Award Number: W81XWH-18-1-0196

TITLE: Cancer-Associated Macrophagelike (CAML) Cells to Enhance Detection of Early-Stage Lung Cancer and Relapse After Definitive Treatment

PRINCIPAL INVESTIGATOR: Martin Edelman, M.D.

CONTRACTING ORGANIZATION: Institute for Cancer Research, Philadelphia, PA

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Approved for public release; distribution unlimited

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14. ABSTRACT

The hypothesis of this study is that Cancer Associated Macrophage Like cells (CAMLs) can enrich for the presence of malignancy in patients with pulmonary nodules.
Specific Aims: 1. Determine the prevalence of CAMLS (+/- CTCs) in patients with indeterminate pulmonary nodules.; 2. Determine the positive and negative predictive value of CAMLS in patients with pulmonary nodules who undergo biopsy.; 3. Model combinations of clinical factors with the presence/absence of CAMLs to refine strategies for assessment of patients with pulmonary nodules.
Subjects will be drawn from pulmonary nodule and thoracic surgery clinics at the Fox Chase Cancer Center (FCCC) and VA Philadelphia (VA). CAMLs will be evaluated at the time of clinically indicated scans and correlated with the presence or absence of cancer. Patients with biopsy confirmed lung cancer within 12 months of the CAML test will be defined as "diseased"; otherwise, they will deemed as "disease free". Positive and negative predictive value of the test will be determined. Logistic regression will be used to assess the utility of this test after accounting for clinical factors and nodule characteristics. To date, the study has been activated and is accruing patients at FCCC and is undergoing IRB review at the VA.

15. SUBJECT TERMS

Lung cancer, pulmonary nodules, screening

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

Background and Hypothesis: The National Lung Screening Trial (NLST), for which the PI was a member of the endpoint verification committee, determined that low dose CT screening could decrease lung cancer death by 20%. However, almost 25% of screened subjects were determined to have pulmonary nodules with only 1.5% actually demonstrated to be malignant. This very high false positive rate results in several critical problems including the requirement for further testing (scans, biopsies), the potential of loss to follow-up, the possibility of false negative biopsy and the resultant patient stress and anxiety. Nodules between from .8-3.0 cm have been described as "indeterminate" and represent a management challenge. Recently we published preliminary data on the presence of CAMLs, specialized myeloid polyploid cells transiting the circulation of patients that have engulfed tumor cells or tumor material in a variety of malignancies and their clinical use in tracking cancer progression and evolution in response to therapy. CAMLs are rarely found in healthy controls and are easily identified by filtration methods

Hypothesis: CAMLs can substantially enrich for the presence of malignancy in the population of patients with pulmonary nodules.

Specific Aims:

1. Determine the prevalence of CAMLS (+/- CTCs) in patients with indeterminate pulmonary nodules.
2. Determine the positive and negative predictive value of CAMLS in patients with pulmonary nodules who undergo biopsy.
3. Model combinations of clinical factors with the presence/absence of CAMLs to refine strategies for assessment of patients with pulmonary nodules.

Subjects will be drawn from pulmonary nodule and thoracic surgery clinics at the Fox Chase Cancer Center and VA Philadelphia. CAMLs will be evaluated at the time of clinically indicated scans and correlated with the presence or absence of cancer, as determined by clinically indicated biopsies. The proportion of patients with presence of CAMLs (CAML+), Positive Predictive Value (PPV), Negative Predictive Value (NPV), sensitivity and specificity of CAMLs (along with two-sided 95% confidence intervals (CI)) will be computed. Patients with biopsy confirmed lung cancer within 12 months of the CAML test will be defined as "diseased"; otherwise, they will deemed as "disease free". Logistic regression will be used to assess the utility of this test after accounting for clinical factors and nodule characteristics. We will also explore whether test performance differs among subsets of the population defined by demographic, clinical and nodule characteristics.

KEYWORDS: Lung cancer, pulmonary nodules, screening

ACCOMPLISHMENTS:

What were the major goals of the project?

1. To conduct an observational study of CAMLs in patients with indeterminate pulmonary nodules.
2. To determine the positive and negative predictive value of CAMLS in patients with pulmonary nodules who undergo biopsy.
3. Model combinations of clinical factors with the presence/absence of CAMLs to refine strategies for assessment of patients with pulmonary nodules.

