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14. ABSTRACT

BACKGROUND: The UCSF Prostate Cancer program continues to serve as a productive and creative participant in the DOD PCCTC, by virtue of 1) Integration and interaction of outstanding basic, translational, and clinical research programs, 2) Institutional commitment towards reduction of health disparities in prostate cancer 3) Extensive experience in translational clinical trials, 4) A strong pipeline of therapeutic and diagnostic modalities including PSMA PET.

OBJECTIVE: The UCSF Prostate Cancer Program seeks to develop novel therapies for men with advanced prostate cancer, with concomitant focus on reducing disparities and improving quality of life.

SPECIFIC AIMS: 1) To promote equity in prostate cancer outcomes and access to clinical trials; **2)** To improve quality of life and support decision-making for prostate cancer patients; **3)** To investigate novel immunotherapeutic approaches and their biomarkers; **4)** To advance the field of targeted radioligand therapy in prostate cancer; **5)** To develop novel therapeutic strategies for oligometastatic prostate cancer; **6)** To improve clinical outcomes of patients with neuroendocrine prostate cancer.

15. SUBJECT TERMS

Prostate cancer, Phase 1, Phase 2, clinical consortium, infrastructure, collaboration

16. SECURITY CLASSIFICATION OF:		17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF USAMRDC RESPONSIBLE PERSON	
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1. Introduction

The mission of the UCSF Prostate Cancer Program is to advance patient care through discovery, innovation and education. Clinical research is administered through the Prostate Cancer Program within the Division of Hematology/Oncology in the Department of Medicine, and the Helen Diller Family Comprehensive Cancer Center at UCSF. While retaining commitment to several legacy areas of expertise, the UCSF Prostate Cancer Program has recently added new competencies and is poised to serve as a productive and creative participant in the Department of Defense (DOD) Prostate Cancer Research Program Clinical Consortium, by virtue of 1) Integration and interaction of outstanding basic, translational, and clinical research programs led by national and international opinion leaders, 2) A robust and mature research infrastructure, 3) Institutional commitment towards reduction of health disparities and inequities in access to clinical trials, 4) Extensive experience in conducting creative thematic, translational clinical trials, 5) A strong pipeline of novel therapeutic agents and imaging modalities including PSMA PET, and lastly, 6) Extensive collaborations in many multi-center clinical trial programs, including the DOD Prostate Cancer Clinical Trials Consortium (PCCTC).

2. Keywords

Prostate cancer, Phase I, Phase II, clinical consortium, infrastructure, collaboration

3. Accomplishments

What were the major goals of the project?

The major goals of the project as stated in the approved SOW include the following:

1) Adhere to performance metrics defined by Coordinating Center

2) Full participation in the consortium as a member of the Clinical Consortium Committee/ Scientific Oversight Committee

3) To promote equity in prostate cancer outcomes and access to clinical trials.

4) To improve quality of life and support decision-making for prostate cancer patients.

5) To investigate novel immunotherapeutic approaches and their biomarkers.

6) To advance the field of targeted systemic radioligand therapy in prostate cancer.

7) To develop novel therapeutic strategies targeting oligometastatic disease.

8) To improve clinical outcomes of patients with neuroendocrine prostate cancer (NEPC).

What was accomplished under these goals?

1) Adhere to performance metrics defined by Coordinating Center

As shown in the **Appendix Table C** of this report, in this annual progress reporting period from 10/01/2022 – 09/30/2023, UCSF enrolled 25 patients to DOD PCCTC therapeutic studies, including 17 patients within the past 6 month reporting period, thereby meeting the pre-specified performance metric for accrual outlined in the grant application. Of these 25 patients, 7 (28%) were from historically underrepresented/minority patient populations, including three Black patients and two patients of Asian/Pacific Islander ethnicity. Of the 25 patients, 12 (48%) were enrolled on studies led by other institutions within the DOD PCCTC, including Dana-Farber Cancer Institute, the University of Michigan, and Weill Cornell.

In addition, in the current grant award period from 10/1/2022 – 09/30/2023, UCSF introduced two new clinical trials that will be run within the DOD PCCTC, including:

- *c23-316: Developing and Testing a Patient-Centered Tumor Genomic Pre-Test Counseling Tool for African-American Men with Metastatic Prostate Cancer <PI: D. Kwon>*

- *c23-329: Radium-223 in Optimally Selected Patients with mCRPC <PI: Thomas A. Hope>*

As of the reporting cut-off date of 10/31/2023, in aggregate, UCSF serves as the Lead Investigational Site for 11 active and upcoming multi-center trials within the PCCTC (**see Appendix, Table A for full list**), including an upcoming study utilizing a decision Support tool for genetic testing in Black patients with prostate cancer to be opened at the San Francisco VA Medical Center (PI: Daniel Kwon, UCSF).

In the aggregate prior and current grant award period from 09/30/2018 – 09/30/2023 (**Appendix, Table B**), UCSF enrolled a total of 191 In the aggregate prior and current grant award period from 09/30/2018 – 09/30/2023 (**Appendix, Table B**), UCSF enrolled a total of 182 patients, for an average rate of accrual is 38.2 patients/year, exceeding the accrual metrics set forth in the DOD PCCTC grant.

