AWARD NUMBER: W81XWH-21-1-0098

TITLE: Addressing Health Literacy with a Tailored Survivorship Care Plan to Improve Access in Underserved African American Prostate Cancer Patients

PRINCIPAL INVESTIGATOR: Kerry Kilbridge, MD, MSc

CONTRACTING ORGANIZATION: Dana-Farber Cancer Institute, Boston, MA

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6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Dana-Farber Cancer Institute, Inc.
450 Brookline Avenue
Boston, MA 02115-5418

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

In our previous work, we have documented that health literacy barriers impact the ability of many underserved African American prostate cancer patients to understand cancer treatment and its side effects. To address these barriers, the research team designed a scripted, low literacy educational supplement that demonstrated a statistically significant improvement in understanding of prostate cancer treatment side effects, and a statistically significant decrease in decisional conflict compared to usual care. Our project is a randomized comparative effectiveness study that is a direct extension of these findings. Our study randomizes 150 African American prostate cancer patients, in a 1:1 ratio, to a standard survivorship care plan (SCP) based on the American Society of Clinical Oncology (ASCO) template versus a tailored SCP combined with the low literacy educational supplement. The team has encountered multiple Covid-related delays in the project period. The first major subtask was completed: the subcontract between Dana-Farber Cancer Institute and Emory University was executed in month 12. The completion of this subtask will allow the research team to move forward with crucial next subtasks to achieve the first to fifth major milestones starting with multi-institutional IRB/HRPO approvals and initial data collection in the next reporting period.

15. SUBJECT TERMS

Health disparities, health literacy, survivorship, African American prostate cancer patients, survivorship care plan, access

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1. INTRODUCTION:

In our previous work, we have documented that health literacy barriers impact the ability of many underserved African American prostate cancer patients to understand cancer treatment and its side effects. To address these barriers, the research team designed a scripted, low literacy educational supplement that demonstrated a statistically significant improvement in understanding of prostate cancer treatment side effects, and a statistically significant decrease in decisional conflict compared to usual care. Our project is a randomized comparative effectiveness study that is a direct extension of these findings. Our study randomizes 150 African American prostate cancer patients, in a 1:1 ratio, to a standard survivorship care plan (SCP) based on the American Society of Clinical Oncology (ASCO) template versus a tailored SCP combined with the low literacy educational supplement. We compare 1) understanding of survivorship care and recommendations, 2) understanding of treatment side effects and their prevalence, 3) decisional conflict, 4) decision regret 5) access to survivorship care. Results will be immediately applicable for early-stage African American prostate cancer survivors with low literacy skills. Improving understanding of treatment side effects and cancer surveillance directly addresses the PCRP Overarching Challenge of "improving quality of life for survivors of prostate cancer".

2. KEYWORDS:

Health disparities, health literacy, survivorship, African American prostate cancer patients, survivorship care plan, access

3. ACCOMPLISHMENTS:

- **What were the major goals of the project?**

The major goals of the project as stated in the approved SOW during the initial year of the project are listed in the chart below. Target completion date and completion or percent completion are shown in columns 2 and 3.

	Target Completion Date	Completion Date or % Completion
Milestone 1 – IRB & HRPO approvals Emory, DFCI, HRPO	Month 9	10% complete
• Subtask 1– subcontract between DFCI & Emory executed	Month 1-2	May 2022 (Month 12)
• Subtasks 2 to 6 – prepare regulatory documents and obtain IRB approvals	Month 1-9	5% complete
Milestone 2 – access database operational	Months 4-8	0% complete
Milestone 3 – research staff trained	Months 9-10	0% complete
Milestone 4 – initial accrual and data analysis	Months 11-13	0% complete

DFCI – Dana-Farber Cancer Institute
IRB – Institutional Review Board

HRPO – Human Research Protection Office

- **What was accomplished under these goals?**
  The goals of completing Milestones 1-3 and initiating Milestone 4 were not met. However, the first and most important rate-limiting subtask was accomplished at the end of the reporting period: the subcontract between Dana-Farber Cancer Institute and Emory University was executed in month 12. The completion of this subtask will allow the research team to move forward with crucial next subtasks to achieve the first major milestone of IRB/HRPO approvals:
  Subtask 3: Perform multidisciplinary review of updated script by team members in urology, radiation oncology and medical oncology
  Subtask 4: Approval of consent forms & human subjects protocol for Emory, Grady, Atlanta VAMC (Grady & VAMC are contingent on Emory)
  Subtask 5: Approval of retrospective records review protocol by DFCI IRB (contingent on Emory, Grady & VAMC approvals)
  Subtask 6: 2nd level IRB review & approval by ORP/HRPO (contingent on DFCI, Emory, Grady & VAMC approval)

  Once subtask 3 is accomplished, the research team will work in parallel to complete the second and third milestones. These milestones are not contingent on IRB approvals.
  Milestone Achieved: Access database operational
  Milestone Achieved: Research staff trained

- **What opportunities for training and professional development has the project provided?**
  Nothing to report

- **How were the results disseminated to communities of interest?**
  Nothing to report

- **What do you plan to do during the next reporting period to accomplish the goals?**
  In the next reporting period, we will meet the major goals of the project initially scheduled for the first year of the project. We will:
  1. Prepare regulatory documents and research protocols for all 4 project sites.
  2. Obtain approval of consent forms and human subjects protocols at the Emory University IRB, Grady Memorial Hospital, and the Atlanta VAMC. Grady and VAMC approvals are contingent on Emory IRB approval. The Dana-Farber Cancer Institute (DFCI) IRB Approval of retrospective records review protocol (initially scheduled in months 7-8) is contingent on Emory, Grady and VAMC human subjects approvals (initially scheduled months 1-6).
  3. Obtain second level IRB review and approval by ORP/HRPO.
  4. Program the Access database and train research staff with the database
  5. Complete initial target subject accrual and initial data analysis.
  6. Begin initial data analysis in preparation for dissemination of interim reports to senior staff and co-investigators when initial data analysis is complete.