What was accomplished under these goals?

At this time, we have met the following milestones:

Aim 1: To conduct an observational study of CAMLs in patients with indeterminate pulmonary nodules.

1. Drafting of the clinical trial protocol.

2. IRB (Fox Chase) submission and approval of the protocol.

3. Activation and commencement of accrual to the protocol.

4. Creation of computerized data base for entry of data and future analysis.

5. Approval of the trial to the IRB at the Veterans Administration Hospital of Philadelphia/University of Pennsylvania.

6. Activation and accrual at the University of Pennsylvania. Accrual on hold at the VA due to COVID. Due to the change in assessment of pulmonary nodules and consultative approach at the VA, there was no accrual at the VA.

7. As of 7.15.2022, 180 subjects (123 at FCCC and 57 at UPENN) have been enrolled and 177 (120 at FCCC and 57 at UPENN) are evaluable. We have therefore accrued approximately 90% of the required evaluable patients necessary to complete the study.

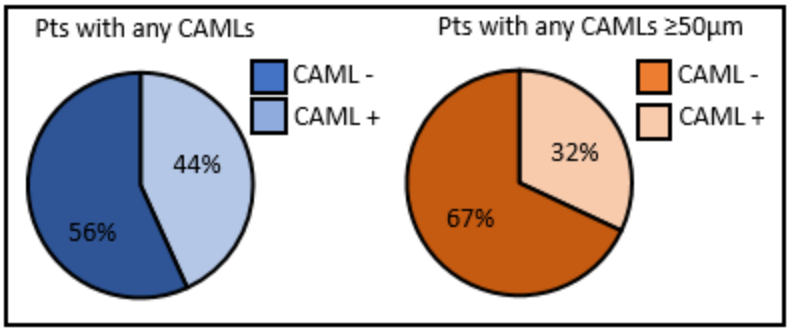
Aim 2: To determine the positive and negative predictive value of CAMLS in patients with pulmonary nodules who undergo biopsy.

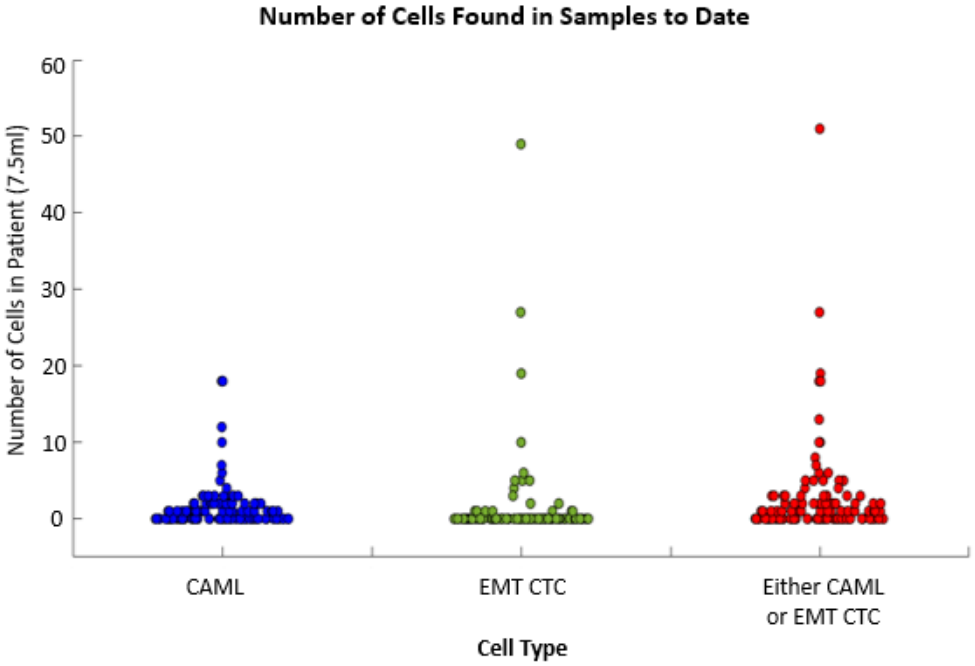
Below (sections 1-3) summarizes key findings generated by CREATV. A more complete description of analytical aspects of CAMLS and circulating tumor cells (CTCs) is found in their separately submitted report.