Within the reporting period from 10/1/22 – 09/30/23, we have achieved several milestones for additional PCCTC trials:

- Study accrual completed for *c22-312: A Modular Phase 2a Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients with Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE).*

- Study accrual completed for *c21-273: A Phase 1b Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Delta-like Protein 3 Half-life Extended Bispecific T-cell Engager AMG 757 in Subjects with De Novo or Treatment Emergent Neuroendocrine Prostate Cancer*

- Interim results from the Phase 2a trial of BXCL701 in combination with pembrolizumab were presented at the ASCO GU Symposium as a Rapid Oral Abstract in February 2023 (San Francisco, CA)

- Final results from the Phase 2a trial of BXCL701 in combination with pembrolizumab in patients with adenocarcinoma and small cell neuroendocrine prostate cancer were presented at the Prostate Cancer Foundation Annual Scientific Meeting in Carlsbad, CA in October 2023.

2) Full participation in the consortium as a member of the Clinical Consortium Committee/ Scientific Oversight Committee

UCSF has participated in every scheduled DOD PCCTC PI monthly teleconference and Scientific Oversight Committee meeting held during the reporting period, including at ASCO GU 2023, ASCO 2023, and the Prostate Cancer Foundation meeting in October 2023. UCSF (Dr. Aggarwal and Early Career Investigator Dr. Ivan de Kouchkovsky) presented at the PI monthly meeting in May 2023, with a focus on utilizing hyperpolarized ^{13}C pyruvate MR imaging as a metabolic tool to detect early resistance and response in prostate cancer patients with bone metastases.

3) To promote equity in prostate cancer outcomes and access to clinical trials.

Dr. Hala Borno, Co-Principal Investigator, has recently developed a clinical trial matching tool (www.ucsftrials.com) that has been widely utilized to facilitate clinical trial referrals from community oncologists and affiliate sites, including areas of the catchment area with underrepresented minority patient populations. She has utilized this initial experience to subsequently spin out an independent company (TrialLibrary) which serves as a patient navigation and support tool which aims to increase diversity of clinical trial participants and reduce financial and logistical barriers to clinical trial participation amongst historically underrepresented patient populations. UCSF has partnered with Trial Library for the incorporate of all prostate cancer studies using their web- and app-based platform.

Dr. Aggarwal, site PI, in his role as Associate Director for Clincial Research in the UCSF Comprehensive Cancer Center, has led efforts with the UCSF Cancer Center to promote equity in clinical trial enrollment. He has promoted the fostering of patient advocates and community advisory board members to be standing members of the disease group review committees for new clinical research studies, and also also piloted a Recruitment Science Research Hub with pilot funding awarded to Prostate Cancer program members to promote equity in clinical trial enrollment via use of patient navigators and community liaisons. In addition, he has established Cancer Center-wide agreements with industry sponsors including BMS, Janssen, and Amgen to foster inclusion of diverse patient patient populations. He partners with the Office of Community Engagement, led by Dr. Kim Rhoads, and meets regularly with the Community Advisory Board and East Bay Men's Health groups to promote equity in access to prostate cancer clinical research efforts and to bring more studies to the community via affiliate organizations including the San Francisco VA, Zuckerberg San Francisco General Hospital, Highland Hospital in Alameda/Oakland area, and Washington Hospital in Fremont.

Dr. Franklin Huang, a member of the UCSF Prostate Cancer program based at the San Francisco VA Hospital, has opened a metastatic biopsy acquisition protocol aimed to capture the genomic and transcriptional features of prostate cancer in Black and Hispanic patients seen within the VA hospital system. He has published extensively on the genomic features of Black prostate cancer patients and is a nationally recognized thought leader in this area.

In the current grant award period from 10/1/2022 – 09/30/2023, of the 25 patients enrolled in the current grant award period, 7 patients (25%) are from disproportionately underrepresented patient populations, including 3 Black patients, two patients of Hispanic background, and two Asian/Pacific Islander patients.

4) To improve quality of life and support decision-making for prostate cancer patients.

We have completed enrollment on our "STAND" randomized pilot study (PI: Rahul Aggarwal) investigating multi-disciplinary supportive care among men with prostate cancer within 6 months of initiating androgen deprivation therapy. The overall study results indicate a high degree of feasibility with > 90% patient visit completion rate. Preliminary data suggests a trend towards improved quality of life and lessened metabolic toxicity (e.g. insulin resistance, increased body fat) compared with usual care treatment arm.

We have collaborated with Drs. Alicia Morgans (Dana-Farber Cancer Institute) in the development of a randomized phase 2 study to evaluate the cognitive impact of AR targeting therapy in men with castration-resistant prostate cancer ("ARACOG"). The study is currently open to accrual through the DOD PCCTC, in part on correlative science developed at UCSF including fMRI brain imaging as a potential biomarker of

early cognitive changes observed on androgen receptor targeting therapy. UCSF GU Oncology junior faculty member Dr. Hala Borno has integrated analysis of financial toxicity experienced by patients as a correlative biomarker in the ARACOG study.

