

AWARD NUMBER: W81XWH-21-1-0731

TITLE: Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses

PRINCIPAL INVESTIGATOR: Robert Motzer

CONTRACTING ORGANIZATION: Sloan Kettering Institute for Cancer Research, New York, NY

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**PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012**

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| 14. ABSTRACT Clinical trial development has been critical for improving the outcomes of patients with kidney cancer, with the approval of 13 new treatments in the last 15 years. With proper oversight, clinical trials provide patients safe, early access to new medications that are promising. However, access to these novel treatments can be limited by the availability of expertise. Clinical research nurses (CRNs) are critical members of the patient's medical team that ensure that new medications can be delivered ethically, safely, and effectively. We hypothesize that having CRNs that are specialized in kidney cancer will improve the safety and tolerability of patients treated on clinical trials by improving the management of side effects and making sure patients adhere to the schedule and rules of the clinical trial. To improve the access of disease-specific CRNs, we propose a project with two specific aims: Specific Aim 1: Establish a kidney cancer-specific CRN training program (partnering PI) Specific Aim 2: Perform a pilot project to study the safety and quality of care when integrating telemedicine into clinical trial nursing | | | | | |
| 15. SUBJECT TERMS None listed. | | | | | |
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1. INTRODUCTION:

Clinical trial development has been critical for improving the outcomes of patients with kidney cancer, with the approval of 13 new treatments in the last 15 years. With proper oversight, clinical trials provide patients safe, early access to new medications that are promising. However, access to these novel treatments can be limited by the availability of expertise. Clinical research nurses (CRNs) are critical members of the patient's medical team that ensure that new medications can be delivered ethically, safely, and effectively. We hypothesize that having CRNs that are specialized in kidney cancer will improve the safety and tolerability of patients treated on clinical trials by improving the management of side effects and making sure patients adhere to the schedule and rules of the clinical trial.

To improve the access of disease-specific CRNs, we propose a project with two specific aims:
Specific Aim 1: Establish a kidney cancer-specific CRN training program (partnering PI)
Specific Aim 2: Perform a pilot project to study the safety and quality of care when integrating telemedicine into clinical trial nursing

2. KEYWORDS:

Clinical trial nursing, Training, Telemedicine

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: To establish a kidney cancer-specific fellowship program for CRNs

- Major Task 1: Train and orient CRN trainees who have limited experience in management of kidney cancer patients in research setting
- Major Task 2: Educate CRN trainees on kidney cancer pathophysiology, disease and symptom management, clinical research nursing practice, nursing research, and clinical trial operations

Specific Aim 2: To conduct a pilot research project providing research training experience to CRNs

- Major Task 1: Train and orient CRN trainees and CRA
- Major Task 2: Collection of safety and protocol compliance data from target populations
- Major Task 3: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption
- Major Task 4: To determine safety and protocol compliance as defined by rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption
- Major Task 5: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs

What was accomplished under these goals?

Specific Aim 2: To conduct a pilot research project providing research training experience to CRNs

- **Major Task 1** (*Train and orient CRN trainees and CRA*): We have completed Subtasks 1-3, which include identification and training of Stanley Liang as the CRA for the research project. We have also training Robert Goodman as CRN Trainee #1 for the research project, and Alisa Ritea is currently undergoing training and orientation as CRN Trainee #2.
- **Major Task 2** (*Collection of safety and protocol compliance data from target populations*): We have completed the design and generated the RedCap Database for data collection and formulated the dataline queries that will allow us to identify the patient who have been designated for telemedicine cohort 1 and 2. Retrospective chart review is ongoing.
 - o Ongoing: Subtask 4 (ongoing patient accrual as per timeline), Subtask 5 (ongoing data collection as per timeline)
- **Major Task 3** (*To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption*):
 - o Nothing to report
- **Major Task 4** (*To determine safety and protocol compliance as defined by rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption*):
 - o Completed: We have put together the dataline query that allows us to collate the rates of SAEs and grade 3/4 toxicities.
- **Major Task 5** (*To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs*):
 - o Completed: We have generated the questionnaire for both patients and providers regarding their perceptions of health outcomes. The questionnaire was IRB approved and integrated into our RedCap database.
 - o Ongoing: Subtask 3 as per schedule

What opportunities for training and professional development has the project provided?

CTN trainee 1, 2, 3 attending didactic lectures
CTN trainee 2, completed one on one mentoring
CTN trainee 1 completed participation in research project, trainee 2 has ongoing participation in research project,
CTN trainee 1, 2, 3 participated in journal club and weekly clinical trial research meetings.