1. CAML determinations (as of July 15, 2022), are demonstrated in the table:

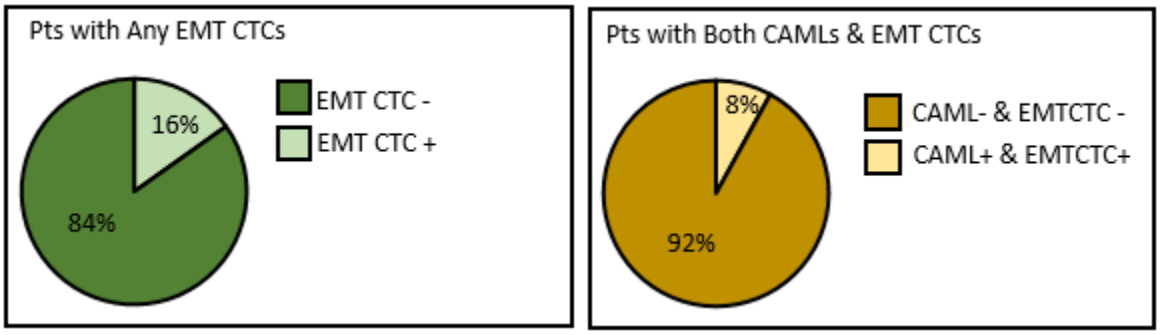
	All Patients Recruited	Patients Evaluable	All Patients Run Creatv	All Samples Run Creatv (2X)
FCCC	123	120	123	120x2=**240**
UPenn	57	57	57	57x2=**114**
Total Patients Recruited	**180**	**177**	**180**	180x2=**360**
Follow up Patient Samples	**24**	**24**	**24**	24x2=**48**
Total Samples	**204**	**201**	**204**	[(204x2)-6}=**402***

2. CAMLs have been detected in a substantial portion of samples to date. These numbers are highly variable.





3. Circulating tumor cells have also been detected and are classified based upon whether they demonstrate epithelial to mesenchymal transition (EMT).



4. As of 15 July 2022, a total of 62 of the 177 evaluable patients have documented or presumed malignancy. This will allow for robust assessment of correlation between CAMLs and the presence/absence of malignancy.

Aim 3: Model combinations of clinical factors with the presence/absence of CAMLs to refine strategies for assessment of patients with pulmonary nodules.

1. Data base created and data entered that will allow for analysis.

2. Radiologist review of all studies at Fox Chase completed (i.e. analyzes for specified characteristics of nodules).

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?

We anticipate completion of accrual by December 2022. At that time, study will be unblended. Abstract for appropriate national meeting will be submitted at that time.

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.

CHANGES/PROBLEMS:

Changes in approach and reasons for change

As in our annual report of 2021, an analysis of the rate of positive biopsies (over 25%) indicates that we can complete the trial with fewer patients (n = 200 rather than 1000). Of the first 85 subjects entered, 30 were biopsied with 27 positive for malignancy. The study was therefore modified March 2021 to decrease sample size based upon much higher rate of positive biopsies than anticipated. Amendment approved by FCCC and DOD HRPO.

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

Accrual was halted due to COVID. A one year no-cost extension was sought and approved. A second year NCE to complete enrollment (anticipated by the end of the calendar year 2022 was submitted and approved.

Changes that had a significant impact on expenditures

Though the number of patients to be tested has decreased, the extended time period for accrual and increased work regarding analytic testing will result in similar fund expenditure.

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

See above. Decreased number of subjects.

