AWARD NUMBER: W81XWH-22-1-0277

TITLE: Data Science to Improve Treatment Planning for Advanced Prostate Cancer Patients Treated with Radiotherapy

PRINCIPAL INVESTIGATOR: Issam El Naqa, Ph.D.

CONTRACTING ORGANIZATION: H. Lee Moffitt Cancer Center and Research Institute, Inc.
Tampa, FL

REPORT DATE: July 2023

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
July 2023	Annual	01Jun2022-31May2023

4. TITLE AND SUBTITLE

Data Science to Improve Treatment Planning for Advanced Prostate Cancer Patients Treated with Radiotherapy

5a. CONTRACT NUMBER
W81XWH-22-1-0277

5b. GRANT NUMBER
W81XWH-22-1-0277

5c. PROGRAM ELEMENT NUMBER

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)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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

10. SPONSOR/MONITOR'S ACRONYM(S)
CDMRP

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES
none

14. ABSTRACT

Radiotherapy can cause short- and long-term bladder and bowel toxicities, with corresponding quality of life (QoL) detriments, in up to 60% of prostate cancer patients. This study focuses on improving radiation treatment planning with innovative combination of novel datasets and new advances in data science and artificial intelligence. We will use deep learning techniques developed by our research group to predict clinician-rated toxicity and patient-reported outcomes (PROs) using dosiomics (i.e., a recently-developed methodology to create very high-resolution three-dimensional maps of radiation dosage) and radiomics (i.e. imaging of novel tumor features such as shape and texture, that may affect radiation outcomes). We will develop and validate our prediction algorithms using detailed, existing retrospective datasets from 1,948 prostate cancer patients treated with radiation at Moffitt and 794 treated at the VA, respectively. To date, we have built and refined our retrospective data query and we are currently creating the Moffitt radiotherapy QoL database.

15. SUBJECT TERMS
Prostate cancer, quality of life, radiotherapy, data science, deep learning

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	16	19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

Radiotherapy can cause short- and long-term bladder and bowel toxicities, with corresponding quality of life (QoL) detriments, in up to 60% of men with prostate cancer. As men can live for many years with prostate cancer, it is increasingly important to mitigate toxicity and preserve high levels QoL. The current study will address this problem using an innovative combination of novel datasets and new advances in data science and artificial intelligence. Our study will incorporate large-scale patient-reported outcomes (PROs), or QoL and toxicity from the patient perspective. We have one of the largest real-world PRO datasets to our knowledge, with 16,896 QoL and patient-reported toxicity surveys from 1,948 prostate cancer patients treated with radiation. We will integrate different '-omics' into machine learning models. This will include the use dosiomics, a recently-developed methodology to create very high-resolution three-dimensional maps of radiation dosage. Dosiomics can be used to identify radiation dosage to small areas with much greater precision than before. We will also use radiomics, or imaging of novel tumor features such as shape and texture, that may affect radiation outcomes. We will apply deep learning techniques developed by our research group to predict clinician-rated toxicity and PROs from the above data with much greater accuracy than previous approaches. We will externally validate our prediction algorithms using a detailed, existing retrospective dataset from 794 prostate cancer patients treated with radiation at the VA. Across both datasets, there 2,742 patients (526 patients Black, about 274 Hispanic). Study aims are as follows: 1) to develop deep learning models incorporating dosiomics and radiomics for actuarial multi-endpoint prediction of clinician-rated toxicities among prostate cancer patients treated with radiation, 2) to develop deep learning models incorporating dosiomics and radiomics for actual multi-endpoint prediction of PROs among prostate cancer patients treated with radiation, and 3) to validate deep learning models for actuarial multi-endpoint prediction of clinician-rated toxicities and PROs among prostate cancer patients treated with radiation in the VA. Upon completion of this study, we will have fulfilled our short-term objective to identify risk of short-and long-term toxicity and detriments in quality of life based on precise spatial evaluation of radiation dosage. This knowledge can immediately impact radiation treatment planning procedures. The longer-term objective of this line of research is to improve national guidelines to reduce toxicity and detriments of quality of life in men with prostate cancer.

