Division	Brigham and Women's Hospital (BWH), Boston, MA
10/2017 – 11/2022	Institute Physician	Medical Oncology	DFCI

Other Professional Positions

2004-	Member, Scientific Advisory Board (Scientific Founder)	Leuchemix Inc. Woodside, CA	1 day per month
2004-2009	Member, Scientific Advisory Board	Semafore Pharmaceuticals, Indianapolis, IN	
2006-2011	Member, Data Safety Monitoring Board (DSMB)	French Genito-Urinary Group and the French Association of Urology (GETUG-AFU) Trial #13, Unicancer, Paris, France	1 half day every 6 months
2008-2011	Member, Scientific Advisory Board	Patrys, Melbourne, Australia	
2008 – 2015	Member, Scientific Advisory Board	Bionomics, Adelaide, Australia	
2010-2012	Member, Scientific Advisory Board	Blend Therapeutics, Waltham, MA	
2010-2016	Member, Scientific Advisory Board	BIND Therapeutics, Inc., Cambridge, MA	1 day per month

2013	External Advisor	National Institute for Health Research - Cancer Research Network (prostate cancer program), London, England, UK	Ad hoc
2015	Member, Consensus Panel	Advanced Prostate Cancer Consensus, St Gallen, Switzerland	2-day meeting
2014-	External Advisor, Advisory Board	PacNorthWest Prostate Cancer Specialized Programs of Research Excellence (SPORE)	2-day meeting once per year
2015	External Advisor	Clinical and Translational Research Program, Chris O'Brien Lifehouse (Royal Prince Alfred Hospital Cancer Center, University of Sydney), Sydney, Australia	Ad hoc
2015-	External Advisor	Irish Cancer Society, Prostate Cancer Forum	Ad hoc
2015-	External Advisor	Movember Revolutionary Translational Research Award, University of Adelaide	Ad hoc
2015-18	Member, Data Safety Monitoring Board	ARAMIS Trial, Bayer Health Care and Orion Corporation, Espoo, Finland	Half day every 6 months
2017	Member, Consensus Panel	Advanced Prostate Cancer Consensus, St Gallen, Switzerland	2-day meeting
2015, 2017, 2019, 2021, 2022	Member, Consensus Panel	Advanced Prostate Cancer Consensus, St Gallen, Switzerland	2-3-day meeting
2022-	Member, Global Cancer Advisory Committee	Movember	
2023-	Member, Scientific Advistory Board	Garvan Institute, Sydney, NSW, Australia	
2023-	Member, Research Advistory Committee	National Breast Cancer Foundation	

Major Administrative Leadership Positions

Local

2003 – 2007	Co-Leader, Experimental and Developmental Therapeutics Program	IU Simon Cancer Center
2006 – 2007	Associate Director, Clinical Research	IU Simon Cancer Center
2008 – 2009	Director, Clinical Trials	Royal Adelaide Hospital Cancer Center
2010-2014	Co-Director and principal organizer, CME course, Advances in the Treatment of Genitourinary Cancers	Dana-Farber/Brigham and Women's Cancer Center, Boston, MA

2012 – 2014	Clinical Director, Lank Center for Genitourinary (GU) Oncology	DFCI
2017-2020	Prostate Cancer Program Co-Leader	Dana-Farber/Harvard Cancer Center

National

2006-2007	Chairman	Hoosier Oncology Group (HOG), now Hoosier Cancer Research Network, Indianapolis, IN

Committee Service

Local

2001-2007	Institutional Review Board (IRB) 2001-2003 2004-2007	IU Full Member Ad hoc Member
2002-2005	Scientific Advisory Committee	IU General Clinical Research Center
2005-2007	Scientific Review Committee	IU Simon Cancer Center
2006	Search Committee: Associate Dean, Clinical Research	IU Simon Cancer Center
2011-	Chair, Gelb Center Clinical Data Committee	DFCI
2013-2014	Inpatient Hospitalist Search Committee	DFCI
2013-2014	Pharmacy and Therapeutics Committee	DFCI
2013-2015	Quality Improvement Leadership Team	DFCI
2013-2016	Scientific Review Committee	DFCI
2013-2019	Executive Committee for Clinical Programs	DFCI
2021	Translational Investigator Search (Chair)	DFCI

Regional

2003-2007	Prostate Cancer Advisory Committee	Indiana Cancer Consortium

National

1997-	Genitourinary Group 2003-2007	Eastern Co-operative Oncology Group (ECOG) Genitourinary Core Committee
2001-2007	Executive Committee	Hoosier Oncology Group
2013-2016	Co-Chair, Prostate Cancer Committee	Via Oncology, Pittsburgh, PA
2022	NBCF Professor Review Committee	National Breast Cancer Foundation Australia

International

2008-	Scientific Advisory Committee	Australian and New Zealand Urogenital Prostate Cancer Group, Sydney, Australia

2013-2019	Testis Cancer Research Advisory Committee (Global Action Plan GAP 5)	Movember, Melbourne, Australia
2022-	Movember Global Advisory Committee	Movember, Melbourne, Australia

Professional Societies

1994-2002	American College of Physicians (ACP)	
	1996-1997	Chair of Associates, Wisconsin Chapter
1997-	American Society of Clinical Oncology (ASCO)	
	2001-2003	Member, Cancer Education Committee
	2006-2007	Member, Program Committee
	2010-2013	Member, GU ASCO Program Committee
	2012	Chair, Testis Cancer Subcommittee
2013-2014	Society of Urological Oncology	Member, Program Committee
2013-	Australia New Zealand Urogenital Prostate cancer	Member

Grant Review Activities

2002, 2007, 2008	Grant Review Panel	Cancer Research UK Ad hoc Member
2004	Special Emphasis Panels, National Cooperative Drug Discovery Group for Cancer Program	National Institutes of Health (NIH) Ad hoc member
2004, 2006	Loan Repayment Grants Review Panel	NIH Ad hoc member
2004 – 2007	Internal Grants Review Committee	IU-Purdue University, Indianapolis, IN
2006	Testicular Cancer Grants Review Panel	Lance Armstrong Foundation Ad hoc member
2007	Special Emphasis Panels, RFA-CA-07-131, Early Clinical Trials of New Anti-Cancer Agents with Phase I Emphasis (U01)	NIH Ad hoc member
2008 – 2009	Grant Review Panel	National Health Medical Research Council (Australia) Ad hoc member
2008 – 2009	Internal Grants Review Committee	Royal Adelaide Hospital Permanent member
2009	Grant Review Panel	Dutch Cancer Society Ad hoc Member
2010	Grant Review Panel, Population-Based Research	US Department of Defense Ad hoc member
2011	Grant Review Panel, Post-doctorate Fellowship Award	The Prostate Cancer Charity Ad hoc member

2011	Mock Study Section, Prostate SPORE Applications	Karmanos Cancer Center Ad hoc member
2012	Scientific Review Committee, 2013 Millennium Fellowship Prostate Cancer Research	American Association for Cancer Research (AACR) Ad hoc member
2012, 2013	Grants Review Panel, Mazzone Challenge Grants	Prostate Cancer Foundation Ad hoc member
2013	Grant Review Panel, Prostate Clinical Study Group Progress Review	National Cancer Research Institute – UK Ad hoc member
2018	Grant Review Panel UH2 and UH3 "Assay Validation of High-Quality Markers for Clinical Studies in Cancer (UH2/UH3)	National Cancer Institute, Special Emphasis Panel
2020	Grant Review Panel SBIR/STTR	National Cancer Institute

Editorial Activities

Ad hoc Reviewer
Annals of Oncology
Archives of Internal Medicine
Cancer Chemotherapy and Pharmacology
Cancer Research
Clinical Cancer Research
Investigational New Drugs
Journal of Clinical Oncology
Journal of Laboratory and Clinical Medicine
Journal of Urology
Lancet Oncology
Molecular Cancer Therapeutics
New England Journal of Medicine
Obesity Research & Clinical Practice
Urology
European Urology

Other Editorial Roles

2003	Ad hoc Reviewer	Medical Knowledge Self-Assessment Program – Medical Oncology, American Board of Internal Medicine
2004	Ad hoc Reviewer	Testis cancer chapter, Principles and Practice of Oncology. 7th ed (DeVita, Hellman and Rosenberg. editors)
2005 – 2008	Associate Editor, Genitourinary Oncology	Journal of Clinical Oncology
2013	Editor	Hematology Oncology Clinics of North America; issued devoted to Prostate Cancer, vol 27, no 6 (December 2013)

Honours and Prizes

1998	Merit Award	ASCO	Research

2000	Travel Award	ASCO	Research
2003	Walther Collaborator of the Year Award	Walther Cancer Institute, Indianapolis, IN	Research
2004	Outstanding Young Investigator	IU, Department of Medicine	Research
2012	Ellen and Stephen Fine Outstanding Teaching in Cancer Medicine	DFCI	Teaching
2014	George Canellos Award for Excellence in Clinical Investigation and Patient Care	DFCI	Research
2020	Clinical Trial of the Year Award (joint awardee with Ian Davis, MBBS)	Australian Clinical Trials Alliance	Research
2020	STInG Award for Excellence in Trial Statistic	Australian Clinical Trials Alliance	Research
2020	Consumer Involvement Award	Australian Clinical Trials Alliance	Research
2021	Statistical Partnerships Among Academe, Industry, and Government (SPAIG) Award (joint awardee with ICECaP biostatisticians)	American Statistical Association	Research

Recognition

2010 - 2022	Boston's Top Docs	Boston Magazine
2015	"Hero of the Match" Award—bestowed in honor of my care of a patient who was treated for testis cancer and my participation alongside the patient as riders in the PMC (A "Hero of the Match" award is made in person before every Revolution home game to someone making a difference in his or her community.)	New England Revolution Soccer Team
2023	Christopher J. Sweeney, MBBS, Seminar in Prostate Cancer	Harvard Medical School and Dana-Farber Cancer Institute

Report of Funded and Unfunded Projects

Funding Information

Past

2001-2002 An Open Label, Multicenter, Phase II Study To Evaluate the Ability of STI571 To Produce a Sustained Biochemical Response in Patients with Hormone-Refractory Prostate Cancer
Novartis
Site PI
The major goal of this study was to demonstrate the activity of this agent (imatinib) in prostate cancer.

2001-2002 A Phase I Trial of Feverfew in Patients with Cancer
CaP Cure (now the Prostate Cancer Foundation)
PI
The major goal of this study was to assess the pharmacokinetics of parthenolide in patients with cancer when treated with Tenacetum parthenium, which had been processed to ensure standardized amounts of parthenolide.

2001-2003 A Multicenter Randomized Phase II Study of Docetaxel plus Vinorelbine and Docetaxel plus Estramustine in Combination for Hormone Refractory Prostate Cancer
Aventis/Glaxo-Smith-Kline
PI—Investigator Initiated Trial
The major goal of this randomized trial was to determine the feasibility (toxicity and efficacy) for performing a phase 3 trial combining vinorelbine with docetaxel in hormone refractory prostate cancer.

2001-2003 A Phase 2, Multicenter, Randomized, Double-Blind, Safety, Pharmacokinetic, Pharmacodynamic, and Efficacy Study of Two Doses of 2-Methoxyestradiol Administered Orally in Patients With Hormone Refractory Prostate Cancer
EntreMed
PI
The major goal of this study was to determine the activity of this agent in patients with prostate cancer.

2001-2004 A Phase I Trial of Feverfew in Patients with Cancer and A Phase I Trial of Weekly Paclitaxel and Interferon alfa-2b in Patients with Refractory Malignancies
Pharmaceutical Research and Manufacturers of America Foundation: Faculty Development Award
PI
The major goal of this grant was to provide salary support while conducting investigator initiated clinical trials with pharmacokinetic and pharmacodynamic monitoring endpoints.

2001-2004 A Phase I Dose Escalation Pharmacokinetic and Pharmacodynamic Trial of Paclitaxel with Interferon in Patients with Solid Tumor
Bristol-Myers-Squibb/Schering Corp
PI – Investigator Initiated Trial
The major goal of this study was to perform a phase 1 dose-escalation trial evaluating the adverse events, pharmacokinetics and efficacy of this novel anti-cancer therapy.

2001-2004 A Phase II Trial of Irinotecan, 5-fluorouracil, Leucovorin, Combined with Celecoxib and Glutamine as First Line Therapy for Advanced Colorectal Cancer: A Hoosier Oncology Group Study
PI - Investigator Initiated Trial
Pharmacia (merged with Pfizer in 2002)
The major goal of this project was to determine whether the addition of celecoxib and glutamine could mitigate the toxicities and enhance the efficacy of this chemotherapy regimen.

2002-2004 A Phase I Study of DX-8951f (Exatecan Mesylate for Injection) in Patients with Liver Dysfunction and A Phase I Study of DX-8951f (Exatecan Mesylate for Injection) in Patients with Renal Dysfunction
Daiichi Pharmaceuticals
Site PI
The major goal of this study was to determine the pharmacokinetics and toxicity of this topoisomerase inhibitor in patients with hepatic or renal dysfunction as part of the Food and Drug Administration (FDA) biopharmaceuticals requirements.

2002-2005 Targeting Nuclear Factor Kappa B for the Treatment of Prostate Cancer
U.S. Department of Defense (DOD): New Investigator Award/DAMD17-02-1-1-0072
PI
The major goals of this study were to conduct the preclinical evaluation of a natural product's (parthenolide's) ability to inhibit nuclear factor kappa B in prostate cancer and to determine the efficacy of this agent in vitro and in vivo prior to taking it to clinical trials.

