

# **SCIENCE PORTFOLIO 2009-2022**

**JUNE 2022** 

June 2022

This is where the end of cancer begins. When together, We become a force unmistakable. A movement undeniable. A light that cannot dim. When we take Our wild impossible dreams And make them possible Make them true We rise up as one When we stand up To Cancer.

Dear Members of the Stand Up To Cancer Community:

On behalf of our dedicated scientists, partners, staff, and patient advocates that make up the Stand Up To Cancer community, I am pleased to be able to share with you our June 2022 SU2C Science Portfolio.

This document presents the extraordinary work of Stand Up To Cancer, advancing translational research and health equity to speed the development of new treatments for cancer while ensuring these advances are available to everyone who needs them. Since 2009, this network has been supported by generous pledges of more than \$746 million, funding the work of more than 2,000 scientists and contributing to the US Food and Drug Administration approval of nine new cancer therapies.

In this booklet, you will find information on more than 125 team science grants and awards, more than 50 grants to individuals, and information about the 260-plus clinical trials conducted by our vast network of researchers. Their work has provided countless insights into potential new treatments for cancer. We are so grateful to all the donors that have made this research possible. SU2C continues, with help from our media and entertainment allies, to bring messages about the importance of cancer prevention and participation in cancer clinical trials to communities across the nation. These awareness campaigns are a crucial part of our work to ensure that everyone has access to the most effective cancer treatments.

All of this has been accomplished as the result of the dedication of the scientists and advocates participating in SU2C research projects and the staff both at SU2C and the American Association for Cancer Research. Thank you all for your commitment and dedication to this work.

With warm regards,

Russell Chew President and CEO Stand Up To Cancer



Stand Up To Cancer 10880 Wilshire Boulevard Suite 1400 Los Angeles, CA 90024

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Stand Up To Cancer is a division of the Entertainment Industry Foundation, a 501(c)(3) charitable organization. Federal ID 95-1644609

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#### 61 SU2C Epigenetics Dream Team Bringing Epigenetic Therapy to the Forefront of Cancer Management Team Leader: Stephen B. Baylin, MD, Johns Hopkins University

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- 71 SU2C-CRUK Pediatric Cancer New Discoveries Challenge Research Team Combinatorial Targeting of Oncogene-Driven Childhood Cancer Team Leader: John Anderson, MBBS, MRCP, PhD, University College London Great Ormond Street Institute of Child Health
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- 85 SU2C-Lustgarten Foundation Pancreatic Cancer Interception Research Team Developing Novel Approaches to Detect and Treat Early Pancreatic Cancer Team Leader: David P. Ryan, MD, Massachusetts General Hospital
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- 87 SU2C-Lustgarten Foundation Translational Research Team Chimeric Antigen Receptor T-cell (CAR T) Therapy for Pancreatic Cancer Team Leader: Carl H. June, MD, University of Pennsylvania
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   Team Leader: Siddhartha Mukherjee, MD, Columbia University
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- 90 SU2C-Dutch Cancer Society Translational Research Team Prospective Use of DNA-Guided Personalized Cancer Treatment Team Leader: Emile E. Voest, MD, PhD, Netherlands Cancer Institute

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#### 92 SU2C Convergence 3.1416 Research Team

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Team Leader: Ileana Cristea, PhD, Princeton University

#### 94 SU2C Convergence 3.1416 Research Team

Integrating Gnotobiotic, Organoid, and Metabolomic Pipelines to Probe the Cancer-Microbiome Connection **Team Leader:** Kenya Honda, MD, PhD, Keio University, Japan

#### 96 SU2C Convergence 3.1416 Research Team

Integrating Microbiome and Organoid Analyses of Patient Cohorts for Immuno-oncology Therapeutic Development **Team Leader:** Calvin Kuo, MD, PhD, Stanford University

#### 98 SU2C Convergence 3.1416 Research Team Multi-omic Analysis of Immune System and Microbiota Influence on Temporal and Spatial Evolution of Tumor Microenvironments Team Leader: Dan Littman, MD, PhD, New York University Grossman School of Medicine

#### **100** SU2C Convergence 3.1416 Research Team

Intra-team Collaboration: The Multi-organ Organoid Chemostat Group Team Leader: Calvin Kuo, MD, PhD, Stanford University

#### **101** SU2C Convergence Research Team

Correlating Immunological Health to Cancer Susceptibility Team Leader: Mark M. Davis, PhD, Stanford University

## **102** SU2C Convergence Research Team

Single-Cell Functional Multi-omics to Characterize and Monitor CAR T Therapy **Team Leader:** Rong Fan, PhD, Yale University

#### **103 SU2C Convergence Research Team** Machine Learning for Cancer Immunotherapy

Team Co-leader: Ernest Fraenkel, PhD, Massachusetts Institute of Technology Team Co-leader: Regina Barzilay, PhD, Massachusetts Institute of Technology

#### 104 SU2C-Lustgarten Foundation Convergence Research Team Computational Deconstruction of Neoantigen-TCR Degeneracy for Cancer Immunotherapy Team Co-leader: Benjamin Greenbaum, PhD, Memorial Sloan Kettering Cancer Center Team Co-leader: Vinod Balachandran, MD, Memorial Sloan Kettering Cancer Center

#### 105 SU2C Convergence Research Team Integrating Experimental and Computational Pipelines to Develop Biomarkers of Tumor Cell Resistance to NK Cells Team Leader: Constantine S. Mitsiades, MD, PhD, Dana-Farber Cancer Institute

106 SU2C Convergence Research Team Responders and Non-responders to Endometrial Cancers With Mismatch Repair Team Leader: Alessandro D. Santin, MD, Yale University

#### 107 SU2C Convergence Research Team Connecting Immune Health and Tumor Biology in Gynecologic Cancers Team Leader: E. John Wherry, PhD, University of Pennsylvania

- 108 SU2C-Breast Cancer Research Foundation Convergence Research Team Ecology of the Tumor Microenvironment in Breast Cancer Team Leader: Peter P. Lee, MD, City of Hope
- 109 SU2C-National Science Foundation Convergence Research Team Rational Design of Anticancer Drug Combinations with Dynamic Multi-Dimensional Input Team Leader: Anthony G. Letai, MD, PhD, Dana-Farber Cancer Institute
- 110 SU2C-National Science Foundation Convergence Research Team Genetic, Epigenetic, and Immunological Underpinnings of Cancer Evolution Through Treatment Team Leader: Ross Levine, MD, Memorial Sloan Kettering Cancer Center

Team Co-leader: Jedd Wolchok, MD, PhD, Memorial Sloan Kettering Cancer Center

111 SU2C-National Science Foundation-Lustgarten Foundation Convergence Research Team Liberating T-Cell Mediated Immunity to Pancreatic Cancer Team Co-leader: Peter O'Dwyer, MD, University of Pennsylvania Team Co-leader: Jeffrey Drebin, MD, Memorial Sloan Kettering Cancer Center

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- 115 Lung Cancer Health Equity SU2C Catalyst® Research Team Technology-Enabled Immunotherapy Monitoring in NYC Minority NSCLC Patients Team Leader: Vamsidhar Velcheti, MD, New York University Grossman School of Medicine
- 116 SU2C Catalyst® Research Team Grant Program With Support From Mirati Therapeutics Targeting Adaptive and Acquired Resistance to Direct KRAS Inhibition Team Leader: Ryan B. Corcoran, MD, PhD, Massachusetts General Hospital
- 117 SU2C Catalyst® Research Team With Support From Genentech Atezolizumab, Abiraterone, and SBRT in Hormone Sensitive Prostate Cancer Team Leader: Sean M. McBride, MD, Memorial Sloan Kettering Cancer Center
- 118 SU2C Catalyst® Research Team With Support From Genentech Combination Sacituzumab and Atezolizumab to Prevent Recurrence in Triple Negative Breast Cancer (TNBC) Team Leader: Elizabeth A. Mittendorf, MD, PhD, Dana-Farber Cancer Institute
- 119 Pediatric SU2C Catalyst® Research Team With Support From Bristol Myers Squibb Clinical Translation of Novel Immune-Based Combination Therapies for Pediatric Hypermutant Cancers Team Leader and Clinical Lead: Uri Tabori, MD, The Hospital for Sick Children
- 120 Pediatric SU2C Catalyst® Research Team With Support From Bristol Myers Squibb Immunomodulation to Treat Poor-Prognosis Pediatric Brain Tumors Team Leader: Maryam Fouladi, MD, Nationwide Children's Hospital

- 121 Pediatric SU2C Catalyst® Research Team With Support From Bristol Myers Squibb Targeting Epigenetic Dysregulation in Pediatric Cancer Team Leader: Kimberly Stegmaier, MD, Dana-Farber Cancer Institute
- 122 SU2C Catalyst® Research Team With Support From Genentech Neoadjuvant Therapy for Patients With High-Risk Stage III Melanoma Team Leader: Matthew S. Block, MD, PhD, Mayo Clinic
- 123 SU2C Catalyst® Research Team With Support From Genentech Immunotherapy Combination Strategies in ER-Positive Metastatic Breast Cancer Team Leader: Ingrid A. Mayer, MD, Vanderbilt University
- 125 SU2C Catalyst® Research Team With Support From Genentech Overcoming Urothelial Cancer Atezolizumab Resistance by Epigenetic Therapy Team Leader: Peter A. Jones, PhD, DSc, Van Andel Institute
- 126 SU2C Catalyst® Research Team With Support From Bristol Myers Squibb Tumor Infiltrating Lymphocyte Adoptive T-Cell Therapy for Non-small Cell Lung Cancer (NSCLC) Team Co-leader: Eric B. Haura, MD, H. Lee Moffitt Cancer Center & Research Institute Team Co-leader: Scott J. Antonia, MD, PhD, Duke University
- 127 SU2C Catalyst® Research Team With Support From Bristol Myers Squibb Immunotherapy to Prevent Progression in Multiple Myeloma Team Leader and Clinical Lead: Irene M. Ghobrial, MD, Dana-Farber Cancer Institute
- 128 SU2C Catalyst® Research Team With Support From Merck Pembrolizumab and Radiation Therapy to Improve Outcome in High-Risk Sarcoma Team Leader and Clinical Lead: David G. Kirsch, MD, PhD, Duke University Medical School
- 129 SU2C Catalyst® Research Team With Support From Bristol Myers Squibb Reversing Primary Anti-PD-1 Resistance with Ipilimumab and Nivolumab Team Leader: Antoni Ribas, MD, PhD, University of California, Los Angeles
- 130 SU2C Catalyst® Research Team With Support From Merck Targeting VDR to Make Pancreatic Cancer Competent for Immunotherapy Team Leader and Clinical Lead: Daniel D. Von Hoff, MD, Translational Genomics Research Institute
- 132 SU2C Catalyst® Research Team With Support From Merck Combined Epigenetic Therapy and Pembrolizumab for Advanced Non-small Cell Lung Cancer (NSCLC) Team Leader: Stephen B. Baylin, MD, Johns Hopkins University
- 134 SU2C Catalyst® Research Team With Support From Bristol Myers Squibb Combined Approaches by Immune Checkpoint Inhibition for Hypermutant Cancers Team Leader: Uri Y. Tabori, MD, The Hospital for Sick Children
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# **SU2C Scientific Advisory Committee**

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#### Waun Ki Hong, MD (In Memorium) The University of Texas MD Anderson Cancer Center

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Advocate President Team Finn Foundation

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Executive Director Meharry-Vanderbilt Alliance

# Robert A. Winn, MD

Director Massey Cancer Center Virginia Commonwealth University

# **ABOUT SU2C**



# Stand Up To Cancer: A Groundbreaking Movement Transforming Cancer Research

Founded in 2008 by women leaders in the entertainment and media industries, Stand Up To Cancer is a groundbreaking movement that accelerates cancer research and gets new therapies to patients quickly to save lives now.

Since our founding, Stand Up To Cancer has supported more than 175 science projects to multi-year, multi-institution collaborations with budgets of up to \$22 million. More than \$746 million has been pledged for these efforts. We have funded 125 team science projects, as well as 50 individuals through our Innovative Research Grants for early-career researchers and other grants. And more than 260 clinical trials enrolling more than 19,000 patients have been launched. To date, SU2C research has contributed to nine FDA approvals of cancer therapies.

SU2C's research projects bring together top investigators from different institutions to accelerate the discovery and delivery of new therapies, and they have evolved to include an array of industry collaborations, as well. Focusing on accelerating the development of new therapies, new methods of cancer interception, and new approaches to making these treatments and screening available to all, we have created grant mechanisms that fund meaningful team-based research projects. Collectively, they offer opportunities for cancer science and cancer treatment questions to be answered using a variety of techniques.

- Our flagship Dream Team grants fund multidisciplinary, multi-institutional, collaborative teams to take innovative ideas from concept to patient.
- Research Teams bring together scientists from different institutions answering important questions about cancer research and treatment.

- SU2C Convergence Grants unite physical and computational scientists with oncologists to ask fundamental questions about cancer biology, producing insights that can be rapidly applied for patient benefits.
- SU2C Catalyst® teams use funding, compounds, and other materials from the pharmaceutical and biotechnology industries to rapidly assess new treatment combinations.
- Innovative Research Grants support cuttingedge cancer research that might not receive funding through traditional channels.
- And the Phillip A. Sharp Innovation in Collaboration Award, the Ziskin Prize, the Jim Toth Sr. Breakthrough Lung Cancer Research Award, the Peggy Prescott Early Career Award, and the Golden Arrow Award provide support for smaller projects to rapidly explore the newest and most exciting ideas emerging from the cancer research community.

To further support development of cancer treatments that are effective across all communities, the SU2C Health Equity Committee continues to help us find ways to lower the barriers of access to new treatments for all cancer patients.

With mounting evidence for the need to develop precision medical treatments and interventions to serve diverse patient populations, we are supporting the inclusion of historically under-represented racial and ethnic minority populations in clinical trials that we fund. SU2C staff continue to produce educational materials for the public to drive awareness of clinical trials and participation, as well.

# DREAM TEAMS



# Community Collaboration to Advance Racial/Ethnic Equity in CRC Screening

GRANT TERM: September 2021 - August 2024

#### **KEY PERSONNEL:**



Team Leader: Jennifer Haas, MD, MSc, Massachusetts General Hospital



- Tinka Duran, MPH, Great Plains Tribal Chairmen's Health Board
- Sapna Syngal, MD, MPH, Dana-Farber Cancer Institute
- Staci J. Wendt, PhD, Providence System Research Hub
- Bill Wright, PhD, Providence System Research Hub

#### **Specific Aims:**

AIM 1. Develop and conduct a two-arm, multilevel, multicomponent, pragmatic trial randomized at the level of the community health center to compare two population outreach approaches, Cologuard or fecal immunochemical test (FIT), to increase CRC screening.

**AIM 2.** Conduct patient follow-up after an abnormal Cologuard or FIT screening test result.

**AIM 3.** Mentor a new generation of underrepresented in medicine and underrepresented in public health researchers focused on CRC prevention and control.

AIM 4: Design and deploy a community-based campaign to increase CRC screening rates in a demographically diverse impact zone within Los Angeles County.

#### **Project Managers:**

 Suzanne Brodney, PhD, Massachusetts General Hospital, Sbrodney@mgh.harvard.edu

Team Co-leader:

Anton Bilchik, MD,

Cancer Institute

Saint John's

• Rhea Cabardo, Providence Saint John's Health



#### **Team Co-leader:**

Folasade P. May, MD, PhD, University of California, Los Angeles

#### Advocates:

- Marsha Baker, Fight CRC; Steve Baker Colorectal Cancer Alliance
- Cathy Jeffries
- Kimberly Schoolcraft, Fight CRC
- Helena L Williams

#### Website:

https:// standuptocancer.org/ research/researchportfolio/dream-teams/ colorectal-cancerhealth-equity-dreamteam/

#### DREAM TEAMS

SU2C COLORECTAL CANCER I COMMUNITY COLLABORATION EQUITY IN CR

September 2021

#### **Community Engagement Grants:**

Local organizations are supporting grassroots engagement to increase colorectal cancer screening in each Stand Up To Cancer Zone.

#### Boston

Greater Boston Nazarene Compassionate Center Whittier Street Health Center

#### **Los Angeles**

Black Women for Wellness Corazon y Caracter TRAPMedicine

#### Great Plains Tribal Communities in South Dakota

Oyate Health Center

# DISRUPT: Diversity and IncluSion in Research Underpinning Prevention and Therapy Trials

GRANT TERM: May 2021 - April 2025

### **KEY PERSONNEL:**



# Team Leader:

Nina A. Bickell, MD, MPH, Icahn School of Medicine at Mount Sinai

AIM 1. Address community norms regarding participation in cancer

AIM 2. Disrupt current practice by making cancer clinical trials an easy and

AIM 3. Disrupt norms in clinical trial design and methods by supporting basic

science discovery that will increase its relevance to questions essential to

### **Principals:**

- Bruce Rapkin, PhD, Albert Einstein College of Medicine
- Mary Beth Terry, PhD, Columbia University

### **Project Managers:**

- Nicholas Bove, Albert Einstein College of Medicine, nicholas.bove@ einsteinmed.edu
- Kimberly Burke, Columbia University, krb2160@ cumc.columbia.edu

accessible choice for every patient.

reducing cancer health inequities.

**Specific Aims:** 

research.