2. KEYWORDS:

Quality of life, treatment toxicity, prostate cancer, radiation, data science, deep learning

3. ACCOMPLISHMENTS:

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

Specific Aim 1: To develop deep learning models incorporating dosiomics and radiomics for actuarial multi-endpoint prediction of clinician-rated toxicities among prostate cancer patients treated with radiation.	**Timeline**	**Moffitt**	**Thomas Jefferson University**
Major Task 1: Study start-up	Months		
Subtask 1: Complete subcontract with Thomas Jefferson University (Jim, El Naqa, Dicker)	1-2	100%	100%
Subtask 2: Obtain Moffitt Scientific Review Committee approvals for Aims 1-2, IRB determination of non-human subjects research, and USAMRDC ORP HRPO approval (Jim, El Naqa)	1-2	100%	100%
Subtask 3: Request and obtain retrospective data from the Moffitt Collaborative Data Services Core for Aims 1-2 (Jim, El Naqa)	3	50%	
Milestone(s) Achieved: Subaward with Thomas Jefferson executed, regulatory approvals obtained, Moffitt retrospective clinical dataset obtained		50%	
Major Task 2: Data cleaning, scoring, and analyses for Aim 1			
Subtask 1: Cleaning and scoring of clinical, demographic, and PRO data as needed for Aims 1-2 (Jim)	4-5	50%	
Subtask 2: Dosiomic and radiomic feature extraction for Aims 1-2 (El Naqa)	6-7	0%	
Subtask 3: Data integration for Aims 1-2 (Jim, El Naqa)	8-9	0%	
Subtask 4: Design and optimize deep neural network for Aim 1 (El Naqa)	10-13	25%	

Subtask 5: Model interpretation, evaluation, and internal validation for Aim 1 (Jim, El Naqa, Dicker)	14-16	0%	0%
Milestone(s) Achieved: Internally-validated model for Aim 1		25%	25%
Specific Aim 2: To develop deep learning models incorporating dosiomics and radiomics for actual multi-endpoint prediction of PROs among prostate cancer patients treated with radiation	**Timeline**	**Moffitt**	**Thomas Jefferson University**
Major Task 3: Data analyses for Aim 2			
Subtask 1: Deep neural network optimization for Aim 2 (El Naqa)	17-19	0%	
Subtask 2: Model interpretation, evaluation, and internal validation for Aim 2 (Jim, El Naqa, Dicker)	20-22	0%	0%
Subtask 3: Write and submit abstract and manuscript describing process of dataset integration (Jim, El Naqa, Dicker)	23-25	0%	0%
Milestone(s) Achieved: Internally-validated model for Aim 2, abstract focused on dataset integration			
Specific Aim 3: To validate deep learning models for actuarial multi-endpoint prediction of clinician-rated toxicities and PROs among prostate cancer patients treated with radiation in the VA			
Major Task 4: Obtain, clean, score data for Aim 3			
Subtask 1: Obtain deidentified HINGE dataset (i.e., facilitated by Dr. Katsoulakis, Moffitt personnel obtain VA approvals, data sharing agreement, data transfer) (Jim, El Naqa)	13-23	50%	
Subtask 2: Cleaning and scoring of clinical, demographic, and PRO data, as needed for Aim 3 (Jim, El Naqa)	24	0%	
Milestone(s) Achieved: cleaned scored dataset ready for analyses related to Aim 3		0%	
Major Task 5: Data analyses for Aim 3			
Subtask 1: Dosiomic and radiomic feature extraction for Aim 3 (El Naqa)	25-27	0%	
Subtask 2: Data integration for Aim 3 (Jim, El Naqa)	28-29	0%	
Subtask 3: Deep neural network optimization for Aim 3 (El Naqa)	30-32	0%	
Subtask 4: Model interpretation, evaluation, and internal validation for Aim 3 (Jim, El Naqa, Dicker)	33-35	0%	0%
Subtask 5: Write and submit abstracts and manuscripts describing final results (Jim, El Naqa, Dicker)	34-36	0%	0%
Milestone(s) Achieved: Validated model for Aim 3, manuscripts and abstracts describing final results			

- **What was accomplished under these goals?**
  We have spent the first year in an iterative process of: 1) specifying retrospective data requests from the Moffitt Collaborative Data Service Core and VA HINGE ; 2) reviewing data received as a full, multidisciplinary research group for accuracy, comprehensiveness, and completeness; 3) modifying our data requests accordingly; and 4) designing the deep neural network architectures. We now have a comprehensive set of the correct elements and a data request on the full Moffitt sample is being processed.