2003-2004 Novel PET Tracers to Assess the in vivo Activity of New Agents in Prostate Cancer
NIH P20 CA86350; Indiana In vivo Cellular and Molecular Imaging Center (ICMIC) Planning Grant
Project PI
The major goal of this study was to evaluate the ability of two novel positron emission tomography (PET) tracers to assess the in vivo anti-cancer activity of parthenolide, docetaxel and 2-methoxyestradiol in prostate cancer xenografts. The tracers were [18F]Fluoromethylcholine to assess cellular proliferation and [11C] Carbon Monoxide to assess blood volume in the tumors.

2003-2004 A Phase II Open Label, Multicenter Clinical Trial to Evaluate the Efficacy and Safety of rhuMAb2C4 (pertuzumab) in Subjects with Castration-Resistant Prostate Cancer (CRPC)
Genentech
Site PI
The major goal of this study was to demonstrate whether this agent had any meaningful activity to further evaluate this drug in castrate resistant prostate cancer.

2003-2005 Phase II Study of Pemetrexed for Second-Line Treatment of Transitional Cell Cancer of the Urothelium
Eli Lilly
PI
The major goal of this study was to define the activity and toxicity of this anti-folate cytotoxic in the second line setting of transitional cell carcinoma.

2003-2005 Phase I Study of Trisenox (Arsenic Trioxide) Injection in Adult Cancer Patients with Renal Dysfunction
Cell Therapeutics
PI
The major goal of this study was to define the pharmacokinetics of arsenic and its metabolites in patients with varying degrees of renal dysfunction.

2003-2005 A Phase I Study of Intravenous TZT-1027 and Gemcitabine, Administered on Day 1 and Day 8 of a Three-Week Course in Patients with Advanced Solid Tumors
Daiichi
Site PI
The major goal of this study was to determine the toxicity and pharmacokinetics of this anti-cancer combination.

2003-2005 A Phase I, Open Label, Dose Escalation Study of Weekly Intravenous CRx-026 in Patients With Advanced Solid Tumors
CombinatoRx
Site PI
The major goal of this study was to perform a dose escalation toxicity and pharmacokinetic study of two agents with no known anticancer activity as single agents but were found to have significant anti-cancer in a combinatorial screen. This was a first in human trial.

2003-2006 A Phase I and Pharmacokinetic Trial of OSI-774 in Combination with Weekly Docetaxel in Patients with Taxane Naïve Malignancies
Aventis Pharmaceuticals - Investigator Initiated Trial
PI
The major goal of this study was to perform a phase 1 dose escalation trial of these agents in combination.

2003-2009 A Randomized, Double-blind, Placebo-Controlled Trial Evaluating the Ability of Risedronate to Prevent Skeletal Related Events in Patients with Metastatic Prostate Cancer Commencing Hormonal Therapy, Hoosier Oncology Group GU02-41
Aventis/Proctor and Gamble - Investigator Initiated Trial
PI
The major goals of this study were to assess the efficacy of an oral bisphosphonate in hormone sensitive metastatic prostate cancer and to perform biomarkers studies.

2004-2005 Bringing Parthenolide From the Laboratory to the Clinic
NIH/National Cancer Institute (NCI): Rapid Access to Intervention Development (RAID) Program
PI
This grant provided funding for the preclinical pharmacology and toxicology studies that determined parthenolide was not viable for clinical development.

2004-2006 A Single-Center, Open-Label, Dose Escalation, Safety and Pharmacokinetic Study of Panzem Nanocrystal Colloidal Dispersion Administered Orally to Patients with Advanced Cancer
EntreMed
PI
The major goal of this study was to define the pharmacokinetics and toxicity profile of this nanoparticle formulation of 2-methoxyestradiol in patients with cancer in a first in human trial.

2004-2006 Phase I Dose Escalation Study to Determine the Safety, Pharmacokinetics and Pharmacodynamics of BMS-582664 in Patients With Advanced or Metastatic Solid Tumors
Bristol-Myers Squibb
Site PI
The major goal of this study was to determine the pharmacokinetics, pharmacodynamics, toxicity and recommended phase 2 dose of this pan-VEGFR tyrosine kinase inhibitor in a first in human trial.

2004-2007 A Phase 1 Safety and Pharmacokinetic Study of SU011248 and Capecitabine in Patients with Advanced Solid Tumors
Pfizer
PI
The major goal of this study was to define the pharmacokinetics of capecitabine and sunitinib in three different schedules, and this data informed the dosing for subsequent phase 3 trials.

2005-2006 Bringing Dimethylaminoaparthenolide From the Laboratory to the Clinic
NIH/NCI: Rapid Access to Intervention Development (RAID) Program
PI (Funding to NIH contractors)

This grant provided funding for the preclinical pharmacology and toxicology studies that determined dimethylaminoparthenolide was viable for clinical development and supported the subsequent clinical trial.

2005-2007 Phase I Dose Escalation Study of BMS-690514 in Patients with Advanced or Metastatic Solid Tumors
Bristol-Myers-Squibb
Site PI
The major goal of this study was to define the pharmacokinetics and toxicity profile of a novel VEGFR2 / EGFR tyrosine kinase inhibitor in a first in human trial.

2005-2007 A Phase I open-label study of E7974 administered on days 1, 8, and 15 of a 28-day cycle in patients with solid malignancies
Eisai, Co., Ltd.
Site PI
The major goal of this study was to perform the first in human trial that defined the pharmacokinetics and toxicity of this new cytotoxic chemotherapeutic agent.

2005-2008 A Phase II Study of Pemetrexed (Alimta) as Second-Line Therapy for Hormone Refractory Prostate Cancer: Hoosier Oncology Group (GU03-67)
Eli Lilly - Investigator-Initiated Trial
PI
The major goal of this study was to assess the toxicity and efficacy of this anti-folate cytotoxic agent in the second line setting of hormone refractory prostate cancer.

2005-2008 A Mechanistic and In Vivo Evaluation of Dimethylaminoparthenolide (DMAPT), A New Agent to Treat Prostate Cancer
U.S. Department of Defense: Idea Award/W81XWH-06-1-0225
PI
The major goal of this grant was to perform the preclinical in vitro and in vivo evaluation of a water soluble and bioavailable analogue of parthenolide called dimethylamino-parthenolide.

2005-2008 Phase I, Pharmacokinetic, Pharmacodynamic Trial of PTK787 and Paclitaxel in Combination for Advanced Solid Tumors
Novartis – Investigator Initiated Trial
PI
The major goal of this trial was to perform a dose escalation trial to define the schedule and doses for this combination of anti-cancer agents.

2005-2009 A Pharmacokinetic Pharmacogenetic Trial of Drugs Used to Cure Testis Cancer
Lance Armstrong Foundation
PI
The major goal of this grant was to determine if the pharmacokinetic disposition of etoposide and the large patient inter-individual variability can be explained by differences in each patient's constitutional genetic make-up.

2005-2009 Phase II Trial of Cisplatin, Gemcitabine and Bevacizumab in Combination for Metastatic Transitional Cell Cancer
Genentech - Investigator Initiated Trial
PI
The major goal of this study was to provide the toxicity, dosing guidelines and efficacy data for the subsequent randomized phase 3 trial sponsored by the NCI.

2005 –2015 CHAARTED - Chemohormonal Therapy Versus Androgen Ablation Randomized Trial in Patients with Extensive Disease: E3805
NIH/NCI/ Cancer Therapy Evaluation Program (CTEP)
PI (Funding from NCI to Eastern Co-operative Oncology Group)
The major goal of this randomized phase 3 trial of 790 patients with metastatic hormone sensitive prostate cancer disease was to determine whether early chemotherapy prolonged overall survival.

2006-2007 Developing DMAPT as an NF-kappa-B Inhibitor for Bladder Cancer
Flight Attendant Medical Research Institute
Co-PI
The major goal of this grant was to evaluate the anti-cancer properties of DMAPT for bladder cancer.

2006-2007 APT: the Analytical Proteomics Team
NIH/NCI U24 CA126480
Co-PI until returned to Australia in late 2007
The major goal of this research project was to develop a platform for precise detection and quantification of biomarkers of relevance for breast and prostate cancer. My role was to write and oversee the clinical protocols to access the specimens for analysis.

2006-2007 Phase I Study of Anti-Platelet Derived Growth Factor Receptor Alpha (PDGFRα) Monoclonal Antibody IMC-3G3 in Patients with Advanced Solid Tumors Who No Longer Respond to Standard Therapy or For Whom No Standard Therapy is Available
ImClone
Site PI
The major goal of this study was to complete the first in human study and determine the toxicity and pharmacokinetics of an antibody directed against the PDGR alpha receptor. This trial defined the recommended phase 2 dose that led to the phase 3 trial that showed a survival benefit as a single agent in gastric cancer.

2006-2007 A Phase 1, Escalating Dose Study of CT-322, a VEGFR-2 Antagonist, as Monotherapy in Patients with Advanced Solid Tumors and Non-Hodgkin's Lymphoma
Adnexus Therapeutics
PI
The major goal of this study was to complete the first in human study to evaluate the toxicity and pharmacokinetics of a new class of therapeutic called adnectins. This trial defined the recommended phase 2 dose.

2006-2007 An Open Label Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of the AKT Inhibitor GSK690693 Given on Various Schedules in Subjects with Solid Tumors or Lymphoma
Glaxo-Smith-Kline
Site PI
The major goal of this study was to conduct the first in human study to define the pharmacokinetics and toxicity of this AKT inhibitor. Toxicity events defined the inability to take this product to phase 2 setting on the schedule studied.

2008-2009 NPI-0052 and Vorinostat in Patients with Non-Small Cell Lung Cancer, Pancreatic Cancer, Melanoma or Lymphoma
Nereus
Site PI
The major goal of this study was to assess the pharmacokinetics and toxicity of this novel anti-cancer therapy combination.

2008 - 2009 Randomized Study of Larotaxel + Cisplatin (LC) vs. Gemcitabine + Cisplatin (GC) in the First Line Treatment of Locally Advanced / Metastatic Urothelial Tract or Bladder Cancer
Sanofi-Aventis
Site PI
The major goal of this study was to compare the efficacy of a new platinum based combination against the standard in urothelial cancers. Toxicity prevented further development of the new combination.

2008 - 2010 A Phase 1b/2 Study to Assess the Safety and Efficacy of AMG 102 in Combination with Mitoxantrone and Prednisone in Subjects with Previously Treated Castrate Resistant Prostate Cancer
Amgen
Site PI
The major goal of this study was to assess the toxicity and activity of this regimen in second line setting for castrate resistant prostate cancer.

2008 - 2010 Randomized Study of Larotaxel + Cisplatin (LC) vs. Gemcitabine + Cisplatin (GC) in the First Line Treatment of Locally Advanced / Metastatic Urothelial Tract or Bladder Cancer
Sanofi-Aventis
Site PI
The major goal of this study was to compare the efficacy of a new platinum based combination against the standard in urothelial cancers. Toxicity prevented further development.

2009 - 2010 A Multicenter, Open-label Phase 1b/2 Study to Assess the Safety and Clinical Activity of Intravenous Combretastatin A1 Diphosphate (OXi4503) as Monotherapy in Subjects with Primary or Secondary Hepatic Tumor Burden
Oxigene
Site PI
The main goal of this study was to define the tolerability and activity of this agent in patients with hepatic involvement with cancer and with premedication with amlodipine to mitigate therapy induced hypertension.

2009 - 2010 A Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of Aflibercept Versus Placebo Administered Every 3 Weeks in Patients Treated with Docetaxel /Prednisone for Metastatic Androgen-Independent Prostate Cancer
Sanofi-Aventis
Site PI
The major goal of this study to compare the efficacy of chemotherapy with and without an antiangiogenic agent in castrate resistant prostate cancer.

2009 - 2010 A Phase I, Open-Label, Multiple-Dose, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of the BRAF Inhibitor GSK2118436 in Subjects with Solid Tumors
Glaxo-Smith-Kline
Site PI
The major goal of this first in human study was to define the tolerability, pharmacokinetics and activity of this novel anti cancer agent in patients.

2009 - 2015 Nanotechnology for Prostate Cancer Treatment
Prostate Cancer Foundation
Brigham and Women's Hospital/Harvard Cancer Center
Co-Investigator
PI: Omid Farokhzad
The major goal of this grant was to complete the preclinical work to support the clinical development of the nanotechnology application in prostate cancer.
Role: provided guidance on clinical applications of the technology developed by the grant.

2010 - 2012 A Phase I, Open-Label, Two-Stage Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of the Oral AKT Inhibitor GSK2141795 in Subjects with Solid Tumors or Lymphomas
GlaxoSmithKline
Site PI
The main goal of this study was to define the tolerability, pharmacokinetics and activity of this novel anti cancer agent in patients.

2010 - 2015 A Phase I/IIa Study of Safety and Efficacy of Alpharadin® with Docetaxel in Patients with Bone Metastases from Castration-Resistant Prostate Cancer
Algeta
Site PI
This main goal of this study was to define the tolerability, pharmacokinetics and activity of this novel anti cancer regimen in patients.

2011 - 2013 Evaluating a Parthenolide Analogue as a New Bladder and Kidney Cancer Therapy
NCI /1R03CA156048-01
PI
This major goal of this study was to assess the ability of a multi-functional agent, dimethylaminoparthenolide, to enhance standard anti-cancer therapies in the in vivo models.