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

PRODUCTS:

Nothing to report

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)

N/A

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

Nothing to report

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	*Martin Edelman, M.D.*
Project Role:	*Principal Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Edelman is the PI of the project and during this period, submitted and gained approval of the study, assembled the study team, designed the case report forms and coordinated all efforts related to the study.*
Funding Support:	

Name:	*Anil Vachani, M.D.*
Project Role:	*Site PI/Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*Dr. Vachani leads the project at the University of Pennsylvania/VA. He is actively recruiting patients at Penn.*
Funding Support:	

Name:	*Rohit Kumar, M.D.*
Project Role:	*Co-Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Kumar is a pulmonary physician who leads the accrual effort at Fox Chase.*
Funding Support:	

Name:	*Dana Hagan*
Project Role:	*Clinical Research Coordinator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*6*

Contribution to Project:	*Ms. Hagan has consented patients identified in the pulmonary clinic and collected and entered appropriate data. She has also provided valuable assistance in terms of data collection methods and protocol mechanics.*
Funding Support:	

Name:	*Michelle Andronov*
Project Role:	*Research Coordinator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*4*
Contribution to Project:	*Ms. Andronov has provided assistance with subject recruitment and regulatory management.*
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?

Please see attached updated Other Support for Dr. Vachani. Changes are marked with a line in the right hand margin. There has been no change in the Other Support for Drs. Edelman, Kumar and Anaokar.

What other organizations were involved as partners?

Organization Name: VA Philadelphia (University of Pennsylvania)

Location of Organization: Philadelphia, PA

Partner's contribution to the project *(identify one or more)*

Financial support: N/A

In-kind support: N/A

Facilities: The VA pulmonary clinic facilities (and possibly U Penn) will serve as the sites for evaluation and recruitment of patients.

Collaboration: See above.

Personnel exchanges: N/A

Other: N/A

SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not applicable.

QUAD CHARTS: Not applicable.

APPENDICES: Award Chart is attached.

OTHER SUPPORT

Dr. Vachani holds a dual appointment at The University of Pennsylvania (UPENN) and the Philadelphia VA Medical Center (VA) (4/8ths). A memorandum of understanding exists between UPENN and VA that allocates Dr. Vachani's time as 30 hours per week at UPENN and 20 hours per week at VA.

Name of Individual: VACHANI, ANIL
Commons ID: AVACHANI

ACTIVE

ACTIVE UPENN FUNDING

Title: *Cancer Associated Macrophage-Like (CAML) Cells to Enhance Detection of Early-Stage Lung Cancer and Relapse after Definitive Treatment*
Major Goals: Prospective study to determine the diagnostic accuracy of CAML cells for the diagnosis of early-stage lung cancer.
Status of Support: Active
Project Number: W81XWH-18-1-0196
Name of PD/PI: Edelman, M
Source of Support: DOD
Primary Place of Performance: Fox Chase Cancer Center/University of Pennsylvania
Project/Proposal Start and End Date: 07/15/18-07/14/23 (NCE)
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2018	0.12 calendar
2. 2019	0.12 calendar
3. 2020	0.12 calendar
4. 2021	0.12 calendar
5. 2022	0.6 calendar

Title: *Center for Research to Optimize Precision Lung Cancer Screening in Diverse Populations (PROSPR II)*
Major Goals: The goal of this Center is to build a comprehensive data ecosystem of the entire lung cancer screening process and to assess associated multilevel factors to conduct high impact multilevel studies including interventions to address gaps in care that may lead to lung cancer health disparities.
Status of Support: Active
Project Number: 5UM1CA221939-03
Name of PD/PI: Ritzwoller, D. and Vachani, A.
Source of Support: NIH/NCI
Primary Place of Performance: University of Pennsylvania/Kaiser Permanente Colorado/Kaiser Permanente Hawaii/Henry Ford Health System/Marshfield Clinic
Project/Proposal Start and End Date: 04/15/18–03/31/23
Total Award Amount (including Indirect Costs):
Person Months:

Year (YYYY)	Person Months (##.##)
1. 2018	1.2 calendar
2. 2019	1.2 calendar
3. 2020	2.4 calendar
4. 2021	1.8 calendar
5. 2022	1.8 calendar

Title: *Center of Excellence in Environmental Toxicology*
Major Goals: The CEET's mission is to elucidate the mechanistic links between environmental exposures and human disease and translate its findings into action to improve the health of vulnerable individuals, and local, national and global communities. This is accomplished through thematic areas of research, facility cores, community outreach and engagement and through the funding of pilot projects. The Integrated Health Science Facilities Core provides transdisciplinary services including study design, population exposure measurement, human exposure laboratories, access to biorepositories, and biostatistical analyses for center investigators.
Status of Support: Active
Project Number; 5-P30-ES-013508-16
Name of PD/PI: Penning, T.
Source of Support: NIH/NIEHS
Primary Place of Performance: University of Pennsylvania
Project/Proposal Start and End Date: 04/01/20-03/31/25
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2020	1.2 calendar
2. 2021	1.2 calendar
3. 2022	1.2 calendar
4. 2023	1.2 calendar
5. 2024	1.2 calendar