We have completed enrollment to the CHAMP study (PI: Stacey Kenfield, UCSF), a randomized phase 2 study of supervised exercise training among men with minimally symptomatic metastatic castration resistant prostate cancer. The results demonstrate the feasibility of accruing with remote lifestyle interventions via web-based interface, and support the ongoing phase 3 study (GAP4, sponsored by Movember Foundation).

With the successful completion of STAND pilot study, UCSF investigators (Aggarwal, Kenfield, June Chan, Hala Borno) have opened a follow-on multi-institutional study of resistance exercise training, involving community oncology sites in the Greater Bay Area. The multi-institutional study utilizes web-based exercise instruction and activity monitoring to facilitate patient accrual and access to the study for men initiating treatment with androgen deprivation.

UCSF GU Medical Oncology faculty member Dr. Daniel Kwon has developed several studies aimed at improving decision making in patients with prostate cancer. He has opened a prospective clinical study implementing audio recordings during clinic visits to improve decision making among men considering docetaxel chemotherapy for the treatment of their prostate cancer. The pilot results were recently published (see Publications list), and is currently enrolling on the phase 2 portion of the study (MENCORE-2, n = 44 out of 50 patients enrolled to date) to investigate the impact of audio recording to reduce decisional conflict in men with mCRPC contemplating chemotherapy versus alternative treatment options. Dr. Kwon has also developed a decision support tool for Black patients with prostate cancer concerning role of germline and somatic genomic testing. A pilot study evaluating the utility of the tool will be open at UCSF and Karmanos Cancer Institute (PI: Elisabeth Heath) by Q1 2024.

5) To investigate novel immunotherapeutic approaches and their biomarkers.

Dr. Aggarwal leads a number of bi-specific T cell engager trials at UCSF, including serving as site Principal Investigator for AMG 509 (bi-specific targeting STEAP1 and CD3), AMG 757 (bi-specific targeting DLL3 and CD3), and AMG 160 (bi-specific targeting PSMA and CD3). The interim results from the AMG 509 study were recently presented at ESMO 2023 by Dr. Kelly from Thomas Jefferson University, demonstrating an impressive PSA50 and objective response rate, many of which are durable.

Dr. Felix Feng (UCSF Radiation Oncology), Dr. David Oh (UCSF medical oncology), and Dr. Carissa Chu (UCSF Urology) have recently developed a concept of neoadjuvant AMG 509 prior to radical prostatectomy in patients with high-risk localized/locally advanced prostate cancer, with a number of correlative endpoints pertaining to ascertainment of immune cell infiltrates and response on metabolic imaging. The study concept was presented at the DOD PCCTC scientific oversight meeting with plan to initiate enrollment in the first half of 2024. The study will be also opened at MSKCC and Thomas Jefferson.

UCSF GU Oncology faculty member Dr. Lawrence Fong is a nationally recognized expert in prostate cancer immunotherapy and also leads a number of immunotherapy trials including novel checkpoint inhibitor combinations including those involving the adenosine receptor, as well as second- and third-generation bi-specific Abs with adjusted avidity and altered binding ratios to minimize risk of cytokine release syndrome. A number of these studies are open for accrual within the PCCTC including the Harpoon study.

Dr. David Oh, an Early career physician-scientist within the UCSF prostate cancer program, has collaborated with Dr. Aggarwal and Dr. Michael Evans in the Department of Radiology to develop a novel granzyme B PET imaging probe. The first-in-human granzyme B PET imaging study recently enrolled the first patient with metastatic castration resistant prostate cancer within the past three months, and is currently enrolling patients who are receiving immunotherapies including pembrolizumab combinations (e.g. Lu-PSMA) as well as novel bi-specific and CAR-T cell products. Successful completion of the first phase of this trial would enable subsequent multi-center roll-out to other sites within the DOD PCCTC.

6) To advance the field of targeted systemic radioligand therapy in prostate cancer.

Dr. Thomas Hope at UCSF has led a registrational study in collaboration with investigators at UCLA, investigating the use of ^{68}Ga-PSMA PET as a diagnostic imaging tool for patients with biochemically recurrent prostate cancer. The study results were published in JAMA Oncology, indicating overall positive predictive value of PET lesion detection of > 90% (see publication citation below). Drs. Hope and Small have undertaken a retrospective analysis of lesion detection rates among men with CRPC and no evidence of metastases by conventional imaging. The results indicate that over 90% of patients have PET-avid lesions. Dr. Hope has collaborated with investigators at UCLA to demonstrate improved sensitivity for lesion detection by PSMA vs. fluciclovine PET (see Publication List). PSMA PET imaging was rFDA approved for use at UCSF and UCLA for the detection of disease in the newly diagnosed and biochemically recurrent settings, the first two institutions in the country to able to image patients as standard of care.