2011 - 2015 A Systems Biology Approach to Link Nuclear Factor Kappa B Activation with Lethal Prostate Cancer
U.S. Department of Defense Impact Award/
PC101749
PI ($750,000)
The main goal of this grant is to develop a biomarker of indolent versus lethal prostate cancer.

2012 - 2013 Dana-Farber Harvard Cancer Center Specialized Programs of Research Excellence (SPORE) in Prostate Cancer, Project 6
NIH 5P50 CA090381-10
Project 6, Co-PI
(PI: Philip Kantoff)
The major goals of this project were to credential the importance of EZH2 as a therapeutic target for prostate cancer as well as understand the genes and pathways controlled by it, which drive prostate cancer. We also aimed to determine whether NF-Kappa B activation, and/or loss of DAB2IP, predict outcome in a large cohort of individuals with prostate cancer with the ultimate goal of establishing the most accurate, predictive markers of progression.

2012 – 2013 Dana-Farber Harvard Cancer Center SPORE in Prostate Cancer, Developmental Project
NIH/5P50 CA 090381-10
Developmental Project: Co-Targeting the Microenvironment and Tumor to Enhance Abiraterone Efficacy
(PI: Philip Kantoff)
The major goal of this development project was to assess the ability of an NFkappaB inhibitor (dimethylaminoparthenolide) or cabozantinib to enhance the activity of abiraterone in a CRPC soft tissue and bone model and assess its efficacy by Fludeoxyglucose (18F) (FDG)- Positron Emission Tomography (PET) and Sodium Fluoride (NaF) PET imaging. I was the lead investigator on the developmental project.

2012 - 2015 An in vivo evaluation of XL184 and abiraterone alone and in combination using soft tissue and orthotopic bone models
Exelixis
PI
The main goal of this research project was to function as a co-clinical trial and compare the anti-prostate cancer activity of XL184 (cabozantinib) combined with abiraterone to the activity of the single agents.

2014 - 2015 Defining The Epigenetic Landscape of Germ Cell Tumors (GCTs)
Dana-Farber Cancer Institute Medical Oncology Internal Grant
PI
The main goal of this grant is to define the epigenetic features of different subtypes of germ cell tumors by assessing methylation and histone mark patterns and correlate this with the transcriptional data from RNAseq analysis being performed by the Broad Institute of the Massachusetts of Technology (MIT) and Harvard with National Human Genome Research Institute (NHGRI) funding.

2014 - 2015 Defining The Genomic Landscape of Germ Cell Tumors
Dana-Farber Cancer Institute Medical Oncology Internal Grant - Wong Family
Co-PI and Mentor (PI: Elizabeth O'Donnell, MD, Medical Oncology Fellow)
The main goal of this grant was to define the gene mutations in germ cell tumors by using whole exome sequencing.

2015 Mechanistic Study of Why Chemohormonal Therapy Was Successful in Prostate Cancer
Louis B. Mayer Foundation
The main goal of this grant was to develop preliminary data to identify the basis of why docetaxel plus androgen receptor inhibition was more successful than androgen receptor inhibition alone.

2014 - 2016 GWAS Evaluation Assessing single-nucleotide polymorphism (SNP) Response to Androgen Deprivation Therapy
Mazzone Award
Co-Investigator
The main goal of this grant makes use of samples from the Gelb Center and the E3805 CHAARTED trial to assess for germline variants associated with good versus poor response to ADT. My role is to oversee the clinical data management and analysis of the ECOG samples and harmonize with the Gelb Center samples.

2012 - 2018 A Dose Finding Clinical Trial of Cabozantinib (XL184) Administered in Combination with Abiraterone in Post-chemotherapy Castration Resistant Prostate Cancer
Exelixis
PI ($270,000) – Investigator Initiated Trial
The main goal of this study is to conduct a phase 1 trial with expansion cohorts combining for the first time two drugs that have activity in castration resistant prostate cancer. The imaging and serum correlative studies will help elucidate the activity of the combination in the soft tissue and/or bone microenvironment.

2013-2018 A Randomized Phase II Study Evaluating OGX-427 in Patients with Metastatic Castrate-Resistant Prostate Cancer Who Have PSA Progression While Receiving Abiraterone: Ono Oncogenex
US PI and Site PI (~$100,000)
The main goal of this study is to assess the ability of heat-shock protein inhibition to restore sensitivity to abiraterone.

2016 - 2019 A Mechanistic Study to Explain the Survival Benefit of Chemo-Hormonal Therapy in Metastatic Castration Sensitive Prostate Cancer.
Department of Defense; US Army Prostate Cancer Research Program
PI: Total Direct Cost: $375,000
This grant proposes to investigate the role of an epigenetic factor, KDM5D, in regulating androgen receptor (AR) mediated gene transcription that drives resistance to docetaxel therapy in prostate cancer.

2016 - 2020 Analysis of Blood Borne Markers in Hormone Sensitive Metastatic Prostate Cancer
National Institutes of Health/The National Cancer Institute R01
PI: Total Direct Cost: $1,359,000
This grant proposes to assess the prognostic value of blood-borne androgens and proteins of bone turnover, inflammation and metabolism in metastatic hormone sensitive prostate cancer

2017-2020 Prospective-Retrospective Analysis of PTEN Immunohistochemistry Assay for Prediction of Outcomes in Recurrent and Metastatic Prostate Cancer (PC160783)
Johns Hopkins University
Role: Co-Investigator $22,962
To determine whether loss of PTEN in the primary is associated with poorer survival with ADT and whether this poor prognosis is overcome by adding in early docetaxel.

Current

2006–2023 Pharmacogenetic and Proteomic Analysis of Specimens from E3805; CHAARTED - Chemohormonal Therapy Versus Androgen Ablation Randomized Trial
Frontier Science
PI ($220,000)
The main goal of this grant is to provide funding to collect and store samples from the multi-center trial and to conduct preliminary pharmacogenetic and proteomic studies. These preliminary data are being used for an R01 grant submission to perform the definitive studies to evaluate biomarkers for good versus poor response to androgen deprivation therapy.

2013-2023 Intermediate Clinical Endpoints in Prostate Cancer (ICECaP)
Prostate Cancer Foundation
PI ($1,100,000)
The main goal of this grant is to perform a meta-analysis of randomized prostate cancer trials assessing localized therapies and attempt to identify a clinical endpoint that reflects overall survival. This will in turn aid the expeditious conduct of future adjuvant therapy trials.

2014-ongoing Randomized phase 3 trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer: ENZAMET
Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group (ANZUP)/Astellas Grant for Co-operative Group Study: approx. $12.5 million
Co-Study Chair/ International PI of Investigator-Initiated Trial
(Wrote the concept and application to Astellas and co-ordinated conduct of study with ANZUP and University of Sydney with participation from UK, Ireland, Canada and Dana-Farber Cancer Institute
The main goal of this study is to assess whether the combination improves overall survival. This is the first study that will include a subset of patients who get ADT, docetaxel and enzalutamide and assess whether this triple therapy strategy improves upon ADT plus docetaxel. The study has incorporated biological and quality of life studies.

2014-ongoing
Randomized Phase 3 Trial of Enzalutamide in Androgen Deprivation Therapy with Radiation Therapy for High Risk, Clinically Localized, Prostate Cancer: ENZARAD
Australian and New Zealand Urogenital and Prostate Cancer Trials Group
Co-Study Chair (Medical Oncology) of Investigator-Initiated Trial
(Wrote the concept and application to Astellas and coordinated conduct of study with ANZUP and University of Sydney with participation from UK, Ireland, Canada and Dana-Farber Cancer Institute)
(ANZUP)/Astellas Grant for Co-operative Group Study: approx. $12.5 million
The main goal of this study is to assess whether adding enzalutamide improves survival when added to androgen deprivation therapy and radiation for high risk localized prostate cancer. The study has incorporated biological and quality of life studies.

2018-2025
Molecular origins and evolution to chemoresistance in germ cell tumors
National Institutes of Health/The National Cancer Institute R01
Co-Investigator: Total Direct Cost: $1,250,000
The goal of this grant is to define the epigenomic and DNA mutation and RNA profiles associated with poor outcomes with GCT

2018-2020
Surrogate Endpoints of Overall Survival in Men with Metastatic Hormone Sensitive Prostate Cancer
Prostate Cancer Foundation; 2018 VAlor Challenge Award
Role: Partnering PI $19,200 (DFCI only)
The goal of this grant is to assess whether intermediate clinical endpoints (ICEs) are surrogate for OS in men with mHSPC.

2019-2023
Dual Targeting of Cooperating Drivers of Prostate Cancer: PC180361
Department of Defense (Sweeney)
PCRP Idea Development Award
Role: Principal Investigator $600,000
Goals/Aims: The aims of this project are to determine if PTEN loss plus NF-kappa B activation results in more aggressive prostate cancer and define the RNA profiles of PTEN null vs TTP null vs PTEN null plus TTP null tumors and define the efficacy of AR targeting with NF-kappa B.

2020-2023
Defining Overexpression of MYBL2 as a Driver of Lethal Prostate Cancer
Department of Defense (Ellis)
PCRP Translational Science
Role: Co-Investigator $1,271,960
Goals/Aims: To test the hypothesis that MYBL2 is a master regulator that drives resistance to androgen-deprivation therapies (ADT) via chromatin remodeling and lineage plasticity.

2020-2023
Genetically Directed HSD3B1 Therapeutics for Metastatic Prostate Cancer
Cleveland Clinic (Sharifi)
DOD W81XWH-19-PCRP-TSA
Role: Co- Investigator (Site Investigator) $73,131 (DFCI)
Goals/Aims: This project will determine whether patients with the variant of HSDB31 associated with more rapid DHT production are the patients who benefit from early enzalutamide from the ENZAMET trial.

2020-2025
Comprehensive genomic profiling of aggressive hormone sensitive prostate cancer
NIH/NCI (Sweeney)
R01CA238020
Role: Principal Investigator ($2,333,927)
Aims: Aim 1: To define he impact of tumor suppressor gene (TSG) alterations (TP53, PTEN, RB1) on clinical outcomes of patients with mHSPC treated with ADT or ADT plus docetaxel in the CHAARTED trial. Aim 2: To determine whether transcriptional profiles are associated with poor prognostic clinical features and/or TSG alterations and result in more accurate prognostication of outcomes with ADT or ADT plus docetaxel. Aim 3: To determine whether transcriptional profiles result in more accurate predictive models for benefit from adding docetaxel to ADT.
Overlap: None

2019-enrollment completion	Darolutamide Augments Standard Therapy for Localised Very High-Risk Cancer of the Prostate (DASL-HiCaP) Australian and New Zealand Urogenital and Prostate Cancer Trials Group Co-Study Chair (Medical Oncology) of Investigator-Initiated Trial (Wrote the concept and application to Astellas and coordinated conduct of study with ANZUP and University of Sydney with participation from UK, Ireland, Canada and Dana-Farber Cancer Institute) (ANZUP)/Astellas Grant for Co-operative Group Study: approx. $40 million The main goal of this study of 1,100 men is to assess whether adding darolutamide improves survival when added to androgen deprivation therapy and radiation in patients with high risk localized prostate cancer undergoing primary or salvage radiation. The study has incorporated biological and quality of life studies

Training Grants

2013-2015	Molecular Epidemiology Investigation of Obesity and Lethal Prostate Cancer US Army Prostate Cancer Research Program Post-Doctoral Fellowship Mentor of Dr. Ericka Noonan The work covered by the training grant is assessing biomarkers in prostate tissue related to obesity.
2014-2016	Investigation of Physical Activity in the Primary and Secondary Prevention of Prostate Cancer. US Army Prostate Cancer Research Program Post-Doctoral Fellowship Mentor of Dr. Sarah Markt The work covered by this grant is assessing the biological changes of physical activity that prevent prostate cancer.
2020-2022	Genomic Predictors of Clinical Outcomes and Benefit of (Chemo) Hormonal Therapy in Metastatic Hormone Sensitive Prostate Cancer PC190530 PAIR (Hamid) DoD/ W81XWH-19-PCRP-EIRA Mentor of Dr. Anis Hamid The work covered by this grant is determining the genomic features of baseline prostate cancer and response to ADT and ADT plus docetaxel

Report of Local Teaching and Training

Teaching of Students in Courses

2008-2009	Prostate Cancer Problem Based Learning 3rd Year Medical Students	University of Adelaide Medical School 1hr session for two weeks/per year
2009	Clinical Skills Training 4th Year Medical Students	University of Adelaide Medical School 1hr session for four weeks

Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs)

2002 - 2007	Introduction to Cancer Hematology-Oncology Fellows Internal Medicine Residents	IU One-hour lecture/tutorial per year
2002 - 2007	Introduction to Prostate Cancer Hematology-Oncology Fellows	IU One-hour lecture per year
2002 - 2007	Introduction to Bladder Cancer	IU

	Hematology-Oncology Fellows	One-hour lecture per year
2008 - 2009	Introduction to Cancer Medical Oncology Registrars Internal Medicine Residents	Royal Adelaide Hospital One-hour lecture/tutorial per year
2008 - 2009	Introduction to Prostate Cancer Medical Oncology Registrars	Royal Adelaide Hospital One-hour lecture per year
2008 - 2009	Introduction to Bladder Cancer Medical Oncology Registrars	Royal Adelaide Hospital One-hour lecture per year
2009	Introduction to Clinical Trials Medical Oncology Registrars	Royal Adelaide Hospital One-hour lecture per year
2010 –	Medical Oncology Fellows Teaching Conference: Overview of Germ Cell Tumors	DFCI Fellowship Program Single one hour lecture each year
2010 -	Medical Oncology Fellows Monday Morning Conference: Special Guest	DFCI Fellowship Program Supervise and comment on cases – one-hour sessions twice per year
2012 – 2014	Development of GU Tumor Board and Case Based Discussions as formal process for teaching Urology and Radiation Oncology Residents and Medical Oncology Fellowship	In my role as Clinical Director for the Lank Center for GU Oncology at DFCI, I was involved in the development of these educational conferences and incorporation into DFCI's education mission; was also an active participant in teaching at the conferences. 3 hours per month

Clinical Supervisory and Training Responsibilities

2001 – 2007	Medical Oncology Outpatient Clinic, Preceptor Richard L. Roudebush VA Medical Center, Indianapolis, IA	Two days per week
2003 – 2007	Genitourinary Outpatient Clinic Preceptor IU	Two days per week
2008 – 2009	Medical Oncology Outpatient Clinic Preceptor, Royal Adelaide Hospital	Two days per week
2010 - 2022	Medical Oncology Outpatient Clinic Preceptor DFCI	Tow days per week

Laboratory and Other Research Supervisory and Training Responsibilities

2003-2007	Supervision of post-doctoral research fellow / IU	Daily mentorship for 48 months
2005-2007	Supervision of post-doctoral research fellow / IU	Daily mentorship for 24 months
2013-2014	Supervision of post-doctoral research fellow / DFCI	Daily mentorship for 24 months

2014-2015	Supervision of post-doctoral research fellow / DFCI	Daily mentorship for 24 months

Formally Mentored Medical, Dental and Graduate Students

2014 – 2015 Carlos Lago-Hernandez

Mentor – HMS student who completed two projects related to testicular cancer using a DFCI hospital registry and Surveillance, Epidemiology, and End Results (SEER) registry. One first-author article was published in the Annals of Oncology in 2015 (Research investigation 113) and another article was published in Cancer in 2016 as a co-first author (Research investigation 141).