Title: *Increasing Equitable Adherence to Annual Lung Cancer Screening and Diagnostic Follow-Up*
Major Goals: The objective of this project is to test the effectiveness of patient and clinician nudge strategies on rates of annual adherence and diagnostic follow-up in patients eligible for lung cancer screening.
Project Number: Non-Small Cell Lung Cancer RFP
Name of PD/PI: Rendle, K/Vachani, A (MPIs)
Source of Support: NCCN
Primary Place of Performance: University of Pennsylvania
Project Start and End Date: 01/01/2022-12/31/2023
Total Award Amount:
Role: PI

Year (YYYY)	Person Months (##.##)
1. 2022	0.6 calendar
2. 2023	0.6 calendar

Title: *Optimizing Biomarker Based Approaches for Lung Cancer Screening*
Major Goals: Use microsimulation modeling to modeling to assess the potential impact of emerging screening and diagnostic biomarkers on the health benefits, harms, and cost-effectiveness of LCS
Status of Support: Active
Project Number: 2021-13
Name of PD/PI: Vachani, A and Wisnevisky J**.**
Source of Support: Lungevity Foundation
Primary Place of Performance: University of Pennsylvania/Mt. Sinai Medical Center
Project/Proposal Start and End Date: 11/01/21-10/30/23
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2022	0.6 calendar
2. 2023	0.6 calendar

Title: *Comparing Ways to Promote Quitting Smoking for People Referred for Lung Cancer Screenings*
Major Goals: Pragmatic randomized trial comparing approaches to tobacco dependence treatment among patients undergoing lung cancer screening.
Status of Support: Active
Project Number: PCS-2018C1-11326
Name of PD/PI: Halpern, SD
Source of Support: PCORI
Primary Place of Performance: University of Pennsylvania/Henry Ford Health System/Kaiser Permanente Southern California/Geisinger Health System
Project/Proposal Start and End Date: 03/01/19-02/28/24
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2019	1.2 calendar
2. 2020	1.2 calendar
3. 2021	1.2 calendar
4. 2022	0.6 calendar
5. 2023	0.6 calendar

Title: *Improving Diagnostic Quality and Safety in Lung Cancer Screening*
Major Goals: Multicenter study that will utilize qualitative and quantitative methods to develop and test quality metrics for lung cancer screening.
Status of Support: Active
Project Number: 99908
Name of PD/PI: Rendle K. and Vachani A.
Source of Support: Moore Foundation
Primary Place of Performance: University of Pennsylvania/Kaiser Permanente Colorado/Kaiser Permanente Hawaii/Henry Ford Health System/Marshfield Clinic
Project/Proposal Start and End Date: 10/26/20-04/25/22
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2021	1.2 calendar
2. 2022	1.2 calendar

Title: *Watch the Spot Trial: Pragmatic Trial of More versus Less Intensive Strategies for Active Surveillance of Patients with Small Pulmonary Nodules*
Major Goals: Pragmatic trial of more versus less intensive strategies for active surveillance of patients with small pulmonary nodules.
Status of Support: Active
Project Number: PCS-1403-12653
Name of PD/PI: Gould, MK
Source of Support: PCORI
Primary Place of Performance: Kaiser Permanente Southern California coordinating center for 14 site pragmatic trial.
Project/Proposal Start and End Date: 07/01/15-12/31/22
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2015	1.2 calendar
2. 2016	1.2 calendar
3. 2017	1.2 calendar

Year (YYYY)	Person Months (##.##)
4. 2018	0.6 calendar
5. 2019	0.6 calendar
6. 2020	0.6 calendar
7. 2021	0.6 calendar
8. 2022	0.6 calendar