Dr. Aggarwal and Hope have extended diagnostic PSMA PET to develop theranostic treatment strategies for patients with metastatic castration resistant prostate cancer. Dr. Aggarwal and Hope lead an active investigator-initiated trial evaluating a priming dose of ^{177}Lu-PSMA-617 followed by checkpoint blockade with pembrolizumab in patients with chemotherapy-naïve metastatic castration resistant prostate cancer, and recently published in Lancet Oncology [see publication list]. We utilized a solitary priming dose of ^{177}Lu-PSMA-617 followed by the immune checkpoint inhibitor pembrolizumab, and observed objective and PSA responses in over 50% of patients, the majority of which were durable lasting more than 6 months. Building upon these results, Drs. Aggarwal, Hope and Fong have an upcoming IIT of a phase 2 study of ^{177}Lu-PSMA-617 using an adaptive dose schema based upon PSA kinetics in combination with pembrolizumab in patients with metastatic castration resistant prostate cancer, which will be distributed within the PCCTC. The clinical trial is supported by two NIH grants as well as DOD PCRP program.

Drs. Hope, Koshkin, and Feng have undertaken pre-clinical CRISPR screens to identify regulators of PSMA expression, and have identified CDK 4/6 as one of the top targets. This has led to an ongoing investigator-initiated trial of the CDK4/6 inhibitor abemaciclib as a priming lead-in followed by ^{177}Lu-PSMA-617 in patients with metastatic castration resistant prostate cancer. The clinical trial is currently enrolling patients in dose escalation, and has demonstrated acceptable safety profile with respect to hematologic toxicities thus far. Upon ascertainment of the recommended phase 2 dose, the study will enter dose expansion and expand to a multi-center trial within the PCCTC.

Dr. Aggarwal and Dr. Flavell within the Department of Radiology have developed a novel PET tracer targeting a tumor-specific epitope of CD46, and translated this into a first-in-human imaging study in patients with mCRPC. Soon to enter the clinic is an alpha particle emitting ^{225}Ac labeled Ab targeting CD46, which has demonstrated impressive pre-clinical data in prostate cancer models, and recently published in Cancer Research (see Publications list).

7) To develop novel therapeutic strategies targeting oligometastatic disease.

Drs. Aggarwal, Hope, Feng, and Small at UCSF have designed a randomized phase 2 study of apalutamide with or without stereotactic body radiation therapy to oligometastatic sites of disease on PSMA PET among patients with CRPC. The study (“PILLAR”) is currently open to accrual within the PCCTC at UCSF and the University of Wisconsin, and is in the activation phase of startup at the University of Washington. We are nearing 50% of the target accrual. The screen failure rate has been approximately 25%, primarily due to detection of polymetastatic disease on PSMA PET. We have adjusted the eligibility criteria to allow up to five radiation fields, as opposed to individual metastatic lesions on PSMA PET, to expand the potential eligible patient population and enhance accrual feasibility.

Drs. Small and Kwon have led a retrospective, single institution study evaluating serial SBRT for oligoprogressive castration sensitive and castration resistant prostate cancer, evaluating outcomes including time interval to subsequent radiation and systemic therapy. The results were recently published demonstrating the feasibility of re-capturing response with successive rounds of metastasis-directed radiation (see Publications list).

8) To improve clinical outcomes of patients with neuroendocrine prostate cancer.

Leveraging our SU2C/PCF/AACR West Coast Dream Team biopsy acquisition study, Drs. Aggarwal and Small published a prospective study analyzing the clinical and genomic features of treatment-emergent small cell neuroendocrine prostate cancer (Aggarwal et al. J Clin Oncol 2018). The results indicate an overall incidence of t-SCNC of 17% among all patients with mCRPC and a lesion amenable to percutanoues metastatic biopsy. This stands in stark contrast to the less than 1% incidence of *de novo* small cell prostate cancer detected at the time of diagnosis.

Leveraging these findings, Dr. Aggarwal and Small have helped develop a number of clinical trials to investigate novel therapies and treatment strategies for t-SCNC. These include:

- Led the basket study Phase 1b study of rovalpituzumab tesirine in patients with DLL3-expressing solid tumor malignancies. Study has been completed and manuscript has been submitted for publication.
- Analysis of the subset of patients with clinical and/or genomic features of t-SCNC treated on the PCCTC trial of oral BET inhibitor ZEN-3696 in combination with enzalutamide. This analysis has led to the successful grant application for an investigator-initiated trial of ZEN-3694 + enzautamide + pembrolizumab in patients with neuroendocrine prostate cancer. This trial is open to accrual at UCSF, University of Michigan, and the University of Chicago within the DOD PCCTC. We are nearing completion of accrual to the SCNC/transdifferentiated cohort with expected completion in the first half of 2024. The preliminary results from this study demonstrate durable objective responses in patients with platinum-refractory neuroendocrine prostate cancer, a very high risk group of patients with no currently available treatment options.
- Development of anti-CD46 targeting drug FOR46 as a novel therapeutic strategy in t-SCNC. The therapeutic target and ADC (FOR46) were discovered in the Liu laboratory at UCSF, and the pre-clinical and translational results were published in JCI Insight (see publication list). The ongoing PCCTC phase 1 first-in-human study of FOR46 includes a Dose Expansion cohort for patients with histologic evidence of t-SCNC. Participating PCCTC institutions for this study include: Northwestern University, Oregon Health & Science University, University of California Los Angeles, and Karmanos Cancer Institute. The initial phase 1, dose escalation portion of the results were presented at the 2022 ASCO Annual Meeting (PI: Aggarwal), with a manuscript under development.
- Ongoing collaboration with multiple industry partners to develop novel DLL3-targeting immunotherapy including investigation of DLL3 expression and treatment effect with patient-derived xenograft models of NEPC. This pre-clinical work has led to the ongoing Phase 1b/2 study of tarlatamab (AMG 757), a CD3xDLL3 bi-specific Ab, in patients with *de novo* or treatment-emergent small cell neuroendocrine prostate cancer. The AMG757 study has completed accrual within DOD PCCTC with UCSF as the lead investigational site. The results demonstrated a durable response rate in patients with DLL-expressing NEPC, and have led to the development of an investigator-initiated trial of tarlatamab in DLL3-positive mCRPC to be co-led by UCSF (PI: Aggarwal) and MSKCC (PI: Autio).
- UCSF serves as the lead site for an ongoing phase 1b/2 study of pembrolizumab in combination with talabostat (Bioexcel Therapeutics, Inc.) focused on men with treatment-emergent or *de novo* small cell neuroendocrine prostate cancer. The study has completed accrual phase 2 portion of the study, with interim results from the Phase 2a portion of the NEPC study presented at the 2023 ASCO GU meeting in February 2023 in San Francisco, CA. The results demonstrate durable responses in a subset of patients with platinum-refractory NEPC. These data have led to ongoing efforts to develop a registrational trial of pembrolizumab plus talabostat in patients platinum-pretreated neuroendocrine prostate cancer.

Describe the Regulatory Protocol and Activity Status (if applicable).

Describe the Protocol and Activity Status for sections a-c, as applicable, using the format described for each section. If there is nothing significant to report during this reporting period, state "Nothing to Report."

(a) ***Human Use Regulatory Protocols***

See Appendix.

(b) Use of Human Cadavers for Research Development Test & Evaluation (RDT&E), Education or Training

TOTAL ACTIVITIES: *No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW)."*

(c) Animal Use Regulatory Protocols

TOTAL PROTOCOL(S): *No animal use research will be performed to complete the Statement of Work."*

What do you plan to do during the next reporting period to accomplish the goals and objectives?

We plan to continue to open and accrue to trials within the DOD PCCTC as outlined with the metrics of the support grant.

We plan to introduce a new study concept to the PCCTC for a funded phase 2 investigator-initiated trial of Lu-PSMA-617 plus pembrolizumab in patients with metastatic castration resistant prostate cancer.

We also plan to submit a concept to the PCCTC evaluating the combination of abemaciclib plus Lu-PSMA-617 as an additional funded, investigator-initiated trial, upon completion of dose escalation portion of the study.

We plan to continue enrollment on the phase 1, first in human PET imaging study of granzyme B in prostate cancer patients receiving various forms of immunotherapy including checkpoint inhibitor combinations.

We plan to initiate enrollment on Dr. Kwon's decision making tool study for Black prostate cancer patients at the VA who are undergoing germline and somatic genomic testing discussions with their medical providers at the San Francisco VA Medical Center.

We also plan to initiate enrollment on the phase 2 optimally-selected radium-223 study in mCRPC (PI: Hope).

4. Impact

What was the impact on the development of the principal discipline(s) of the project?

The recently completed Phase 2a study of pembrolizumab plus talabostat (BXCL701) in patients with de novo or treatment-emergent neuroendocrine prostate cancer was presented at the ASCO GU symposium in February 2023, demonstrating durable responses in patients with platinum chemotherapy refractory disease. The results of this study have led to a planned registrational study of the combination in patients with NEPC.

The phase 1b study of Lu-PSMA plus pembrolizumab was recently published in Lancet Oncology, and has helped to spur additional drug development with radioimmunotherapeutic approaches in patients with advanced prostate cancer.

UCSF has led the development of PSMA PET which led to registrational approval of the imaging agent at UCSF and UCLA in December 2020, the first two institutions in the country to have the agent available for clinical use.

Dr. Hala Borno has founded TrialLibrary to enhance patient access to clinical trials and reduce disparities in clinical trial participation. She has broadened the impact of her navigation-based company to the Greater Bay Area and beyond to extend her impact to the national level.

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. Changes/Problems. The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever

there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Nothing to report.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Significant changes in use or care of vertebrate animals.