Other Mentored Trainees and Faculty:

2003-2007 Noah Hahn, MD/Associate Professor of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
Mentor -Dr. Hahn was mentored by me during his Medical Oncology Fellowship at IU and this resulted in gaining a faculty position at IU in 2006 and a successful NIH 2009 Loan Repayment Grant. He was then recruited to Johns Hopkins in 2014.

2003-2007 Rajasubramanium Shanmugam, PhD /Indian Council of Medical Research, Jabalpur, India
Mentor – I supervised Dr. Shanmugam while he was post-doctoral research fellow while he was in my laboratory at IU, which resulted in 3 first author publications.

2003-2007 Elena Gabriela Chiorean, MD/ Associate Professor of Medicine, University of Washington, Seattle, WA
Mentor - Dr. Chiorean was mentored by me at IU during her junior faculty years with a focus on phase 1 and drug development. She has since moved to University of Washington and been promoted to Associate Professor.

2004-2007 Robert Matthew Strother, MD/ Medical Oncologist, Canterbury District Health Board, Christchurch, New Zealand
Mentor - Dr. Strother was mentored by me during his Medical Oncology Fellowship at IU, and this resulted in gaining a faculty position at IU in 2009. This supervision resulted in one original research paper, one review article, and in 2008 an oral abstract at ASCO. This work and training also led to a successful NIH 2007 Loan Repayment Grant and 2009 ASCO Young Investigator Award.

2005-2007 Praveen Kusumanchi, PhD / Assistant Research Professor, Indiana University Purdue University Indianapolis (IUPUI)
Mentor – I supervised Dr. Kusumanchi while he was post-doctoral research fellow in my laboratory at IU, which resulted in 2 co-author publications.

2010-2012 Jaya Sharma, MD. Medical Oncology Fellow, Tufts Medical Center, Boston, MA
Mentor - Dr Sharma worked with me correlating serum protein levels with clinical outcomes in patients with metastatic prostate cancer when she was medicine resident at St. Elizabeth's Medical Center. This led to her writing 2 publications as first author.

2012 Sarah Rudman, MBBS: Medical Oncologist from Guy's Hospital, London, UK
Mentor - Dr. Rudman spent 2 months shadowing and commencing collaborative clinical research projects while she was in her medical oncology trainining in London. The mentoring has since resulted in presentations at national meetings and publications, including two first-author peer-reviewed publications.

2012-2013 Elizabeth O'Donnell, MD, Hematology/Oncology, Massachusetts General Hospital (MGH)
Mentor – Dr. O'Donnell worked alongside me in the clinic and performed clinical database research during her DFCI Medical Oncology Fellowship. This work

resulted in three ASCO abstracts as first author, one first author publication under review, and two ASCO merit awards.

2012-2013 Ericka Noonan, Sc.D. Harvard T.H. Chan School of Public Health, Boston, MA
I provided medical oncology input for the training of this epidemiology trainee on her post-doctorate DOD training grant.

2013 Praful Ravi, MBBS. Internal Medicine Resident, Mayo Clinic, Rochester, MN
Mentor – Dr. Ravi spent one month as an elective student while a medical student in Cambridge, UK; as a mentee, he worked on the testis cancer database and performed a meta-analysis. This resulted in a first author publication.

2013-2014 Xiaodong Wang, PhD / Industry, China
Mentor – I supervised Dr. Wang while he was post-doctoral research fellow, and the work resulted in 1 first author publication.

2013-2015 Katherine Zukotynski, MD, University of Toronto, Toronta, Ontario
Mentor –I supervised Dr. Zukotynski when she was a radiologist at DFCI and conducting a PET imaging research project as a part of a clinical trial. This resulted in a first author publication.

2013- Stephanie Howard, MD. Radiologist, DFCI; Assistant Professor, HMS
Mentor – I am supervising Dr. Howard on imaging of germ cell tumors. This work has led to one first author publication, and she is currently lead investigator under my supervision of a follow-on validation protocol.

2013- Lauren Harshman, MD, Medical Oncologist, DFCI; Assistant Professor, HMS
Mentor – I have served as mentor on Dr. Harshman's Prostate Cancer Foundation Young Investigator Award and NIH Loan Repayment Award. This work has led to conduct of investigator-initiated trials, poster presentations at ASCO as first author, and manuscripts are in preparation.

2014-2015 Laurence Albiges, MD. Medical Oncologist, Institut Gustave Roussy, Villejuif, France
Mentor – I have served as mentor on a research project for Dr. Albiges that resulted in a research poster presentation at ASCO as first author.

2014-2015 Kazumasa Komura, Post-doctoral Research Fellow Memorial Sloan Kettering Cancer Center, New York, NY
Mentor – I mentored Dr. Komura on a project while he was a Urology trainee and post-doctoral fellow at DFCI, which resulted in a first author publication.

2014-2016 Rowan Miller, MBBS: Medical Oncology Registrar, London Hospital system, UK
Mentor - Dr. Miller spent 2 months shadowing me in clinic and learning clinical data-base research. She continued the research projects in London, as an ongoing collaboration with my supervision until 2016

2014-2016 Brandon Bernard, MD, Clinical Research Fellow, DFCI
Mentor - Dr. Bernard is a Medical Oncologist who completed his training in Vancouver, Canada, at the British Columbia Cancer Agency, was awarded a two-year Clinical Research Fellowship, and performed prostate and testicular cancer translational research. In 2015 he had 2 review publications, and he is writing the results of 2 original research investigations. In 2017 he will be an Assistant Professor of Medicine in Medical Oncology at the University of Colorado, Denver.

2012-2014 Travis Gerke, ScD., AM, Assistant Professor of Epidemiology, College of Public Health and Health Professions and College of Medicine, University of Florida, Gainesville, FL

I served on Dr. Gerke's dissertation advisory committee for a thesis entitled "Discovering and Validating Prognostic Biomarkers in Prostate Cancer by Focusing on Population Impact." This dissertation was submitted to the Faculty of the Harvard T. H. Chan School of Public Health in partial fulfillment of the requirements for the degree of Doctor of Science in the Department of Epidemiology. I have since been overseeing a project correlating a biomarker with prostate cancer relapse after prostatectomy.

2014-2018 Sarah Coseo Markt, ScD., Epidemiologist; Research Fellow, Harvard T.H. Chan School of Public Health
Mentor - Dr. Markt is completing a post-doctoral fellowship at the Harvard T.H. Chan School of Public Health. She joined my research program to conduct testicular cancer research, gain experience in analyzing hospital registry data and the SEER registry, and address pertinent and clinically focused questions. This has resulted in one first author publication and another under review.

2017-2018 Cecile Vicier, MD, Research Fellow
Mentor – Dr Vicier is a French medical oncologist who spent 12 months interrogating the DFCI data-base and performed correlative analyses of patients with localized and metastatic prostate cancer. This has resulted in three pieces of original peer reviewed research (1 publication and 2 poster presentations at an international meeting)

2017- 2023
Anis Hamid, MD, Research Fellow and Uni Melbourne PhD Candidate
Mentor - Dr Hamid is an Australian medical oncologist who spent 2.5 years interrogating the DFCI and CHAARTED data-base and correlative analyses of patients with localized and metastatic prostate cancer. This has resulted in 8 pieces of original peer reviewed research.

2018-2022
Alok Tewari, MD, PhD Research Fellow then Junior Faculty (DFCI, HMS)
Mentor – Dr. Tewari is a DFCI medical oncology fellow who developied subject matter expertise in germ cell tumor and prostate cancer management under my supervision in clinic and performing genomic analyses in the Van Allen lab as part of out germ cell tumor collaboration.

2018-2022
Praful Ravi, MD, Research Fellow then Junior Faculty (DFCI, HMS)
Mentor - Dr. Ravi is a DFCI medical oncology fellow who is developing subject matter expertise in germ cell tumor and prostate cancer management under my supervision in clinic and interrogating clinical databases and performing database and performing correlative studies of localized and metastatic prostate cancer and germ cell tumors.

2017-2019 Edoardo Francini. MD
Mentor - Dr Francini is an Italian medical oncologist who spent 2.5 years interrogating the DFCI data-base and correlative analyses of patients with localized and metastatic prostate cancer. This has resulted in 5 pieces of original peer reviewed research.

2020-2022 Irbaz Riaz, MD
Mentor – Dr Riaz is an US medical oncologist who spent 2.0 years interrogating the DFCI data-base and correlative analyses of patients with localized and metastatic prostate cancer and learned machine learning at HMS under supervision of Dr. Van Allen.

2020-2021 Nicita Mehta, MD, PhD candidate Combined MIT HMS program
Mentor: providing oversight and input and funding support for germ cell tumor machine learning of pathology H&E and IHC specimens tied to clinical outcomes

Formal Teaching of Peers (e.g., CME and other continuing education courses)

2000-2006	ASCO Review – Genitourinary Oncology IU CME program	Single presentation each year Indianapolis, IN
2010	Management of Biochemical Hormone Sensitive Relapse 15th Biennial Urologic Cancer Course, HMS CME	Single presentation Boston, MA
2011	How Should a Patient be Managed With All the New Approved Therapies for CRPC: Patient Selection and Sequencing Advances in the Treatment of Genitourinary Cancers CME Course, Dana-Farber/Brigham Women's Cancer Center.	Single presentation Boston, MA
2012	Prostate Cancer: Recurrent and Metastatic Disease Session: Update on Chemotherapy 16th Biennial Urologic Cancer Course, HMS CME	Single presentation Boston, MA
2012	Testis Cancer Session Management of Advanced Disease – Chemotherapy 16th Biennial Urologic Cancer Course, HMS CME	Single presentation Boston, MA
2012	A Structured Approach for Treating Patients with Biochemical Recurrence Advances in the Treatment of Genitourinary Cancers CME Course, Dana-Farber/Brigham Women's Cancer Center.	Single presentation Boston, MA
2013	Prostate and Bladder Cancer Brigham and Women's Hospital Internal Medicine Board Review Course	Single presentation Boston, MA
2013	Update on Kidney Cancer Genitourinary Oncology Advances in the Treatment of Genitourinary Cancers CME Course, Dana-Farber/Brigham Women's Cancer Center.	Single presentation Boston, MA
2013, 2014	Bladder and Prostate Cancer Review Brigham and Women's Hospital Intensive Review in Internal Medicine	Single presentation each year Boston, MA
2014	Prostate Cancer: Where Does Chemotherapy Fit in? 17th Biennial Urologic Cancer Course, HMS	One presentation Boston, MA
2014	Testis Cancer: Management of Advanced Disease-Chemotherapy 17th Biennial Urologic Cancer Course, HMS	One presentation Boston, MA
2014	Post-Chemotherapy Surgery for Metastatic Germ Cell Tumors: When and Whom? Advances in the Treatment of Genitourinary Cancers CME Course, Dana-Farber/Brigham Women's Cancer Center.	Single presentation Boston, MA
2015	Management of Stage I Testicular Cancer Advances in the Treatment of Genitourinary Cancers CME Course, Dana-Farber/Brigham Women's Cancer Center.	Single presentation Boston, MA
2018	Chemotherapy for castration sensitive and resistant M1 PC	One presentation Boston, MA

	19th Biannual Jerome P. Richie Harvard Course in Urologic Oncology. Dana-Farber/Brigham Women's Cancer Center.	
2018	Post-Chemotherapy Surgery for Metastatic Germ Cell Tumors: When and Whom? 20th Biannual Jerome P. Richie Harvard Course in Urologic Oncology Dana-Farber/Brigham Women's Cancer Center.	Single presentation Boston, MA
2021	Chemotherapy for castration sensitive and resistant M1 PC 19th Biannual Jerome P. Richie Harvard Course in Urologic Oncology. Dana-Farber/Brigham Women's Cancer Center.	Single presentation Boston, MA
2021	Post-Chemotherapy Surgery for Metastatic Germ Cell Tumors: When and Whom? 20th Biannual Jerome P. Richie Harvard Course in Urologic Oncology Dana-Farber/Brigham Women's Cancer Center.	Single presentation Boston, MA