- **What opportunities for training and professional development has the project provided?**
  Dr. Denis Dudas was hired as a post-doctoral fellow on the project and have acquired necessary skills to develop and apply machine learning techniques to treatment planning datasets. An initial neural network design is tready to be tested on the acquired Moffitt dataset.

- **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?**
  We anticipate receiving the full dataset from Moffitt in the next month. We will then clean the data in parallel with manually pulling pdf information from the medical record. Once this process has occurred, we will complete the scope of work described for Aim 2. Although the process of specifying data elements took longer than anticipated, this investment of time will pay off during Aim 2, which will be conducted more efficiently with a dataset that is already known to be comprehensive and accurate.

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
     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
     - 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:	*Issam El Naqa, PhD*
Project Role:	*Principal Investigator (PI)*
Researcher Identifier (e.g. ORCID ID):	*ORCID ID: 0000-0001-6023-1132*
Nearest person month worked:	*2 calendar months*
Contribution to Project:	*Dr. Issam El Naqa has worked as the Principal Investigator of the technical part of the study, overseeing all aspects of model development and implementation.*
Funding Support:	*N/A*

Name:	*Denis Dudas*
Project Role:	*Post-Doc*
Researcher Identifier (e.g. ORCID ID):	*ORCID ID: 0000-0003-0667-3727*
Nearest person month worked:	*12.0*
Contribution to Project:	*Denis has worked as a machine learning analyst assisting in the data integration process and development of the proposed machine learning algorithms for the proposed aims.*
Funding Support:	*N/A*

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

PD/PI: ISSAM EL NAQA-CHANGES IN ACTIVE SUPPORT	
Title: Data Science to Improve Treatment Planning for Advanced Prostate Cancer Patients Treated with Radiotherapy **Goals:** Radiation can cause short- and long-term toxicities, including problems with urinary and bowel functioning which can negatively impact quality of life, in up to 60% of patients. Improving patient quality of life is a FY21 PCRP Overarching Challenge. Our team believes we can improve the lives of prostate cancer patients who receive radiation through this innovative proposal that incorporates the latest advances in artificial intelligence. The current study will address this problem using an innovative combination of novel datasets and cutting-edge data science. **Specific Aims:** Aim 1: To develop a machine learning algorithm to predict quality of life outcomes among men with advanced prostate cancer treated with radiation, surgery, or androgen deprivation therapy. Aim 2: To validate the algorithm in an independent dataset. Aim 3: To explore clinical implementation of the algorithm via integration in the electronic medical record. **Project Number:** W81XWH-22-1-0277 **PD/PI:** Jim, H., El Naqa, I. **Time Commitment:** 1.80 calendar months **Supporting Agency:** US Army/CDMRP-PCRP **Agency Contact Info:** Joshua McKean, Grants Officer, Joshua.d.mckean3.civ@mail.mil, ph.: **Agency Address:** 820 CHANDLER ST FORT DETRICK MD 21702-5014 **Performance Period:** 06/01/2022-05/31/2025 **Total Award Amount:**	New Active Award *(This Award)*