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**
  Nothing to report

- **What was the 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:**

- **Changes in approach and reasons for change**
  Nothing to report - There have been no changes in objectives and scope of the project.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  We have encountered two Covid-related delays since we submitted our semi-annual technical progress report. First, the execution of the subcontract between Dana-Farber Cancer Institute and Emory University was delayed from months1-2 to month 12. Second, the principal investigator, Dr Kilbridge, is recovering from additional pandemic-related serious health issues. To resolve these problems, Dr Kilbridge is taking intermittent family and medical leave to decrease her clinical activities and is beginning to increase her research activities. There are no changes to the budget or budget justification. There is no change to the scope of work. We are offsetting the project timeline (SOW) by one year and anticipate requesting a no cost extension of one year.

- **Changes that had a significant impact on expenditures**
  Due to the delay in the execution of the subcontract between Dana-Farber Cancer Institute and Emory University, no Emory University personnel have drawn on the budget. Due to the necessity of medical leave, Dr. Kilbridge effort has been less than budgeted in the initial reporting period. There are no changes to the budget or budget justification. There is no change to the scope of work. We are offsetting the project timeline (SOW) by one year and anticipate requesting a no cost extension of one year.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
  Nothing to report

- **Significant changes in use or care of human subjects**
  Nothing to report

- **Significant changes in use or care of vertebrate animals**
  Nothing to report

- **Significant changes in use of biohazards and/or select agents**
  Nothing to report

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**
  Nothing to report

- **Website(s) or other Internet site(s)**
  Nothing to report

- **Technologies or techniques**
  Nothing to report

- **Inventions, patent applications, and/or licenses**
  Nothing to report

- **Other Products**
  Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	*Kerry Kilbridge*
Project Role:	Co-Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0001-7460-6273
Nearest person month worked:	0 (0.18 Cal Months)
Contribution to Project:	*Dr. Kilbridge is coordinating the preparation of regulatory documents and IRB approvals. She will oversee study design, data collection, data analysis, manuscript preparation, presentation and dissemination of findings.*
Funding Support:	

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

Previous, Current, and Pending Support

Kilbridge, Kerry

PREVIOUS (past five years):

W81XWH-13-1-0274 (Kilbridge, Master)
Department of Defense 09/30/13 – 09/29/17
Improving Health Literacy in African-American Prostate Cancer Patients
Goals/Aims: 1) Characterize health literacy in a group of newly diagnosed, early stage, African American prostate cancer patients across five empirical domains; 2) Assess comprehension of prostate cancer treatment options and side effects in this group of patients after they meet with their urologist to discuss their treatment alternatives; 3) Deliver a scripted, low literacy educational supplement that explicitly addresses each domain of health literacy to tailor content and augment the information that patients receive from their urologists; 4) Compare outcomes after patients meet with their urologist and after receiving the low literacy supplement to quantify the potential benefit of a targeted health literacy supplement over and above standard practice; 5) Compare urologists' assessment of patients' health literacy, preferences for side effects, stage of decision making, treatment choice or predisposition toward treatment choice, preference for role in decision making; to measures obtained from patients.
Role: Co-Principal Investigator
POC: Contracting Officer: Janet P. Kuhns; email: janet.p.kuhns.civ@mail.mil; phone: 301-619-2827

CURRENT:
R01HG011928-01 (Rana) **08/01/21 – 07/31/25** **0.60 CM**
National Institutes of Health
A Stakeholder Informed Randomized Trial of Pretest Video Education vs Standard Genetic Counseling for Cancer Patients: Evaluating the Impact on Patients, Providers and Practices
Goals/Aims: Major Goals: This proposal is relevant to public health because it will optimize the delivery of genetic testing and counseling services to cancer patients who are otherwise undertested and underdiagnosed with cancer predisposition. We will compare behavioral and patient reported outcomes of pretest Video Education with Result Dependent disclosure (VERDI) vs standard genetic counseling, to provide an evidence-based approach to modern cancer genetics care. We will evaluate the evolving role of genetic counselors as vital stakeholders in ensuring widespread implementation to expand access to genetics care.
Role: Co-Investigator
POC:
Program Director: Heather Colley; email: heather.colley@nih.gov; phone:

Prostate Cancer Disparities (Kilbridge, Master) 04/01/21 – 03/31/23 1.20 CM
American Cancer Society and Pfizer
Addressing Health Literacy to Improve Shared Decision Making in Newly Diagnosed African American Prostate Cancer Patients
Goals/Aims: 1) Identify a shared vocabulary for common prostate cancer terms based on patients' preferred terminology for urinary, bowel and sexual function and using the video-based educational tool; 2) Use this shared vocabulary to review the patient's treatment choices, to assess his preferences and values, and to teach pertinent prostate anatomy; 3) Supply the patient's provider with each patient's preferred terms for GU function, his values and preferences associated with cancer treatment options, and his desired role in decision making -- to foster shared decision making.
Role: Co-Principal Investigator
POC:

Pfizer Grant Officer: Jacqueline Waldrop; email: Jacqueline.Waldrop@pfizer.com
Director, Information: Karla Wysocki; email: Karla.Wysocki@cancer.org

W81XWH-21-1-0098 (Kilbridge, Master) 4/15/21-4/14/24 2.40 CM Department of Defense

Addressing Health Literacy with a Tailored Survivorship Care Plan to Improve Access in Underserved African American Prostate Cancer Patients.