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. Products

Relevant publications include the following:

1. Lim E, Schweizer M, Chi K, Aggarwal R, Agarwal N, Gulley J, Attiyeh E, Greger J, Wu S, Jaiprasart P, Loffredo J, Bandyopadhyay N; Xie H, Hansen A. Phase 1 study of safety and preliminary clinical activity of JNJ-63898081, a PSMA and CD3 bispecific antibody, for metastatic castration-resistant prostate cancer. Clinical Genitourinary Cancer 2023 [in press; accepted for publication 24 FEB 2023].
2. Bidkar A, Wang S, Bobba K, Chan E, Bidlingmaier S, Egusa E, Peter R, Ali U, Meher N, Wadhwa A, Dhrona S, Dasari C, Beckford-Vera D, Su Y, Tang R, Zhang L, He J, Wilson D, Aggarwal R, VanBrocklin H, Seo Y, Chou J, Liu B, and Flavell R. Treatment of prostate cancer with CD46 targeted 225Ac alpha particle radioimmunotherapy. Clinical Cancer Research 2023 [in press; accepted for publication 22 FEB 2023].
3. Langlais CS, Chen YH, Van Blarigan EL, Ryan CJ, Zhang L, Newton RU, Luke A, Bang AS, Panchal N, Tenggara I, Schultz B, Lavaki E, Pinto N, Borno H, Aggarwal R, Friedlander T, Koshkin VS, Harzstark AL, Small E, Chan JM, Kenfield SA. Quality of life for men with metastatic castrate-resistant prostate cancer participating in a remote-supervised high-intensity aerobic and resistance exercise intervention pilot study. Urologic Oncology 2022 [in press; accepted for publication 21 NOV 22].
4. Kwon DH, Shakhnazaryan N, Shui D, Hong J, Mohamad O, de Kouchkovsky I, Borno HT, Bose R, Chou J, Desai A, Fong L, Friedlander TW, Koshkin VS, Aggarwal R, Feng FY, Hope TA, Small EJ. Serial stereotactic body radiation therapy for oligometastatic prostate cancer detected by novel PET-based radiotracers. Urologic Oncology 2022 [in press; accepted for publication 28 OCT 22].
5. Feng E, Rydzewski NR, Zhang M, Lundberg A, Bootsma M, Helzer KT, Lang JM, Aggarwal R, Small EJ, Quigley DA, Sjostrom M, Zhao SG. Intrinsic molecular subtypes of metastatic castration-resistant prostate cancer. Clinical Cancer Research 2022 [in press; accepted for publication 07 OCT 22].
6. Chou J, Egusa EA, Wang S, Madura ML, Lee F, Bidkar AP, Zhu J, Shenoy T, Trepka K, Robinson TM, Steri V, Huang J, Wang Y, Small EJ, Chan E, Stohr BA, Ashworth A, Delafontaine B, Rottey S, Cooke KS, Sadraei NH, Yu B, Salvati M, Bailis JM, Feng Y, Flavell RR, Aggarwal R. Immunotherapeutic targeting and PET imaging of Delta-like ligand 3 (DLL3) in small cell/neuroendocrine prostate cancer. Cancer Research 2022 [in press; accepted for publication 30 SEP 22].
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7. Participants and Other Collaborating Organizations

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Name:	Rahul Aggarwal, MD, no change
Name:	Hala Borno, MD, no change
Name:	Eric Small, MD, no change
Name:	Kaitlin Zablotsky, no change
Name:	Audrey Phone, no change
Name:	Erik Hernandez Romero, no change
Name:	Li Zhang, Ph.D., no change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed. Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other*

Academic Institutions:

Organization Name: Oregon Health & Science University
Location of Organization: Portland, OR
Partner's contribution to the project:
OHSU is a participating site on the following trials: FOR46, ARN-509-002, ZEN-3694 + enzalutamide

Organization Name: University of Washington
Location of Organization: Seattle, Washington
Partner's contribution to the project:
University of Washington is a participating site on the following projects: ARN-509-002

Organization Name: The University of Chicago
Location of Organization: Chicago, Illinois
Partner's contribution to the project:
The University of Chicago is a participating site on the following projects: Ribociclib + docetaxel, ARN-509-002

Organization Name: Northwestern
Location of Organization: Evanston, IL
Partner's contribution to the project:
Northwestern is a participating site for the following projects: Ribociclib + docetaxel, FOR46

Organization Name: University of Michigan
Location of Organization: Ann Arbor, MI
Partner's contribution to the project:
University of Michigan is a participating site for the following projects: Ribociclib + docetaxel, pembrolizumab/ZEN-3694/enzalutamide, randomized phase 2 enzalutamide +/- ZEN-3694

Organization Name: University of Wisconsin
Location of Organization: Madison, WI
Partner's contribution to the project:
The University of Wisconsin is a participating site for the upcoming randomized phase 2 study of apalutamide +/- SBRT in oligometastatic CRPC.

Academic Institutions (Continued)

Organization Name: Memorial Sloan Kettering Cancer Center
Location of Organization: New York City, NY
Partner's contribution to the project (c15-165)
Memorial Sloan Kettering Cancer Center is a lead site on: CC-115 + enzalutamide, and participating site on PLANETTE

Organization Name: University of California Los Angeles
Location of Organization: Los Angeles
Partner's contribution to the project (c15-165)
The University of California Los Angeles is a participating site on the following projects: FOR46, ZEN-3694 + enzalutamide

Industry & Other Contributions:

Organization Name: Janssen
Location of Organization: Headquarters – Titusville, New Jersey
Partner's contribution to the project:
Janssen is provides financial support, and manufactures and supplies the study drug for apalutamide +/- SBRT, and ARN-509-002

Organization Name: Novartis
Location of Organization: Headquarters – Basel, Switzerland
Partner's contribution to the project:
Novartis provides financial support and supply of the study drug for project: Ribociclib + docetaxel

Organization Name: Zenith Epigenetics
Location of Organization: US Office – San Francisco, CA
Partner's contribution to the project:
Zenith Epigenetics provides financial support, and the study drug for project ZEN-3694 + enzalutamide.