Title: An Ionizing Radiation Acoustics Imaging (iRAI) Approach for guided Flash Radiotherapy **Goals:** This proposal will address the current challenge of effective and safe FLASH-RT clinical delivery by developing an image-guidance system utilizing technological advances in radiation acoustic imaging and machine learning detection. Our approach is based on developing a real-time radiation acoustic and ultrasound dual-modality imaging system and deep learning reconstruction algorithms for guiding and safeguarding electron or proton FLASH- RT delivery. The feasibility and versatility of the dual image-guidance system will be evaluated using computer simulations, phantoms, and in vivo preclinical models. **Specific Aims:** **SA1:** Develop and test a dedicated 3D iRAI-US dual-modality system that can simultaneously map FLASH-RT pulse-by-pulse dose deposition and its exposed tissue morphology. **SA2:** Evaluate the in vivo performance of iRAI-US dual-modality imaging during electron FLASH-RT and proton FLASH-RT. **SA3:** Adapt and improve iRAI volumetric representation and error detection for FLASH-RT applications using deep learning algorithms (DeepRAI). **Project Number:** R01 CA266803-01A1 **PD/PI:** El Naqa, I, Bortfeld, T., Wang, X. **Time Commitment:** 1.20 calendar months **Supporting Agency:** NIH/NCI **Agency Contact Info:** Monica Benjamin, monica.benjamin@nih.gov, ph.: **Agency Address:** 9000 Rockville Pike, Bethesda, Maryland 20892 **Performance Period:** 09/20/2022-08/31/2027 **Total Award Amount:**	New Active Award
Title: Federated Learning for Optimal Decision Making in Radiotherapy Using Panomics Analytics (Supplement) **Goals:** Here we propose to develop and test federated learning in collaboration with Radiologics and demonstrate its potential in multi-institutional setting for optimal decision making in radiotherapy. **Specific Aims:** We well extend the original specific aims SAs: SA1:Develop and evaluate integrative machine learning models from imaging and molecular biomarkers for predicting response in RT. SA2: Develop and evaluate reinforcement learning framework to optimize adaptation of radiotherapy. SA3: Test and evaluate a clinical decision support systems (CDSS) prototype for radiotherapy in multiple institutions. **Project Number:** 3R01 CA233487-05S1 **PD/PI:** El Naqa, I. **Time Commitment:** 0.60 calendar months **Supporting Agency:** NIH/NCI **Agency Contact Info:** Viviana Knowles, GMS, viviana.knowles@nih.gov, Ph: **Agency Address:** 9000 Rockville Pike, Bethesda, Maryland 20892 **Performance Period:** 09/01/2022-05/31/2024 **Total Award Amount:**	New Active Award
Title: Characterizing cytotoxic therapy induced shifts in the cost-to-benefit ratio of high ploidy **Goals:** Our long-term goal is to develop a personalized cytotoxic therapy strategy that confines therapy-induced selection of resistant tumor clones. As the next step towards this goal, we aim to translate our understanding of a cell's proximity to the CNV limit into a predictive model of response to cytotoxic agents.	New Active Award

Specific Aims: Aim 1. Quantify cells' robustness to chromosome missegregations conferred per copy of haploid genome. Aim 2. Characterize cell-extrinsic resources that cap ploidy in gastric and brain tissue environments. **Project Number:** R37 CA266727-01A1 **PD/PI:** Andor, N. (Role: Co-Inv) **Time Commitment:** 0.36 calendar months **Supporting Agency***:* NIH/NCI **Agency Contact Info:** Monica Desiree Benjamin, monica.benjamin@nih.gov, **Agency Address:** 9000 Rockville Pike, Bethesda, Maryland 20892 **Performance Period:** 09/01/2022-08/31/2027 **Total Award Amount:**	
Title: Artificial Intelligence for Effective MR-Linac Adaptive Radiotherapy **Goals:** Magnetic resonance imaging guided linear accelerators (MRI-Linac) has brought the unique ability of MRI soft tissue discrimination into the radiation delivery room. This technology allows the precise localization of moving tumors as well as it enables new opportunities for treatment adaptation both geometrically and physiologically. This combination of accurate delivery and treatment adaptation could potentially realize the promise of personalized cancer treatment in radiotherapy. However, to fulfil the promise of MRI-Linac in clinical practice improved and robust computational methods still need to be developed, evaluated and deployed. Therefore, in this proposal, we plan to develop and validate a toolkit of artificial intelligence (AI) based techniques that can effectively leverage the wealth of information that an MRI-Linac generates to provide a robust solution to personalized and adaptive radiotherapy and address the unmet clinical need of improved treatment outcomes in solid cancers using this advanced technology. **Specific Aims:** SA1: Develop and evaluate AI/ML solutions for geometrical adaptation on MRI-Linacs. SA2: Develop and evaluate AI/ML techniques to improve response prediction and fractionation adaptation of MRI-Linacs. **Project Number:** 22082611 **PD/PI:** El Naqa, I., Rosenberg, S. **Time Commitment:** 0.36 calendar months **Supporting Agency:** VIEWRAY Technologies, Inc. **Agency Contact Info:** **Agency Address:** **Performance Period:** 10/31/2022-10/30/2024 **Total Award Amount:**	New Active Award
Title: Engineering Model-Based Systems to Monitor and Steer Subclonal Dynamics **Goals:** we propose to engineer how in-vitro and in-silica experiments interact into a software solution called CLONEID. An SOL database in the backend, a Java core and an R user interface will come together to form two modules: One will record the pedigree of lineages grown in a lab and use computer vision to monitor phenotypic changes, such as variable growth rates. The second module will link subclonal multi-omics profiles from different high throughput assays to each other and to the phenotypes from the first module. **Specific Aims:** 1. Develop CLONEID's lineage tracing module to increase the temporal reach and resolution on in-vitro growth. 2. Expand CLONEID with a multi-omics module to link temporal phenotypic measurements with -omics views on cellular heterogeneity. **Project Number:** 1 R21-CA269415-01A1 **PD/PI:** Noemi Andor (Role: Co-Investigator)	New Active Award