Goals/Aims: 1) To characterize health literacy in a group of early stage, African American prostate cancer survivors following primary treatment across five empirical domains; 2) To assess comprehension of survivorship care recommendations and prostate cancer treatment side effects in this group of patients after they have received standard care from their providers (standard practice) including an unmodified ASCO prostate cancer survivorship care plan; 3) To deliver an adapted, low literacy version of the ASCO prostate cancer survivorship care plan with a scripted, one-time, educational supplement that explicitly addresses each domain of health literacy to tailor content and augment the information that patients receive from their providers; 4) To compare outcomes after patients receive usual care from their providers, and after they receive the low literacy survivorship care plan with the educational supplement, to quantify the potential benefit of a tailored survivorship care plan over and above standard practice.

Role: Co-Principal Investigator

POC:

Grants Specialist: Michelle L. Cromwell; email: michelle.l.cromwell.civ@mail.mil; phone: 301-619-4024

Overlap:

There is no budgetary or scientific overlap

PENDING:

None

Previous, Current, and Pending Support

Master, Viraj

PREVIOUS (past five years):

AP311736 (Master) 03/06/2014-03/06/2020
Quintiles/IQVIA RDS, Inc.
Adjuvant Axitinib Treatment of Renal Cancer: A Randomized Double-Blind Phase 3 Study of Adjuvant Axitinib vs. Placebo in Subjects at High Risk of Recurrent RCC
The primary objective of this study is to demonstrate an improvement in disease free survival in patients at high risk of recurrent RCC randomly assigned to adjuvant axitinib vs. Placebo after nephrectomy.
Contact: Jodi Andrews
333 West San Carlos St., Suite 800
San Jose, CA 95110
Sfj-atlas-payments@protrials.com

(Gillespie) 03/01/2015-03/01/2020
Movember/LiveStrong
Prostate Survivorship Research Network- True NTH
Objectives are: Improve the physical and mental wellbeing of men diagnosed and living with prostate cancer, together with their partners, caregivers and families; Develop and implement scalable, sustainable interventions that significantly improve the quality of lives of people impacted by prostate cancer; Design, implement, and evaluate a novel, web-based resource for prostate cancer symptom identification and self-management of the symptom dysfunctions that occur from prostate cancer or its treatment or from caring for prostate cancer survivors.
Role: Co-Investigator
Contact: Movember Foundation Livestrong Foundation
8559 Higuera St 2201 E 6th St
Culver City, CA 90232 Austin, TX 78702

R01CA156775 (Fei) 01/01/2011-06/30/2019
NIH
Molecular Imaging Directed, 3D Ultrasound-guided, Biopsy System
The major goal of this project is to develop a molecular image-directed, 3D ultrasound-guided biopsy system for targeted biopsy of the prostate.
Specific Aim 1: To modify a real-time, mechanically assisted, 3D ultrasound-guided device. Compared to conventional 2D image guidance, 3D images of the prostate will be used to guide the biopsy.
Specific Aim 2: To develop fast deformable and statistical appearance model-based segmentation methods for 3D ultrasound images of the prostate. Statistical shape models will be developed from our database and will be used to guide automatic segmentation of the prostate.
Specific Aim 3: To combine FACBC molecular images with 3D ultrasound for targeted biopsy. New deformable image registration methods based joint saliency map and fuzzy point correspondence will be developed in order to solve major limitations of mutual information-based image registration.
Specific Aim 4: To test the accuracy of the integrated biopsy system in phantoms and animals.
Role: Co-Investigator
Contact: Pushpa Tandon
tandonp@mail.nih.gov

ESC-15-002 (Master) 05/31/2016-05/30/2017

Ethicon Endo-Surgery
A Prospective, Randomized, Controlled, Multi-Center Evaluation of a Powered Vascular Stapler in Laparoscopic Nephrectomies and Nephoureterectomies
The primary objective of this trial is to demonstrate that the frequency of hemostatic interventions/procedures required intra-operatively or post-operatively related to the transection of the rental artery and renal vein during laparoscopic nephrectomies and nephroureterectomies with powered vascular stapler is not increased when compared to standard of care.
Contact: Jaime Connelly
4545 Creek Rd
Cincinnati, OH 45242

W81XWH-13-1-0274 (Kilbridge) 02/01/2016-09/29/2018
Department of Defense/Dana-Farber Cancer Institute (Emory subcontract only)
Improving Health Literacy in African American Prostate Cancer
Specific Aims:
1) Characterize health literacy in a group of newly diagnosed, early stage, clinical T1-T2 African American prostate cancer patients across five empirical domains and
2) Assess comprehension of prostate cancer treatment options and side effects in a group of patients after they meet with their urologist to discuss their treatment alternatives
3) Primary Study – Deliver a scripted, low literacy educational supplement that explicitly addresses each domain of health literacy to tailor content and augment the information that patients receive from their urologists.
4) Using interview data, compare outcomes after patients meet with their urologist and after receiving the low literacy supplement to quantify the potential benefit of a targeted health literacy supplement over and above standard practice.
5) Compare urologists' assessment of patients' health literacy, preferences for side effects, stage of decision making, treatment choice, and preference for role in decision making to measures obtained from patients.
Role: Co-Investigator
Contact: Robert Dean, Contract Specialist,
Robert.t.doan4.civ@mail.mil

Pfizer, Inc. (Protocol #A6181109) (Master) 08/25/2010-08/24/2018
S-TRAC Clinical Trial
Sunitinib Treatment of Renal Adjuvant Cancer A Randomized Double-Blind Phase 3 Study of Adjuvant Sunitinib vs. Placebo in Subjects at High Risk of Recurrent RCC.
Contact: Pfizer Inc., HQ strategy Lead
235 E. 42nd St
MS 685/13/1
New York, New York 10017