Organization Name: Celgene Corporation
Location of Organization: San Francisco, CA
Partner's contribution to the project:
Celgene Corporation provides financial support, and the study drug for project: CC-115 + enzalutamide

Organization Name: Fortis Therapeutics, Inc.
Location of Organization: La Jolla, CA
Partner's contribution to the project:
Fortis Therapeutics provides financial support, and the study drug for project FOR46.

8. Special Reporting Requirements

Nothing to Report.

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

SUPPORTING DATA:
University of California, San Francisco

Table A. Active Trials Introduced to the DOD PCCTC by UCSF (as of 09/30/2023)
Table B. Cumulative Patient Accrual by UCSF during the prior and current grant award period (09/30/2018 – 09/30/2023)
Table C. Patient Accrual by UCSF during the progress report period (10/1/2022 – 09/30/2023)

Table A. Active and Upcoming Trials Introduced by UCSF to the Prostate Cancer Clinical Trials Consortium (As of 09/30/2023)

Target Accrual	Accrual to date - UCSF	IRB Approval Date	Open to Accrual Date	Closed to Accrual Date	Participating PCCTC Sites
LOI# c15-165: A Phase 1 Safety and Tolerability Study of ZEN003694 in Patients with Metastatic Castration-resistant Prostate Cancer <PI:R. Aggarwal>					
44	9	3/6/2016	5/6/2016	10/1/2017	**OHSU, MSKCC, UCLA, WSU**
LOI# c15-166: A Phase 1 Safety and Tolerability Study of ZEN003694 in Combination with Enzalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer <PI:R. Aggarwal>					
58	15	5/5/2016	11/15/2016	11/2019	**OHSU, MSKCC, UCLA, WSU**
c18-221: A Phase 1b Dose Escalation/Expansion Study of FOR46 in Patients with Metastatic Castration Resistant Prostate Cancer <PI: R. Aggarwal>					
42	27	12/13/2018	2/4/2019	4/18/2022	**OHSU, UCLA, Northwestern, Karmanos**
c19-242: A randomized phase 2 study of apalutamide with or without stereotactic body radiation to PSMA PET-avid sites of disease in oligometastatic CRPC <PI: R. Aggarwal>					
60	20	6/15/2019	12/15/2019	Accrual ongoing	**Wisconsin, University of Washington**
c20-263: A Phase 1b/2 Study of BXCL701, a small molecule inhibitor of dipeptidyl peptidases (DPP), adiminstered in combination with anti-programmed cell death 1 (PD-1) monoclonal antibody pembrolizumab, in patients with small cell neuroendocrine prostate cancer <PI: R. Aggarwal>					
68	20	5/1/2019	10/3/2019		**Weill-Cornell, Ohio State University, Moffitt Cancer Center**
c21-273: A Phase 1b Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Delta-like Protein 3 Half-life Extended Bispecific T-cell Engager AMG 757 in Subjects with De Novo or Treatment Emergent Neuroendocrine Prostate Cancer <PI: R. Aggarwal>					
10	4	8/5/2021	11/8/2021	Accrual ongoing	**University of Chicago, Weill-Cornell, Washington University, MD Anderson Cancer Center, Wake Forest University**
c21-285: A Phase 2 Study of BET Bromodomain Inhibitor ZEN-3694 in Combination with Enzalutamide Plus Pembrolizumab in Metastatic Castration Resistant Prostate Cancer <PI: R. Aggarwal>					

54	32	6/10/2020	12/7/2020	Accrual ongoing	**University of Michigan**
c22-298: A Randomized Phase 2b Study of ZEN003694 in Combination With Enzalutamide Versus Enzalutamide Monotherapy in Patients With Metastatic Castration-Resistant Prostate Cancer <PI: R. Aggarwal>					
200	3	10/11/2021	6/28/2022	Accrual ongoing	**University of Michigan**
c22-312: A Modular Phase 2a Multicentre Open-Label Study to Investigate DNA-damage Response Agents (or Combinations) in Patients with Advanced Cancer Whose Tumours Contain Molecular Alterations (PLANETTE) <PI: R. Aggarwal & W. Abida>					
52	9	3/7/2021	10/7/2021	Accrual ongoing	**Memorial Sloan Kettering,**
c23-316: Developing and Testing a Patient-Centered Tumor Genomic Pre-Test Counseling Tool for African-American Men with Metastatic Prostate Cancer <PI: D. Kwon>					
80	Pending	Pending	Pending	Study not yet open to accrual	**Karmanos**
c23-329: Radium-223 in Optimally Selected Patients with mCRPC <PI: Thomas A. Hope>					
50	Pending	Pending	Pending	Study not yet open to accrual	**OHSU**

Table B. Cumulative Accrual in Prior and Current Grant Award Period (09/30/2018 – 03/31/2023)