Local Invited Presentations

2001	Prostate Cancer for the Internist/Noon Conference / Lecture Department of Medicine, IU
2001	The Future of Oncology: Enhancing Chemotherapy with Biological Therapies / Lecture Clinical Pharmacology Seminar Series, IU
2002	Targeted Therapy: Futuristic or Futile / Grand Rounds IU Cancer Center, IU
2002	Transitional Cell Cancer for the Internist/ Noon Conference/ Lecture Department of Medicine, IU
2002	Hormonal Therapy for Prostate Cancer/ Einhorn Symposium/ Lecture IU Cancer Center, IU
2003	Prostate Cancer for the Internist/ Noon Conference Lecture Department of Medicine, IU
2003	Individualizing Therapy for Patients with Prostate Cancer / Weekly Grand Rounds Department of Medicine, IU
2004	Transitional Cell Cancer for the Internist/ Noon Conference Lecture Department of Medicine, IU
2004	Individualizing Therapy for Patients with Prostate Cancer/ Regenstrief Work in Progress/ Lecture Regenstrief Institute, IU
2005	Hormone Refractory Prostate Cancer for the Internist/ Noon Conference Lecture Department of Medicine, IU
2005	Overcoming Resistance to Anti-angiogenesis Therapy / Lecture Department of Radiology, Indiana Center for Vascular Biology and Medicine Retreat, IU
2006	Bringing a Drug from the Lab to the Clinic – Parthenolide as a Case Study / Grand Rounds IU Cancer Center, IU

2008 Introduction to Phase 2 Clinical Trials / Lecture
Australia and Asia Pacific Clinical Oncology Research Development Workshop
Sunshine Coast, Queensland, Australia

2008 Landscape of Clinical Trials for Prostate Cancer / Weekly Grand Rounds
Department of Medicine, Royal Adelaide Hospital

2011 Testis Cancer 101 / Lecture
Biostatistics and Computational Biology Program, DFCI

2011 Will We Ever Get Beyond Testosterone Suppression as the Only Systemic Therapy for Newly Metastatic Prostate Cancer?
Dana-Farber Cancer Institute, GU Seminar Series

2014 Insights into the CHAARTED Trial / Lecture
DFCI, Londonderry, NH

2014 Insights into the CHAARTED Trial/ Lecture
DFCI, South Shore Hospital, South Weymouth, MA

2014 Insights into the CHAARTED Trial / Lecture
DFCI, Milford Hospital, Milford, MA

2016 How I Treat Prostate Cancer?
DF/BWCC Affiliate Symposium and Education Day, Boston, MA

2017 Charting A New Course For Investigations Post-CHAARTED
DFCI, Australian Prostate Cancer Expertise (APACE) Preceptorship, Boston, MA

2019 Advances in Prostate Cancer Management
DFCI GU Seminar Series
Boston, MA

Report of Regional, National and International Invited Teaching and Presentations

Regional

2001 The Future of Targeted Therapy in Oncology / Lecture
Eli Lilly Young Investigators Meeting, Indianapolis, IN (Eli Lilly)

2002 Issues in Developing Drugs and Clinical Trials for Cancer Patients / Lecture
Department of Medicinal Chemistry, Purdue University, West Lafayette, IN

2003 Prostate Cancer – One Size Does Not Fit All / Grand Rounds
Department of Medicine, Beaumont Hospital, Royal Oak, MI (Aventis)

2004 Advances In Chemotherapy for Bladder Cancer / Lecture
Marion General Hospital Tumor Board, Marion, IN (Eli Lilly)

2004 Prostate Cancer – One Size Does Not Fit All / Grand Rounds
Department of Medicine, Ball Memorial Hospital Cancer Center, Muncie, IN
(Sanofi-Aventis)

2004 Advances in Hormone Refractory Prostate Cancer / Lecture
Department of Medicine, Beaumont Hospital Cancer Center, Royal Oak, MI
(Sanofi Aventis)

2010 Making Sense of Prostate Cancer Screening Data / Lecture
Department of Medicine, Lawrence Memorial Hospital, New London, CT

2010 Advances in Advanced Prostate Cancer / Medicine Grand Rounds

Lowell General Hospital, Lowell, MA

2012 Treatment of Testicular Cancer / Lecture
Department of Medicine, St. Anne's Hospital, Fall River, MA

2013 Maximizing Efficacy; Minimizing Morbidity: Germ Cell Tumor / Grand Rounds
Tufts Cancer Center, Boston, MA

2014 How Do the Results of CHAARTED Impact the Treatment Landscape of Metastatic Prostate Cancer / Lecture
Sanofi Advisory Board Meeting, Boston, MA (Sanofi)

National

Those presentations below sponsored by outside entities are so noted and the sponsors are identified.

2001 Why COX-2 Inhibition plus Chemotherapy? / Lecture
Radiation Therapy Oncology Group – Cyclo-oxygenase-2 Symposium, Philadelphia, PA

2001 The Future of Targeted Therapy – The Future is Now! / Grand Rounds
Thomas Jefferson Cancer Center, Philadelphia, PA

2002 The History and Future of Metastatic Prostate Cancer / Lecture
Department of Medicine, University of Alabama, Birmingham, AL

2002 Management Issues of Clinical Stage I Testis Cancer / Meet the Professor Session
ASCO Annual Meeting, Chicago, IL

2002 Combining Targeted Therapy with Chemotherapy / Lecture
ASCO Satellite Symposium, Orlando, FL (Aventis)

2002 Anti-angiogenic Therapy for Prostate Cancer / Lecture
ASCO Molecular Therapeutics Meeting, San Diego, CA

2003 Anti-angiogenic Therapy for Prostate Cancer / Lecture
Fifth International Symposium of Anti-angiogenesis Agents, Recent Advances and Future Directions in Cell Biology and Clinical Research, San Diego, CA

2004 Therapy for Metastatic Bladder Cancer: State of the Art / Lecture
Lilly Investigators Meeting, Plenary Session, Phoenix, AZ (Eli Lilly)

2004 Alimta Activity in Relapsed Bladder Cancer / Lecture
Chemotherapy Foundation Symposium XXI, New York, NY

2004 Overcoming Resistance to Anti-angiogenesis Therapies / Lecture
Aventis Satellite Symposium, ASCO Annual meeting, Orlando, FL

2004 Nuclear Factor Kappa B as a Target for the Treatment of Prostate Cancer / Grand Rounds
Department of Genitourinary Medical Oncology, MD Anderson Cancer Center
Houston, TX

2005 Advances in Prostate Cancer from Translational Research / Lecture
Department of Medicine, Oregon Health Sciences University, Portland, OR

2005 New Paradigms for the Treatment of Metastatic Prostate Cancer / Grand Rounds
5th Annual Multidisciplinary GU Oncology Course, Cleveland Clinic Cancer Center; Cleveland, OH

2005 Recommendations for Defining and Treating High Risk Disease -Systemic Therapy Alone Innovations and Challenges in Prostate Cancer / Lecture

Department of Urology, University California, San Francisco, CA

2005 Current Status of Biomarkers Potentially Associated with Prostate Cancer Outcomes
Pharmacogenetics of Prostate Cancer: Correlative Studies to be Done in CHAARTED, an NCI sponsored Phase III Trial / Lecture
University of Colorado Cancer Center, Denver, CO

2006 Advances in Cancer Therapy from Translational Research – Prostate Cancer as a Model / Grand Rounds
Mayo Clinic Cancer Center, Rochester, MN

2007 Early Clinical Development: Phase I designs, Pharmacokinetic (PK)/Pharmacodynamic (PD) and Biomarker Development
Visiting Professor Lecture Series
Genentech, South San Francisco, CA (Genentech)

2007 Systemic Therapy for Prostate Cancer from Adjuvant Therapy to Second-Line Therapy for Hormone Refractory Prostate Cancer / Prostate Cancer Symposium Lecture
Department of Medicine, University of Kentucky, Lexington, KY

2007 Phase I Dose-Escalating Study of CT-322 as Monotherapy in Patients with Advanced Solid Tumors and Non-Hodgkin's Lymphoma: First Human Clinical Trial of an Adnectin Therapeutic / Lecture
Targeted Therapeutics, Washington, DC

2007 Bringing Dimethylaminoparthenolide from the Laboratory to the Clinic / Lecture
Lank Center for Genitourinary Oncology, DFCI/HMS

2008 Neoadjuvant Therapy for Bladder Cancer / Lecture
New South Wales Uro-Oncology Society, Sydney, New South Wales, Australia

2008 Personalized Medicine and Prostate Cancer - Defining Our Future / Lecture
Trans Tasman Radiation Oncology Group Prostate Cancer Research
Sydney, New South Wales, Australia

2008 An Overview of Prostate Cancer Clinical Trials / Lecture
Prostate Cancer Foundation of Australia, Queensland, Australia

2008 The Landscape of Prostate Cancer Clinical Trials / Lecture
Clinical Oncology Society of Australia, Sydney, New South Wales, Australia

2008 Why we need personalized medicine? / Education Session Lecture
Australian Health and Medical Research Congress, Brisbane, Queensland, Australia

2008 Neoadjuvant Therapy for Bladder Cancer / Lecture
New South Wales (NSW) Uro-Oncology Society, Sydney, Australia

2009 Do You Treat a Man with a Rising Prostate Specific Antigen (PSA) After Radical Prostatectomy / Lecture
10th National Prostate Cancer Symposium, Melbourne, Australia

2009 Is Nuclear Factor Kappa B a Target for Prostate Cancer / Lecture
10th National Prostate Cancer Symposium, Melbourne, Australia

2010 Scientific Advances in Cancer / Lecture
Hoosier Oncology Group Scientific Symposium, Indianapolis, IN

2010 The Case for Non-hormonal Therapy Clinical Trials for Patients with Low Volume Hormone Sensitive Metastatic Prostate Cancer / Lecture
Multi-institutional Prostate Cancer SPORE Meeting, Fort Lauderdale, FL

2010 Triaging the Prostate Cancer Pipeline / Lecture
Prostate Cancer Foundation Scientific Retreat, Washington, DC

2011 General Session V: Penile, Urethral, and Testicular Cancers / Chair of Session
GU ASCO 2011, Orlando, FL

2011 GU ASCO Webinar – Penile, Kidney and Germ Cell Tumors / Lecture
ASCO University Webinar Series

2011 The Case for Abiraterone Plus Cabozantinib / Lecture
Multi-institutional Prostate Cancer SPORE Meeting, Fort Lauderdale, FL

2011 Non-Prostate Cancer Sessions: Discussant of Three Germ Cell Tumor Presentations
ASCO Annual Meeting Oral Genitourinary Presentations, Chicago, IL

2011 What's New in Urothelial Cancer / Lecture
ASCO Annual Meeting Education Session, Chicago, IL

2012 Treating Hormone Sensitive Metastatic Prostate Cancer - Where to Next / Grand Rounds
Taussig Cancer Center, Cleveland Clinic, Cleveland, OH

2012 Using NaF-PET and FDG-PET to Delineate XL184 Site of Action – Bone, Tumor or Both – in a Phase 1 Trial of Abiraterone Plus XL184 / Lecture
Multi-institutional Prostate Cancer SPORE Meeting, Fort Lauderdale, FL

2012 General Session II: Castration-Resistant Prostate Cancer -- Treatment Sequencing and Implementation / Chair and Case Presenter
GU ASCO 2012, San Francisco, CA

2013 Clinical Problems in Oncology: Difficult to Treat Germ Cell Tumors – Should There be a Standard of a Clinical Trial? / Lecture
ASCO Annual Meeting, Chicago, IL

2013 Optimal Value Based Use of Molecular Biomarkers in Oncology: The Expert's Perspective on How I Treat My Patients With Prostate Cancer / Lecture
Global Biomarkers Consortium Conference: Clinical Approaches to Targeted Technologies, Boston, MA

2013 Ingenious Delivery of an Old Drug / Lecture
Prostate Cancer Foundation Annual Retreat, National Harbor, MD

2014 Is Chemoswitch the New Standard for Poor Risk Non-Seminomatous (NS) CGT with Slow Tumor Marker Decline / Lecture
GU ASCO, San Francisco, CA

2014 ICECaP: A Project to Identify Intermediate Clinical Endpoint(s) (ICE) that Serve as Surrogate(s) for Overall Survival (OS) in Prostate Cancer Clinical Trials / Lecture
Prostate Cancer Foundation, Santa Monica, CA

2014 The Case and The Process for Developing an Intermediate Clinical Endpoint in Cancer of the Prostate / Lecture
Prostate Cancer Foundation Retreat, Carlsbad, CA

2014 Docetaxel in Hormone Sensitive Prostate Cancer / Lecture
US Food and Drug Administration, Silver Spring, MD

2014 The Evolving Role of Chemotherapy for Hormone Sensitive Metastatic Prostate Cancer / Lecture
Chemotherapy Foundation Symposium, New York, NY

2015 Lessons from CHAARTED and GETUG-AFU; What Have We Learned? / Lecture
Orlando, FL (Sanofi)

2015 The Changing Face of Prostate Cancer Treatment: ADT and Early Chemotherapy (CHAARTED trial) / Lecture

Society of Urological Oncology - Special Session,
American Urological Association Annual Meeting, New Orleans, LA