- Kelly Smith Elgart, Albert Einstein College of Medicine, kellysmith176@gmail.com
- Leo Spychala, MPH, City College of New York, Ispychala@ccny.cuny.edu
- Ariana Tao, Albert Einstein College, of Medicine ariana.tao@ einsteinmed.org
- Radhi M. Yagnik, MS, Icahn School of Medicine at Mount Sinai, Radhi.Yagnik@mountsinai.org



#### **Team Co-leader:** Karen Hubbard, PhD,

City College of New York

#### Advocates:

- Rev. Zorina Costello, DMin, MDiv, MS, Center for Spirituality and Health, Icahn School of Medicine at Mount Sinai
- Ivis Sampayo, SHARE Cancer Support
- Desiree Walker

# Websites:

https:// standuptocancer. org/research/ research-portfolio/ dream-teams/healthequity-breakthroughdream-team/

https://www. stopcancernyc.org/



SU2C HEALTH EQUITY BREAKTHROU DISRUPT: DIVERSITY & INCLUSION IN RESEAS PREVENTION & THERAPY TRI

May 2021-April 2025

The SUBD Health Equity Breaktrough Team Research Grant Program ends participation by tacket and ethnic minority populations in cancer research des disease in those proups. Health dispartices research healthaditionally been hap

# DREAM TEAMS

SU2C Canada-Lustgarten Foundation-Pancreatic Cancer Canada PASS Convergence Dream Team CV6179, CV6185

# PASS-01- Pancreatic Adenocarcinoma Signature Stratification for Treatment-01

Daniel Laheru, MD,

Eileen O'Reilly, MD,

Cancer Center

Kenneth Yu, MD,

Cancer Center

Johns Hopkins University

Memorial Sloan Ketterina

Memorial Sloan Kettering

GRANT TERM: August 2020 - February 2024

#### **KEY PERSONNEL:**



**Team Co-leader:** Jennifer Knox, MD, University Health Network



- Andrew Aquirre, MD, PhD, Dana-Farber Cancer Institute
- Steven Gallinger, MD, Ontario Institute for Cancer Research
- Daniel King, MD, Northwell Health Center for Advanced Medicine



**Team Co-leader:** Elizabeth Jaffee, MD, John Hopkins University

#### Collaborator:

 David Tuveson, MD, PhD, Cold Spring Harbor Laboratory

#### **Project Manager:**

Anna Dodd, University Health Network, Anna.Dodd@uhn.ca

#### **Specific Aims:**

**AIM 1.** Determine the PFS benefit of modified FOLFIRINOX (mFFX) compared with gemcitabine/nab-paclitaxel (GA) as first-line treatment in metastatic pancreatic ductal adenocarcinoma (PDAC) in a randomized phase II trial.

**AIM 2.** Explore biomarker correlation to treatment response and patient outcomes.

**AIM 3.** Evaluate concordance between patient response and outcomes with model (PDO) profiles, signatures, and pharmacotyping.

**AIM 4.** Compile a detailed genomic annotation of advanced PDAC patients on first-line chemotherapy.

#### **Clinical Trial:**

A Randomized Multicentre Phase II Trial to Evaluate the Two Standard Chemotherapy Regimens, Modified FOLFIRINOX (mFFX) and Gemcitabine/ Nab-Paclitaxel (GA), in Patients With Untreated Metastatic Pancreatic Ductal Adenocarcinoma; NCT04469556; Recruiting

#### Website:

https:// standuptocancer. ca/the-science/passdream-team/

#### PASS CONVERGENCE DREAM TEAM

Stand Up to Cancer Conado-Lustgarten Foundation-Pa Canada PASS Convergence Dream Team: PASS-01-Pan Adenocarcinoma Signature Strattification for Treatment



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# Targeting mRNA Translation to Effectively Treat Metastatic Breast Cancer

GRANT TERM: July 2019 - September 2022, administered by the American Association for Cancer Research

**Project Manager:** 

Harvey W. Smith, PhD,

harvey.smith2@mcgill.ca

McGill University,

#### **KEY PERSONNEL:**



**Team Leader:** Nahum Sonenberg, PhD, McGill University

#### **Principals:**

- Lynne-Marie Postovit, PhD, Queens University
- Poul H. B. Sorenson, MD, PhD, BC Cancer Research Institute



# Team Co-leader:

Michael N. Pollak, MD, Lady Davis Institute for Medical Research

#### Advocates:

- Candace Cook
- Lynn Gentile, Lynn and Joe Gentile Hope Fund

#### **Specific Aims:**

**AIM 1.** Run clinical trial of the MNK inhibitor EFT508 in patients with metastatic breast cancer.

AIM 2. Conduct pharmacodynamic studies of the MNK inhibitor EFT508 in patients with metastatic breast cancer.

#### **Clinical Trial:**

Trial to Assess the Safety, Pharmacodynamic Effects, Pharmacokinetics, and Efficacy of the MNK Inhibitor Tomivosertib (eFT508) in Combination With Paclitaxel, Following a Run-In Period of Tomivosertib Monotherapy, in Patients With Advanced Breast Cancer; NCT04261218; Recruiting

#### Website:

http://www. standuptocancer.ca/ en/dream\_teams/view/ metastatic\_breast\_ cancer\_dream\_team



# Tailoring CAR-based Immunotherapy Strategies to T-Cell Lymphoma

GRANT TERM: March 2019 - August 2022, administered by the American Association for Cancer Research

**Project Manager:** 

Advocates:

at Houston

Reynaldo Herrera, Baylor

Reynaldo.Herrera@bcm.edu

Gustavo Ayala, University of

Texas Health Science Center

College of Medicine,

#### **KEY PERSONNEL:**



## Team Leader:

Helen E. Heslop, MD, Baylor College of Medicine

#### **Principals:**

- Bayard L. Powell, MD, Wake Forest University Health Sciences
- Katy Rezvani, MD, PhD, The University of Texas MD Anderson Cancer Center



#### Team Co-leader:

Gianpietro Dotti, MD, University of North Carolina at Chapel Hill

- Bambi Grilley, Baylor College
   of Medicine
- Ruth Sorelle, Baylor College
   of Medicine
- Patty Spears, University of North Carolina at Chapel Hill

## **Specific Aims:**

**AIM 1.** Conduct a series of phase I clinical trials of CAR-ACT targeting different T-cell antigens in patients with resistant TCLs.

**AIM 2.** Identify factors that shape responses to CAR-ACT and thus inform the next generation of immune cell engineering.

**AIM 3.** Test additional modifications of CAR-ACT to improve their function against resistant TCLs.

#### **Clinical Trials:**

Phase I Study of Relapsed CD30 Expressing Lymphoma Treated With CD30 CAR T Cells (RELY-30); NCT02917083; Recruiting

Phase I Study of the Administration of T Lymphocytes Co-expressing the CD30 Chimeric Antigen Receptor (CAR) and CCR4 for Relapsed/Refractory CD30+ Hodgkin Lymphoma and CD30+ Non-Hodgkin Lymphoma; NCT03602157; Recruiting

Phase II Study of the Administration of T Lymphocytes Expressing the CD30 Chimeric Antigen Receptor (CAR) for Relapsed/Refractory CD30+ Peripheral T-Cell Lymphoma; NCT04083495; Recruiting

Phase I Study Evaluating the Safety and Activity of Allogeneic Chimeric Antigen Receptor Epstein-Barr Virus-Specific T Lymphocytes (CD30.CAR-EBVSTs) in Patients With Relapsed or Refractory CD30-Positive Lymphomas; NCT04288726; Recruiting

#### Website:

https:// standuptocancer.org/ research/researchportfolio/dream-teams/ t-cell-lymphomadream-team

#### DREAM TEAMS

Research > Research Portfolio > Dream Teams > T-Cell Lympt

SU2C MEG VOSBURG T-CELL TAILORING CAR-BASED IMM TO T-CELL L

# **Screening and Interception of Precursor Myeloma**

GRANT TERM: September 2018 - August 2022, administered by the American Association for Cancer Research

**KEY PERSONNEL:** 



## Team Leader:

Irene M. Ghobrial, MD, Dana-Farber Cancer Institute

#### Principals:

- Gad A. Getz, PhD, Broad Institute
- Jeremiah A. Johnson, PhD, Massachusetts Institute of Technology
- Prashant Kapoor, MBBS, Mayo Clinic
- Timothy R. Rebbeck, PhD, Harvard T. H. Chan School of Public Health

#### **Project Director:**

Elizabeth Kitzenberg
 Dana-Farber Cancer Institute



# Team Co-leader:

Ivan M. Borrello, MD, Johns Hopkins University School of Medicine

#### **Project Manager:**

Julia Colchie,
 Dana-Farber Cancer Institute,
 julia\_colchie@dfci.harvard.edu

#### Advocates:

- Jenny M. Ahlstrom, Crowd Care Foundation
- Cheryl A. Boyce (deceased)
- Marie Cherisol
- Rebecca A. Nutley
- Kelly Smith
- Yaphet Smith

#### **Specific Aims:**

AIM 1. Establish a screen-detected prospective cohort study of monoclonal gammopathy of undetermined significance (MGUS)/ smoldering multiple myeloma (SMM) patients at risk for multiple myeloma (MM) (Predicting Progression of Developing Myeloma in a High-Risk Screened Population, PROMISE).

**AIM 2.** Dissect genomic characteristics of clonal evolution from MGUS/SMM to MM and germline variants of high-risk individuals at risk of developing MGUS/SMM.

**AIM 3.** Evaluate the role of race, obesity, and health-related comorbidities on progression from pre-MM states to MM.

AIM 4. Define the permissive tumor microenvironment in MGUS/SMM.

AIM 5. Develop novel imaging and therapeutic approaches to detect and intercept disease progression at the precursor stages of the disease.

#### **Clinical Trial:**

Predicting Progression of Developing Myeloma in a High-Risk Screened Population (PROMISE); NCT03689595; Recruiting

#### Websites:

#### https://

standuptocancer.org/ research/researchportfolio/dream-teams/ precursor-myelomadream-team/

https://www.enroll. promisestudy.org/



SU2C-LUNGevity Foundation-American Lung Association Lung Cancer Interception Dream Team DT6045

# Intercept Lung Cancer Through Immune, Imaging, and Molecular Evaluation (InTIME)

GRANT TERM: March 2018 - August 2022, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Avrum E. Spira, MD, Boston University

#### **Principals:**

- Charles Swanton, MD, PhD, Francis Crick Institute
- Carina Mari Aparici, MD, Stanford University
- Julie R. Brahmer, MD, Johns Hopkins University
- Matthew L. Meyerson, MD, PhD, Dana-Farber Cancer Institute



# **Team Co-leader:** Steven M. Dubinett, MD,

University of California, Los Angeles

#### **Project Manager:**

 Sarah Mazilli, PhD, Boston University, mazzilli@bu.edu

#### Advocates:

- Marcia Horn, JD, International Cancer Advocacy Network
- Kim Norris, Lung Cancer Foundation of America

#### **Specific Aims:**

**AIM 1.** Establish a Pre-Cancer Genome Atlas (PCGA) to identify genomic, transcriptomic, and immune determinants of lung squamous and adenomatous premalignancy.

**AIM 2.** Identify molecular and imaging markers that distinguish malignant from benign indeterminate pulmonary nodules and circulating DNA markers that predict tumor recurrence.

**AIM 3A.** Develop molecular biomarkers to enable precision interception approaches in ongoing clinical trials of lung cancer interception.

**AIM 3B.** Discover baseline biomarkers predictive of therapeutic response to neoadjuvant therapy with immune checkpoint inhibitors and temporal markers of therapeutic efficacy.

**AIM 3C.** Assess therapeutic efficacy of adjuvant chemotherapy and immunotherapy among patients with subclinical evidence of lung cancer recurrence using ctDNA.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ dream-teams/lungcancer-interceptionintime-dream-team/

#### DREAM TEAMS

Research > Research Portfolio > Dream Teams > Long Cancer Interception

SU2C-LUNGEVITY FOUNDATION-AMERI LUNG CANCER INTERCEPTIOI INTERCEPT LUNG CANCER THROUGH MOLECULAR EVALUATIO

# SU2C-LUNGevity Foundation-American Lung Association Lung Cancer Interception Dream Team DT6045

#### **Clinical Trials:**

Neoadjuvant Nivolumab, or Nivolumab in Combination with Ipilimumab, in Resectable Non-small Cell Lung Cancer; NCT02259621; Recruiting

18F-FSPG PET/CT and Integrated Biomarkers for Early Lung Cancer Detection in Patients With Indeterminate Pulmonary Nodules; NCT03824535; Recruiting

Phase III, Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Determine the Efficacy of Adjuvant Durvalumab in Combination With Platinum-Based Chemotherapy in Completely Resected Stage 2-3 NSCLC (MERMAID-1); NCT04385368; Recruiting

# Intercepting Pancreatic Cancer in High-Risk Cohorts

GRANT TERM: February 2018 - July 2022, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



Team Leader:

Anirban Maitra, MBBS, The University of Texas MD Anderson Cancer Center



- Tyler Jacks, PhD, Massachusetts Institute of Technology
- Gloria M. Petersen, PhD, Mayo Clinic
- Sapna Syngal, MD, Dana-Farber Cancer Institute



**Team Co-leader:** Michael G. Goggins, MD, Johns Hopkins University

## Project Manager:

Pamela Constantinou Papadopoulos, PhD, The University of Texas MD Anderson Cancer Center, pcpapadopoulos@ mdanderson.org



### **Team Co-leader:** Scott M. Lippman, MD, University of California, San Diego

#### Advocates:

- Barbara J. Kenner, PhD, Kenner Family Research Fund
- Scott Nelson

#### Specific Aims:

AIM 1. Enhance access to germline testing and screening protocols for cancer interception in high-risk cohorts and combine this with novel imaging algorithms to diagnose early PDAC lesions that are currently undetectable.

**AIM 2.** Intercept pancreatic cancer in high-risk cohorts using targeted immune prevention.

**AIM 3.** Develop a blood test for identifying individuals at risk for PDAC who would be candidates for early detection using imaging.

#### **Clinical Trial:**

GENetic Education Risk Assessment and TEsting Study (GENERATE); NCT03762590; Active, not recruiting

Pooled Mutant KRAS-Targeted Long Peptide Vaccine Combined with Nivolumab and Ipilimumab for Patients with Resected MMR-p Colorectal and Pancreatic Cancer; NCT04117087; Recruiting

Mutant KRAS-Targeted Long Peptide Vaccine for Patients at High Risk of Developing Pancreatic Cancer; NCT05013216; Not yet recruiting

#### Website:

https:// standuptocancer.org/ research/researchportfolio/dreamteams/pancreaticinterception-high-riskcohorts-dream-team/

## DREAM TEAMS

Research > Research Portfolio > Dream Teams > Pancreatic Inter

SU2C-LUSTGARTEN FOUNDATI-INTERCEPTION D INTERCEPTING PANCREATIC CAN

# Immunogenomics to Create New Therapies for High-Risk Childhood Cancers

GRANT TERM: December 2017 - May 2022, administered by the American Association for Cancer Research

### **KEY PERSONNEL:**



# Team Leader:

John M. Maris, MD, Children´s Hospital of Philadelphia

## **Principals:**

- Nabil M. Ahmed, MD, Baylor College of Medicine
- Lia Gore, MD, University of Colorado
- Rimas Orentas, PhD,
   Seattle Children's Hospital
- Paul M. Sondel, MD, PhD, University of Wisconsin, Madison
- Poul H. B. Sorenson, MD, PhD, BC Cancer Research Institute
- Michael D. Taylor, MD, PhD, The Hospital for Sick Children

#### Investigators:

- Kenneth B. DeSantes, MD, University of Wisconsin, Madison
- Dimiter Dimitrov, PhD, University of Pittsburgh
- Terry J. Fry, MD, University of Colorado

- Stephan Grupp, MD, PhD, Children's Hospital of Philadelphia
- Rosandra N. Kaplan, MD, National Cancer Institute
- Michelle Monje, MD, Stanford University
- Daniel Morgenstern, MA, MBBChir, PhD, The Hospital for Sick Children
- Julie R. Park, MD, Seattle Children's Hospital
- D. William Parsons, MD, PhD, Texas Children's Hospital
- Kirk R. Schultz, MD, BC Cancer Research Institute
- Nirali N. Shah, MD, MHSc, National Cancer Institute

#### **Project Manager:**

 Jennifer L. Baldi, Children's Hospital of Philadelphia, baldij@email.chop.edu



# Team Co-leader:

Crystal L. Mackall, MD, Stanford University

#### Advocates:

- Kelly Cotter, University
   of Wisconsin
- Kelly Forebough, Seattle Children's Hospital
- Bambi J. Grilley, Baylor College of Medicine
- Gavin Lindberg, Children's
   Hospital of Philadelphia
- Melanie Frost Moll, Baylor College of Medicine
- Antonia Palmer, The Hospital for Sick Children
- Kevin Reidy, University of Colorado
- Carlos Sandi, Stanford University and the National Cancer Institute
- Lori Schultz, University of Wisconsin
- Patrick J. Sullivan, BC Cancer Research Institute

#### **Specific Aims:**

**AIM 1.** Discover and validate cell surface proteins as immunotherapeutic targets for high-risk pediatric cancers.

**AIM 2.** Perform preclinical optimization of candidate immunotherapeutics and IND-enabling studies to support the development of clinical trials for pediatric cancers with few therapeutic options.

AIM 3. Conduct pivotal pediatric cancer immunotherapy trials.