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?

Research for specific aim 2 will be published in a manuscript describing the perceptions of telemedicine in clinical trial management.

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.

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report.

Changes that had a significant impact on expenditures

Nothing to report.

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

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to report.

Books or other non-periodical, one-time publications.

Nothing to report.

Other 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: Robert Motzer
Project Role: Principal Investigator
Research Identifier: 0000-0001-6925-2327
Nearest Person Month Worked: 1.8
Contribution to Project: Oversight of the overall project
Funding support: DOD

Name: Chung-Han Lee
Project Role: Key Personnel
Research Identifier: 0000-0001-5511-0635
Nearest Person Month Worked: 1
Contribution to Project: Oversight of the CTN research project and training of the CTNs in retrospective research
Funding support: DOD

Name: Ritesh Kotecha
Project Role: Key Personnel
Research Identifier: 0000-0002-0223-3479
Nearest Person Month Worked: 1
Contribution to Project: Training of the CTNs in retrospective research, management of the RedCap Database
Funding support: DOD

Name: Stanley Liang
Project Role: Clinical Research Associate
Research Identifier:
Nearest Person Month Worked: 8
Contribution to Project: Data entry and data management for the telemedicine research study
Funding support: DOD

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

Please see updated support documentation.

What other organizations were involved as partners?

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: This is a collaborative award between Dr. Robert Motzer, Initiating PI and Dr. Laurent Evans, Partnering PI. Two independent reports have been prepared.

QUAD CHARTS: Not applicable.

9. APPENDICES:

Completed

Title: Characterizing and Targeting the Microenvironmental Barriers to Immunotherapeutic Response in Renal Cell Carcinoma (W81XWH1910792)

Role: Co-Investigator

Sponsoring Agency: Department of Defense/Congressionally Directed Medical Research Programs

Effort: 0.12 CM

Level of Funding Amount (Direct Costs):

Performance Period: 9/30/2019–9/29/2022

Name of Grants Officer at Sponsoring Agency: Joshua McKean

Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014

Goals/Specific Aims: Aim 1, define the microenvironmental and molecular determinants of response to immune checkpoint blockade therapy in renal cell carcinoma. Aim 2, characterize and target macrophages and other microenvironmental features that promote primary resistance to immune checkpoint blockage and combination therapies using mouse models. Aim 3, elucidate the microenvironmental and genetic mechanisms of acquired resistance to immune checkpoint blockade and combination immunotherapy.

Overlap: None.

Title: Human Leukocyte Antigen Evolutionary Diversity—A Population-Specific Biomarker for Kidney Cancer Immunotherapy

Role: Mentor

Sponsoring Agency: Kidney Cancer Association

Effort: 0.60 CM

Level of Funding Amount (Direct Costs):

Performance Period: 10/1/2020–9/30/2021

Name of Grants Officer at Sponsoring Agency: Stephanie Shirley

Contact Information for Grants Officer: sshirley@kidneycancer.org |

Goals/Specific Aims: The goal of this project is to determine whether specific subtypes of localized and advanced renal cell carcinoma are more prevalent in different racial and ethnic subgroups.

Overlap: None.

Active

Title: Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses (KC200301)

Role: Principal Investigator

Sponsoring Agency: Department of Defense / Congressionally Directed Medical Research

Effort: 1.8 CM

Level of Funding (Direct Costs):

Performance Period: 09/30/2021 – 09/29/2023

Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer

Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014

Project Goals/Specific Aims: We propose the development of a formal RCC CRN fellowship program to provide clinical training alongside RCC-specific mentorship, didactic lectures, and clinical and translational research training. CRN Trainees will be paired one-to-one with CRN and Physician Mentors during the fellowship, which will contain a clinical orientation phase, an education phase, and a research phase.

Aim 1: To establish a kidney cancer-specific fellowship program for CRNs

Aim 2: To conduct a pilot research project providing research training experience to CRNs

Aim 2a: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption

Aim 2b: To determine safety and protocol compliance, defined as rates of SAEs, rates of grade 3 and 4 toxicity, and rates of protocol deviations before and after telemedicine adoption.

Aim 2c: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs.
Overlap: None.