2015 Initial Chemotherapy with Androgen Deprivation Therapy for Newly Diagnosed Men with Hormone-naïve M1 Prostate Cancer: Yes, No, Maybe? / Lecture
American Urological Association Annual Meeting, New Orleans, LA

2015 Chemotherapy Considerations and Radium-223 in Castrate Resistant Prostate Cancer: What Does the Urologist Need to Know in 2015? / Lecture
American Urological Association Annual Meeting, New Orleans, LA

2015 Improving Prostate Cancer Outcomes by Integrating Therapies / Lecture
Department of Medicine, Gundersen Health, La Crosse, WI

2015 Precision Medicine in a Heterogenous World / Lecture
6th International PacRim Breast and Prostate Cancer Meeting, Stevenson, WA

2015 Precision Medicine in a Heterogenous World / Lecture
Gordon Research Conference, Sunday River, ME

2016 Chemohormonal therapy in prostate cancer: Why was it positive? / Lecture.
Cancer Treatment Centers of America, Atlanta, GA

2016 Disease-Free Survival as a Surrogate for Overall Survival in Localized Prostate Cancer Trials / Lecture
Food And Drug Administration, Silver Spring, MD

2016 Determining Efficacy in Prostate Cancer Clinical Trials / Lecture
Multi-institutional Prostate Cancer SPORE Meeting, Fort Lauderdale, FL

2016 Chemotherapy; First or Last in Metastatic Prostate Cancer? / Lecture
Wake Forest University Prostate Cancer Symposium, Winston Salem, NC

2016 Contemporary Issues in Clinical Trial Design in the Era of Precision Medicine / Lecture
NCI SPORE Workshop, Rockville, MD

2016 Prostate and Genitourinary Cancer – Any Progress? / Lecture
First Life Metro Pavia Oncology Center State of the Art Master Classes, San Juan, Puerto Rico

2016 Disease-Free Survival as a Surrogate for Overall Survival in Localized Prostate Cancer Trials / Lecture
Eastern Co-operative Oncology Group (ECOG)- American College of Radiology Imaging Network (ACRIN) Spring Meeting, Boston, MA

2016 Chemotherapy considerations and Radium-223 in Castrate Resistant Prostate Cancer / Lecture
American Urological Association (AUA) Annual Meeting, San Diego, CA

2016 Initial Chemotherapy with Androgen Deprivation Therapy for newly diagnosed men with hormone-naïve M1 prostate cancer / Lecture
AUA Annual Meeting, San Diego, CA

2016 Definition and management of oligometastatic hormone sensitive prostate cancer / Lecture
ASCO Annual Meeting, Chicago, IL

2016 Chemohormonal therapy in prostate cancer: why was it positive? / Lecture
University of California, Los Angeles, Los Angeles, CA

2017 Charting a new course for investigations Post-CHAARTED / Lecture
Mayo Clinic, Scottsdale, AZ

2017 Combination or sequential therapy for castration resistant prostate cancer? / Lecture
American Urological Association Annual Meeting, Boston, MA

2017 The role of chemotherapy in metastatic hormone sensitive and castration resistant prostate cancer / Lecture
American Urological Association Annual Meeting, Boston, MA

2017 Post-plenary discussion / panelist
ASCO Annual Meeting, Chicago, IL

2017 Will Biomarkers Lead to Optimal Management of Prostate Cancer? / Lecture
Gordon Research Conference, Sunday River, ME

2017 Metastatic Prostate Cancer: Which Drug(s) and When at Starting ADT and At CRPC? /Lecture
Cancer Treatment Centers of America, Atlanta, GA

2018 Prostate, Urothelial and Germ Cell Tumors - Precision Medicine Using Clinical Knowledge
Weston Cleveland Clinic, Weston, FL

2018 Novel Agents and Concepts in the Management of Hormone Naïve and Castrate Resistant Prostate Cancer / Lecture
American Urological Association, San Francisco, USA

2018 Advances in Prostate Cancer Management
Weisbach Lecture, University of Michigan Cancer Center
Ann Arbor, MI

2018 Advances in Prostate Cancer Management
Moffit Cancer Cancer Grand Rounds
Tampa, Fl

2019 Fickle, Thy Name Is Androgen Receptor
Hormone Dependent Cancer: Gordon Research Conference
Newry, ME

2019 Optimal Management of Metastatic Castration Sensitive Prostate Cancer
Society of Urological Oncology
Washington, DC

2020 A Strategy to Decrease Deaths from Prostate Cancer
University of Pittsburgh Medical Center Urology Grand Rounds
,Pittsburgh, PA (Virtual)

2021 A Strategy to Decrease Deaths from Prostate Cancer
Prostate Cancer Center of Excellence at the Icahn School of Medicine at Mount Sinai
New York, New York

Relocated to Australia Dec 2022:

2022 Using multi-omics to define which patients with prostate cancer benefit from which therapy: Mult-Omics Meeting
Brisbane, Australia

Abstract Oral Presentations

1999 Results and Outcome of Retroperitoneal Lymph Node Dissection for Clinical Stage I Embryonal Carcinoma Predominant Testis Cancer / Oral Abstract Presentation
ASCO Annual Meeting, Los Angeles, CA

2014 Impact on overall survival (OS) with chemohormonal therapy versus hormonal therapy for hormone-sensitive newly metastatic prostate cancer (mPrCa): An ECOG-led phase III randomized trial /Oral Plenary Lecture
ASCO Annual Meeting Chicago, IL

2019 Overall survival (OS) results of a phase III randomized trial of standard-of-care therapy with or without enzalutamide for metastatic hormone-sensitive prostate cancer (mHSPC): ENZAMET (ANZUP 1304), an ANZUP-led international cooperative group trial / Oral Plenary Lecture
ASCO Annual Meeting Chicago, IL

2020 IMbassador250: A phase III trial comparing atezolizumab with enzalutamide vs enzalutamide alone in patients with metastatic castration-resistant prostate cancer (mCRPC) / Oral Plenary Lecture
AACR Annual Meeting Virtual, San Diego, CA

International

Those presentations below sponsored by outside entities are so noted and the sponsors are identified.

2002 State of the Art with Chemotherapy in Bladder Invasive Carcinoma and Concomitant Chemotherapy and Radiation in Invasive Bladder Carcinoma/ Lecture
XIX Reunion Nacional Medica del Instituto Nacional de Cancerologia, Villahermosa City, Mexico

2003 Novel Therapies for Transitional Cell Cancer / Lecture
Fourth International Bladder Cancer Symposium, Padua, Italy (Eli Lilly)

2004 Resistance to Angiogenic Drugs and Bevacizumab in Breast Cancer/ Lecture
Second International Angiogenesis in Cancer Symposium, Malaga, Spain (Roche)

2005 Second-Line Chemotherapy for Transitional Cell Cancer / Lecture
Sixth Annual International Bladder Cancer Symposium, Seville, Spain (Eli Lilly)

2006 Is there life beyond BEP/VIP/High Dose for Metastatic Germ Cell Cancer? / Lecture
Hot Topics in Urologic Oncology, St. Bartholemew's and St. Mary's Hospital
London, UK

2007 Bringing Parthenolide from the Fields to the Clinic / Lecture
Royal Adelaide Hospital

2007 Treatment of Prostate Cancer, A USA perspective / Lecture
St. Bartholemew's and St. Mary's Hospital

2008 Novel Therapies for Bladder Cancer / Lecture
Education Session, GU ASCO, 2008, San Francisco, CA
(based in Australia in 2008)

2008 Muscle Invasive Bladder Cancer / Lecture
Education Session, ASCO Annual Meeting 2008, Chicago, IL
(based in Australia in 2008)

2009 mTOR Inhibition in Renal Cell Cancer / Lecture
Novartis India Cancer Therapeutics Symposium, Dubai, United Arab Emirates

2011 Will We Cure Prostate Cancer In Harper's Lifetime? – Yes Debate / Lecture
Royal College of Physicians, London, England, UK

2011 How Do You Treat a Patient with a Biochemical Recurrence? / Lecture
Guys Hospital GU Seminar Series, London, England, UK

2011 A Proposal On How to Categorize Cancer Drugs in Development: Prostate Cancer as an Example / Lecture
Trans-tasman Radiation Oncology Group (TROG) Annual Meeting, Glenelg, Australia

2011 Individualized Treatment of the Man with Prostate Cancer Recurrence / Lecture

"Prostate SA," Adelaide, Australia

2011 When to Refer to a Patient with Prostate Cancer to a Medical Oncologist / Lecture
12th Australasian Prostate Cancer Conference, Melbourne, Australia

2011 Status of Clinical Development of Next Generation Hormonal Therapies Beyond Abiraterone / Lecture
12th Australasian Prostate Cancer Conference, Melbourne, Australia

2011 Beyond Chemotherapy – Targeted Therapies for Advanced Disease / Lecture
12th Australasian Prostate Cancer Conference, Melbourne, Australia

2011 The Horizon for New Therapies for Castration Resistant Prostate Cancer is No Longer a Mirage / Lecture
Clinical Oncology Society of Australia, Perth, Australia

2011 Past, Present and Future of Germ Cell Tumors (GCT)? Therapy - Using Biology and Collaborations to Cure All GCT / Lecture
Clinical Oncology Society of Australia, Perth, Australia

2011 Progress Report on Clinical Trials Targeting the Biology of Urothelial Cancer / Lecture
Clinical Oncology Society of Australia, Perth, Australia

2011 How Can We Increase the Number of Patients Cured of Bladder Cancer / Lecture
Clinical Oncology Society of Australia, Perth, Australia

2012 Developing New Systemic Treatments to Revolutionize the Treatment of Prostate Cancer / Lecture
London Urology Cancer Annual Research and Audit Meeting 2012
London, England, UK

2012 New Drugs in Prostate Cancer / Symposium / Lecture
St. Luke's Hospital Cancer Center, Manila, Philippines

2012 Advances in Bladder Cancer / Symposium/ Lecture
St. Luke's Hospital Cancer Center

2013 Development of Dimethylaminoparthenolide as an Anti-cancer Agent / Lecture
Vancouver Prostate Center, Vancouver, Canada

2013 Moving Forward by Going Backwards to Advance Prostate Cancer Therapy / Lecture
British Columbia Cancer Agency, Vancouver, Canada

2013 Enhancing AR Targeting with Non-AR Drugs / Lecture
Current Advances and Future Challenges of Steroid action in Breast and Prostate Cancer: Basic Mechanisms to Clinical Applications, Cancer Research UK Cambridge Institute, Cambridge University, Cambridge, UK

2013 Going Forwards by Moving Backwards - Research Frontiers in Clinical Practice / Lecture
Advances in Prostate Care, Dublin, Ireland

2014 Issues and Controversies in Urological Oncology: Chemo-hormonal Therapy for Hormone-sensitive Metastatic Disease; Immunotherapy and Bone-targeted Therapy in Castrate-resistant Prostate Cancer / Lecture
State-of-the-Art Update: Invasive Bladder Cancer,
Whistler, Canada

2014 Going Forwards by Moving Backwards: Enzalutamide in Earlier Prostate Cancer Stages and Strategy to Define Robust Intermediate Cinical Endpoints for Overall Survival / Lecture National Cancer Institute, Canada Spring Meeting, Toronto, Canada

2014 Overview of ENZAMET: Why Enzalutamide Should be Tested Earlier in Metastatic Prostate Cancer / Lecture

ANZUP, Sydney, Australia

2014 Enhancing Hormonal Therapy Efficacy, Not Reversing Resistance: The Case for Developing Therapies for Hormone Sensitive Disease: Adjuvant and Metastatic / Lecture
Canadian Association of Genitourinary Medical Oncologists 9Th Annual Meeting,
St. John's, Newfoundland, Canada

2014 Place of Early Introduction of Chemotherapy in Prostate Cancer: CHAARTED Study / Lecture
Brussels, Belgium (Sanofi)

2014 How Do the Results of CHAARTED Impact the Treatment Landscape of Metastatic Prostate Cancer / Lecture
Astellas Global Oncology Portfolio Advisory Board Meeting, Melbourne, Australia

2014 How Do the Results of CHAARTED Impact the Treatment Landscape of Metastatic Prostate Cancer / Lecture, Jevtana Advisory Board Meeting,
London, England, UK (Sanofi)

2014 The Case and The Process for Developing an Intermediate Clinical Endpoint in Cancer of the Prostate / Lecture
Transdisciplinary Prostate Cancer Partnership (TOPCaP) Retreat
Reykjavik, Iceland

2014 Advanced Multi-Disciplinary Team (MDT) cases in prostate cancer: Difference between UK and US practice / Lecture
British Urogenital Group, York, UK

2014 Overview of the CHAARTED Data / Lecture
British Urogenital Group

2014 Optimizing Survival in Advanced Prostate Cancer: Early Docetaxel for Hormone Sensitive Prostate Cancer / Lecture
Satellite Symposium at European Society for Medical Oncology
Madrid, Spain (Sanofi)

2014 Treatment Choices in the Post-CHAARTED Landscape / Lecture
Janssen Educational Symposium, Madrid, Spain

2014 Insights into the E3805 CHAARTED Trial / Lecture
Geneva, University Hospital Cancer Center
Geneva, Switzerland (Sanofi)