Title: *Penn Center of Excellence in Population Science: Catchment Area Precision Lung Cancer Screening*
Major Goals: This internal grant supports three projects: 1) Characterize a cohort of patients at the University of Pennsylvania Health System that are eligible for lung cancer screening; 2) conduct community exposomics as a predictor of lung cancer risk; and 3) evaluate the use of circulating and imaging biomarkers for the early detection of lung cancer
Status of Support: Active
Project Number: N/A
Name of PD/PI: Vachani A., Rendle K., Penning TR, Schnall M.
Source of Support: Penn Abramson Cancer Center
Primary Place of Performance: University of Pennsylvania
Project/Proposal Start and End Date: 04/01/18-03/31/22
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2018	0.12 calendar
2. 2019	0.12 calendar
3. 2020	0.12 calendar
4. 2021	0.12 calendar
5. 2022	0.12 calendar

ACTIVE VA FUNDING

Title: *Veterans Affairs Lung Cancer Surgery or Stereotactic Radiotherapy trial (VALOR)*
Major Goals: Multicenter trial to investigate the role of lung cancer surgery compared to stereotactic radiation for individuals with early-stage lung cancer
Status of Support: Active
Project Number: CSP 2005
Name of PD/PI: Harpole D. and Moghanaki D.
Source of Support: VA Cooperative Studies Program
Primary Place of Performance: Multiple VA centers
Project/Proposal Start and End Date: 10/01/21-09/30/23
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2021	0.6 calendar
2. 2022	0.6 calendar
3. 2023	0.6 calendar

PENDING

Title: Advancing cancer care and equity through telehealth, communication science, and behavioral economics
Major Goals: These studies will apply insights from communication science and behavioral economics to design and test synchronous telehealth strategies, supported by asynchronous elements, to improve effectiveness and equity across the cancer care continuum.
Status of Support: Pending
Project Number: GM1XX56LEP58
Name of PD/PI: Bekelman J., Rendle K., and Vachani A.
Source of Support: NIH/NCI
Primary Place of Performance: University of Pennsylvania
Project/Proposal Start and End Date: 07/01/22-06/31/27
Total Award Amount (including Indirect Costs):

Year (YYYY)	Person Months (##.##)
1. 2022	3.0 calendar
2. 2023	3.0 calendar
3. 2024	3.0 calendar
4. 2025	3.0 calendar
5. 2026	3.0 calendar

OVERLAP

There are no scientific or budgetary overlap among the currently active or pending grants. Should any future grants be awarded funding, effort on grants where he is PI will remain unchanged and he will reduce effort as appropriate on other grants. In no event will total active effort exceed 12 CM.

I, Anil Vachani, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

ANIL VACHANI 482775

Digitally signed by ANIL VACHANI 482775
Date: 2022.06.13 13:41:10 -04'00'

LC170215: Cancer Associated Macrophage-Like (CAML) Cells to Enhance Detection of Early Stage Lung Cancer and Relapse after Definitive Treatment

PI: Martin Edelman, M.D., Institute for Cancer Research, PA

Budget: $672,969

Topic Area: Lung Cancer

Mechanism: Translation Research Partnership Award

Research Area(s): 0701 – Clinical Biomarkers

Award Status: 07/15/2018 – 07/14/2023

Study Goals: Cancer Associated Macrophage Like (CAML) cells are a recently discovered immune cell that appears early in the course of malignancy. Indeterminate pulmonary nodules are commonly seen and present a clinical problem regarding the timing and intensity of evaluation for malignancy. Our hypothesis is that CAMLs can substantially enrich for the presence of malignancy in the population of patients with pulmonary nodules and allow for earlier diagnosis in malignancy. Conversely, the absence of CAMLs would predict for absence of malignancy and prevent unnecessary procedures.

Specific Aims:

1. To conduct an observational study of CAMLs in patients with indeterminate pulmonary nodules.
2. To determine the positive and negative predictive value of CAMLS in patients with pulmonary nodules who undergo biopsy.
3. Model combinations of clinical factors with the presence/absence of CAMLs to refine strategies for assessment of patients with pulmonary nodules.

Key Accomplishments and Outcomes:

Publications: none to date

Patents: none to date

Funding Obtained: none to date

BUDGET UPDATE

The estimated balance is total costs (direct costs; consortium costs; and F&A at 83%). The funds are Fox Chase will be spent on biostatistics, radiology, and travel. Our subcontractor is still accruing patients and anticipates all funds will be spent out.