Title: Evaluating HLA Class II Evolutionary Divergence as an Immunotherapy Specific Kidney Cancer Biomarker (KC200127)

Role: Mentor

Sponsoring Agency: Department of Defense/Congressionally Directed Medical Research

Effort: 1.2 CM

Level of Funding (Direct Costs):

Performance Period: 9/30/2021 – 9/29/2025

Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer

Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014 **Project**

Goals/Specific Aims: The goals of this project are to 1) determine whether predicted neoantigens peptides to be presented by HLA class I and II alleles are enriched in clear cell compared to non-clear cell RCC variants ; 2) determine whether HLA class II allelic repertoires and divergence (HED) correlate with treatment outcomes in clear cell RCC patients treated with ICI therapies ; 3) determine whether HLA class I and II alleles and composite HED correlates with treatment outcomes in a non-clear cell RCC prospective clinical trial employing VEGFR TKI and immunotherapy.

Overlap Statement: None.

Title: Integrated Analysis of Somatic Genomic Mutations and Antigen Presentation as Predictive Biomarkers for Combination Immunotherapy in Kidney Cancer (KC190157)

Role: Career Guide

Sponsoring Agency: Department of Defense/Congressionally Directed Medical Research Programs

Effort: 0.60 CM

Level of Funding Amount (Direct Costs):

Performance Period: 9/30/2020–9/30/2023 NCE

Name of Grants Officer at Sponsoring Agency: Joshua McKean

Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014 **Goals/**

Specific Aims: Aim 1, determine how tumor-specific mutations alter tumor mutation burden and the expression of mutated genes. Aim 2, determine the contribution of human leukocyte antigen diversity, tumor mutation burden, and somatic mutations as key components of tumor antigen burden and correlate tumor antigen burden to responses to nivolumab, tyrosine-kinase inhibitors and PD-1/PDL-1 inhibitors, and PD-1/PDL-1 and anti-CTLA-4 inhibitors.

Overlap: None.

Title: TOWARDS PRECISION IMMUNO-ONCOLOGY: UNRAVELING THE GENOMIC DETERMINANTS AND MECHANISMS UNDERLYING IMMUNOTHERAPY EFFICACY AND RESISTANCE

Role: Collaborator

Sponsoring Agency: National Cancer Institute

Effort: 0.80 CM

Level of Funding Amount (Direct Costs):

Performance Period: 5/1/2020 - 8/31/2025

Name of Grants Officer at Sponsoring Agency:

Contact Information for Grants Officer:

Goals/Specific Aims: The purpose of the MSK subcontract is to include Dr. Ming Li, Dr. Robert Motzer, and Dr. Michel Sadelain in this project. Dr. Li will collaborate for immune phenotyping and immune functional studies. Dr. Motzer will collaborate to study the mechanisms of immunotherapy response in patients with kidney cancer and other cancers with his experience in establishing new treatment paradigms. Dr. Sadelain will contribute to the analysis of immune cells, microenvironment analysis and analysis of T cell repertoire data as well as provide expertise, programmatic guidance, and laboratory reagents. Cleveland Clinic Lerner College of Medicine is the prime institution.

Overlap: None.

Completed/Active Support
Lee, Chung-Han

Completed

None since the last reporting period.

Active

Title: Evaluating HLA Class II Evolutionary Divergence as an Immunotherapy Specific Kidney Cancer Biomarker

Role: Collaborator

Project Number: W81XWH-21-1-0942

Sponsoring Agency: Department of Defense/Congressionally Directed Medical Research

Effort: 0.6 CM

Level of Funding Amount (Total Costs):

Performance Period: 9/30/2021 – 9/29/2025

Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer

Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014 **Project**

Goals/Specific Aims: The goals of this project are to 1) determine whether predicted neoantigens peptides to be presented by HLA class I and II alleles are enriched in clear cell compared to non-clear cell RCC variants; 2) determine whether HLA class II allelic repertoires and divergence (HED) correlate with treatment outcomes in clear cell RCC patients treated with ICI therapies ; 3) determine whether HLA class I and II alleles and composite HED correlates with treatment outcomes in a non-clear cell RCC prospective clinical trial employing VEGFR TKI and immunotherapy.

Overlap: None.

Title: Integrated Analysis of Somatic Genomic Mutations and Antigen Presentation as Predictive Biomarkers for Combination Immunotherapy in Kidney Cancer

Role: PI

Project Number: W81XWH-20-1-0917

Sponsoring Agency: Department of Defense/Congressionally Directed Medical Research Programs

Effort: 4.0 CM

Level of Funding Amount (Total costs):

Performance Period: 9/30/2020–9/29/2023 NCE

Name of Grants Officer at Sponsoring Agency: Joshua McKean

Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014 **Goals/**

Specific Aims: Aim 1, determine how tumor-specific mutations alter tumor mutation burden and the expression of mutated genes. Aim 2, determine the contribution of human leukocyte antigen diversity, tumor mutation burden, and somatic mutations as key components of tumor antigen burden and correlate tumor antigen burden to responses to nivolumab, tyrosine-kinase inhibitors and PD-1/PDL-1 inhibitors, and PD-1/PDL-1 and anti-CTLA-4 inhibitors.