R01CA204254 (Fei) 12/08/2016-11/30/2021
NIH (years 4 & 5 only)
Academic-Industrial Partnership for Translation of PET/TRUS Guided Intervention
Through this academic-industrial partnership between Emory and Eigen, we will combine highly sensitive PET molecular imaging with real-time ultrasound for the management of prostate cancer patients on active surveillance.
Hypothesis: PET/ultrasound fusion targeted biopsy can detect more high-risk cancers than the standard transrectal ultrasound (TRUS) guided biopsy in prostate cancer patients on active surveillance.
Aim 1: Develop a learning-based 3D segmentation algorithm for the prostate on PET/CT images. Segmentation of the prostate on PET/CT is challenging but is important for the guidance of targeted biopsy. Sub-Aim 1a: Create a training and

incremental learning algorithm based on our PET/CT data of 130 patients. Sub-Aim 1b: Develop and validate a learning-based segmentation method for the prostate on CT images.
Aim 2: Optimize a fast, graph theory based segmentation method for 3D ultrasound of the prostate. The current segmentation approach in Artemis requires manual segmentation and editing by the urologist and occupies 20% of the biopsy time for each patient. We will develop fast, random walk segmentation methods to save the urologist's time. Our benchmark is to achieve a Dice similarity coefficient (DSC) of ≥ 90%.
Aim 3: Optimize our deformable registration and validate the accuracy of our targeted biopsy system. Sub-Aim 3a: Optimize our deformable registration method for prostate PET/CT and 3D ultrasound images. Sub-Aim 3b: Create deformable phantoms to validate the accuracy of PET/ultrasound targeted biopsy. Sub-Aim 3c: Validate the accuracy of the targeted biopsy for follow-up biopsy of the original tumor site. Aim 4: Test the PET/ultrasound fusion targeted biopsy system in active surveillance (AS) patients. Sub-Aim 4a: Conduct and compare 68Ga-PSMA and 18F-FACBC PET/CT in active surveillance patients. Sub-Aim 4b: Determine whether our PET/ultrasound targeted biopsy can identify patients with high-risk cancer who may not be legible for AS but are missed by the standard TRUS-guided biopsy in this pilot study.
Role: Co-Investigator
Contact: George O Redmond
redmondg@mail.nih.gov

(Protocol # AGS-003-007) (Master) 12/05/2012 – 12/04/2020
Medpace, Inc.
An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS 003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT)
The purpose of this study is to determine the effectiveness of AGS-003 against kidney cancers.
Primary Objective:
• To compare overall survival (OS) between study arms in subjects treated with AGS-003 in combination with standard treatment (combination arm) versus active control of standard treatment alone (control arm)
Secondary Objectives:
• To compare safety assessments between study arms
• To compare progression free survival (PFS) based on Response Evaluation Criteria in Solid Tumors (RECIST)1.1 between study arms
• To compare tumor responses based on RECIST 1.1 between study arms
Contact: Jennifer L Cutter
5375 Medpace Way
Cincinnati, OH, 45227
j.cutter@medpace.com

CURRENT:
PTC1101.011-C (Master) 08/18/2017-08/17/2027 0.12 calendar
CryoLife, Inc.
Prospective, Multicenter, Multidisciplinary, Controlled Clinical Investigation Evaluating the Safety and Efficacy of PerClot® Polysaccharide Hemostatic System
The purpose of this research study is to find out if PerClot is safe and effective as a part of surgery to stop bleeding. This research study will look at how safe and effective PerClot is compared to another currently approved topical hemostat. We plan to include about 324 patients.
The primary objective of this investigation is to demonstrate non-inferiority in the achievement of hemostasis of the treated bleeding site at 7 minutes in subjects receiving PerClot compared to subjects receiving a control hemostatic device. The secondary objective of this investigation is to compare th achievement of hemostasis of

the treated bleeding site at 5 minutes in subjects receiving PerClot compared to subjects receiving a control hemostatic device.
Contact: Scott B Capps
1655 Roberts Blvd NW
Kennesaw, GA 30144
Capps.scott@cryolife.com

WO39210 (Master) 12/01/2016-11/30/2026 0.12 calendar
Genentech /Hoffmann-LaRoche
Phase III, Multicenter, Randomized Placebo-Controlled, Double-Blind Study of Atezolizumab (ANTI-PD-L1 Antibody) as Adjuvant Therapy in Patients with RCC at High Risk of Developing Metastasis Following Nephrectomy
Primary Efficacy Objective: To evaluate the efficacy of adjuvant treatment with atezolizumab
Other Objectives:
To evaluate the efficacy of adjuvant treatment with atezolizumab
To evaluate the safety and tolerability of atezolizumab in the adjuvant setting
To characterize the PK profile of atezolizumab
To evaluate the immune response to atezolizumab
To explore the potential relationship of the immunogenic response
To assess predictive, prognostic, and pharmacodynamic exploratory biomarkers in archival and/or fresh tumor tissue and blood and their association with disease recurrence
To document patients' perspective regarding treatment tolerability and health-related quality of life
To measure health status for health economic modeling
To assess surgical outcomes including complications rates
Contact: Nan Wang
1 DNA Way
South San Francisco, CA 94080
Wang.nan@gene.com

BMS (Master) 09/24/2018-089/23/2028 0.36 calendar
Bristol Myers Squibb
CA209-9UT-0056: A Phase 2, Randomized, Open-label Study of Nivolumab or Nivolumab/BMS-986205 Alone or Combined with Intravesical BCG in Participants with BCG-Unresponsive, High-Risk, Non-Muscle Invasive Bladder Cancer
The current study aims to demonstrate that treatment with nivolumab, alone or in combination with BMS-986205, and with or without intravesical bacillus Calumette-Guerin (BCG) will be efficacious in participants with BCG-unresponsive non-muscle-invasive bladder cancer (NMIBC). Additional objectives of the study include characterization of safety and tolerability, pharmacokinetics, potential predictive biomarkers, and changes in patient-reported outcomes (PRO) for quality of life assessments.
Contact: Gary D. Grossfeld, MD, MPH, Study Director / Medical Monitor
3401 Princeton Pike
Lawrenceville, NJ 08648
Gary.Grossfeld@bms.com