# St. Baldrick's Foundation-SU2C Pediatric Cancer Dream Team DT6065

#### **Clinical Trials:**

Phase I Study of HER2-Specific CAR T Cell Locoregional Immunotherapy for HER2-Positive Recurrent/Refractory Pediatric Central Nervous System Tumors; NCT03500991; Recruiting

Phase I Dose-Escalation Study of CD19/CD22 Chimeric Antigen Receptor T Cells in Children and Young Adults With Recurrent or Refractory CD19/CD22-Expressing B-Cell Malignancies; NCT03448393; Recruiting

Pediatric and Young Adult Leukemia Adoptive Therapy (PLAT)-06: Phase I/ Il Study of CD19-Specific CAR T Cells With a Fully Human Binding Domain for CD19+ Leukemia or Lymphoma; NCT03684889; Active, not recruiting

Phase 1 Study of EGFR806-Specific CAR T Cell Locoregional Immunotherapy for EGFR-Positive Recurrent or Refractory Pediatric Central Nervous System Tumors; NCT03638167; Recruiting

#### Website:

https:// standuptocancer.org/ research/researchportfolio/dream-teams/ intractable-pediatriccancers-dream-team/



ST. BALDRICK'S FOUNDATION-SU2C PEDIATRIC TEAM: IMMUNOGENOMICS TO CREATE NEW THER RISK CHILDHOOD CANCERS

Phase I Study of EGFR806 CAR T Cell Immunotherapy for Recurrent/Refractory Solid Tumors in Children and Young Adults; NCT03618381; Recruiting

Phase II Study of Humanized CD19-Directed Chimeric Antigen Receptor-Modified T Cells (huCART19) for Very High Risk Subsets of B-Cell Acute Lymphoblastic Leukemia (B-ALL); NCT03792633; Recruiting

Treatment of CMV Infections With Viral-Specific T Cells Against CMV in Pediatric and Adult Immunocompromised Patients or Recipients of Allogeneic Stem Cell Transplantation; NCT03798301; Recruiting

Phase I Dose-Escalation Study Evaluating Safety and Tolerability of Viral-Specific T Cells Against CMV in Adult Kidney Transplant Recipients; NCT03950414; Recruiting

GD2-CAR PERSIST: Production and Engineering of GD2-Targeted, Receptor-Modified T Cells (GD2CART) for Sarcoma and Neuroblastoma to Increase Systemic Tumor Exposure; NCT04539366; Not yet recruiting

Open-Label Dose-Escalation, Efficacy, and Safety Study of CLR 131 in Children, Adolescents, and Young Adults With Select Solid Tumors, Lymphoma, and Malignant Brain Tumors; NCT03478462; Recruiting

Phase I Study of B7-H3-Specific CAR T Cell Locoregional Immunotherapy for Diffuse Intrinsic Pontine Glioma/Diffuse Midline Glioma and Recurrent or Refractory Pediatric Central Nervous System Tumors; NCT04185038; Recruiting

Phase I/II Study of Anti-CD33 Chimeric Antigen Receptor-Expressing T Cells (CD33CART) in Children and Young Adults With Relapsed/Refractory Acute Myeloid Leukemia; NCT03971799; Recruiting

Phase I Study of B7H3 CAR T Cell Immunotherapy for Recurrent/Refractory Solid Tumors in Children and Young Adults; NCT04483778; Recruiting

Phase Ib Clinical Trial of Autologous CD22 Chimeric Antigen Receptor (CAR) T Cells in Children and Young Adults With Recurrent or Refractory B-Cell Malignancies; NCT04088864; Recruiting

Phase I Clinical Trial of Autologous GD2 Chimeric Antigen Receptor (CAR) T Cells (GD2CART) for Diffuse Intrinsic Pontine Gliomas (DIPG) and Spinal Diffuse Midline Gliomas (DMG); NCT04196413; Recruiting

Phase I Trial of Autologous HER2-Specific CAR T Cells in Pediatric Patients With Refractory or Recurrent Ependymoma; NCT04903080; Not yet recruiting

# Targeting Genomic, Metabolic, and Immunological Vulnerabilities of Colorectal Cancer

GRANT TERM: July 2017 - June 2023, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



Team Leader: Luis A. Diaz Jr., MD, Memorial Sloan Kettering Cancer Center



**Team Co-leader:** Lewis C. Cantley, PhD, Weill Cornell Medical College



Team Co-leader:

Zhenghe J. Wang, PhD, Case Western Reserve University

#### **Principals:**

- Nilofer S. Azad, MD, Johns Hopkins University
- Ryan B. Corcoran, MD, PhD, Massachusetts General Hospital

### **Project Manager:**

 Michelle F. Lamendola-Essel, DrHSc, Memorial Sloan Kettering Cancer Center lamendom@mskcc.org

#### Advocates:

- Erika Brown, Paltown Development Foundation
- Anjee Q. Davis, Fight Colorectal Cancer
- Joanna R. Fuchs, MD, Dana-Farber/ Harvard SPORE
- Manju George, Paltown Development Foundation
- Ivelisse Page, Believe Big
- Martha Raymond, Michael's Mission
- Nancy Roach, Fight Colorectal Cancer
- Steven Schwarze, Paltown Development Foundation

#### **Specific Aims:**

AIM 1. Harness the immune system to treat colorectal cancer.

AIM 2. High impacted targeted pathway blockade in colorectal cancer.

**AIM 3.** Develop high-dose vitamin C as a therapy for KRAS/BRAF mutant colorectal cancer.

**AIM 4.** Target the glutamine dependence of PIK3CA mutant CRC in combination therapy with novel glutaminase inhibitor CB-839 plus capecitabine.

AIM 5. "Precision prevention" for colorectal cancer.

#### Website:

https:// standuptocancer.org/ research/researchportfolio/dream-teams/ colorectal-cancervulnerabilities-dreamteam/

#### DREAM TEAMS

SU2C COLORECTAL CANCER DREA TARGETING GENOMIC, METABOLIC, AND IB VULNERABILITIES OF COLORECTAL

Grant Term: July 2017-June 202

# SU2C Colorectal Cancer Dream Team DT6044

#### **Clinical Trials:**

Phase II Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors; NCT01876511; Completed

Phase III Study of Pembrolizumab (MK-3475) Versus Chemotherapy in Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Stage 4 Colorectal Carcinoma (KEYNOTE-177); NCT02563002; Active, not recruiting

Phase I/II Study of CB-839 and Capecitabinein Patients With Advanced Solid Tumors and Fluoropyrimidine Resistant PIK3CA Mutant Colorectal Cancer; NCT02861300; Recruiting

Nivolumab and Ipilimumab and Radiation Therapy in Microsatellite Stable (MSS) and Microsatellite Instability (MSI) High Colorectal and Pancreatic Cancer; NCT03104439; Recruiting

Phase II Study of High-Dose Vitamin C Intravenous Infusion in Patients With Resectable or Metastatic Solid Tumor Malignancies; NCT03146962; Recruiting

Phase II Study of Dabrafenib and Trametinib in Combination With PDR001 in Patients With BRAFV600E Metastatic Colorectal Cancer; NCT03668431; Recruiting

Phase Ib/II Open-Label Dose Escalation Study of Entinostat in Combination With Pembrolizumab in Patients With Non-small Cell Lung Cancer, With Expansion Cohorts in Patients With Non-small Cell Lung Cancer, Melanoma, and Mismatch Repair–Proficient Colorectal Cancer; NCT02437136; Withdrawn

Phase I/II Study of PI3Kinase Inhibition (Copanlisib) and Anti-PD-1 Antibody Nivolumab in Relapsed/ Refractory Solid Tumors With Expansions in Mismatch Repair-Proficient (MSS) Colorectal Cancer; NCT03711058; Recruiting

Early Identification and Treatment of Occult Metastatic Disease in Stage 3 Colon Cancer; NCT03803553; Recruiting

Phase II Study of Induction PD-1 Blockade in Subjects With Locally Advanced Mismatch Repair–Deficient Solid Tumors; NCT04165772; Recruiting

Phase II Study of Temozolomide, Cisplatin, and Nivolumab in MMR-Proficient Colorectal Cancer; NCT04457284; Recruiting

# Translational Development of Novel Drugs Targeting Tumor Vulnerabilities

GRANT TERM: January 2016 - June 2022, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Tak W. Mak, PhD, Campbell Family Institute for Breast Cancer Research at Princess Margaret Cancer Centre

#### **Principals:**

- Karen A. Gelmon, MD, British Columbia Cancer Agency
- Morag Park, PhD, Goodman Cancer Research Centre and McGill University
- Kathleen I. Pritchard, MD, University of Toronto, Sunnybrook Health Sciences Centre of Toronto



### **Team Co-leader:** Samuel Aparicio, BM, BCh, PhD, University of British Columbia

#### **Project Manager:**

 Thorsten Berger, PhD, University Health Network tberger@uhnres.utoronto.ca

#### Advocates:

- Wendie den Brok, MD, BC Cancer Agency Research Centre
- Randy Mellon, Think Pink Direct
- Zuri Scrivens, The Beautiful Gift

#### **Specific Aims:**

AIM 1. Pursue basic and translational development of CFI-400945, CX5461, and CFI-402257.

AIM 2. Conduct proof-of-concept clinical trials of CFI-400945, CX5461, and CFI-402257.

#### **Clinical Trials:**

Phase I Study of CX5461; NCT02719977; Active, not recruiting

Open-Label Dose-Escalation, Safety, and Pharmacokinetic Study of CFI-400945 Fumarate Administered Orally to Patients With Advanced Cancer; NCT01954316; Active, not recruiting

Open-Label Dose-Escalation, Safety, and Pharmacokinetic Study of CFI-402257 Administered Orally to Patients With Advanced Solid Tumors; NCT02792465; Recruiting

#### Website:

https:// standuptocancer. ca/su2c-canadacanadian-cancersociety-breast-cancerdream-team/

#### BREAST CANCER DREAM TEAM

SU2C Conado-Conadian Concer Society Breast Concer D Translational Development of Novel Drugs Targeting Tumor



# SU2C Canada-Canadian Cancer Society Breast Cancer Dream Team DT6144

### Clinical Trials (Cont'd):

Phase Ib and Open-Label Phase II Study of CFI-402257 in Combination With Weekly Paclitaxel in Patients With Advanced/Metastatic HER2-Negative Breast Cancer; NCT03568422; Recruiting

Phase II Study of CFI-400945 in Patients With Advanced/Metastatic Breast Cancer; NCT03624543; Recruiting

Phase II Study of CFI-400945 and Durvalumab in Patients With Advanced/Metastatic Triple-Negative Breast Cancer (TNBC); NCT04176848; Recruiting

# Reprogramming of Transcriptional Circuitry to Control Pancreatic Cancer

GRANT TERM: January 2016 - June 2020, administered by the American Association for Cancer Research

## **KEY PERSONNEL:**



Team Leader:





**Team Co-leader:** Gerard I. Evan, PhD, University of Cambridge

Advocates:

Devah Pager, PhD,

Harvard University (deceased)

Howard Young, General

Wholesale Beer Company

Jill E. Pechacek, MD (deceased)



Suzanne Berenger, Bain & Company, Inc.

Team Co-leader: Ronald M. Evans, PhD, Salk Research Institute for Biological Studies

#### **Principals:**

- David J. Propper, MBChB, MD, PhD, Barts Cancer Institute and London NHS Trust
- Joshua D. Rabinowitz, MD, PhD, Princeton University

#### **Project Managers:**

- Jatan Clark, TGEN
- Stacie Smith, TGEN

#### **Specific Aims:**

**AIM 1.** Define super-enhancer networks in the cellular milieu of pancreatic cancer.

**AIM 2.** Determine the mechanisms that mediate crosstalk between super-enhancer networks both within cells and between them, including metabolic dependencies.

AIM 3. Determine the utility of super-enhancer disruption in treating pancreatic cancer. (Work on this Aim is continuing as an SU2C subproject.)

#### Website:

https:// standuptocancer.org/ research/researchportfolio/dream-teams/ reprogramming-ofpancreatic-cancerdream-team/

#### DREAM TEAMS

Research > Research Public > Deast Teams > Reproputiting of Percentic Device Deast Team

SU2C-CANCER RESEARCH UK-LUSTGARTEN FOUNDAI PANCREATIC CANCER DEIAM TEAM: REPROBRAMMING OF TEAMICERPTIOHAL CIRCUIT TO CONTROL PANCREATIC CANCER

Brant Berry, Amorey 2016 December 2018

The 15005 - Cancer Present I-UE (20126) - Ladgerine Translation Processis Concer Tream Team spoke survival of parcmetric concer galaxies, with a goal of at least disabling the area year survival a percendic concer from 2015 to more from 10%. The form also area to metalon remains in participant segmented to frequency, extending, and entering the fore of pargins with find theses

#### SU2C-Cancer Research UK-Lustgarten Foundation Pancreatic Cancer Dream Team DT6014

#### **Clinical Trials:**

Phase II Pilot Trial of Nivolumab + Albumin-Bound Paclitaxel +Paricalcitol + Cisplatin + Gemcitabine (NAPPCG) in Patients With Previously Untreated Metastatic Pancreatic Ductal Adenocarcinoma; NCT02754726; Active, not recruiting

Phase II Study of Cabiralizumab (BMS-986227, FPA008) Administered in Combination With Nivolumab (BMS-936558) With and Without Chemotherapy in Patients With Advanced Pancreatic Cancer; NCT03336216; Active, not recruiting

Phase Ib/II Trial of High-Dose Ascorbic Acid (AA) + Nanoparticle Paclitaxel Protein Band + Cisplatin + Gemcitabine (AA NABPLAGEM) in Patients Who Have Received No Prior Therapy for Their Metastatic Pancreatic Cancer; NCT03410030; Active, not recruiting

Phase II Pilot Trial of Paclitaxel Protein Bound Plus Cisplatin Plus Gemcitabine and the Addition of Paricalcitol Upon Disease Progression in Patients With Previously Untreated Metastatic Pancreatic Ductal Adenocarcinoma (NABPLAGEMD); NCT03415854; Active, not recruiting

Vitamin D Receptor Agonist Paricalcitol Plus Gemcitabine and Nab-Paclitaxel in Patients With Metastatic Pancreatic Cancer; NCT03520790; Active, not recruiting

Phase Ib/II Randomized Clinical Trial of Chemotherapy With Nab-Paclitaxel/Gemcitabine/Cisplatin +/the AXL Inhibitor Bemcentinib for Patients With Metastatic Pancreatic Cancer; NCT03649321; Recruiting

Phase I Multicenter, Open-Label, Dose-Escalation and Dose-Expansion Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Antitumor Activity of MSC-1 in Patients With Advanced Solid Tumors; NCT03490669; Terminated (safety and PK/PD data from dose escalation support further development; dose expansion canceled)

MinPAC: Phase II, International, Open-Label Trial of Minnelide™ in Patients With Refractory Pancreatic Cancer; NCT03117920; Completed

### Targeting Brain Tumor Stem Cell Epigenetic and Molecular Networks

GRANT TERM: October 2015 - March 2021, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Peter B. Dirks, MD, PhD, The Hospital for Sick Children

#### **Principals:**

- Cheryl H. Arrowsmith, PhD, University of Toronto
- Gary D. Bader, PhD, University of Toronto
- Nada Jabado, MD, PhD, McGill University
- Mathieu Lupien, PhD, University Health Network
- Marco A. Marra, PhD, University of British Columbia
- Michael W. Salter, MD, PhD, The Hospital for Sick Children
- Michael D. Taylor, MD, PhD, The Hospital for Sick Children
- Michael Tyers, PhD, Université de Montreal



**Team Co-leader:** Samuel Weiss, PhD, University of Calgary

#### **Project Managers:**

- Fiona J. Coutinho, PhD, The Hospital for Sick Children Fiona.coutinho@sickkids.ca
- Tracey Richards, The Hospital for Sick Children tracey.richards@sickkids.ca

#### Advocates:

- Wendy M. Durigon, Jessica's Footprint Foundation
- Patrick J. Sullivan, Team Finn Foundation

#### **Specific Aims:**

**AIM 1.** Conduct a comprehensive investigation of genomic, epigenomic, and metabolomic profiles of BTSCs to define networks of self-renewal, therapeutic resistance, and targetable vulnerabilities.

AIM 2. Identify targets whose pharmacological inhibition is efficacious on BTSCs from GBM and PFA ependymoma.

AIM 3. Preclinically test five targets to accelerate translation to the clinic.

#### **Clinical Trial:**

Phase I/Ib Trial of Combined 5-Azacitidine and Carboplatin for Recurrent/ Refractory Pediatric Brain and Solid Tumors; NCT03206021; Recruiting

#### Websites:

<u>www.</u> <u>cancerstemcellteam.</u> <u>com</u>

https:// standuptocancer.ca/ su2c-canada-cancerstem-cell-dream-team/



### **Targeting KRAS-Mutant Lung Cancers**

GRANT TERM: August 2015 - January 2021, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



Team Co-leader: Jedd D. Wolchok, MD, PhD, Memorial Sloan Kettering Cancer Center



#### **Team Co-leader:** Pasi A. Jänne, MD, PhD, Dana-Farber

Cancer Institute



#### Team Co-leader:

Justin F. Gainor, MD, Massachusetts General Hospital Cancer Center

#### **Principals:**

- David R. Gandara, MD, University of California, Davis
- Gad A. Getz, PhD, Broad Institute
- Roy S. Herbst, MD, PhD, Yale University
- John V. Heymach, MD, PhD, The University of Texas MD Anderson Cancer Center
- Frank McCormick, PhD, University of California, San Francisco
- Drew M. Pardoll, MD, PhD, Johns Hopkins University
- Charles M. Rudin, MD, PhD, Memorial Sloan Kettering Cancer Center

#### **Specific Aims:**

AIM 1. Target KRAS and downstream pathways.