2014 Insights into the E3805 CHAARTED Trial / Lecture, Sanofi Advisory Board,
Zurich, Switzerland (Sanofi)

2014 Insights into the E3805 CHAARTED Trial / Lecture, University Hospital
Zurich, Switzerland (Sanofi)

2014 Insights into the E3805 CHAARTED Trial / Lecture, Sanofi Advisory Board
Lausanne, Switzerland (Sanofi)

2014 The Role of Chemotherapy in Prostate Cancer/ Lecture
Sociedad Mexicana de Oncología, Ixtapa Zihuatanejo, Mexico

2014 Clinical Impact of CHAARTED in Metastatic Hormone-Sensitive Prostate Cancer and Metastatic Castration Resistant Disease / Lecture
Montreal, Canada

2014 CHAARTED (ECOG3805): Trial Insights, Perspectives and Consequences for the Treatment of Advanced Prostate Cancer. Curietherapies and Oncology Group of Quebec (GROUQ) Prostate Cancer Forum / Lecture

Montreal, Canada

2014 The Case and The Process for Developing an Intermediate Clinical Endpoint in Cancer of the Prostate / Lecture
Swedish Prostate Cancer Study Group, Prostate Cancer Foundation Retreat, Stockholm, Sweden

2014 Role of Chemotherapy in the Treatment of Prostate Cancer – Perspectives on MDT, Monitoring for Progression and Choice of Treatment Sequence / Lecture
Nordic-Baltic Prostate Cancer Symposium
Arlanda, Sweden (Sanofi)

2014 CHAARTED: What are the Implications for the Future? / Lecture
European Meeting on Urological Cancer Satellite Symposium
Lisbon, Portugal (Sanofi)

2014 Quality Assessment in Uro-oncology: Medical Treatment / Lecture
European Meeting on Urological Cancer
Lisbon, Portugal

2014 What Are the Implications of Androgen Deprivation Therapy Plus Chemotherapy in Metastatic Prostate Cancer for the Future / Lecture
Prostate Cancer Summit Forum
Ningbo, China (Sanofi)

2014 Impact of the CHAARTED Results on the Treatment of Castration Sensitive Metastatic Prostate Cancer / Lecture
Prostate Cancer Summit
Kowloon, Hong Kong, China (Sanofi)

2014 Chemo-hormonal Combination Therapy in Hormone Sensitive Prostate Cancer - Moving into un-CHAARTED territory / Lecture
National Cancer Centre
Singapore, Singapore (Sanofi)

2014 Chemo-hormonal Combination Therapy in Hormone Sensitive Prostate Cancer - Moving into un-CHAARTED territory / Prostate Cancer Symposium/ Lecture
Kuala Lumpar, Malaysia (Sanofi)

2014 What Are the Implications of ADT plus Chemotherapy in Prostate Cancer for the Future / Lecture
Taiwan National Prostate Cancer Meeting
Taipei, Taiwan (Sanofi)

2015 Integrated Treatment of Prostate Cancer in the CHAARTED Universe
McGill/University of Montreal, Visiting Professor Program with lectures at Montreal General Hospital, Hôpital Notre Dame, Jewish General Hospital
Montreal, Quebec, Canada

2015 Role of Chemotherapy in Metastatic Prostate Cancer
Visiting Professor: Tumor Boards, Case Conferences and Hot Topics Symposium
Radboud University Nijmegen, Nijmegen, The Netherlands (Sanofi)

2015 Duration of Response to ADT and How This Informs Us Clinically / Lecture
Advanced Prostate Cancer Consensus Conference, St. Gallen, Switzerland

2015 CHAARTED Results and its Implications
Sanofi Sponsored Satellite Symposium, / Lecture
European Urology Association Annual Meeting Madrid, Spain (Sanofi)

2015 Chemotherapy in Hormone Sensitive Patients / Plenary Lecture
European Urology Association Annual Meeting, Madrid, Spain

2015 mCRPC Treatment: Is Multidisciplinary Partnership the Future? / Lecture
Athens, Greece (Bayer)

2015 Improving Prostate Cancer Outcomes by Integrating Therapies/ Lecture
Royal College of Physicians Ireland, Dublin, Ireland (Sanofi)

2015 Precision Medicine in Prostate Cancer: How Close Are We? / Lecture
ANZUP Cancer Trials Group, Annual Scientific Meeting, Sydney, Australia

2015 Immediate Docetaxel in Metastatic Prostate Cancer / Lecture
ANZUP Cancer Trials Group, Annual Scientific Meeting, Sydney, Australia

2015 New insights in Germ Cell Tumor / Lecture
ANZUP Cancer Trials Group, Annual Scientific Meeting, Sydney, Australia

2015 Prolonging Survival In Early Chemo-Sensitive Populations/Lecture
Global Summit on Genitourinary Malignancies, Banff, Canada

2015 Chemohormonal Therapy in Prostate Cancer: Why Was It Positive? Lecture
Princess Margaret Cancer Center Grand Rounds, Toronto, Ontario

2015 BREAKING NEWS – Paradigm Change in the Treatment of Hormone Sensitive Prostate Cancer/Urology Update / Lecture
University of Toronto, Toronto, Canada

2015 CHAARTED and its Clinical Implications / Lecture
Atlantic Canada Urologic Oncology Meeting, Halifax, Nova Scotia

2015 Precision Medicine in a Heterogeneous World/ Lecture
Atlantic Canada Urologic Oncology Meeting, Halifax, Nova Scotia

2015 Metastatic Castration Naïve Prostate Cancer (mCNPC): Yes, to chemotherapy treatment / Lecture
Spanish Oncology Genitourinary Group, Madrid, Spain

2015 Chemohormonal Therapy in Prostate Cancer: Why Was it Positive? / Lecture
Istanbul, Turkey (Sanofi)

2016 Disease-Free Survival as a Surrogate for Overall Survival in Localized Prostate Cancer Trials / Lecture
Canadian Cancer Trials Group Spring Meeting, Toronto, Canada

2016 Chemohormonal Therapy: Who with Metastatic, Hormone Sensitive Disease Should be Offered it? / Lecture
John Fitzpatrick Prostate Cancer Symposium, Dublin, Ireland

2016 Understanding the Heterogeneity of Prostate Cancer / Lecture
Sanofi 2nd Middle East Solid Tumors Meeting, Beirut, Lebanon (Sanofi)

2016 Best Sequencing of Current Therapies in mCRPC / Lecture
Sanofi 2nd Middle East Solid Tumors Meeting, Beirut, Lebanon (Sanofi)

2016 Paradigm Change in Prostate Cancer Management /Lecture
Sanofi 2nd Middle East Solid Tumors Meeting, Beirut, Lebanon (Sanofi)

2016 Predictive Markers of Resistance in Prostate Cancer / Lecture
4th Global Congress on Prostate Cancer, Vienna, Austria

2016 New Insights into GCT / Lecture
Guy's Hospital, London, UK

2016 Is There a Role for Docetaxel in Oligometastatic Hormone Sensitive Prostate Cancer?/Lecture

Royal Adelaide Hospital, Adelaide, Australia (Janssen)

2016 Precision Medicine in a Heterogeneous World / Lecture
Asia-Pacific Prostate Cancer Conference 2016, Melbourne, Australia

2016 Going Forwards by Moving Backwards after CHAARTED and STAMPEDE? / Lecture
Asia-Pacific Prostate Cancer Conference 2016, Melbourne, Australia

2016 Intermediate Clinical Endpoints in Cancer of the Prostate (ICECaP) as Surrogates of Overall Survival / Lecture
Asia-Pacific Prostate Cancer Conference 2016, Melbourne, Australia

2016 Does KDM5D Have a Role in Explaining Why AR Inhibition Augments Docetaxel Activity? / Lecture
Asia-Pacific Prostate Cancer Conference 2016, Melbourne, Australia

2016 Going Forwards by Moving Backwards / Lecture
Janssen PROSPECT Medical Education Meeting, Sydney, Australia (Janssen)

2016 Is There a Role for Docetaxel in Oligometastatic and Low volume disease? / Lecture
Janssen PROSPECT Medical Education Meeting, Sydney, Australia (Janssen)

2016 Sequencing of Agents in Advanced Prostate Cancer is Important / Lecture
Janssen PROSPECT Medical Education Meeting, Sydney, Australia (Janssen)

2016 Is There Still a Role for Cytotoxics in CRPC? / Lecture
Janssen PROSPECT Medical Education Meeting, Sydney, Australia (Janssen)

2016 How Do We Measure Tumour Heterogeneity in mCRPC / Lecture
Janssen PROSPECT Medical Education Meeting, Sydney, Australia (Janssen)

2016 Treatment Burden and Quality of Life / Lecture
Janssen PROSPECT Medical Education Meeting, Sydney, Australia (Janssen)

2016 Why was chemohormonal therapy beneficial in prostate but not breast cancer? /Lecture
Royal College of Surgeons Ireland, Dublin, Ireland

2016 Charting A New Course Post-CHAARTED / Lecture
Curietherapies and Oncology Group of Quebec (GROUQ) Prostate Cancer Forum, Montreal, Quebec

2016 Combined or sequential systemic treatment for castration resistant disease / Lecture
9th European Multidisciplinary Meeting on Urological Cancers, Milan Italy

2017 Your patient received ADT plus docetaxel for M1 castration-sensitive/naive disease - now what? / Lecture
Advanced Prostate Cancer Consensus Conference, St Gallen, Switzerland

2017 mHSPC and mCRPC: Targeted Therapy in Heterogeneous Disease – Is It Possible? / Lecture
Winter Meeting: Treatment of renal and prostate cancer, Oslo, Norway

2017 Defining different molecular pathways in patients with mCRPC / Lecture
Uro-Oncology Meeting, Barcelona, Spain

2017 How to optimize treatment in CRPC: We should use clinical factors / Lecture
Uro-Oncology Meeting, Barcelona, Spain

2017 How to manage metastatic hormone-naive PCa patients in 2017? Challenges and solutions / Lecture
Asia Pacific Urology Consortium, Taipei, Taiwan

2017 Biomarkers: leading the way towards optimal management of PCa? / Lecture

Asia Pacific Urology Consortium, Taipei, Taiwan

2017 Sequencing in mCRPC: Choosing the right path to the top / Lecture
Asia Pacific Urology Consortium, Taipei, Taiwan

2017 Clinical benefit of chemotherapy in metastatic prostate cancer / Lecture
Seoul National University Hospital, Seoul, Korea (Sanofi)

2017 Clinical benefit of chemotherapy in metastatic prostate cancer / Lecture
Department of Urology, National Cancer Center, Seoul Korea (Sanofi)

2017 Clinical benefit of chemotherapy in metastatic prostate cancer / Lecture
Korea University Anam Hospital, Seoul, Korea (Sanofi)

2017 Over-treatment in the name of cure: Revisiting adjuvant therapy in the modern era / Lecture
Asia-Pacific Prostate Cancer Conference 2017, Melbourne, Australia

2017 Is it worth evaluating immune checkpoint blockade in prostate cancer? / Lecture
Asia-Pacific Prostate Cancer Conference 2017, Melbourne, Australia

2017 Is it worth evaluating immune checkpoint blockade in prostate cancer? / Lecture
Asia-Pacific Prostate Cancer Conference 2017, Melbourne, Australia

2017 My Patient Received CHAAARTED, now what? / Lecture
Prostate Cancer Forum, Rio De Janeiro, Brazil (Janssen)

2017 Metastatic Hormone Sensitive Prostate Cancer: Timing and Volume of Metastases Drives Destiny … Why? / Lecture
Imperial College London, London UK

2017 Castration Sensitive Prostate Cancer CHAARTED (DOCETAXEL) versus LATITUDE (ABIRATERONE) / Lecture
5th International Oncoclinicas Symposium, Sao Paulo, Brazil

2017 Oligometastatic prostate cancer: Definitions, clinical outcomes, and treatment considerations / Lecture
30th Annual Meeting Association pour la Rechere sur les Tumeurs de la Prostate. Paris, France

2018 Chemohormonal therapy / Lecture
John Fitzpatrick Irish Genitourinary Cancer Conference 2018, Dublin, Ireland

2018 Biomarkers in Prostate Cancer / Lecture
Latin American Prostate Cancer Summit, Barranquilla, Columbia (Janssen)

2018 Update on the management of prostate cancer / Lecture and case-based discussion
Rajiv Gandhi Institute, New Delhi, India

2018 Update on the management of prostate cancer / Lecture and case-based discussion
Tata Memorial Hospital, Mumbai, India

2018 Optimizing the treatment sequence in the management of prostate cancer / Lecture
ICON Oncology Conference, Trivandrum, India

2018 Metastatic Prostate Cancer: Which Drug(s) and When Starting ADT and At CRPC?
Tokyo, Japan (Takeda)

2018 Optimizing Outcomes in Advanced Prostate Cancer / LectureGU Rounds at London Health Sciences Centre / London, Ontario, Canada (Bayer)
Optimizing Outcomes in Advanced Prostate Cancer / Lecture; Brampton Learning Program, William Osler Health System, Brampton Ontario, Canada (Bayer)

2018 Medical Oncology Journal Club / Reviewer; Princess Margaret Cancer Centre, Toronto Ontario, Canada (Bayer)
Optimizing Outcomes in Advanced Prostate Cancer – A Multi-Disciplinary Discussion of Treatment; Toronto, Ontario, Canada (Bayer)

2018 Updates in Advanced Prostate Cancer / Lecture; Odette Cancer Centre (Sunnybrook) GU MDT Rounds (Bayer)

2018 Global trials having an impact: what do we know and what's coming: Germ cell tumors Australian and New Zealand Urogenital and Prostate Cancer Clinical Trials Group Sydney, Australia

2018 Crossfire Debates: Intermittent vs Continous ADT for M1 HSPC
Australian and New Zealand Urogenital and Prostate Cancer Clinical Trials Group Sydney, Australia