ECD-AUR87A001 (Master) 12/03/2019-12/02/2029 0.12 calendar
Elypta AB
AURORAX-0087A (AUR87A) Study Protocol

Glycosaminoglycan scores for surveillance of recurrence in Leibovich points ≥5 non-metastatic clear cell renal cell carcinoma
The primary objective is to produce level 1b evidence that a blood or urine or combined GAG score increase - indicative of GAG recurrence - detects post-operative radiological recurrence in LP ≥5 non-metastatic ccRCC justifying the intended use as monitoring biomarkers.
The secondary objectives are:
• To demonstrate that GAG recurrence predicts post-operative radiological recurrence justifying the intended use as post-operative prognostic biomarkers.
• To determine the correlation between pre-operative GAG scores and survival outcomes justifying the intended use as pre-operative prognostic biomarkers.
Grant Official: Saeed Dabestani, M.D. Ph.D.

saeed.dabestani@gmail.com
Overlap: None

IST76 WINSHIP4643-19 (Bilen) 07/15/2019-07/14/2024 0.12 calendar
EXELIXIS
A Phase 2 Study of Neoadjuvant Cabozantinib in Patients with Locally Advanced Non-metastatic Clear Cell Renal Cell Carcinoma
Role: Co-Investigator
Primary objective:
• To assess the objective response rate (complete and partial responses), following the administration of cabozantinib for 12 weeks in patients with locally advanced biopsy-proven non-metastatic ccRCC prior to undergoing surgery.
Secondary Objectives:
• To assess the safety, and tolerability of neoadjuvant cabozantinib.
• To determine the clinical outcome (DFS, OS) of patients with non-metastatic ccRCC who treated with neoadjuvant cabozantinib.
• To evaluate the surgery related outcomes.
• To evaluate correlative studies, including biomarkers, quality of life, and frailty/sarcopenia assessment of patients with non-metastatic ccRCC who are treated with neoadjuvant cabozantinib.
Program Official: Gisela Schwab, President, Product Dev and Med Affairs & CMO
1801 Harbor Bay Parkway
Alameda, CA 94502
Overlap: None

R01CA226992 (Jani, Shuster, MPI) 05/01/2019-04/30/2024 0.24 calendar
NIH/NCI
Advanced PET-CT Directed Post-Prostatectomy Radiotherapy to Enhance Prostate Cancer Outcomes
Specific Aim 1: Improve the outcomes of post-prostatectomy radiotherapy prostate cancer patients via selection and treatment optimization with advanced molecular imaging with dose escalation. We will conduct a prospective 140 patient trial with subjects randomized (70 in each arm) to either fluciclovine (^{18}F) or ^{68}Ga PSMA PET/CT, in each case boosting areas of PET uptake. The hypothesis is that advanced molecular imaging in either or both arms will increase 2-year disease-free survival by 15% (over the disease free survival in the current trial without dose-escalation), without added toxicity.
Exploratory Sub-aim 1A: We hypothesize that positive specific tissue biomarker signatures, when combined with standard risk criteria and findings from molecular imaging with fluciclovine or PSMA
PET, have added value in predicting successful salvage radiotherapy outcomes. To this end, we will build a regression model predictive of outcome (which also includes standard pathologic risk factors and PSA kinetics)

in a subset of the estimated 100 recurrence patients for whom we will have access to previously resected primary prostate tissue obtained from our ongoing EDRN.
Specific Aim 2: Establish the role of advanced molecular imaging with fluciclovine (18F) and 68Ga PSMA PET/CT in influencing post-prostatectomy radiotherapy decision-making.
We will analyze the two cohorts of patients in Specific Aim 1, comparing initial (pre-PET/CT) versus final (post-PET/CT) treatment decisions regarding (a) the decision to offer post-prostatectomy radiotherapy, (b) the delineation of extent (bed versus pelvis) and clinical and planning target volumes, and (c) boosting areas of PET/CT uptake.
Specific Aim 3: Establish the role of advanced molecular imaging with fluciclovine (18F) or 68Ga PSMA in altering radiotherapy treatment volumes.
For this technical aim, we will determine the impact of advanced PET/CT on the two patient cohorts with respect to (a) target volumes, and (b) the planned dose delivered to surrounding normal structures (bladder, rectum, and penile bulb), and (c) toxicity profiles.
Program Official: Bhadrasain Vikram
vikramb@mail.nih.gov

Overlap: None

Misp#58517 (Bilen, Master) 05/07/2020-05/06/2030 0.3 calendar
Merck and Company
Phase 2 Neoadjuvant Lenvatinib Plus Pembrolizumab in Locally Advanced, Non-Metastatic Clear Cell Renal Cell Carcinoma
Role: Co-Investigator
Specific Aims:
Primary Objective: To assess the objective response rate (complete and partial responses), following the administration of lenvatinib and pembrolizumab for a total of 4 cycles (12 weeks) in patients with locally-advanced, biopsy-proven non-metastatic ccRCC prior to undergoing nephrectomy (partial or radical).
Secondary Objectives
- To assess the safety and tolerability of neoadjuvant lenvatinib plus pembrolizumab in apresurgical population.
- To determine the clinical outcomes including disease-free survival (DFS) and overall survival (OS) of patients with non-metastatic ccRCC treated with neoadjuvant lenvatinib and pembrolizumab.
- To evaluate surgery-related complications and outcomes as per the Clavien-Dindo classification system

Exploratory Objectives
- To evaluate changes in biomarkers of immune activation and gene expression before, during and after treatment
- To assess the quality of life, frailty and sarcopenia of patients before and after treatment

Program Official: Christina McAnally
Christina.mcanally@merck.com
Overlap: None

W81XWH2010526 (Kissick, Initiating PI) 09/15/2020-09/14/2023 0.6 calendar
Department of Defense
CD8 T-Cell Infiltration as a Predictor of Renal Cancer Progression after Surgery
Role: Partnering PI
Specific Aims:
Improved patient survival caused by CD8 T-cell infiltration in RCC requires an APC niche in the tumor