**AIM 2.** Target the immune system for treatment of KRAS-mutant lung cancers. (Work on this Aim is continuing as an SU2C subproject.)

AIM 3. Integrate targeted therapies with immunotherapies for KRAS-mutant lung cancers.

#### **Clinical Trials:**

Identifying Genetic Predictors of Durable Clinical Benefit to Pembrolizumab in Advanced Non-small Cell Lung Cancer Alone and in Combination With Chemotherapy; NCT02710396; Active, not recruiting

Phase Ib Trial of Pembrolizumab (MK-3475) and Trametinib Focused on Advanced KRAS-Mutant Non-small Cell Lung Cancer; NCT03299088; Active, not recruiting

#### **Project Managers:**

- Lalitha Ramanathapuram, PhD, Memorial Sloan Kettering Cancer Center
- Cam Anh Tran, Dana-Farber Cancer Institute

#### Advocates:

- Andrea E. Ferris, LUNGevity Foundation
- Jeffrey L. Wigbels, Cypress Group at Morgan Stanley

#### Websites:

https://standuptocancer. org/research/researchportfolio/dream-teams/ targeting-kras-mutant-lungcancers-dream-team/

#### DREAM TEAMS

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DREAM TEAMS

#### SU2C-American Cancer Society Lung Cancer Dream Team DT5977

#### Clinical Trials (Cont'd):

BATTLE-2 Program: Biomarker-Integrated Targeted Therapy Study in Previously Treated Patients With Advanced Non-small Cell Lung Cancer; NCT03225664; Active, not recruiting

Phase I Trial of RO5126766 (CH5126766) in Patients With Advanced KRAS-Mutant Lung Adenocarcinomas; NCT03681483; Active, not recruiting

Phase I Trial of Trametinib and Ponatinib in Patients With KRAS-Mutant Advanced Non-small Cell Lung Cancer; NCT03704688; Active, not recruiting

Open-Label, Two-Part, Phase Ib/II Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of the MEK Inhibitor Trametinib and the BCL-2-Family Inhibitor Navitoclax (ABT-263) in Combination in Subjects With KRAS or NRAS Mutation-Positive Advanced Solid Tumors; NCT02079740; Recruiting

Neoadjuvant Nivolumab, or Nivolumab in Combination With Ipilimumab, in Resectable Non-small Cell Lung Cancer. NCT02259621; Recruiting

Phase I/II Trial Immunotherapy With Durvalumab and Tremelimumab With Continuous or Intermittent MEK Inhibitor Selumetinib in NSCLC; NCT03581487; Recruiting

Phase I/II Open-Label Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 510 Monotherapy in Subjects With Advanced Solid Tumors With KRAS p.G12C Mutation and AMG 510 Combination Therapy in Subjects With Advanced NSCLC With KRAS p.G12C Mutation (CodeBreaK 100); NCT03600883; Recruiting

Phase I/II Multiple Expansion Cohort Trial of MRTX849 in Patients With Advanced Solid Tumors With KRAS G12C Mutation; NCT03785249; Recruiting

Phase I Open-Label, Multi-Centre Study to Assess the Safety, Tolerability, and Preliminary Anti-tumour Activity of Ascending Doses of Selumetinib (AZD6244 Hyd-sulfate) in Combination With MEDI4736 and Selumetinib in Combination With MEDI4736 and Tremelimumab in Patients With Advanced Solid Tumours; NCT02586987; Completed

#### SU2C-Ovarian Cancer Research Alliance-National Ovarian Cancer Coalition Ovarian Cancer Dream Team DT5978

### **DNA Repair Therapies for Ovarian Cancer**

GRANT TERM: July 2015 - June 2019, administered by the American Association for Cancer Research

**Project Managers:** 

#### **KEY PERSONNEL:**



**Team Leader:** Alan D. D'Andrea, MD, Dana-Farber Cancer Institute



- Gini F. Fleming, MD, University of Chicago
- Maria Jasin, PhD, Memorial Sloan Kettering Cancer Center
- Scott H. Kaufmann, MD, PhD, Mayo Clinic, Rochester
- Karen H. Lu, MD, The University of Texas MD Anderson Cancer Center

## (2)

Alexandra Feinstein, Dana-

Farber Cancer Institute

Farber Cancer Institute

Donald R. Watson, Dana-

**Team Co-leader:** Elizabeth M. Swisher, MD, University of Washington

#### Advocates:

- Jamie Crase, University of Washington
- Sue Friedman, FORCE
- Kathleen A. Gavin,
   Minnesota Ovarian
   Cancer Alliance
- Deborah Polinsky, SHARE

#### **Specific Aims:**

**AIM 1.** Characterize mechanisms of sensitivity and resistance to PARPi that can identify individual ovarian cancers that are hypersensitive to PARPi monotherapy.

**AIM 2.** Evaluate novel drug combinations that extend the use of PARPi to HR-proficient ovarian cancers.

**AIM 3.** Develop ovarian cancer genetic testing and surgical prevention models, which could increase access to ovarian cancer genetic testing and ovarian cancer prevention.

#### Websites:

#### https://

standuptocancer.org/ research/researchportfolio/dream-teams/ dna-repair-thearpiesfor-ovarian-cancerdream-team/

#### DREAM TEAMS

issearch > Research Portfolio > Dream Teams > DAX.Repair Therag

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Dront Term: July 2015-

#### SU2C-Ovarian Cancer Research Alliance-National Ovarian Cancer Coalition Ovarian Cancer Dream Team DT5978

#### **Clinical Trials:**

Phase 1 Trial of ABT-888 and SCH727965 in Patients With Advanced Solid Tumors; NCT01434316; Recruiting

Stand Up To Cancer: MAGENTA (Making Genetic Testing Accessible); NCT02993068; Recruiting

WISP (Women Choosing Surgical Prevention); NCT02760849; Active, not recruiting

Phase I Study of the Oral Pl3kinase Inhibitor BKM120 or BYL719 and the Oral PARP Inhibitor Olaparib in Patients With Recurrent Triple-Negative Breast Cancer or High Grade Serous Ovarian Cancer; NCT01623349; Completed

Phase I/II Clinical Study of Niraparib in Combination With Pembrolizumab (MK-3475) in Patients With Advanced or Metastatic Triple-Negative Breast Cancer and in Patients With Recurrent Ovarian Cancer; NCT02657889; Active, not recruiting

A Phase II, Open-Label Study of Rucaparib in Patients With Platinum-Sensitive, Relapsed, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (ARIEL2); NCT01891344; Active, not recruiting

#### SU2C-Dutch Cancer Society Colorectal Cancer Early Detection Dream Team DT5916

### Molecular Early Detection of Colorectal Cancer (MEDOCC)

GRANT TERM: April 2015 - September 2022, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

Gerrit A. Meijer, MD, PhD, Netherlands Cancer Institute

#### **Principals:**

- Veerle Coupé, PhD, VU University Medical Center
- Evelien Dekker, MD, PhD, University of Amsterdam
- Manon van Engeland, PhD, Maastricht University Medical Center
- James G. Herman, MD, University of Pittsburgh
- Miriam Koopman, MD, PhD, University Medical Center Utrecht
- Ernst J. Kuipers, MD, PhD,
   Erasmus University Medical Center



#### **Team Co-leader:** Victor E. Velculescu, MD, PhD, Johns Hopkins University

#### Project Manager:

 Meike de Wit, PhD, Netherlands Cancer Institute, m.d.wit@nki.nl

#### Advocates:

- Joop Kroes, Foundation for Patients With Cancer of the Digestive Tract (Stichting Voor Patiënten met Kanker aan het Spijsverteringskanaal, SPKS)
- Marcia Horn, JD, International Cancer Advocacy Network
- Huig Schipper (inactive)

#### **Specific Aims:**

**AIM 1.** Develop and clinically validate a cost-effective molecular screening test for CRC that outperforms the current state-of-the-art FIT.

**AIM 2.** Develop and clinically validate a better test for residual disease detection and monitoring in comparison with a cancer stem cell-based DNA promoter methylation prognostic biomarker.

#### **Clinical Trial:**

Prospective Data Collection Initiative on Colorectal Cancer—A Prospective Observational Cohort Study; sub-study of NCT02070146; Recruiting

#### Website:

https:// standuptocancer.org/ research/researchportfolio/dream-teams/ colorectal-cancerearly-detection-dreamteam/



SU2C-DUTCH CANCER SOCIET EARLY DETECTION DREAM TEAM: MI OF COLORECTAI

### Bringing Epigenetic Therapy to the Forefront of Cancer Management, II

GRANT TERM: October 2014 - December 2022

#### **KEY PERSONNEL:**



#### Team Leader:

Peter A. Jones, PhD, DSc (h), Van Andel Institute

#### **Principals:**

- Anthony B. El-Khoueiry, MD, University of Southern California
- Kirsten Grønbæk, MD, DMSc, Rigshospitalet and Biotech Research and Innovation Centre (BRIC)
- Jean-Pierre J. Issa, MD, Coriell Institute for Medical Research
- Kenneth P. Nephew, PhD, Indiana University School of Medicine

#### **Specific Aims:**

AIM 1. Conduct a phase I study of guadecitabine combined with irinotecan followed by a randomized phase II study of SGI-110 combined with irinotecan versus regorafenib or TAS-102 in previously treated metastatic colorectal cancer patients.

•

AIM 2. Conduct a phase I/II study of combination therapy with the DNA methyltransferase inhibitor (DNMTi) SGIE110 and the poly ADP ribose polymerase (PARP) inhibitor BMN673 (talazoparib) for acute myeloid leukemia (AML) in adult patients unfit for cytotoxic chemotherapy or with relapsed/refractory disease.

**AIM 3.** Conduct a phase I/II multicenter study combining guadecitabine, a DNA methyltransferase inhibitor, with Atezolizumab, an immune checkpoint inhibitor, in patients with intermediate or high-risk myelodysplastic syndrome or chronic myelomonocytic leukemia.

**AIM 4.** Conduct a randomized phase II study of epigenetic priming with azacitidine and entinostat or oral azacitidine alone prior to nivolumab in subjects with recurrent metastatic non-small cell lung cancer.



Feyruz V. Rassool, PhD,

of Medicine

Cancer Center

St. Jude Children's

Research Hospital

University of Maryland School

Charles M. Rudin, MD, PhD,

Benjamin A. Youngblood, PhD,

Memorial Sloan Kettering

#### Team Co-leader: Stephen B. Baylin, MD,

Johns Hopkins University

#### **Project Managers:**

- Penny Berger, Van Andel Institute, Penny.Berger@vai.org
- Ryan Burgos, Van Andel Institute, ryan.burgos@vai.org
- Revathi Penumatsa,
   Van Andel Institute,
   Revathi.Penumatsa@vai.org

#### Advocate:

Beth Flory

#### Websites:

https://vari.vai.org/vaisu2c-dream-team/

### https://

standuptocancer.org/ research/researchportfolio/dream-teams/ epigenetics-dreamteam-ii/



#### Van Andel Institute-SU2C Cancer Epigenetics Dream Team DT5957

#### Specific Aims (Cont'd):

**AIM 5.** Conduct a study of epigenetics, vitamin C, and abnormal hematopoiesis—restoring physiological vitamin C levels to the normal range: influence on epigenetic regulation in normal and malignant hematopoiesis.

**AIM 6.** Conduct a phase Ib clinical trial to assess the safety and tolerability followed by a phase II trial to evaluate efficacy of guadecitabine and durvalumab in patients with hepatocellular carcinoma (HCC), cholangiocarcinoma (CLG), and pancreatic cancer.

**AIM 7.** Conduct a phase I dose-escalation study of E7727, an oral cytidine deaminase inhibitor (CDAi), with oral decitabine in subjects with solid tumors.

AIM 8. Conduct a phase I/II study of DS-3201b, an EZH1/2 inhibitor, in combination with irinotecan in patients with recurrent small cell lung cancer.

#### **Clinical Trials:**

Phase II Study of Epigenetic Therapy With Azacitidine and Entinostat With Concurrent Nivolumab Versus Nivolumab Alone in Subjects With Recurrent Metastatic Non-Small Cell Lung Cancer; NCT01928576; Active, not recruiting

Epigenetics, Vitamin C, and Abnormal Hematopoiesis—Role of Vitamin C in Epigenetic Regulation in Hematopoiesis Sub-study on CCUS, Low-Risk MDS, and CMML-0/1; NCT03682029; Recruiting

Multicenter Phase I/II Study of Combination Therapy w/DNA Methyltransferase Inhibitor Decitabine and Poly ADP Ribose Polymerase Inhibitor Talazoparib for Untreated AML in Adults Unfit for Cytotoxic Chemotherapy or R/R AML; NCT02878785; Completed

Phase I/II Multicenter Study Combining Guadecitabine, a DNA Methyltransferase Inhibitor, With Atezolizumab, an Immune Checkpoint Inhibitor, in Patients With Intermediate or High-Risk Myelodysplastic Syndrome or Chronic Myelomonocytic Leukemia; NCT02935361; Active, not recruiting

Phase Ib Study of Guadecitabine (SGI-110) and Durvalumab (MEDI 4736) in Patients With Advanced Hepatocellular Carcinoma, Pancreatic Adenocarcinoma, and Cholangiocarcinoma/Gallbladder Cancer; NCT03257761; Active, not recruiting

Phase I Dose-Escalation Study of E7727, an Oral Cytidine Deaminase Inhibitor (CDAi), With Oral Decitabine in Subjects With Solid Tumors; NCT03875287; Recruiting

Phase I/II Study of DS-3201b, an EZH1/2 Inhibitor, in Combination With Irinotecan in Patients With Recurrent Small Cell Lung Cancer; NCT03879798; Recruiting

Phase I Study of SGI-110 Combined With Irinotecan Followed by a Randomized Phase II Study of SGI-110 Combined With Irinotecan Versus Regorafenib or TAS-102 in Previously Treated Metastatic Colorectal Cancer Patients; NCT01896856; Completed

Restoring Physiological Vitamin C Levels to the Normal Range: Influence on Epigenetic Regulation in Normal and Malignant Hematopoiesis; NCT02877277; Completed

Combining Active and Passive DNA Hypomethylation: A Randomized, Placebo-Controlled Phase II Study of the Efficacy and Safety of Oral Vitamin C in Combination With Azacitidine in Patients With Higher-Risk MDS, CMML-2, or Low Blast Count AML; NCT03999723; Recruiting

Phase I Study of ASTX727 Plus Talazoparib in Patients With Triple-Negative or Hormone-Resistant/Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Metastatic Breast Cancer; NCT04134884; Recruiting

A Multicenter, Single-Arm, Pilot Study of The Efficacy and Safety of Metformin in Clonal Cytopenia of Undetermined Significance and Lower-Risk Myelodysplastic Syndrome; NCT04741945; Recruiting

### Transforming Pancreatic Cancer to Treatable Disease

GRANT TERM: July 2014 - June 2023, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

Elizabeth M. Jaffee, MD, Johns Hopkins University

#### **Principals:**

- Philip Greenberg, MD, Fred Hutchinson Cancer Research Center
- Robert D. Schreiber, PhD, Washington University in St. Louis

#### **Project Manager:**

 Stephanie Porter, Johns Hopkins University, sporter@jhmi.edu



#### Team Co-leader:

Robert H. Vonderheide, MD, DPhil, Abramson Cancer Center University of Pennsylvania

#### Advocates:

- Betty Booher, Oregon Health
   & Science University
- Stuart Rickerson, University of California, San Francisco

#### **Specific Aims:**

**AIM 1.** Conduct a multicenter phase 2 study designed to test the safety and clinical activity of a PD-1 inhibitor (cemiplimab) with a CXCR4 inhibitor (plerixafor).

**AIM 2.** Conduct a trial to treat patients with their own T cells that have been engineered to recognize mesothelin, a clinical target expressed specifically by pancreatic cancer cells.

**AIM 3.** Conduct a trial to explore whether vaccinating PDA patients with neoantigens derived from their own tumors can reactivate preexisting neoantigen specific T cells, induce T cell responses to additional vaccine induced tumor neoantigens, and induce a measurable clinical response.