Time Commitment: 0.60 calendar months **Supporting Agency:** NIH/NCI **Agency Contact Info:** Sean Hine, hines@mail.nih.gov, ph# **Agency Address:** 9000 Rockville Pike, Bethesda, Maryland 20892 **Period of Performance:** 5/01/2023-4/30/2025 **Total Award Amount:**	
Title: Creation of an Infrastructure to Support Delivery of mHealth Interventions for Cancer Patients Throughout Florida **Goals:** To develop an mHealth resource to support tobacco-related research at institutions throughout Florida and to conduct 3 demonstration smoking cessation projects (screening and recruitment, intervention delivery and referral, and data processing via machine learning) to test the utility and flexibility of the infrastructure and to assess feasibility-, acceptability-, and implementation-related variables. **Specific Aims:** Aim 1. To develop an mHealth resource to support tobacco-related research at institutions throughout Florida. Aim 2. To conduct 3 demonstration smoking cessation projects (screening and recruitment, intervention delivery and referral, and data processing via machine learning) to test the utility and flexibility of the infrastructure and to assess feasibility-, acceptability-, and implementation-related variables. **Project Number:** 23K01 **PD/PI:** Vidrine, D., Simmons, V. (Role: Co-I) **Time Commitment:** 0.60 calendar months **Supporting Agency:** FDOH-Florida Biomedical Research Program (FBRP)-JEKBRP **Agency Contact Info:** Jason Roland-Contract Analyst, Jason.Roland@flhealth.gov **Agency Address:** 4052 Bald Cypress Way, Tallahassee, FL 32399-1701 **Period of Performance:** 04/01/2023-03/31/2026 **Total Award Amount:**	New Active Award
Title: Cancer Research Workforce Development in FAIR Artificial Intelligence and Machine Learning **Goals:** We plan to complement our successful T32 program that is focused on data science in cancer biology with the addition of the necessary component on AI/ML data readiness. The overarching goal of our T32 program is to train a cohort of outstanding cancer-focused postdoctoral fellows to be leaders in collaborative science who can address cancer research problems using computational approaches, including advanced AI and ML. For this experience, trainees are immersed in research that involves both cancer biology and computational/quantitative sciences through a program entrenched in "team science." A large impediment to this type of work is the lack of FAIR data that is ready for analysis. For this reason, the supplement will be of immense value to our training mission to learn about AI/ML data readiness and ensure compliance with the FAIR principles to safeguard the implementation of AI/ML in cancer research and discovery. **Aims:** N/A **Project Number:** 3T32 CA233399-03S1 **PD/PI:** Cress, W., Flores, El, Fridley, B. (Role: Co-Inv) **Time Commitment:** 0.24 calendar **Supporting Agency:** NIH/NCI **Agency Contact Info:** Agency Contact: sabrina.oasan@nih.gov; **Performance Period**: 09/01/2021-08/31/2022 **Total Award Amount:**	Project Ended/Closed
Predictors of Immunotherapeutic Benefits in Patients with Advanced Malignancies Treated with Immune Checkpoint Inhibitors	Project Ended/Closed