The objectives of this proposal are to use this hypothesis to develop a biomarker to decide which patients will rapidly progress after surgery, and to understand the fundamental biology that causes low T-cell infiltration into kidney tumors. This will be achieved by completing the following aims:
1. Validate FFPE quantification of CD8 infiltration into tumors as a biomarker of disease progression and response to immunotherapy
2. Determine the role of de-novo generated fibroblastic reticular cells (FRCs) in the maintenance of a supportive antigen-presenting niche
Grants Officer: CDMRP

help@eBRAP.com
Overlap: None

RAD-IFN-CS-003 (Master) 12/15/2016-12/14/2024 0.12 calendar
MedPace
A Phase III, Open Label Study to Evaluate the Safety and Efficacy of INSTILADRIN® (rAd-IFN/Syn3) Administered Intravesically to Patients with High Grade, BCG Unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC)
Role: PI
Aims: To evaluate the incidence of Event-Free Survival at 12 months, where Event-Free Survival is defined as High-Grade-Recurrence Free Survival.
Contact: Brad Hansman

Overlap: None

42756493BLC2003 (Master) 09/10/2020-09/09/2030 0.12 calendar
Janssen Research and Development, LLC
A Randomized, Phase 2 Study of Erdafitinib versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guerin (BCG) and Recurred with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR
Role: PI
Aims: To evaluate RFS in subjects treated with erdafitinib vs Investigator's Choice, for subjects with high-risk NMIBC who harbor FGFR mutations or fusions, and who recurred after BCG therapy
Contact: Mahadi Baig
Mbaig8@its.jnj.com

Overlap: None

UWSC11289 / PO: BPO41997 (Gore) 02/01/2019-01/31/2024 0.12 calendar
PCORI/University of Washington
CISTO: Comparison of Intravesical Therapy and Surgery as Treatment Options for Recurrent Bladder Cancer
Role: Emory Sub PI
Aims: We believe that bladder removal will be better than medical management with respect to patient-reported, caregiver-reported, and patient-centered outcomes for some patients based on their personal characteristics and preferences.
Contact: Julie Taylor
Office of Sponsored Programs
Box 359472
Seattle, WA 98195-9472
jultay@u.washington.edu

Overlap: None

QBGJ398-302 (Master) 06/20/2020-06/19/2030 0.24 calendar
QED Therapeutics
Phase 3, Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial of Infigratinib for the Adjuvant Treatment of Subjects with Invasive Urothelial Carcinoma with Susceptible FGFR3 Genetic Alterations (PROOF 302)
Role: PI
Aims:
Contact:
Overlap: None

89Zr-TLX250 (Master) 07/22/2020-07/21/2030 0.60 calendar
Telix International Pty, LTD
A confirmatory, prospective, open-label, multi-centre phase 3 study to evaluate diagnostic performance of 89Zirconium-labelled girentuximab(89Zr-TLX250) to non-invasively detect clear cell renal cell carcinoma (ccRCC) by positron emission tomography/CT (PET/CT) imaging in patients with indeterminate renal masses (ZIRCON study)
Role: PI
Aims: To evaluate sensitivity and specificity of qualitative assessment of PET/CT imaging with 89Zr-TLX250 to noninvasively detect ccRCC in patients with indeterminate renal masses, using histology as standard of truth.
Contact:
Overlap: None

CMN-001-01 (Master) 05/25/2021-05/24/2031 0.12 calendar
Medpace
A Phase 2b Randomized Trial of Autologous Dendritic Cell Immunotherapy (CMN-001) plus Standard Treatment of Advanced Renal Cell Carcinoma
Role: PI
Aims: To evaluate CMN-001 in a randomized trial between SOC (first line pilimumab+nivolumab followed by second line lenvatinib+everolimus) with or without CMN-001
Contact:
Overlap: None

PENDING

(Gore) 11/01/2022-10/31/2027 0.12 calendar
PCORI/University of Washington
Chemo Radiation or Cystectomy for Urothelial Bladder Cancer Study (CROCUS)
Role: Emory Sub PI
Aims: To compare patient-reported and patient-centered clinical outcomes between patients undergoing radical cystectomy and those receiving bladder-sparing chemoradiation for muscle-invasive bladder cancer (MIBC). To characterize the heterogeneity of treatment effects for patients undergoing radical cystectomy and bladder-sparing chemoradiation and corresponding patient and provider preferences for MIBC.
Contact: Julie Taylor
Office of Sponsored Programs
Box 359472
Seattle, WA 98195-9472
jultay@u.washington.edu

Overlap: None

R01CA269891 (Kissick) 09/01/2022-08/31/2027 0.6 calendar
NIH/NCI
Mechanisms controlling the CD8 T-cell response to Renal Cell Carcinoma
Role: Co-Investigator
Specific Aims:
Aim 1: Define the cells that make up the neighborhoods of TCF1+ CD8 T-cells in kidney tumors
Aim 1A) Characterization of the composition immune outposts in renal cell tumors by IF
Aim 1B) Compare co-stimulatory molecules expression in the immune niche of hot and cold tumors
Aim 2: Determine which co-stimulatory molecules and cytokines are sufficient to cause TCF1+ CD8 T-cells to differentiate to effectors
Aim 2A) Identify which IgSF and TNF family co-stimulatory molecules can cause differentiation of stem-like CD8 T-cells to the effector state
Aim 2B) Determine the role of 1L-18 and TNF family cytokines on differentiation of stem-like cells
Aim 3: Determine if co-stimulation and downstream signaling pathways are required for responsiveness to PD1 blockade using mouse models
Aim 3A) Determine if costimulatory molecules are required for stem-like CD8 T-cell differentiation to the effector state after PDL1 blockade
Aim 3B) Determine if constitutively active AP1 signaling can rescue anti-PDL1 refractory tumors
Program Official: Yin Liu
liuy@mail.nih.gov