#### Website:

https:// standuptocancer.org/ research/researchportfolio/dreamteams/transformingpancreatic-cancerdream-team/

#### DREAM TEAMS

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SU2C-LUSTGARTEN FOUNDATION PANCREATIC CANCER DREAM TEAM ANSFORMING PANCREATIC CANCER TO TREA

art Tarm: July 2014-June 2019

The BUDD-Lealgerien Reundation Panceradio Dancer Deam Team is tooseed on pano (PDH), one of the deadlest types of cancer. This team is rearrang to understand the to type of cancer presents, in order to develop new therapies that will effer

#### SU2C-Lustgarten Foundation Pancreatic Cancer Dream Team DT5915

#### **Clinical Trials:**

Phase I Clinical Trial to Evaluate the Safety and Immunogenicity of a Neoantigen Peptide Vaccine Strategy in Pancreatic Cancer Patients Following Surgical Resection and Adjuvant Chemotherapy; NCT03956056; Recruiting

Phase II Study of Plerixafor and Cemiplimab in Metastatic Pancreatic Cancer; NCT04177810; Recruiting

Phase I Study of Autologous Transgenic T Cells Expressing High Affinity Mesothelin-Specific T-Cell Receptor (TCR) (FH-TCR T<sub>MSLN</sub>) in Patients With Metastatic Pancreatic Ductal Adenocarcinoma; NCT04809766; Recruiting

Study to Assess the Safety of Continuous IV Administration of the CXCR4 Antagonist Plerixafor (Mozobil) and Assess Its Impact on the Immune Microenvironment in Patients With Advanced Pancreatic, High-Grade Serous Ovarian, and Colorectal Adenocarcinomas; NCT02179970; Completed

First-in-Human Phase I Dose-Escalation Trial of Hu5F9-G4 in Patients With Advanced Solid Malignancies; NCT02216409; Completed

Randomized Phase II Study of the Safety, Efficacy, and Immune Response of GVAX Pancreas Vaccine (With Cyclophosphamide) and CRS-207 With or Without Nivolumab in Patients With Previously Treated Metastatic Pancreatic Adenocarcinoma; NCT02243371; Completed

Study of the Safety, Immunopharmacodynamics and Anti-tumor Activity of Ibrutinib Combined With Gemcitabine and Nab-Paclitaxel in Patients With Metastatic Pancreatic Adenocarcinoma; NCT02562898; Completed

Phase I Study of Neo-adjuvant RO7009789 Alone or Neo-adjuvant RO7009789 Plus Nab-Paclitaxel and Gemcitabine Followed by Adjuvant RO7009789 Plus Nab-Paclitaxel and Gemcitabine for Patients With Newly Diagnosed Resectable Pancreatic Carcinoma; NCT02588443; Completed

### A New Preclinical Model for Drug Sensitivity Analysis

GRANT TERM: April 2014 - April 2019, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Hans C. Clevers, MD, PhD, Hubrecht Institute

#### **Principals:**

- Sir Michael R. Stratton, PhD, Wellcome Trust Sanger Institute
- Lodewyk Wessels, PhD,
   Netherlands Cancer Institute

#### **Project Manager:**

• Johan H. van Es, PhD, Hubrecht Institute

#### **Specific Aims:**

**AIM 1.** Build and validate a large "living" biobank for colon, pancreatic, and breast cancer using organoid technology, thus capturing the genetic variability of these three tumor types.

**AIM 2.** Correlate drug sensitivity with genotype and gene expression in vitro to identify putative biomarkers of drug sensitivity.

**AIM 3.** Validate the dual "genetic/organoid" approach as a predictor of drug response for individual cancer patients.

AIM 4. Identify molecular mechanisms of drug sensitivity and resistance.

#### Website:

Team Co-leader:

Pauline Evers, Leven Met Kanker

Jeannette Janzen, Leven Met Kanker

Margreet Jonker, Leven Met Kanker

Catherine Transler, Leven Met Kanker

Advocates:

Johannes L. Bos, PhD,

University Medical Center Utrecht

https:// standuptocancer. org/research/ research-portfolio/ dream-teams/tumororganoids-preclinicalmodels-dream-team/

#### DREAM TEAMS

SU2C-DUTCH CANCER SOCIE TUMOR ORGANOIDS DREAM TE A NEW PRECLINICAL MODEL FOR DRUG SENS

et Terrs: April 2014-April 201

The BUEC Dubit Cancer Society Tumor Organistic Desam Team developed a gr atows tumor samples isolated from patients to be maintained and provin in the lators which are called "tumor organisms", "provide an unprecedented opportuni

### Immunogenomics to Create New Therapies for High-Risk Childhood Cancers

GRANT TERM: July 2013 - June 2018, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

John M. Maris, MD, Children's Hospital of Philadelphia

#### **Principals:**

- Michael C. Jensen, MD, Seattle Children's Research Institute
- Donald W. Parsons, MD, Baylor College of Medicine
- Paul M. Sondel, MD, PhD, University of Wisconsin, Madison
- Poul H. B. Sorenson, MD, PhD, BC Cancer Research Institute
- Michael D. Taylor, MD, PhD, The Hospital for Sick Children

#### **Project Manager:**

• Jennifer L. Baldi, Children's Hospital of Philadelphia

#### **Specific Aims:**

AIM 1. Discover and validate cell surface targets for immunotherapy of high-risk pediatric cancers.

**AIM 2.** Generate and develop therapeutic proteins targeting prioritized cell surface molecules.

AIM 3. Conduct pivotal multi-institution pediatric cancer immunotherapy trials.

#### **Clinical Trials:**

Administration of HER2 Chimeric Antigen Receptor Expressing T Cells for Subjects With Advanced Sarcoma (HEROS); NCT00902044; Recruiting

Pediatric and Young Adult Leukemia Adoptive Therapy (PLAT)-02: A Phase I/ II Feasibility and Safety Study of CD19-CAR T-cell Immunotherapy for CD19+ Leukemia; NCT02028455; Recruiting



**Team Co-leader:** Crystal L. Mackall, MD, Stanford University

#### Advocates:

- Beth Anne Baber, PhD, Nicholas Connor Institute
- Kelly Cotter
- Jay Scott, Alex's Lemonade Stand Foundation
- Liz Scott, Alex's Lemonade Stand Foundation
- Patrick J. Sullivan, Team Finn Foundation
- Lisa Tichenor, QuadW Foundation
- Mac Tichenor, QuadW Foundation

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ dream-teams/highrisk-pediatric-cancersdream-team/

#### DREAM TEAMS

Research > Research Portfulis > Dream Teams > High-Res Pediatric Cancers

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#### SU2C-St. Baldrick's Foundation Pediatric Cancer Dream Team DT5908

#### Clinical Trials (Cont'd):

Engineered Neuroblastoma Cellular Immunotherapy (ENCIT)-01: A Phase I Feasibility and Safety Study of Cellular Immunotherapy for Recurrent/Refractory Neuroblastoma Using Autologous T Cells Lentivirally Transduced to Express CD171-Specific CARs; NCT02311621; Recruiting

Phase I Dose Escalation Study of Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults With Recurrent or Refractory CD22-expressing B-cell Malignancies; NCT02315612; Recruiting

Pilot Study of Redirected Autologous T Cells Engineered to Contain Humanized Anti-CD19 Attached to TCR and 4-1BB Signaling Domains in Patients With Relapsed or Refractory CD19+ Leukemia and Lymphoma Previously Treated With Cell Therapy; NCT02374333; Recruiting

Phase I Study of Intracranial Injection of T Cells Expressing HER2-Specific Chimeric Antigen Receptors (CAR) in Subjects With Glioblastoma; NCT02442297; Recruiting

TCR-Alpha/Beta and CD19+ Depleted KIR/KIR Ligand-Mismatched Haploidentical Hematopoietic Stem Cell Transplant and Zolendronate for Pediatric Relapsed/Refractory Hematologic Malignancies and High-Risk Solid Tumors; NCT02508038; Recruiting

Pilot Study of Autologous Anti-CD22 Chimeric Antigen Receptor Redirected T Cells in Pediatric Patients With Chemotherapy-Resistant or Refractory Acute Lymphoblastic Leukemia; NCT02650414; Recruiting

Phase I Study of 131-1 Meta-iodobenzylguanidine (mIBG) Followed by Nivolumab and Chimeric 14.18 Anti-GD2 Monoclonal Antibody Produced in Chinese Hamster Ovary Cells (ch14.18/CHO) in Children With Relapsed/Refractory Neuroblastoma; NCT02914405; Recruiting

Pilot Feasibility and Safety Study of CD19t T-Antigen Presenting Cells (T-APCs) Following CAR T Cell Immunotherapy for CD19+ Leukemia; NCT03186118; Recruiting

Treatment of Relapsed or Refractory Neuroblastoma With Ex Vivo Expanded and Activated Haploidentical NK Cells and Hu14.18-IL2; NCT03209869; Recruiting

Phase I Dose-Escalation Study of CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Children and Young Adults With Recurrent or Refractory B-cell Malignancies; NCT03241940; Recruiting

Pediatric and Young Adult Leukemia Adoptive Therapy (PLAT)-05: Phase I Feasibility and Safety Study of Dual Specificity CD19 and CD22 CAR T Cell Immunotherapy for CD19+CD22+ Leukemia and Lymphoma; NCT03330691; Recruiting

Pediatric Leukemia Adoptive Therapy (PLAT)-01: Phase I Feasibility and Safety Study of Cellular Immunotherapy for Relapsed Pediatric CD19+ Acute Lymphoblastic Leukemia Using Autologous T Cells Lentivirally Transduced to Express a CD19-Specific Chimeric Antigen Receptor; NCT01683279; Active, not recruiting

Phase II, Single-Arm, Multicenter Trial to Determine the Efficacy and Safety of CTL019 in Pediatric Patients With Relapsed and Refractory B-Cell Acute Lymphoblastic Leukemia; NCT02435849; Active, not recruiting

Pilot Study of Nonviral, RNA-Redirected Autologous T Cells Engineered to Contain Anti-CD19 Linked to TCR and 4-1BB Signaling Domains in Patients With Refractory or Relapsed Hodgkin Lymphoma; NCT02624258; Active, not recruiting

#### SU2C-St. Baldrick's Foundation Pediatric Cancer Dream Team DT5908

#### Clinical Trials (Cont'd):

Two-Cohort Pilot Study of the Tocilizumab Optimization Timing for CART19 Associated Cytokine Release Syndrome (CRS) Management in Pediatric Patients With CD19 Expressing Relapsed/Refractory B-cell Acute Lymphoblastic Leukemia (ALL); NCT02906371; Active, not recruiting

Pediatric and Young Adult Leukemia Adoptive Therapy (PLAT)-04: Phase I Feasibility and Safety Study of CD22-CAR T Cell Immunotherapy for CD22+ Leukemia and Lymphoma; NCT03244306; Active, not recruiting

Administration of HER2 Chimeric Receptor and TGF Beta Dominant Negative Receptor (DNR) Expressing EBV Specific Lymphocytes for Subjects With Advanced HER2-Positive Malignancy (HERCREEM); NCT00889954; Completed

Administration of HER2 Chimeric Antigen Receptor Expressing CMV-Specific Cytotoxic T Cells in Patients With Glioblastoma Multiforme (HERT-GBM); NCT01109095; Completed

Phase I Study of T Cells Expressing an Anti-CD19 Chimeric Receptor in Children and Young Adults With B-cell Malignancies; NCT01593696; Completed

CHP959-Phase I/IIa Study of Redirected Autologous T Cells Engineered to Contain Anti-CD19 Attached to TCR Zeta and 4-1BB Signaling Domains in Patients With Chemotherapy-Resistant or Refractory CD19+ Leukemia and Lymphoma; NCT01626495; Completed

Phase I Trial of T Cells Expressing an Anti-GD2 Chimeric Antigen Receptor in Children and Young Adults With Non-neuroblastoma, GD2+ Solid Tumors; NCT02107963; Completed

Phase II, Single-Arm, Multicenter Trial to Determine the Efficacy and Safety of CTL019 in Pediatric Patients With Relapsed and Refractory B-Cell Acute Lymphoblastic Leukemia; NCT02228096; Completed

Phase I, Open-Label, Dose-Escalation Study of MGA271 in Pediatric Patients With B7-H3-Expressing Relapsed or Refractory Solid Tumors; NCT02982941; Completed

### Immunologic Checkpoint Blockade and Adoptive Cell Transfer in Cancer Therapy

GRANT TERM: March 2013 - February 2018, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



James P. Allison, PhD, The University of Texas MD Anderson Cancer Center



**Team Co-leader:** Drew M. Pardoll, MD, PhD, Johns Hopkins University

#### **Principals:**

- Glenn E. Dranoff, MD,
   Dana-Farber Cancer Institute
- Philip D. Greenberg, MD, Fred Hutchinson Cancer Research Center
- James R. Heath, PhD, California Institute of Technology
- F. Stephen Hodi, MD, Dana-Farber Cancer Institute
- Michel Sadelain, MD, PhD, Memorial Sloan Kettering Cancer Center
- Ton N. Schumacher, PhD, Netherlands Cancer Institute
- Jedd D. Wolchok, MD, PhD, Memorial Sloan Kettering Cancer Center

#### **Specific Aims:**

**AIM 1.** Interrogate immune responses within the tumor microenvironment before and after treatment with immune checkpoint blockade.

**AIM 2.** Interrogate the targets of T and B cell responses after checkpoint blockade.

**AIM 3.** Provide therapeutic benefit to patients with advanced tumors by improving the quality of cancer-specific T lymphocytes generated for adoptive cell transfer (ACT) therapy.

**AIM 4.** Develop novel combinatorial therapies based on immune checkpoint blockade.



**Team Co-leader:** Antoni Ribas, MD, PhD, University of California, Los Angeles



**Team Co-leader:** Cassian Yee, MD, The University of Texas MD Anderson Cancer Center

#### **Project Manager:**

 James J. Mancuso, The University of Texas MD Anderson Cancer Center

#### Advocates:

- Robert E. Behrens, REB Investments, Inc.
- Debra Black, Melanoma Research Alliance
- Roy Doumani, JD, University of California, Los Angeles (deceased)
- Valerie Guild, AIM at Melanoma
- Jonathan W. Simons, MD, Prostate Cancer Foundation
- Mary Elizabeth Williams, Salon.com

#### Website:

https://standuptocancer. org/research/researchportfolio/dreamteams/immunologiccheckpoint-blockadedream-team/

DREAM TEAMS

SUDC-CANCER RESEARCH INSTITUTE CANCER IMMU DREAM TEAMI IMMUNOLOGIC CHECKPOINT BLOCK. ADOPTIVE CELL TRANSFER IN CANCER THERAS

#### SU2C-Cancer Research Institute Cancer Immunology Dream Team DT5907

#### **Clinical Trials:**

Neoadjuvant Nivolumab, or Nivolumab in Combination With Ipilimumab, in Resectable Non-small Cell Lung Cancer; NCT02259621; Recruiting

Phase I Clinical Trial of Malignant Pleural Disease Treated With Autologous T Cells Genetically Engineered to Target the Cancer-Cell Surface Antigen Mesothelin; NCT02414269; Recruiting

Phase Ib Study of Cellular Adoptive Immunotherapy Using Autologous Cd8+ Antigen-Specific T Cells and Anti-CTLA4 For Patients With Metastatic Uveal Melanoma; NCT03068624; Recruiting

Adoptive Transfer of NY-ESO-1 TCR Engineered Peripheral Blood Mononuclear Cells (PBMC) After a Nonmyeloablative Conditioning Regimen, With Administration of NY-ESO-1157-165 Pulsed Dendritic Cells and Interleukin-2, in Patients With Advanced Malignancies; NCT01697527; Active, not recruiting

Phase I/II, Open-Label Study of Nivolumab Monotherapy or Nivolumab Combined With Ipilimumab in Subjects With Advanced or Metastatic Solid Tumors; NCT01928394; Active, not recruiting

Phase II Study of Cellular Adoptive Immunotherapy Using Autologous CD8+ Antigen-Specific T Cells and Anti-CTLA4 for Patients With Metastatic Melanoma; NCT02027935; Active, not recruiting

Pilot Randomized Tissue-Based Study Evaluating Anti-PD1 Antibody or Anti-PD1 +Bevacizumab or Anti-PD1 + Anti-CTLA-4 in Patients With Metastatic Renal Cell Carcinoma Who Are Eligible for Cytoreductive Nephrectomy, Metastasectomy, or Post-treatment Biopsy; NCT02210117; Active, not recruiting

Phase II, Single-Arm Clinical Trial of Nivolumab (BMS-936558) in Subjects With Metastatic or Unresectable Urothelial Cancer Who Have Progressed or Recurred Following Treatment With a Platinum Agent; NCT02387996; Active, not recruiting

Phase I/II Study in WT1-Expressing Non-small Cell Lung Cancer and Mesothelioma, Comparing Cellular Adoptive Immunotherapy With Polyclonal Autologous Central Memory to Naive CD8+ T Cells That Have Been Transduced to Express a WT1-Specific T-cell Receptor; NCT02408016; Active, not recruiting

Pilot Study of Feasibility and Safety of Personalized Autologous CD8+ T-cell Therapy Plus Anti-PD-1 Antibody in Advanced Solid Malignancies; NCT02757391; Terminated

Exploratory Study of the Biologic Effects of Nivolumab and Ipilimumab Monotherapy and Nivolumab in Combination With Ipilimumab Treatment in Subjects With Advanced Melanoma (Unresectable or Metastatic); NCT01621490; Completed

Feasibility Study to Determine T-Cell Responses to Neoantigens Following Treatment With Ipilimumab in Men With Metastatic Castration-Resistant Prostate Carcinoma; NCT02113657; Completed

Phase Ib Safety and Dose-Assessment Study of Neoadjuvant Ipilimumab Monotherapy in Patients With Urothelial Carcinoma Undergoing Surgical Resection; NCT00362713; Completed

Neoadjuvant Phase IIa Study of Ipilimumab (Formerly known as MDX-010 (BMS-734016)) Plus Hormone Ablation in Men With Prostate Cancer Followed by Radical Prostatectomy; NCT01194271; Completed

Phase II Study of Ipilimumab Plus Androgen Deprivation Therapy in Castrate-Sensitive Prostate Carcinoma; NCT01377389; Completed

NY-ESO-1 TCR Engineered Adoptive Cell Transfer Therapy With Nivolumab PD-1 Blockade; NCT02775292; Completed

# Targeting Adaptive Pathways in MetastaticCastration-Resistant Prostate Cancer

GRANT TERM: January 2013 - December 2016, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### **Team Leader:** Eric J. Small, MD, University of California, San Francisco

#### **Principals:**

- Tomasz M. Beer, MD, Oregon Health & Science University
- Christopher P. Evans, MD, University of California, Davis, Comprehensive Cancer Center
- Martin E. Gleave, MD, University of British Columbia
- Joshua M. Stuart, PhD, University of California, Santa Cruz



#### **Team Co-leader:** Owen N. Witte, MD, University of California, Los Angeles

#### **Project Manager:**

Kelly McNeill, University of California, San Francisco

#### Advocates:

- Roy Doumani, JD, University of California, Los Angeles (deceased)
- Arthur H. Kern, American Media, Inc.