Overlap: None.

Title: Circulating T follicular helper cells as a predictive marker for immunotherapy response in renal cell carcinoma. (KC200301)

Role: Physician Mentor

Sponsoring Agency: Department of Defense / Congressionally Directed Medical Research

Effort: 0.0 CM (*No measurable effort/no salary support requested*)

Level of Funding (Total Costs):

Performance Period: 09/30/2021 – 09/29/2023

Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer

Contact Information for Grants Officer: joshua.d.mckean3.civ@mail.mil | | Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014

Project Goals/Specific Aims: We propose the development of a formal RCC CRN fellowship program to provide clinical training alongside RCC-specific mentorship, didactic lectures, and clinical and translational research training. CRN Trainees will be paired one-to-one with CRN and Physician Mentors during the fellowship, which will contain a clinical orientation phase, an education phase, and a research phase.

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Aim 2: To conduct a pilot research project providing research training experience to CRNs

Aim 2a: To compare healthcare utilization via outpatient and inpatient points of care before and after telemedicine adoption

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Aim 2c: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs.

Overlap: None.

Active/Completed Support
Kotecha, Ritesh

Completed

None since project being funded.

Active

Title: Implementation of Kidney Cancer-Specific Training for Clinical Research Nurses

Role: Co-Investigator

Project Number: W81XWH-21-1-0731

Sponsoring Agency: Department of Defense / Congressionally Directed Medical Research

Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer

Contact Information for Grants Officer at Sponsoring Agency: joshua.d.mckean3.civ@mail.mil ||

Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014

Effort: 0.6 CM

Level of Funding (Including Indirect Costs):

Performance Period: 09/30/2021 – 09/29/2023

Project Goals/Specific Aims: We propose the development of a formal RCC CRN fellowship program to provide clinical training alongside RCC-specific mentorship, didactic lectures, and clinical and translational research training. CRN Trainees will be paired one-to-one with CRN and Physician Mentors during the fellowship, which will contain a clinical orientation phase, an education phase, and a research phase.

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Aim 2c: To compare patient and provider perceptions of telemedicine as a contributor to encountered SAEs.

Overlap: None.

Title: Evaluating HLA Class II Evolutionary Divergence as an Immunotherapy Specific Kidney Cancer Biomarker

Role: Principal Investigator

Project Number: W81XWH-21-1-0942

Sponsoring Agency: Department of Defense / Congressionally Directed Medical Research

Effort: 3.0 CM

Level of Funding (Including Indirect Costs):

Performance Period: 9/30/2021–9/29/2025

Name of Contracting/Grants Officer: Joshua D. McKean, Grants Officer

Contact Information for Grants Officer at Sponsoring Agency: joshua.d.mckean3.civ@mail.mil ||

Department of the Army, US Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014

Project Goals/Specific Aims: The goals of this project are to 1) determine whether predicted neoantigen peptides to be presented by HLA class I and II alleles are enriched in clear cell compared to non-clear cell RCC variants ; 2) determine whether HLA class II allelic repertoires and divergence (HED) correlate with treatment outcomes in clear cell RCC patients treated with ICI therapies ; 3) determine whether HLA class I and II alleles and composite HED correlates with treatment outcomes in a non-clear cell RCC prospective clinical trial employing VEGFR TKI and immunotherapy.

Overlap: None.

Title: Human Leukocyte Antigen Evolutionary Diversity – A Population-Specific Biomarker for Kidney Cancer Immunotherapy

Role: Principal Investigator

Sponsoring Agency: Kidney Cancer Association

Effort: 1.2 CM

Level of Funding (including Indirect Costs):

Performance Period: 10/1/2020- 9/30/2023 (NCE)

Name of Grants Officer at Sponsoring Agency: Not stated.

Contact Information for Grants Officer at Sponsoring Agency: Not stated.

Project Goals / Specific Aims: Characterize genomic ancestry via HLA and SNP analyses and associate ancestry with specific RCC tumor variants and analyze clinical outcomes within this context.

Overlap Statement: This grant is focused on computing genomic ancestry and admixture using HLA and SNP studies to genomically evaluate the population structures that are seen within patients with RCC tumors beyond self-reported race and ethnicity. The second aim is to better evaluate clinical outcomes in patients with RCC given this proposed novel population structure.