Overlap: None

Previous, Current, and Pending Support

Filson, Christopher

PREVIOUS (past five years):

U24CA086368 (Wei, PI) 04/01/18-03/31/21
Univ. of Michigan/NIH/Fred Hutch CRC
EDRN Prostate MRI Biomarker Study and Reference Set
Sponsor Contact: Guillermo Marquez, Program Official, gm186p@nih.gov
The overall aims of the proposed renewal of the Data Management and Coordinating Center (DMCC) are to

(i) provide coordination of EDRN in order to enhance communication and collaboration among EDRN investigators and with general scientific communities;
(ii) coordinate EDRN validation studies;
(iii) disseminate cancer biomarker information to broader scientific communities and the public; and
(iv) manage the EDRN Core funds.

The project we will collect scans and samples to assist in the creation of a reference set.
Role: Site PI
Overlap: None

R01 CA208758 (Howard, PI) 04/01/17-03/31/20
NCI/NIH
Targeted Payment Cuts to Reduce Unproven Care
Sponsor Contact: Martinson Owusu, Grants Management Specialist, owusumo@mail.nih.gov, 240-276-6297
The study will examine the impact of Medicare payment cuts for intensity-modulated radiation therapy on the use of this treatment in breast and prostate cancer treatments.
1) To describe indication-specific trends in the use of IMRT
2) To estimate the impact of Medicare payment cuts on the use of IMRT
3) To estimate the impact of Medicare payment cuts on spending on IMRT
Role: Co-I
Overlap: None

R21 CA178296 (Allen, PI) 09/25/13-08/30/17
Tufts University Medical Center/NIH
Addressing Prostate Cancer Information Disparities with E-Health Technologies
Sponsor Contact: Veronica Chollette, Program Official, vc24a@nih.gov
Specific aims are to estimate the impact of PCSPrep on: (1) patients' PCS knowledge, decision self-efficacy, and decisional consistency; (2) providers' perceptions of patient engagement, concordance between provider/patient ratings of SDM; and (3) feasibility and acceptability of integrating PCSPrep into primary care practice. The ultimate goal is to reduce disparities in access to high quality information about PCS and to empower AA men to be active participants in their care. Results will not only inform decision-making for PCS, but can inform the development of interventions for other conditions or procedures that call for SDM.
Role: Site PI (Emory)
Overlap: None

R01 NR009692 (Berry, PI) 07/01/13-06/30/17
Dana Farber Cancer Institute/NIH
Personal Patient Profile-Prostate (P3P): A Randomized Multi-site Trial
Sponsor Contact: Michelle Hamlet, Program Official, hamletm@mail.nih.gov
The major goal of this project is to contribute to adaptation of P3P processes at Emory-affiliated Urology practices including Emory Midtown, Grady Hospital, Atlanta VAMC, and St. Joseph's Hospital.
Role: Site PI (Atlanta VAMC)
Overlap: None

CURRENT:

Mentored Research Scholars Grant 18-015-CPHPS (Filson, PI) 07/01/18 – 06/30/22 7.68 calendar
American Cancer Society
MRI-guided Prostate Biopsy: Maximizing Value and Optimizing Utilization
Sponsor Contact: American Cancer Society, Extramural Grants Department, 250 Williams St, NW, 6th Floor, Atlanta, GA, 30303; 404-329-7558; grants@cancer.org
Aim 1: To evaluate population-level patterns of adoption of MRI-guided prostate biopsies and determine the patient and physician contributions to variations in their use.
Aim 2: To compare effectiveness associated with MRI-guided prostate biopsies versus TRUS-guided biopsies.
Aim 3: To determine the clinical scenarios that provide the greatest value for MRI-guided prostate biopsy versus TRUS-guided biopsies.
Role: PI
Overlap: None

U48DP006377 (Kelger) 0.24 calendar
09/30/19-06/29/24 Centers for Disease Control
Emory Prevention Research Center
Sponsor Contact: Natalie Darling, CDC Project Officer, 1600 Clifton Rd., Atlanta, GA, 30333, 404-918-9767
Aims:
1) Coordinate communication and collaboration across MEW network
2) Lead partnerships with national and local health organizations to create pathways for the adoption and sustainability of self-management programs.
3) Implementation in a diverse Southern population with delivery through epilepsy clinics and community-based organizations; clinical as well as quality of life outcomes will be collected using a mobile phone application
4) Applying the RE-AIM framework (Reach, Efficacy, Adoption, Implementation and Maintenance) to identify organizational and participant-inherent factors that affect program adoption and to facilitate national adoption.
Role: Co-Investigator
Overlap: None

PENDING:

R01 (Filson) 12/01/2022-11/30/2026 2.40 calendar
NIH
Addressing Disparities in Prostate Cancer Active Surveillance through Risk Alignment of Surveillance Intensity

Aims:

Specific Aim 1: Identify factors associated with disparities among underserved AS patients regarding receipt of repeat biopsies *within the context of risk of grade reclassification*.

Specific Aim 2: Use a sequential mixed-methods approach to characterize patient and provider attitudes regarding use of repeat biopsy for AS and patient- and provider-level facilitators and barriers for implementing a risk calculator-based decision-support tool.
Specific Aim 3: Develop implementation strategies for a risk-calculator based intervention to optimize risk-aligned use of repeat biopsies for AS patients.
Role: PI
Overlap: None

- **What other organizations were involved as partners?**
    - **Organization Name:** Emory University
    - **Location of Organization:** Atlanta, Georgia
    - **Partner's contribution to the projec**t
        - **Facilities** –Emory University (including Grady Memorial Hospital and the Atlanta Veteran's Administration Medical Center which are clinical research sites affiliated with Emory).
        - **Collaboration** – Emory personnel are active collaborators including the following. Dr. Master is Co-Principal Investigator. Dr. Filson is Co-Investigator. Dr. Patel is assisting with programming the Access database and will oversee data analysis. Sierra Williams is providing research coordination.