#### **Specific Aims:**

**AIM 1.** Identify adaptive pathways to abiraterone and enzalutamide active in resistant mCRPC tumors.

- AIM 2. Validate that identified adaptive pathways cause resistance.
- AIM 3. Demonstrate the efficacy of co-targeting adaptive pathways.

#### **Clinical Trials:**

Radiologically Guided Biopsies of Metastatic Castration-Resistant Prostate Cancer (mCRPC) to Identify Adaptive Mechanisms of Resistance; NCT02432001; Active, not recruiting

Phase Ib/II Study of the Oral CDK4/6 Inhibitor LEE011 in Combination With Docetaxel Plus Prednisone in Metastatic Castration-Resistant Prostate Cancer; NCT02494921; Active, not recruiting

Phase I/II Trial of Concurrent Chemohormonal Therapy Using Enzalutamide (MDV-3100) and Cabazitaxel in Patients With Metastatic Castration-Resistant Prostate Cancer; NCT02522715; Active, not recruiting

Single-Arm, Open-Label, Two-Stage Phase II Study of the MEK 1/2 Inhibitor Trametinib in Men With Progressive Metastatic Castrate-Resistant Prostate Cancer; NCT02881242; Active, not recruiting

#### Website:

#### https://

standuptocancer.org/ research/researchportfolio/dream-teams/ metastatic-treatmentresistant-prostatecancer-dream-team/



SU2C-PROSTATE CANCER FOUNDATION PROST/ TARGETING ADAPTIVE PATHWAYS IN METASTAT RESISTANT PROSTATE CANCER

#### SU2C-Prostate Cancer Foundation Prostate Cancer Dream Team DT5904

#### Clinical Trials (Cont'd):

Phase II Study Combining Ipilimumab With Abiraterone Acetate Plus Prednisone in Chemotherapy and Immunotherapy-Naive Patients With Progressive Metastatic Castration-Resistant Prostate Cancer; NCT01688492; Active, not recruiting

Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men With Non-Metastatic (M0) Castration-Resistant Prostate Cancer; NCT019462904; Active, not recruiting

Molecular Mechanisms Underlying Tumor Progression Despite Enzalutamide Treatment; NCT02099864; Active, not recruiting

Phase III Trial of Enzalutamide (NSC # 766085) Versus Enzalutamide, Abiraterone, and Prednisone for Castration-Resistant Metastatic Prostate Cancer; NCT01949337; Active, not recruiting

Phase II Randomized, Multicenter Study of Cabazitaxel Versus Abiraterone or Enzalutamide in Poor Prognostic-Metastatic Castration-Resistant Prostate Cancer; NCT02254785; Active, not recruiting

Addition of Pembrolizumab Upon Progression on Enzalutamide in Men With mCRPC; NCT02312557; Active, not recruiting

Phase II Study of MAOA Inhibitor Plus Docetaxel in Patients Receiving and Progressing on Docetaxel Therapy; NCT01253642; Terminated (low enrollment)

Phase II Single-Agent Study of Selinexor (KPT-330) in Patients With Metastatic Castration-Resistant Prostate Cancer (mCRPC) and Prior Therapy With Abiraterone and/or Enzalutamide; NCT02215161; Terminated (risk-to-benefit ratio was not acceptable)

An Open-Label Study of Rovalpituzumab Tesirine in Subjects With Delta-Like Protein 3-Expressing Advanced Solid Tumors; NCT02709889; Terminated (strategic considerations)

PREVAIL: A Multinational Phase III, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Oral MDV3100 in Chemotherapy-Naive Patients With Progressive Metastatic Prostate Cancer Who Have Failed Androgen Deprivation Therapy; NCT01212991; Completed

Phase I Trial of ADIPEG 20 Plus Docetaxel in Advanced Solid Tumors With Emphasis on Castration-Resistant Prostate Cancer (CRPC) and Advanced Non-small Cell Lung Cancer (NSCLC); NCT01497925; Completed

Randomized Phase III Study Comparing Cabazitaxel/Prednisone in Combination With Custirsen (OGX-011) to Cabazitaxel/Prednisone for Second-Line Chemotherapy in Men With Metastatic Castrate-Resistant Prostate Cancer; NCT01578655; Completed

Phase II Study of Increased-Dose Abiraterone Acetate in Patients With Castration-Resistant Prostate Cancer (CRPC); NCT01637402; Completed

Randomized Phase II Trial of Immediate Versus Delayed Anti-CTLA4 Blockade Following Sipuleucel-T Treatment for Prostate Cancer Immunotherapy; NCT01804465; Completed

Randomized, Double-Blind, Multicenter, Parallel-Group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/Pca Versus Placebo in Men With Metastatic Castration-Resistant Prostate Cancer Eligible for First-Line Chemotherapy; NCT02111577; Completed

#### SU2C-Prostate Cancer Foundation Prostate Cancer Dream Team DT5904

# DREAM TEAMS

#### Clinical Trials (Cont'd):

Randomized Phase II Study of Sequencing Abiraterone Acetate and Enzalutamide in Metastatic Castration-Resistant Prostate Cancer; NCT02125357; Completed

Identifying Mechanisms of Resistance to Enzalutamide (MDV3100) Treatment in Men With Castration-Resistant Prostate Cancer; NCT02228265; Completed

Phase I Study of Cabazitaxel, Mitoxantrone, and Prednisone (CAMP) for Patients With Metastatic Castration-Resistant Prostate Cancer and No Prior Chemotherapy; NCT01594918; Completed

STRIVE: A Multicenter Phase II, Randomized, Double-Blind Efficacy and Safety Study of Enzalutamide Versus Bicalutamide in Men With Prostate Cancer Who Have Failed Primary Androgen Therapy; NCT01664923; Completed

Phase II Study of Recombinant Glycosolated Human IL7 (CYT107) After Completion of Standard FDA-Approved Therapy With Sipuleucel-T (Provenge®) for Patients With Asymptomatic or Minimally Symptomatic Metastatic Castration-Resistant Prostate Cancer; NCT01881867; Completed

Three-Arm, Randomized, Open-Label, Phase II Study of Radium-223 Dichloride 50 kBq/kg (55 kBq/kg After Implementation of NIST Update) Versus 80 kBq/kg (88 kBq/kg After Implementation of NISTUpdate), and Versus 50 kBq/kg (55 kBq/kg After Implementation of NIST Update) in an Extended Dosing Schedule in Subjects With Castration-Resistant Prostate Cancer Metastatic to the Bone; NCT02023697; Completed

Phase I Safety and Tolerability Study of ZEN003694 in Patients With Metastatic Castration-Resistant Prostate Cancer; NCT02705469; Completed

### Precision Therapy of Advanced Prostate Cancer

GRANT TERM: August 2012 - July 2016, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

Arul M. Chinnaiyan, MD, PhD, University of Michigan

#### **Principals:**

- Johann S. de Bono, MBChB, MD, Institute of Cancer Research, Royal Marsden NHS Foundation Trust
- Levi A. Garraway, MD, PhD, Broad Institute
- Philip W. Kantoff, MD,
   Dana-Farber Cancer Institute
- Peter S. Nelson, MD, University of Washington, Fred Hutchinson Cancer Research Center
- Mark A. Rubin, MD, Weill Cornell Medical College of Cornell University



#### **Team Co-leader:** Charles L. Sawyers, MD, Memorial Sloan Kettering Cancer Center

#### Advocates:

- Woods Brown, University of Michigan
- Thomas A. Farrington, Prostate Health Education Network
- W. Grant Gregory, Memorial Sloan Kettering Cancer Center
- James Kiefert, EdD, Us TOO International, Inc.
- Stanley Klein, Boston Prostate Cancer Support Group
- Ian S. Liston (deceased)
- Douglas Pergament (deceased)

#### **Project Manager:**

• Karen Giles, University of Michigan

#### **Specific Aims:**

AIM 1. Establish a multi-institutional infrastructure incorporating five leading prostate cancer clinical sites and two sequencing and computational analysis sites, linked with appropriate sample and data coordination.

AIM 2. Establish a prospective cohort of 500 patients (the "CRPC 500") utilizing the multi-institutional infrastructure to support the clinical use of integrative prostate cancer sequencing, analysis, and clinical trial decision making.

AIM 3. Conduct parallel, preclinical in vivo functional studies of resistance biomarkers and of SU2C/PCF-sponsored combination therapies.

**AIM 4.** Identify molecular determinants of abiraterone sensitivity and acquired resistance in patients.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ dream-teams/ prostate-cancerprecision-therapydream-team/

#### DREAM TEAMS

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irant Term: August 2012-i

#### SU2C-Prostate Cancer Foundation Prostate Cancer Dream Team DT5903

#### Specific Aims (Cont'd):

AIM 5. Conduct clinical trials of novel combinations targeting AR and/or the PTEN pathway based on existing preclinical data and an understanding of resistance mechanisms.

**AIM 6.** Identify molecular determinants of sensitivity and acquired resistance to PARP inhibitors in patients.

#### **Clinical Trials:**

Phase II Trial of Olaparib in Patients With Advanced Castration-Resistant Prostate Cancer (TOPARP); NCT01682772; Not recruiting

Phase II Trial of Enzalutamide for Castrate-Resistant Prostate Cancer (CRPC) With Correlative Assessment of Androgen Receptor (AR) Signaling and Whole-Exome and Transcriptome Sequencing; NCT01942837; Active, not recruiting

Phase II Clinical Trial of Abiraterone Acetate Without Exogenous Glucocorticoids in Men With Castration-Resistant Prostate Cancer With Correlative Assessment of Hormone Intermediates; NCT02025010; Active, not recruiting

Phase I Study of Crizotinib in Combination With Enzalutamide in Metastatic Castration-Resistant Prostate Cancer Before or After Progression on Docetaxel; NCT02207504; Active, not recruiting

Randomized Phase II Study of Enzalutamide (MDV3100) in Combination With AZD5363 in Patients With Metastatic Castration-Resistant Prostate Cancer (RE-AKT); NCT02525068; Not recruiting

Open-Label Pharmacodynamic Study of Abiraterone Acetate in the Treatment of Metastatic, Castration-Resistant Prostate Cancer; NCT01503229; Completed

Randomized Gene Fusion Stratified Phase II Trial of Abiraterone With or Without ABT-888 for Patients With Metastatic Castration-Resistant Prostate Cancer; NCT01576172; Completed

ARMOR 2: A 2-Part, Phase II Trial of Galeterone in the Treatment of Castration-Resistant Prostate Cancer; NCT01709734; Completed

Phase Ib Study of ARN509 Plus Everolimus in Men With Progressive Metastatic Castration-Resistant Prostate Cancer After Treatment With Abiraterone Acetate; NCT02106507; Completed

### Personalized Medicine for Patients With BRAF Wild-Type (BRAFwt) Cancer

GRANT TERM: April 2012 - June 2017, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

Jeffrey M. Trent, PhD, Translational Genomics Research Institute

#### **Principals:**

- Joshua LaBaer, MD, PhD, Biodesign Institute at Arizona State University
- Svetomir N. Markovic, MD, PhD, Mayo Clinic
- Brian J. Nickoloff, MD, PhD, Michigan State University
- Emanuel F. Petricoin, PhD, George Mason University
- Neal Rosen, MD, PhD, Memorial Sloan Kettering Cancer Center
- Nicholas J. Schork, PhD, J. Craig Venter Institute
- Aleksandar D. Sekulic, MD, PhD, Mayo Clinic
- Jeffrey A. Sosman, MD, Mayo Clinic
- Kristiina Vuori, MD, PhD, Sanford Burnham Prebys Medical Discovery Institute

#### **Specific Aims:**

**AIM 1.** Conduct a randomized pilot study to assess the feasibility and safety of characterizing BRAFwt MM tumors to identify a molecularly informed therapeutic regimen.

**AIM 2.** Iteratively refine and standardize a set of statistical and informatics methodologies for matching treatments to the patient's tumor, based on its molecular profile.

AIM 3. Evaluate whether molecularly informed personalized therapy selection, based on a tumor's molecular profile (potentially enhanced by the refined methodology for predicting drug response developed in Aim 2), will improve outcomes relative to SoC therapy in BRAFwt MM.

#### **Clinical Trial:**

Stand Up To Cancer Consortium Genomics-Enabled Medicine for Melanoma (G.E.M.M.): Using Molecularly Guided Therapy for Patients With BRAF Wild-Type (BRAFwt) Metastatic Melanoma; NCT02094872; Completed



### Team Co-leader:

Patricia M. LoRusso, DO, Yale Cancer Center

#### **Project Manager:**

 Cassandra L. Lucas, PhD, Translational Genomics Research Institute

#### Advocates:

- Tracy L. Bame, Freeport-McMoRan Copper & Gold Foundation
- Mark Gorman, JD, National Coalition for Cancer Survivorship
- Derrick M. Hall, Arizona Diamondbacks
- Cornelius A. McGillicuddy III, Liberty Partners Group
- Jane Perlmutter, PhD, Gemini Group

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ dream-teams/ melanoma-brafwildtype-dream-team/

#### DREAM TEAMS

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### Cutting Off the Fuel Supply: A New Approach to the Treatment of Pancreatic Cancer

GRANT TERM: December 2009 - October 2017, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Craig B. Thompson, MD, (2009–2011), University of Pennsylvania



**Team Leader:** Jeffrey A. Drebin, MD, PhD (2011–2015) University of Pennsylvania



Team Co-leader:

Daniel D. Von Hoff, MD, Translational Genomics Research Institute

#### **Principals:**

- Chi Van Dang, MD, PhD, University of Pennsylvania
- Joshua D. Rabinowitz, MD, PhD, Princeton University
- Geoffrey M. Wahl, PhD, Salk Institute for Biological Studies

#### Advocates:

- Julie M. Fleshman, JD, Pancreatic Action Network
- Barton A. Kamen, Leukemia and Lymphoma Society (deceased)
- Kerri Kaplan, Lustgarten Foundation
- Randall M. Katz, Milestone Entertainment
- Howard Young

#### **Specific Aims:**

AIM 1. Imaging glucose and/or glutamine uptake in pancreatic tumors.

**AIM 2.** Investigating clinical therapies to impair tumor metabolism and stromal support.

#### **Clinical Trials:**

Phase I Study: PET Imaging of Cancer Patients Using (18F) 4-L-Fluoroglutamine (2S,4R); NCT01697930; Recruiting

Phase I/II Pharmacodynamics Study of Hydroxychloroquine in Combination With Gemcitabine/ Abraxane to Inhibit Autophagy in Pancreatic Cancer; NCT01506973; Active, not recruiting

Randomized Phase III Study of Weekly ABI-007 Plus Gemcitabine Versus Gemcitabine Alone in Patients With Metastatic Adenocarcinoma of the Pancreas; NCT00844649; Completed

Stand Up To Cancer Consortium: Phase II Study of Therapy Selected by Molecular/Metabolic Profiling in Patients With Previously Treated Metastatic Pancreatic Cancer; NCT01196247; Completed

Randomized Pilot/Pharmacodynamic/Genomic Study of Neoadjuvant Paricalcitol to Target the Microenvironment in Resectable Pancreatic Cancer; NCT02030860; Completed

Exploratory Study of Metformin With or Without Rapamycin as Maintenance Therapy After Induction Chemotherapy in Subjects With Metastatic Pancreatic Adenocarcinoma Cancer; NCT02048384; Completed

### Website:

https:// standuptocancer.org/ research/researchportfolio/dream-teams/ cutting-fuel-supply-topancreatic-cancerdream-team/

DREAM TEAMS

SU2C PANCREATIC DREA CUTTING OFF THE FUEL SUPPLY: A NET TREATMENT OF PANCREATI

Inant Term: December 2009-May

### Bringing Epigenetic Therapy to the Forefront of Cancer Management

GRANT TERM: December 2009 - January 2015, administered by the American Association for Cancer Research

Advocates:

#### **KEY PERSONNEL:**



**Team Leader:** Stephen B. Baylin, MD, Johns Hopkins University

#### **Principals:**

- Steven A. Belinsky, PhD, Lovelace Respiratory Research Institute
- Nancy E. Davidson, MD, Fred Hutchinson Cancer Research Center
- Jean-Pierre J. Issa, MD, Coriell Institute for Medical Research

#### **Specific Aims:**

**AIM 1.** Develop molecular markers that predict and monitor the efficacy of cancer epigenetic therapies.

**AIM 2.** Perform clinical trials to bring epigenetic therapy to the forefront of cancer management.

**AIM 3.** Determine whether a key mechanism for efficacy of epigenetic therapy is targeting and exhaustion of self-renewing cancer cells.

**AIM 4.** Develop a clinical trial with a new drug designed to circumvent the instability of 5-AC and DAC.

**AIM 5.** Determine targets in addition to promoter DNA hypermethylation that may be utilized in new cancer epigenetic therapy approaches.