PCCTC #	Lead Institution	Study Title	Accrual Status	Patient Accrual 9/30/2018 – 3/31/2020	Patient Accrual 4/1/2020 – 9/30/2020	Patient Accrual 10/1/2020 – 3/31/2021	Patient Accrual 4/1/2021 – 9/30/2021	Patient Accrual 10/1/2021 – 3/31/2022	Patient Accrual 4/1/2022 – 9/30/2022	Patient Accrual 10/1/2022 – 9/30/2023	Total Patient Accrual 9/30/18 – 9/30/23
c15-149	UCSF	Tax/LEE	Closed	12	0	0	0	0	0	0	12
c15-160	MSKCC	CC-115 + Enzalutamide	Closed	1	0	0	0	0	0	0	1
c15-166	UCSF	Zen/Enza	Closed	9	0	0	0	0	0	0	9
c18-219	JHU	COMBAT	Closed	0	4	0	0	0	0	0	4
c18-221	UCSF	FOR46	Closed	9	1	4	6	6	1	0	27
c18-225	UMich	IMPACT	Closed	0	5	1	1	0	0	0	7
c19-242	UCSF	PILLAR	Open	0	2	2	3	6	3	4	20
c19-244	OHSU	ARV-110	Closed	0	0	0	2	1	0	0	3
c19-241	UCSF	Poseida	Closed	0	0	0	0	3	3	0	6
c20-257	Columbia	HPN424	Closed	3	4	1	2	0	0	0	10
c20-259	UWash	Janssen CD3xPSMA BiTE	Closed	0	1	3	2	0	0	0	6
C20-262	Brown U	Rucaparib + copanlisib	Closed	0	0	0	1	0	0	0	1
c20-263	UCSF	BXCL701	Closed	4	0	7	3	3	3	0	20
c20-268	JHU	ARCUS	Not yet open	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
c21-273	UCSF	AMG 757	Open	0	0	0	0	1	3	0	4
c21-278	OHSU	GAP4	Not yet open	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
c21-282	TJU	AMG 509	Open	0	0	0	0	0	1	2	3
c21-284	MSKCC	AMG 160	Closed	0	0	0	0	1	0	0	1
c21-285	UCSF	ZEN-3694	Open	0	0	2	6	16	2	7	33
c22-298	UCSF/U of Michigan	Enzalutamide +/- ZEN-3694	Open	0	0	0	0	0	1	2	3
c22-312	UCSF	PLANETTE	Closed	0	0	0	0	6	3	0	9
c23-316	UCSF	Genomic Decision Tool	Not yet open	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
c22-205	NWU	ARACOG	Open	0	0	0	0	0	2	3	5
c23-326	Cornell	ARX517	Open	0	0	0	0	0	0	7	7
c23-327	DFCI	Nat History Study Precision Genomics	Not yet open	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
c23-329	UCSF	Ra-223 in Optimally	Not yet open	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

	Selected Patients									
Total Accrual			**38**	**17**	**20**	**26**	**43**	**22**	**25**	**191**

Table C. Accrual in Annual Progress Report Period (10/1/2022 – 9/30/2023)

PCCTC #	Lead Institution	Study Title	Accrual Status at UCSF	Patient Enrollment Accrual Between 10/1/2022 – 3/31/2023	Patient Enrollment Between 4/1/23 – 9/30/2023	Total Patient Enrollment Between 10/1/22 – 9/30/23
c18-221	UCSF	FOR46	Closed	0	0	0
c19-242	UCSF	PILLAR	Open	2	2	4
c19-244	UCSF	ARV-110	Closed	0	0	0
c18-225	UMich	IMPACT	Closed	0	0	0
c19-241	UCSF	Poseida	Open	0	0	0
c20-259	UWash	CD3xPSMA BiTE/ JNJ-63898081	Closed	0	0	0
c20-257	Columbia	HPN424	Closed	0	0	0
c20-263	UCSF	BXCL701	Closed	0	0	0
c20-264	TJU	AMG 509	Open	0	2	2
c20-268	JHU	ARCUS	Pending activation	0	0	0
c21-273	UCSF	AMG 757	Closed	0	0	0
c21-278	OHSU	GAP4	Pending activation	0	0	0
c21-284	MSKCC	AMG 160	Closed	0	0	0
c21-285	UCSF	ZEN-3694	Open	4	3	7
c22-298	UCSF/U of Michigan	ZEN-201	Open	2	0	2
c22-312	UCSF	PLANETTE	Closed	0	0	0
c23-316	UCSF	Tumor genetic pre-test counseling tool for African-American men with prostate cancer	Pending activation	0	0	0
c22-305	Northwestern	ARACOG	Open	0	3	3
c23-326	Weill Cornell	ARX517	Open	0	7	7

c23-327	DFCI	Natural history study of precision-based genomics	Pending activation	0	0	0
c23-328	Duke	SX-682 plus enzalutamide	Pending activation	0	0	0
c23-329	UCSF	Radium-223 in optimally selected mCRPC patients	Pending activation	0	0	0
Total Number				**8**	**17**	**25**