Goals: we hypothesize that interactive immune-related biomarkers related to tumor biology and host immunology may predict the likelihood of benefit from ICIs and can be identified by simultaneously investigating data related to gene expression, somatic mutations and germline genetic variation within the same patient population. We also hypothesize that such immune-related markers are in large part shared among patients with different malignant histologies. We propose to test our hypotheses within the ORIEN Avatar Research Project that is conducted under the TCC protocol and provides an invaluable resource of clinical and genomic data from consenting patients with multiple malignancies treated with ICIs. Avatar provides an important opportunity to simultaneously investigate tumor biology and host immunology allowing us to test our hypotheses as proposed. Therefore, utilizing clinical and genomic data from consenting patients participating in AVATAR, we propose to address our project aims across multiple tumor types. **Aims:** Aim 1: Define biomarkers predictive of immunotherapeutic benefit within each histology separately, by investigating (A) mRNA expression profiles, (B) Somatic mutations, (C) Germline genetic variation as assessed individually and in combination based on the common systems biology. Aim 2: Test the hypothesis that predictive immune-related biomarkers and pathways as identified in Aim 1 are in large part are pan-cancer and shared among patients with different malignant histologies (melanoma, NSCLC, RCCA). Aim 3: Conduct exploratory analyses related to the underlying mechanisms of immune response and resistance and toxicity risks. **Project Number:** N/A **PD/PI:** Tarhini, A. (Role: Co-Inv) **Time Commitment:** 0.60 calendar **Supporting Agency:** Tampa Community Foundation-PTE: ORIEN **Agency Contact Info:** ORIEN NOVA, ORIENprojects@m2gen.com **Performance Period:** 06/02/2021-06/01/2023 **Total Award Amount:**	
Title: Machine Learning Techniques to Existing CoE Datasets in Immunotherapy Targeted Therapy in Mice **Goals:** This study will provide proof of principle that deep learning and scRNAseq methods can be used to optimize and adapt combined treatments longitudinally to achieve a sustained anti-tumor response **Aims:** N/A **Project Number:** MOD17 **PD/PI:** El Naqa, I **Time Commitment:** 0.12 calendar **Supporting Agency:** Moffitt Cancer Center/Melanoma and Skin Cancer Center of Excellence **Agency Contact Info:** Rebecca Nickleson, Director of Sponsored Research, rebecca.nickleson@moffitt.org **Performance Period:** 07/01/2021-05/31/2022 **Total Award:**	Project Ended/Closed
Title: Geriatrics Oncology Research **Goals:** We hypothesize that we will identify a number of associations, individual or by clusters, with significant clinical relevance and worthy of focused investigation. This is a new ML application, so we will use methods that are well tested and explainable. The first stage will use decision tree-based ensemble methods, such as random forests and XGboost, to model survival. We will use this approach to pre-screen features for use in a second stage where we will employ a deep learning method called a variational autoencoder (VAE). VAEs	Project Ended/Closed

embed large dimensional feature vectors into a smaller dimensional representation often called a latent vector. The latent vectors may allow us to uncover complex relationships between comorbidities and survival. This approach fills a major research void: Creating evidence for older patients not eligible for clinical trials because of their comorbidities. The results of our ML analysis could enhance personalized prostate cancer care and generate highly innovative approaches to cancer treatment by identifying new rugs/comorbidity/cancer interactions that could lead to original uses such as those explored with metformin. **Aims:** N/A **Project Number:** 09-33426-22-01 **PD/PI:** Extermann, M. (Role: Co Inv) **Time Commitment:** 0.42 calendar **Supporting Agency:** Moffitt Cancer Center Foundation **Agency Contact Info:** Rebecca Nickleson, Director of Sponsored Research, rebecca.nickleson@moffitt.org **Performance Period:** 07/01/2021 - 06/30/2022 **Total Award:**	

- **What other organizations were involved as partners?**
  Nothing to report

8. SPECIAL REPORTING REQUIREMENTS:

- COLLABORATIVE AWARDS:
  An annual progress report has been prepared for both the initiating and collaborating awards (W81XWH-22-1-0276 and W81XWH-22-1-0277).

- QUAD CHARTS:
  Not applicable

9. APPENDICES:

- **Appendix A:** Inclusion Enrollment Report

OMB Number: 0925-0770
Expiration Date: 09/30/2024

PHS Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

Data Science to Improve Treatment Planning for
Advanced Prostate Cancer Patients Treated with Radiotherapy

2. * Using an Existing Dataset or Resource ☐ Yes ☒ No

3. * Enrollment Location Type ☒ Domestic ☐ Foreign

4. Enrollment Country(ies)

USA: UNITED STATES

5. Enrollment Location(s)

Moffitt Cancer Center

6. Comments

Planned

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		**Total**
	Female	**Male**	**Female**	**Male**	
American Indian/ Alaska Native	0	49	0	19	68
Asian	0	75	0	7	82
Native Hawaiian or Other Pacific Islander	0	7	0	1	8
Black or African American	0	451	0	75	526
White	0	1,823	0	149	1,972
More than One Race	0	63	0	23	86
Total	0	2,468	0	274	2,742

Cumulative (Actual)

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			**Total**
	Female	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Report 1 of 1