#### **Clinical Trials:**

Randomized Phase II Study of Epigenetic Priming With Azacitidine and Entinostat or Oral Azacitidine Alone Prior to Nivolumab in Subjects With Recurrent Metastatic Non-small Cell Lung Cancer; NCT01928576; Recruiting

Phase I/II Study of MS275 in Combination With 5-Azacitidine in Patients With Recurrent Advanced Nonsmall Cell Lung Cancer; NCT00387465; Completed

Phase II Study of Azacitidine and Entinostat in Patients With Metastatic Colorectal Cancer; NCT01105377; Completed



Team Co-leader:

Van Andel Institute

Peter A. Jones, PhD, DSc (hc),

Diana T. Chingos, National Cancer Institute

Lillie D. Shockney, Johns Hopkins University

#### https:// standuptocancer.org/ research/researchportfolio/dream-teams/ epigenetics-therapy-

2009-dream-team/

DREAM TEAMS

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SU2C EPIGENETICS DREAM 1 RINGING EPIGENETIC THERAPY TO TH CANCER MANAGEMEN

Grant Term: December 2009-January 20

#### SU2C Epigenetics Dream Team DT5917

#### Clinical Trials (Cont'd):

Phase I Dose-Escalation, Multicenter Study of Two Subcutaneous Regimens of SGI-110, a DNA Hypomethylating Agent, in Subjects With Intermediate-2 or High-Risk Myelodysplastic Syndromes (MDS) or Acute Myelogenous Leukemia (AML); NCT01261312; Completed

Phase II Study of Azacitidine and Entinostat (SNDX-275) in Patients With Advanced Breast Cancer; NCT01349959; Completed

Randomized Phase II Trial of Adjuvant Combined Epigenetic Therapy With 5-Azacitidine and Entinostat in Resected Stage 1 Non-small Cell Lung Cancer Versus Standard Care; NCT01207726; Terminated

Randomized Phase II Trial of Cytotoxic Chemotherapy With or Without Epigenetic Priming in Patients With Advanced Non-small Cell Lung Cancer; NCT01935947; Terminated

### Bioengineering and Clinical Applications of Circulating Tumor Cell Chip

GRANT TERM: December 2009 - November 2013, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### **Team Leader:**

Daniel A. Haber, MD, PhD, Massachusetts General Hospital

#### **Principals:**

- Sangeeta N. Bhatia, MD, PhD, Massachusetts Institute of Technology
- John V. Heymach, MD, PhD, The University of Texas MD Anderson Cancer Center
- Bruce E. Johnson, MD,
   Dana-Farber Cancer Institute
- Mark G. Kris, MD, Memorial Sloan Kettering Cancer Center

#### **Specific Aims:**

AIM 1A. Examine bioengineering optimization and nanosensing for increased sensitivity.

AIM 1B. Perform molecular characterization of CTCs.

AIM 2. Investigate clinical applications of the CTC-chip.

#### **Clinical Trials:**

Circulating Tumor Cell Analysis in Patients With Localized Prostate Cancer Undergoing Prostatectomy; NCT01961713; Recruiting

Phase II Study of Lapatinib in Combination With Trastuzumab in Patients With HER2-Positive, Metastatic Breast Cancer; NCT00470704; Active, not recruiting

First-Line Erlotinib Therapy and the Subsequent Development of Mechanisms of Secondary Resistance in Patients With Non-small Cell Lung Cancer and Known Sensitizing EGFR Mutations; NCT00997334; Completed

Detecting EGFR T790M Mutations From Circulating Tumor Cells; NCT01734915; Completed

Phase II Single-Arm, Open-Label Study to Evaluate the Efficacy and Safety of Trastuzumab and Vinorelbine in Advanced Breast Cancer Patients With Human Epidermal Growth Factor-2 (HER2) Negative Primary Tumors and HER2-Positive Circulating Tumor Cells; NCT01185509; Terminated



#### **Team Co-leader:** Mehmet Toner, PhD, Massachusetts General Hospital

#### Advocates:

- Rebecca Douglass, Douglass Family Foundation
- Jeane Ungerleider, Boston IVF

#### Website:

#### <u>https://</u>

standuptocancer.org/ research/researchportfolio/dream-teams/ circulating-tumor-cellsdream-team/

#### DREAM TEAMS

SU2C CIRCULATING TUMOR C BIOENGINEERING AND CLINICA CIRCULATING TUMOR

### Targeting the PI3K Pathway in Women's Cancers

GRANT TERM: November 2009 - October 2013, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Lewis C. Cantley, PhD, Beth Israel Deaconess Medical Center



#### Team Co-leader:

Gordon B. Mills, MD, PhD, The University of Texas MD Anderson Cancer

#### Team Co-leader:

(2009–2012): Charles L. Sawyers, MD, Memorial Sloan Kettering Cancer Center

#### **Principals:**

- Carlos L. Arteaga, MD, Vanderbilt-Ingram Cancer Center
- José Baselga, MD, PhD, Vall d'Hebron Institute of Oncology (deceased)
- Ramon E. Parsons, MD, PhD, Herbert Irving Comprehensive Cancer Center
- Thomas M. Roberts, PhD, Dana-Farber Cancer Institute
- David B. Solit, MD, Memorial Sloan Kettering Cancer Center

#### Advocates:

- Piru Cantarell, Vall d'Hebron Institute of Oncology
- Ruth Fax, Dana-Farber Cancer Institute
- Elizabeth Frank, Dana-Farber Cancer Institute
- Judi Hirschfield-Bartek, Beth Israel Deaconess Medical Center
- Patricia Lee, Vanderbilt University
- Don Listwin, Canary Foundation
- Jane Perlmutter, Gemini Group
- Sara Weiss, Dana-Farber Cancer Institute

#### Project Manager:

 Donald R. Watson, Dana-Farber Cancer Institute

#### **Specific Aims:**

**AIM 1.** Develop molecular markers and/or imaging modalities that predict the subset of cancers that are likely to respond to PI3K pathway inhibitors.

**AIM 2**. Design and conduct single-agent, molecular marker-driven adaptive trial(s).

**AIM 3.** Develop rational therapeutic combinations of PI3K pathwaytargeted drugs.

**AIM 4.** Design and conduct two multi-arm, molecular marker–driven adaptive trials using a rational combination of a PI3K pathway inhibitor with another targeted therapy.

#### Website:

#### https://

standuptocancer.org/ research/researchportfolio/dream-teams/ womens-cancers-pi3kdream-team/

#### DREAM TEAMS

ech > Research Particle > Onern Teams > Women's Cancers/POK Dr

SU2C PI3K DREAM TI TARGETING THE PI3K PATHWAY IN 1

#### SU2C PI3K Dream Team DT5918

#### **Clinical Trials:**

Randomized Phase I Study With a Safety Lead-In to Assess the Antitumor Efficacy of the MEK Inhibitor Trametinib Alone or in Combination With GSK2141795, an AKT Inhibitor, in Patients With Recurrent or Persistent Endometrial Cancer; NCT01935973; Completed

Phase Ib Trial of BKM120 (a PI3K Inhibitor) or BEZ235 (a PI3K/mTOR Inhibitor) in Combination With Endocrine Therapy in Post-menopausal Patients With Hormone Receptor-Positive Metastatic Breast Cancer; NCT01248494; Completed

Phase Ib Dose-Escalation and Biomarker Study of MK-2206 in Combination With Standard Doses of Weekly Paclitaxel in Patients With Locally Advanced or Metastatic Solid Tumors With an Expansion in Advanced Breast Cancer; NCT01263145; Completed

Phase II Trial of AKT Inhibitor MK2206 in Patients With Advanced Breast Cancer Who Have Tumors With a PIK3CA Mutation, or an AKT Mutation, and/or PTEN Loss/PTEN Mutation; NCT01277757; Completed

Phase Ib Trial of BYL719 (an a-Specific PI3K Inhibitor) in Combination With Endocrine Therapy in Postmenopausal Patients With Hormone Receptor-Positive Metastatic Breast Cancer; NCT01791478; Active, not recruiting

Phase II Study of MK-2206 in the Treatment of Recurrent High-Grade Serous Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer; NCT01283035; Completed

Phase II Trial of BKM120 (a PI3K Inhibitor) in Patients With Triple-Negative Metastatic Breast Cancer; NCT01629615; Completed

Phase I Study of the Oral Pl3kinase Inhibitor BKM120 or BYL719 and the Oral PARP Inhibitor Olaparib in Patients With Recurrent Triple-Negative Breast Cancer or High-Grade Serous Ovarian Cancer; NCT01623349; Completed

Phase II, Two-Stage, Two-Arm PIK3CA Mutation Stratified Trial of MK-2206 in Recurrent or Advanced Endometrial Cancer; NCT01312753; Completed

Phase II Evaluation of AZD6244 (NSC#748727) in the Treatment of Recurrent or Persistent Endometrial Carcinoma; NCT01011933; Completed

Phase I/II Study of XL147 (SAR245408) Administered in Combination With Trastuzumab or Paclitaxel and Trastuzumab in Subjects With Metastatic Breast Cancer Who Have Progressed on a Previous Trastuzumab-Based Regimen; NCT01042925; Completed

Phase I/II Dose-Escalation Study of XL147 (SAR245408) or XL765 (SAR245409) in Combination With Letrozole in Subjects With Hormone Receptor-Positive and HER2-Negative Breast Cancer Refractory to a Nonsteroidal Aromatase Inhibitor; NCT01082068; Completed

Three-Arm, Randomized, Phase II Study of Paclitaxel/Carboplatin/Bevacizumab (NSC #704865), Paclitaxel/Carboplatin/Temsirolimus (NSC #683864), and Ixabepilone (NSC #710428)/Carboplatin/ Bevacizumab as Initial Therapy for Measurable Stage 3 or 4a, Stage 4b, or Recurrent Endometrial Cancer; NCT00977574; Active, not recruiting

Multicenter, Single-Arm, Open-Label, Phase II Study of GDC-0980 for the Treatment of Recurrent or Persistent Endometrial Carcinoma; NCT01455493; Completed

Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Letrozole With or Without BYL719 or Buparlisib for the Neoadjuvant Treatment of Postmenopausal Women With Hormone Receptor-Positive, HER2-Negative Breast Cancer; NCT01923168; Completed

### An Integrated Approach to Targeting Breast Cancer Molecular Subtypes and Their Resistance Phenotypes

GRANT TERM: October 2009 - September 2014, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

Dennis J. Slamon, MD, PhD, University of California, Los Angeles



- Alan Ashworth, PhD, UCSF Helen Diller Family Comprehensive Cancer Center
- Joan S. Brugge, PhD, Harvard Medical School
- Arul M. Chinnaiyan, MD, PhD, University of Michigan
- Gregory J. Hannon, PhD, Cold Spring Harbor Laboratory
- David Haussler, PhD, University of California, Santa Cruz

- Craig V. Jordan, DSc, PhD, Fox Chase Cancer Center
- C. Kent Osborne, PhD, Baylor College of Medicine
- Peter K. Sorger, PhD, Harvard Medical School
- Terence P. Speed, PhD, University of California, Berkeley
- Zena Werb, PhD, University of California, San Francisco (deceased)
- Max S. Wicha, MD, University of Michigan

#### Team Co-leader:

Joe W. Gray, PhD, Oregon Health & Science University

#### Advocates:

- Janice Barlow, Zero Breast Cancer
- Cindy Geoghegan, Patient & Partners, LLC
- Ellen L. Stoval, National Coalition for Cancer Survivorship (deceased)
- Frances M. Visco, National Breast Cancer Coalition

#### **Specific Aims:**

AIM 1. Expand the understanding of the known "driving" initial molecular mechanisms responsible for the pathogenesis and clinical behavior of the three known therapeutic breast cancer subtypes, i.e., estrogen (E2)/estrogen receptor (ER-positive), HER2-positive, and triple-negative (TN) subtypes of breast cancer.

**AIM 2.** Study the "driving" mechanisms responsible for de novo as well as acquired resistance to appropriately targeted treatments of the three known therapeutic breast cancer subtypes, i.e., estrogen (E2)/ estrogen receptor (ER-positive), HER2-positive, and triple-negative (TN) breast cancers.

#### Website:

https://standuptocancer. org/research/researchportfolio/dream-teams/ breast-cancer-resistantphenotypes-dreamteam/

#### DREAM TEAMS

SU2C BREAST CANCER DREAM TE AN INTEGRATED APPROACH TO TARGETING I MOLECULAR SUBTYPES AND THEIR RESISTAN

#### SU2C Breast Cancer Dream Team DT5920

#### Specific Aims (Cont'd):

AIM 3. Investigate the potential initial "driving" pathogenetic as well as de novo or acquired "resistance" mechanisms mediated by "stem/ progenitor" breast cancer cells within each or across all of the three known breast cancer therapeutic subtypes, with the ultimate objective being the design, development, and clinical testing of new and innovative therapies for the "tumorigenic" and "resistance" phenotypes potentially mediated by these stem/progenitor cells.

**AIM 4.** Develop new and/or characterize existing relevant and representative cell line and xenograft models, as well as utilize annotated clinical material to query the contributions of "normal" and "malignancy-derived" matrix/stromal components of each breast cancer subtype, including those that might contribute to or mediate the "resistance" phenotype to targeted therapeutics.

**AIM 5.** Develop an integrated discovery and informatics research unit that cuts across the above aims and is designed to deploy, inform, and facilitate implementation of relevant discovery and informatics platforms needed for these aims.

#### **Clinical Trial:**

Novel (PD 0332991: CDK4/6 Inhibitor, Pfizer) ER-Positive, HER2-Negative Advanced Breast Cancer in Postmenopausal Women; NCT00721409; Completed

# RESEARCH TEAMS

### Southeastern Consortium for Lung Cancer Health Equity

GRANT TERM: February 2022 - January 2025

#### **KEY PERSONNEL:**



#### Team Leader:

Robert A. Winn, MD, Virginia Commonwealth University

#### Principal:

 Louise Henderson, PhD, University of North Carolina at Chapel Hill

#### **Project Managers:**

- Rosuany Vélez Acevedo, PhD, Virginia Commonwealth University, velezrn@vcu.edu
- Kate Shaw, Virginia Commonwealth University, shawsk2@vcu.edu

#### **Specific Aims:**

**AIM 1.** Initiate and evaluate a high-impact, multimodal, and multilevel navigation intervention to promote LCS among Black/African American individuals from both rural and urban medically underserved communities in Virginia, North Carolina, and South Carolina.

AIM 2. Develop a robust, shared population-based cohort and biorepository to further support research in understanding biologic determinants or risk factors for poor lung cancer outcomes among Black/ African American individuals.

#### **Clinical Trial:**

Interventional trial will be registered in 2022.



#### **Team Co-leader:** Marvella E. Ford, PhD, Medical University of South Carolina

#### Advocates:

- Tomma Hargraves, UNC Lineberger
   Comprehensive Cancer Center
- Rudene Mercer Haynes, Virginia
   Commonwealth University
- Deborah Roland-Jaremba, MUSC Hollings
   Cancer Center

#### Website:

https:// standuptocancer. org/southeasternconsortium-for-lungcancer-health-equityresearch-team/

SU2C LUNG CANCER HEALTH EQUITY RESEARCH

December 2021 Rovember 20

The Southeastern Consortium for Lang-Darver Headth-Egally (RCS), being Di Adolet K. Bi extending Paradologikang tean of disearational researches positivate in the Neurol Park Internet producing galaxies and the fee schedules (ECS) transportation team for agree Lang anear accurring, translational emails in long acrease health dispatilise, communit expansions, et al. executing earl entrance and an effect in control and apparents, et al. executing earl entrance and earlier the control entry the volteowned process using available to the data of the team of the schedules and events and the schedules and entrance in a schedules in the schedules. The volteowned process using schedules taxed in steages. As 500 disequent career contex, all context and the schedules and accurring accurring to the schedules. The schedules are appressed to the schedules and the schedules are appressed and the schedule accurring the schedules are appressed and the schedules and the schedules are appressed and the schedules and the schedules are appressed as a schedule accurring the schedules are appressed as a schedules accurring the schedules are appressed as a schedule accurring the schedules are appressed as a schedule accurring the schedules are appressed as a schedule accurring the schedules are appressed as a schedules accurring the schedules are appressed as a schedule accurring the schedules are appressed as a schedule accurring the schedules are appressed as a schedules accurring the schedules are appressed as a sched

Stand Up To Cancer-Fanconi Anemia Research Fund-Farrah Fawcett Foundation Head and Neck Cancer Research Team RT6219

### Precision Therapy for Fanconi Anemia and HPV-Related Head and Neck Cancers

GRANT TERM: October 2021 - September 2024

#### **KEY PERSONNEL:**



#### Team Leader:

Agata Smogorzewska, MD, PhD, The Rockefeller University

#### **Principals:**

- Amanda Paulovich, MD, PhD, Fred Hutchinson Cancer Research Center
- Markus Grompe, MD,
   Oregon Health & Science University
- Jorge Silvio Gutkind, PhD, University of California, San Diego



**Team Co-leader:** Barbara Burtness, MD, Yale School of Medicine

#### **Project Manager:**

• Edward Kaftan, PhD, Yale School of Medicine, edward.kaftan@yale.edu

#### Advocates:

- Allison Breininger
- Peter Krause, MD, Yale School of Medicine

#### **Specific Aims:**

**AIM 1.** Perform proteogenomic and digital histologic analysis of FArelated and HPV-related HNSCCs to identify common and cohortspecific therapeutic approaches.

**AIM 2.** Identify and test novel therapeutic approaches in HPV-related HNSCC.

**AIM 3.** Identify effective chemoprevention and treatments in FAassociated HNSCC.

**AIM 4.** Assess the toxicity of potential cancer therapeutics using FA mice bone marrow function assays.

#### **Clinical Trial:**

In development.