2018 When more is less and less is more: Rationale for patient selection for chemotherapy in metastatic hormone sensitive prostate cancer. Australian and New Zealand Urogenital and Prostate Cancer Clinical Trials Group
Sydney, Australia

2018 When more is less and less is more: Rationale for patient selection for chemotherapy in metastatic hormone sensitive prostate cancer. Australian and New Zealand Urogenital and Prostate Cancer Clinical Trials Group
Sydney, Australia

2018 The future of adjuvant therapy for high risk localized prostate cancer Princess Margaret Hospital Grand Rounds
Toronto, Ontario Canada

2018 Advances in Prostate Cancer Management. Florey Lecture, University of Adelaide Adelaide, Australia

2018 Current and future insights into advanced prostate cancer: where do we stand in 2018? (Astellas/Amgen)
Louvain-La-Neuve, Belgium

2018 Current and future insights into advanced prostate cancer: where do we stand in 2018? (Astellas/Amgen)
Diegen, Belgium

2018 Current and future insights into advanced prostate cancer: where do we stand in 2018? (Astellas/Amgen)
St Marten-Latem, Belgium

2018 Updates on chemotherapy in Hormone Sensitive Prostate Cancer: GROUQ Prostate Cancer Symposium
Montreal, Quebec, Canada

2018 How can collaborative multi-disciplinary research and care can decrease deaths from localized prostate cancer; Timing and Volume of Metastases Drives Destiny of mHSPC Clinical Features to Drive Personalized mCPRC Care: The Ottawa Hospital Ottawa, Ontario

2018 Generating the scientific evidence: the challenges in implementing to daily practice Data sharing: How can we leverage big data? Innovation and Biomarkersmin Cancer Drug Development. Brussels, Belgium

2019 The sequencing conundrum in the management of prostate cancer:
Simplifying the algorithm (Astellas); Cartagena, Columbia

2019 Which systemic therapy for which patient with mHSPC?
10th SOGUG Meeting; Madrid, Spain

2019 Treatment of metastatic hormone sensitive prostate cancer
what is the status? Advanced Prostate Cancer Consensus Conference; Basel, Switzerland

2020 Treatment of polymetastatic hormone sensitive prostate cancer European Association of Urology, Virtual Meeting Amsterdam, Netherlands

2020 Discussant: A prospective randomized study of bicalutamide +/- docetaxel for non metastatic prostate cancer with a rising PSA (SPCG14)
European Association of Urology,
Virtual Meeting Amsterdam, Netherlands

2020 Ideal Patient Profile for Chemotherapy in Hormone Sensitive Prostate Cancer
Janssen Sponsored Educational
Virtual Meeting Bogota, Columbia (Virtual)

2020 Advances in Management of Metastatic Prostate Cancer
Netherlands Cancer Institute, NKI, Urology Grand Rounds
Amsterdam, Netherlands (Virtual)

2020 A Strategy to Decrease Deaths from Prostate Cancer
Juravanski Cancer Center Bayer Sponsored,
Hamilton, Canada (Virtual)

2020 A Strategy to Decrease Deaths from Prostate Cancer
Bayer Sponsored, Princess Margaret Hospital Grand Rounds,
Toronto, Canada (Virtual)

2020 A Strategy to Decrease Deaths from Prostate Cancer
Sunnybrook Cancer Cancer Grand Rounds, Bayer Sponsored,
Toronto, Canada (Virtual)

2021 Advances in Management of Metastatic Hormone Sensitive Prostate Cancer
Hong Kong Society of Urological Oncology,
Hong Kong, China (Virtual)

2021 Advances in Management of Metastatic Hormone Sensitive Prostate Cancer
Journée Enseignement Recherche du GETUG
Paris, France (Virtual)

2021 A Strategy to Decrease Deaths from Prostate Cancer
Sunnybrook Cancer Cancer Grand Rounds, Bayer Sponsored,
Manitoba, Canada (Virtual)

2021 A Strategy to Decrease Deaths from Prostate Cancer
Reunion Virtual Hot Spots Pills
Barcelona, Spain (Virtual)

2021 Advances in Management of Metastatic Hormone Sensitive Prostate Cancer
Taiwan Urology Society
Taipei, Taiwan (Virtual)

2022 Using a Systems Biology Approach to Identify a Regulator of Nuclear-Factor-Kappa B
Lorne Cancer Conference
Lorne, Australia

2022 Personalizing Treatment Selection in Metastatic, Hormone-sensitive
Prostate Cancer Cork Hospital Grand Rounds
Cork, Ireland

2022	Using a Systems Biology Approach to Identify a Regulator of Nuclear Factor-Kappa B - irish Cancer Cociety Guest lecturer Irish Association for Cancer Researcg Cork, Ireland
2022	Treatment intensification strategies in mHSPC: Triplets and More Advanced Prostate Cancer Consensus Conference Lugano, Switzerland
2022	Synchronous vs. metachronous mHSPC: What makes the difference? What is the optimal multimodal approach for high-risk patients? Treatment sequencing Optimal treatment of elderly patients with high volume de novo mHSPC Advanced Prostate Cancer Consensus Conference Summary How should PET-detected oligorecurrent prostate cancer be best treated? Systemic therapy! European Association of Urology Amsterdam, Netherlands
2022	“Where Have We Come from and Where Are We Going in Treating mHSPC?” South Australian Prostate Cancer Coalition Adelaide, Australia
2022	Prostate Cancer Standard of Practice in 2022 and Future Directions XIII Simposio Cientifico SOGUG Madrid, Spain

Relocated to Australia Dec 2022:

Practice Activities

2001-2003	Ambulatory Care	Medical Oncology, VA Roudebush Medical Center, Indianapolis, IN	1 session per week
2001-2007	Ambulatory Care	Medical Oncology, IU Medical Center	4 sessions per week
2001-2007	Inpatient Consult Service	Medical Oncology, VA Roudebush Medical Center	2 months per year
2001-2007	Inpatient Ward and Consult Service	Medical Oncology, IU Medical Center	2 months per year
2008-2009	Ambulatory Care	Medical Oncology, Lyell McEwin Hospital, Adelaide, Australia	2 sessions per week
2008-2009	Ambulatory Care	Medical Oncology, Royal Adelaide Hospital	2 sessions per week
2008-2009	Inpatient Ward and Consult Service	Medical Oncology, Royal Adelaide Hospital	12 weeks per year
2009-	Outpatient GU Clinic	DFCI	4 sessions per week
2009-	Inpatient Oncology Service Attending	Dana-Farber/Brigham and Women’s Cancer Center	4 weeks per year

Clinical Innovations

Web-Based Clinical Trial Flowchart IU	I developed a web-based flowchart to allow physicians to match their patients with clinical trial opportunities at each step of patient's journey through their cancer – from screening to adjuvant therapy to treatment for metastatic disease or palliative care. These maps were developed under my direction as the Associate Director for Clinical Research for the NCI IU Cancer Center. It was acknowledged as an important resource by the NCI reviewers and also facilitated communication amongst the multi-disciplinary teams.
Web-Based Clinical Trial Flowchart Royal Adelaide Hospital	I implemented a web-based flowchart to allow physicians to match their patients with clinical trial opportunities. This was based on the successful model from IU. It influenced the field by leading to an increase in clinical trial participation with more than a 50% increase in annual clinical trial enrollment and supported the development of anti-cancer drugs.
Australian Prostate Cancer Guidelines 2008-2009	After completion of an extensive systematic review of the literature, I was part of the committee that wrote guidelines for use of bisphosphonates and hormonal therapy for prostate cancer. This effort was funded by the National Health and Medical Research Council/Cancer Council NSW, Australia. It provided clear guidance to Australian medical oncologists, radiation oncologists, urologists and primary care physicians on how to screen and manage prostate cancer.
Steering Committee for development of Australian Cancer Research Collaborative 2008-2009	The Steering Committee was formed after a proposition was put forward by me for the development of a state-wide cancer research consortium to guide investments from state government funding and philanthropic resources from Cancer Council SA (CCSA). My role was concept development and creation of a business case with a business consultant after seed investment provided equally by the state government, CCSA, and research branches of three South Australian universities: University SA, University of Adelaide, and Flinders University. This resulted in a plan that was implemented in 2010 and provided a more effective platform for translational prostate cancer research.
Development of Adelaide Cancer Research Institute University of Adelaide, Australia 2008-2009	In my capacity as the Director of Clinical Trials at the Royal Adelaide Hospital, I put forward a grant application to develop a cancer research institute at the University of Adelaide by amalgamating the cancer research efforts of basic science, clinical research, population health and psycho-oncology. In my role as Interim Director of the Institute, I developed the concept, completed the successful application, and was awarded $5,000,000.
Germ Cell Tumor Database and Biorepository Dana-Farber Cancer Institute 2010-	I wrote an IRB-approved protocol and collected clinical data on more than 1,400 patients with germ cell tumors treated at Dana-Farber Cancer Institute since 1997. In addition, I have created a biorepository of highly informative samples. This innovation has led to a number of collaborative and informative publications regarding the biology and outcome of patients with germ cell tumors.
Intermediate Clinical Endpoints in Cancer of the Prostate (ICECaP) Dana-Farber Cancer Institute 2013-	In collaboration with investigators from around the globe, I formed a working group comprised of statisticians, medical oncologists, urologists, radiation oncologists, and patient advocates. This, in turn, led to development of a database of individual patient data from more than 24,000 patients with localized prostate cancer treated on clinical trials. This database is enabling assessment of whether putative intermediate clinical endpoints are surrogates for overall survival.
GU and Via Oncology Pathways Dana-Farber Cancer Institute 2013-2014	I was one of the leaders in the GU Group at DFCI that ran a weekly tumor board to develop a consensus and web-based clinical pathways for Genitourinary Oncology using the Via Oncology clinical pathways platform.

Use of parthenolide to inhibit cancer	US 2003/0125373 A1 Publication Date: Jul 3, 2003 In collaboration with my colleague, Dr Harikrishna Nakshatri, we identified and characterized the anti-cancer activity of parthenolide. This resulted in a use patent being issued and was the foundation for development of analogues and a company (Leuchemix – Scientific Founder). The analogue, dimethylaminoparthenolide (DMAPT), entered phase 1 clinical trials in 2008.
Use of the drug combination of abiraterone and cabozantinib to treat prostate cancer	US 2016/0082019 A1 March 25, 2016 In collaboration with my colleague, Dr. Philip Kantoff, I demonstrated the benefit of cabozantinib with abiraterone in preclinical prostate cancer models and completed the phase 1 trial showing the ability to combine the agents in the clinic. The company, Exelixis, then filed a patent with Dr. Kantoff and myself listed as inventors.
Compositions and methods for screening and diagnosis of prostate cancer	US 11,066,708 B2 Publication Date: Jul . 20 , 2021 Methods of screening for and diagnosing prostate cancer and methods of choosing a therapeutic for prostate cancer based on using KDM5D expression level to identify which patients with hormone sensitive prostate cancer benefit from primary castration and taxane and who with castration resistant prostate cancer would benefit from docetaxel plus an androgen receptor antagonists added to the ongoing castration.
Compositions and methods for screening and identifying clinically aggressive prostate cancer	US 2020/0041515 A1 Publication Date: Feb. 6, 2020 With working stemming from the DOD grant we defined the association of prostate cancer lethality or recurrence with the expression level of ZFP36 or NEDD9 and PTEN in conjunction with ZFP36 loss

Report of Education of Patients and Service to the Community

Activities

No activities below were sponsored by outside entities.

2005, 2007	Man-to-Man support group, St Vincent's Hospital, Indianapolis, IN Participated in the support group by giving a presentation on prostate cancer and clinical trials to patients and partners with prostate cancer
2005, 2006, 2007	Black Expo, Indianapolis, IN Participated in the event by manning a booth at Minority Health Expo and discussed cancer screening to African American men attending the expo
2006	Relay for Life participants, Indianapolis, IN Participated in the event by giving a presentation to participants on the purpose of clinical trials to advance cancer care.
2012	Boston Prostate Cancer Support Group and Education, Boston, MA Participated in the support group by giving a presentation titled "Update on Systemic Therapies for Prostate Cancer"
2013	Massachusetts Prostate Cancer Coalition Participated in this patient education event by giving a presentation titled: "Advances in Prostate Cancer for localized disease to early metastatic disease"

2014	PROSTATE CANCER UK, London Participated in patient education by explaining the results of the CHAARTED study to UK patients and patient advocates
2015	Boston Prostate Cancer Support Group and Education, Boston, MA Participated in the support group by giving a presentation titled: “Use of Docetaxel when starting ADT for metastatic disease prolongs overall survival more than using it for late stage disease”
2016	Prostate Cancer Foundation Australia, Sydney, Australia Participated in videotaped question-and-answer session with patients and patient advocates regarding advances in prostate cancer treatment.

Educational Material for Patients and the Lay Community
No educational materials below were sponsored by outside entities.

2004-2006	People Living with Cancer Website Testicular Cancer (currently cancer.net)	Principal Author, Editor	ASCO patient information website

Recognition

2010 - 2022	Boston’s Top Docs	Boston Magazine
2015	“Hero of the Match” Award—bestowed in honor of my care of a patient who was treated for testis cancer and my participation alongside the patient as riders in the PMC (A "Hero of the Match” award is made in person before every Revolution home game to someone making a difference in his or her community.)	New England Revolution Soccer Team

Publications (updated May 2023)

Peer reviewed publications: Research investigations

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