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:**
  A collaborative report will be submitted to ebrap.org
- **QUAD CHARTS:**

STATEMENT OF WORK – July 13, 2020
PROPOSED START DATE – December 1, 2020

Site 1:	Dana-Farber Cancer Institute		Site 2:	Emory University
	Boston, MA			Atlanta GA
	PI: Kerry L. Kilbridge			Co-PI: Viraj Master
Site 3:	Grady Memorial Hospital		Site 3	Atlanta Veteran's Admin Med Ctr
	Atlanta, GA			Decatur, GA
	Co-PI: Viraj Master			Site-PI: Christopher Filson

Specific Aim 1: Characterize health literacy in a group of early stage, African American prostate cancer survivors across four empirical domains **Specific Aim 2:** Assess comprehension of survivorship care recommendations and prostate cancer treatment side effects in survivors after they receive a standard ASCO prostate cancer survivorship care plan (SCP)	**Timeline**	**DFCI**	**Emory**	**Grady**	**VAMC**
Major Task 1: Obtain IRB approvals	Months				
Subtask 1: Prepare and execute subcontract between DFCI & Emory	1-2	x	x		
Subtask 2: Prepare regulatory documents and research protocol for at all sites	1-4	x	x	x	x
Subtask 3: Perform multidisciplinary review of updated script by team members in urology, radiation oncology and medical oncology	2-4	x	x	x	x

Subtask 4: Approval of consent forms & human subjects protocol for Emory, Grady, Atlanta VAMC Grady & VAMC are contingent on Emory	4-6	x	x	x	x
Subtask 5: Approval of retrospective records review protocol by DFCI IRB contingent on Emory, Grady & VAMC approvals	7-8	x			
Subtask 6: 2nd level IRB review & approval by ORP/HRPO contingent on DFCI, Emory, Grady & VAMC approval	7-9	x	x		
Milestone Achieved: All IRB and HRPO approvals					
Major Task 2: Program Access database					
Major Task 3: Training of Study Staff and Operationalizing Subject Recruitment and Data Flow					
Subtask 1: Program Access database	4-8	x	x		
Subtask 2: Train research staff with database	9-10	x	x		
Subtask 3: Review data flow and operationalize subject recruitment, perform first interviews N=3-5	10-11	x	x	x	x
Milestone Achieved: Access database operational					
Milestone Achieved: Research staff trained					
Major Task 4: Initial Subject Recruitment and Data Collection					
Subtask 1: Initial target subject accrual: N=25-27 [cumulative total 30]	11-12	x	x	x	x
Subtask 2: Initial data analysis	12-13	x	x		
Milestone Achieved: Specific Aim 1: Characterize health literacy in a group of early stage, African American prostate cancer survivors across four empirical domains Specific Aim 2: Assess comprehension of survivorship care recommendations and prostate cancer treatment side effects in survivors after they receive a standard ASCO prostate cancer (SCP)					
Milestone Achieved: Dissemination of interim reports					
Specific Aim 3: Tailor content of the ASCO prostate cancer SCP by explicitly addressing each domain of health literacy and deliver a low literacy educational supplement to augment information that patients get from their providers					
Major Task 5: Interval Subject Recruitment and Data Collection					
Subtask 1: Interval target subject accrual: N=60 [cumulative total 90]	12-24	x	x	x	x
Subtask 2: Interval data analysis	12-24	x	x		

Milestone Achieved: Dissemination of interim reports					
Milestone Achieved: Specific Aim 3 Tailor content of the ASCO prostate cancer SCP by explicitly addressing each domain of health literacy and deliver a low literacy educational supplement to augment the information that patients receive from their providers					
Specific Aim 4 & 5 Compare outcomes after patients receive A standard ASCO SCP versus A standard ASCO SCP + Tailored SCP + Ed Supp Compare providers' assessment of patients' outcomes to measures obtained from patients					
Major Task 6: Final Subject Recruitment and Data Collection					
Subtask 1: Final target subject accrual: N=60 [cumulative total 150]	24-33	x	x	x	x
Subtask 2: Final data entry	32-33	x	x		
Subtask 3: Complete data library	33-34	x	x		
Subtask 4: Complete descriptive statistical analysis and statistical comparisons of interview data	34-36	x	x		
Subtask 5: Perform multivariable modeling on predictors of understanding of survivorship care recommendations and access to survivorship care	34-36	x	x		
Subtask 6: Share output and findings with all investigators	34-36	x	x	x	x
Subtask 7: Complete summary reports, manuscript preparation, and submission	34-36	x	x	x	x
Subtask 8: Disseminate study findings to ASCO, the National Medical Association and the American Urological Association	35-36	x	x	x	x
Milestone Achieved: Specific Aim 4 & 5 Compare outcomes after patients receive A standard ASCO SCP versus A standard ASCO SCP + Tailored SCP + Ed Supp Compare providers' assessment of patients' outcomes to measures obtained from patients					
Milestone Achieved: Report results from data analyses					

Projected Quarterly Enrollment

	Year 1	Year 2	Year 3

Target Enrollment (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Grady				10	5	5	5	5	8	7	7	
Atlanta VAMC				20	10	10	10	10	12	14	12	
Target Enrollment (cumulative)				30	45	60	75	90	110	131	150	

Abbreviations List

ASCO	American Society of Clinical Oncology
DFCI	Dana-Farber Cancer Institute
IRB	Institutional Review Board
ORP/HRPO	Office of Research Protections/Human Research Protection Office
PI	Principal Investigator
SCP	Survivorship Care Plan
VAMC	Atlanta Veterans Administration Medical Center

9. **APPENDICES:**
   Nothing to report