#### Website:

https:// standuptocancer.org/ research/researchportfolio/researchteams/head-and-neckcancer-research-team/

RESEARCH TEAMS

SU2C-FANCONI ANEMIA RESEAR & NECK CANCER PRECISION THERAPY FOR FANC HEAD AND NE

Gront Term: October

### Combinatorial Targeting of Oncogene-Driven Childhood Cancer

GRANT TERM: March 2021 - September 2023

#### **KEY PERSONNEL:**



#### Team Leader:

John Anderson, MBBS, MRCP, PhD, University College London Great Ormond Street Institute of Child Health

#### **Principals:**

- Paul M. Sondel, MD, PhD, University of Wisconsin, Madison
- Darren Hargrave, MD, FRCPCH, MRCP, University College London Great Ormond Street Institute of Child Health
- Laura Donovan, PhD, University College London Great Ormond Street Institute of Child Health



#### Team Co-leader:

Louis Chesler, MD, PhD, FRCPCH, Institute of Cancer Research

#### **Project Managers:**

- Martin Anyim, PhD, University College London, m.anyim@ucl.ac.uk
- Alethea Cope, PhD, MSc, BSc, University College London, a.cope@ucl.ac.uk

#### Advocates:

- Parker Moss
- Lori R. Schultz, UW Health American Family Children's Hospital

#### **Specific Aims:**

**AIM 1.** Evaluate MYC inhibitor combinations with chemotherapy and anti-GD2 antibody in neuroblastoma model.

**AIM 2.** Evaluate MYC inhibitor agents with local delivery of CAR T cells in medulloblastoma model.

AIM 3. Optimize CART to incorporate into combination studies.

AIM 4. Evaluate MYC inhibitor with in situ vaccine in neuroblastoma.

**AIM 5.** Evaluate addition of in situ vaccine to MYC targeting in medulloblastoma.

**AIM 6.** Evaluate addition of in situ vaccine to MYC targeting and systemic CAR T in neuroblastoma.

**AIM 7.** Evaluate addition of in situ vaccine to MYC targeting and systemic CAR T in medulloblastoma.

#### Website:

https:// standuptocancer.org/ pediatric-cancer-newdiscoveries-challenge/



Band Up To Cancer (SUBC) and Cancer Research UK (SRUR) are colls **fee Disceveries Challenge teams** to accolonate the development of n rediatric diseases. Building on the collaborative, multi-disciplinary model final development over two years and then compete for an additional too



### **Targeting R-loop Stability in Ewing Sarcoma**

**Project Manager:** 

Sneha Prabhu, MPH,

UT Health San Antonio,

prabhus@uthscsa.edu

GRANT TERM: January 2021 - September 2023

#### **KEY PERSONNEL:**



**Principal:** 

Chun Wei-Chen, PhD,

of the City of Hope

Beckman Research Institute

#### Team Leader:

Alexander Bishop, DPhil, UT Health San Antonio



**Team Co-leader:** Kevin Hiom, PhD, University of Dundee

#### Advocates:

- Laura Jean Rutledge, Rutledge Cancer Foundation
- Gregory Aune, UT Health San Antonio

#### Specific Aims:

AIM 1. Target SF3B1/SRSF2 complex in EwS to induce toxic levels of R-loops. AIM 2. Disrupt DHX9:EWSR1-FLI1 interaction to promote pathological R-loops.

#### Website:

https:// standuptocancer.org/ pediatric-cancer-newdiscoveries-challenge/



# BRAINatomy: A Validated Anatomical Atlas of Childhood Neuroradiation Damage

GRANT TERM: April 2021 - September 2023

#### **KEY PERSONNEL:**



#### Team Leader:

Martin G. McCabe, MB/BChir, PhD, University of Manchester



#### Team Co-leader:

Thomas E. Merchant, BS, DO, PhD, St. Jude Children's Research Hospital

#### **Principal:**

- Lara Barazzuol, PhD, University Medical Center Groningen
- Kate Vaughan, PhD, University of Manchester, kate.vaughan@manchester. ac.uk

**Project Manager:** 

#### Advocates:

- James Adams
- Helen Bulbeck, Braintrust
- Joshua Goddard
- Adam Thomson, Braintrust

#### **Specific Aims:**

**AIM 1.** Analyze brain regions responsible for cognitive and endocrine damage in a large, retrospective cohort of children treated with cranial radiotherapy.

**AIM 2**. Prospectively evaluate the functional and biological effects of brain irradiation in a well-described rat model.

**AIM 3.** Compare the effects on multiple brain compartments of irradiation with X-ray photons and high-energy protons.

#### Website:

https:// standuptocancer.org/ pediatric-cancer-newdiscoveries-challenge/

PEDIATRIC CANCER NEW DIS

Band Up To Center (BLISC) and Center Research UK (CRUK) are collaboratin New Discoveries Challenge teams to accodencie the development of new texpediatric deseases. Building on the collaborative, multi-disciplinary model of SU initial development over two years and then compute to an additional four vers

Pediatric Cancer New Discoveries Challeng

# Early Detection and Interception of Diffuse and Intestinal Gastric Cancer

GRANT TERM: September 2020 - August 2023, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Andrew T. Chan, MD, Massachusetts General Hospital

#### **Principals:**

- Jeeyun Lee, MD, Samsung Medical Center
- Blase Polite, MD, University of Chicago
- Yanghee Woo, MD, Beckman Research Institute of City of Hope
- Sam S. Yoon, MD, Columbia University Irving Medical Center



**Team Co-leader:** Sandra W. Ryeom, PhD, Columbia University Irving Medical Center

#### **Project Manager:**

 Marina Magicheva-Gupta, Massachusetts General Hospital, mmagicheva-gupta@mgh.harvard.edu

#### Advocates:

- Jason Diaz, Stomach Cancer Awareness Network
- Aki Agata Smith, Stomach Cancer Awareness Network

#### **Specific Aims:**

**AIM 1.** Discover and optimize molecularly specific imaging agents and novel circulating biomarkers for early-stage GC using mouse models recapitulating the major TCGA GC subtypes.

AIM 2. Translate preclinical findings to humans by assessing the feasibility of molecular endoscopic or capsule-based imaging across the spectrum of gastric premalignancy and refine circulating biomarkers within cohorts of individuals undergoing routine GC screening and surgery for early-stage disease.

**AIM 3.** Assess initial performance of a molecular and/or capsule imaging platform for detection of GC and validate circulating biomarkers in locally advanced GC patients enrolled in a clinical trial.

#### **Clinical Trials:**

Feasibility of the LUM Imaging System for Detection of Gastrointestinal Cancers; NCT02584244; Recruiting

Phase II Study of Neoadjuvant NALIRIFOX Followed by Chemoradiation With Paclitaxel and Carboplatin in Locally Advanced Esophagogastric Cancer; NCT04656041; Recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/gastriccancer-interceptionresearch-team/



Research > Research Portfolio > Research Teams > Gastric Cancer

SU2C GASTRIC CANCER INTERC EARLY DETECTION AND INTERCEPTIC GASTRIC C/ Pancreatic Cancer Collective Research Teams—Computational Approaches to Identifying High-Risk Pancreatic Cancer Populations RT6179

# Identification of Genomic and Immune Factors in High-Risk Populations for Pancreatic Cancer

GRANT TERM: May 2019 - February 2022

#### **KEY PERSONNEL:**



**Team Leader:** Raul Rabadan, PhD, Columbia University



**Project Manager:** 

### **Team Co-leader:** Núria Malats, MD, MPH, PhD, Spanish National Cancer Research Centre (CNIO)

#### Principals:

- Tal Korem, PhD, Columbia University
- Gulam Manji, MD, PhD, Columbia University
- Ken Olive, PhD, Columbia University

#### **Specific Aims:**

AIM 1A. Identify de novo and germline alterations.

AIM 1B. Annotate the non-coding landscape of alterations in pancreatic tumors.

AIM 2A. Characterize pathogenic infections in the tumor microenvironment.

AIM 2B. Characterize HLA allele-specific expression.

**AIM 3.** Pursue external validation and integration with other data modalities.

## Paula Ralph-Birkett, Columbia University, pr2470@cumc.columbia.edu

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/pccai-genomic-immunefactors/

**RESEARCH TEAMS** 

ssearch > Research Portfulio > Research Teams > PCC Al Genom

PANCREATIC CANCER COLLEC COMPUTATIONAL APPROACHES 1 PANCREATIC CANCER POPULATI GENOMIC AND IMMUNE FACTORS FOR PANCREATIC

# Identifying Individuals at High Risk of Pancreatic Cancer Through Machine Learning Analysis of Clinical Records and Images

GRANT TERM: May 2019 - April 2022

#### **KEY PERSONNEL:**



**Principals:** 

Peter Kraft, PhD,

Brian Wolpin, MD,

**Team Leader:** Chris Sander, PhD, Dana-Farber Cancer Institute

Harvard T. H. Chan School of Public Health



#### **Team Co-leader:** Regina Barzilay, PhD, Massachusetts Institute of Technology

#### Collaborator:

• Søren Brunak, PhD, University of Copenhagen

#### **Project Manager:**

 Elizabeth Andrews, Dana-Farber Cancer Institute, ElizabethA\_Andrews@dfci.harvard.edu

#### **Specific Aims:**

AIM 1. Curate and annotate data.

Michael Rosenthal, MD, PhD,

Dana-Farber Cancer Institute

Dana-Farber Cancer Institute

- AIM 2. Extract features from data.
- AIM 3. Conduct predictive modeling.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/pcc-aiidentifying-individuals/

#### **RESEARCH TEAMS**

Research > Research Portfolio > Research Teams > PCC Al Identi

PANCREATIC CANCER COLLE COMPUTATIONAL APPROACHES PANCREATIC CANCER POPULATION AT HIGH RISK OF PANCREATIC C.

## Pancreatic Cancer Collective Research Team—New Therapies Challenge RT6156

## **Targeting SHP2 in Pancreatic Cancer**

GRANT TERM: November 2018 - June 2023, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** René Bernards, PhD, Netherlands Cancer Institute



#### **Team Co-leader:** Hana Algül,

MD, PhD, Technical University of Munich



#### Team Co-leader:

Emile E. Voest, MD, PhD, Netherlands Cancer Institute

#### **Project Manager:**

 Henri van Luenen, PhD, Netherlands Cancer Institute, h.v.luenen@nki.nl

- Advocates:
  - Ab Doorn, The Netherlands Cancer Institute
- Otto Lutz, Arbeitskreis der Pankreatektomierten e.V.

#### **Specific Aims:**

**AIM 1.** Evaluate the maximum tolerated dose of the SHP2 inhibitor and MEK inhibitor of choice in non-tumor-bearing mice.

**AIM 2.** Identify qualifying biomarkers for response that will allow us to identify patients most likely to respond to the proposed therapy.

**AIM 3.** Test different treatment schedules in different mouse models of pancreatic cancer, in order to maximize the antitumor effect and to minimize toxicity.

#### **Clinical Trial:**

Phase I/Ib Study With the Combination of RMC-4630 (SHP2 Inhibitor) and LY3214996 (ERK Inhibitor) in Metastatic KRAS Mutant CRC, PDAC, and NSCLC; NCT04916236; Recruiting

#### Website:

https:// standuptocancer.org/ research/researchportfolio/researchteams/targeting-shp2/



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PANCREATIC CANCER COLLECT TARGETING SHP2 IN PANCREA THERAPIES CHALL

# **Exploiting DNA Repair Gene Mutations** in Pancreatic Cancer

GRANT TERM: November 2018 - December 2023, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### **Team Leader:** Alan D. D'Andrea, MD, Dana-Farber Cancer Institute

#### **Principals:**

- Andrew Aguirre, MD, PhD, Dana-Farber Cancer Institute
- Geoffrey I. Shapiro, MD, PhD, Dana-Farber Cancer Institute
- Brian M. Wolpin, MD, Dana-Farber Cancer Institute

#### Specific Aims:

AIM 1. Assess DNA damage repair (DDR) deficiency in pancreatic cancer.

- PARP inhibition has shown efficacy in patients with HR deficiency, leading to FDA approval for Olaparib.
- Hypothesis: Addition of ATR inhibition may enhance the efficacy of PARP inhibition in the maintenance setting.

AIM 2. Target replicative stress in platinum-resistant pancreatic cancer.

- Pancreatic cancers often harbor KRAS, CDKN2A/B, or TP53 mutations which generate replication stress.
- Gemcitabine exacerbates replication stress and causes stalled forks ATR, CHK1, and WEE1 kinases stabilize stalled forks.
- Hypothesis: Combining gemcitabine with ATR/CHK1/WEE1 inhibitors worsen replication stress by inhibiting pathways designed to compensate for replication stress and cause cell death.

#### **Clinical Trials:**

Phase Ib/IIa Two-Part, Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of LY2880070 as Monotherapy and in Combination With Gemcitabine in Patients With Advanced or Metastatic Cancer; NCT02632448; Recruiting



**Team Co-leader:** 

Dana-Farber Cancer Institute, Donald watson@dfci.harvard.edu

**Project Manager:** 

Donald R. Watson,

James M. Cleary, MD, PhD, Dana-Farber Cancer Institute

> https:// standuptocancer.org/ research/researchportfolio/researchteams/exploiting-dnarepair/

> > RESEARCH TEAMS

PANCREATIC CANCER COLLECTIV EXPLOITING DNA-REPAIR GENE MUTA CANCER NEW THERAPIES (

#### Clinical Trials (Cont'd):

Phase II Proof-of-Concept Trial Testing the PARP Inhibitor Niraparib in Patients With Pancreatic Cancer Harboring Deficiencies in Homologous Recombination DNA Repair; NCT03601923; Recruiting

Phase I Trial of Gemcitabine Combined With the BAY 1895344 ATR Inhibitor With Expansion Cohorts in Advanced Pancreatic and Ovarian Cancer; NCT04616534; Suspended

# Adoptive Transfer of TGF-B-Resistant TIL to Defeat Immunosuppressive PDAC

GRANT TERM: November 2018 - September 2020, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Patrick Hwu, MD, The University of Texas MD Anderson Cancer Center



**Team Co-leader:** Chantale Bernatchez, PhD, The University of Texas MD Anderson Cancer Center



**Team Co-leader:** Cliona M. Rooney, PhD, Baylor College of Medicine

#### **Project Manager:**

Karen Millerchip, The University of Texas MD Anderson Cancer Center

#### **Specific Aims:**

- AIM 1. Optimize PDACTIL retroviral transduction method.
- AIM 2. Test the impact of the expression of TGF BDNRII on PDAC TIL function.
- **AIM 3.** Investigate in vivo efficacy of tumor-specific TGF &DNRII- transduced T cells in patient-derived preclinical models of pancreatic cancer.

#### Website:

https:// standuptocancer.org/ research/researchportfolio/researchteams/adoptivetransfer/



Research > Research Portfolio > Research Teams > Adoptive Transfer

PANCREATIC CANCER COLLECTIV ADOPTIVE TRANSFER OF TGF-B RESI IMMUNOSUPPRESSIVE PDAC NEW TH

**JUNE 2022** 

Pancreatic Cancer Collective Research Team-New Therapies Challenge RT6152

## Combined Targeting of MEK1/2 and Autophagy for Pancreatic Cancer Therapy

GRANT TERM: November 2018 - December 2020, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Martin McMahon, PhD, University of Utah

#### **Principal:**

- Conan G. Kinsey, MD, PhD, University of Utah
- Project Manager:Karrie Lasater,
- University of Utah



#### Advocates:

- Phyllis D. Coley, University of Utah
- Thomas Kursar, University of Utah

#### **Specific Aims:**

AIM 1. Test if there is a PDA cell genotype-T/HCQ drug response phenotype in PDA cell lines and PDX models with an initial emphasis on TP53 mutation status.

**AIM 2.** Explore novel targets and agents to inhibit trametinib-induced autophagy in PDA cells.

AIM 3. Initiate clinical trials of the combination of trametinib plus HCQ(T/ HCQ) in PDA patients.

#### **Clinical Trial:**

THREAD: Phase I Trial of Trametinib and Hydroxychloroquine in Patients With Advanced Pancreatic Cancer; NCT03825289; Recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/ combined-targetingand-autophagy-forpancreatic-cancer/

RESEARCH TEAMS

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PANCREATIC CANCER COLLECTI COMBINED TARGETING OF MEK1/MEI PANCREATIC CA

Grant Term: November 2018-De

# Targeting Stem Cell Signals in Pancreatic Cancer

GRANT TERM: November 2018-October 2020, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Tannishtha Reya, PhD, University of California, San Diego



**Team Co-leader:** Andrew M. Lowy, MD, University of California, San Diego



Team Co-leader:

Margaret A. Tempero, MD, University of California, San Francisco

#### Project Manager:

Marcie Kritzik, PhD, University of California, San Diego

#### Specific Aims:

AIM 1. Test inhibition of ROR- $\gamma$  in combination with chemotherapy in preclinical models.

AIM 2. Identify biomarkers predictive of response and define a molecular signature reflective of response to ROR- $\gamma$  inhibition.

#### Website:

https:// standuptocancer.org/ research/researchportfolio/researchteams/targeting-stemcell-signals/

**RESEARCH TEAMS** 

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PANCREATIC CANCER COLLECT TARGETING STEM CELL SIGNALS IN P THERAPIES CHAL

Pancreatic Cancer Collective Research Team—New Therapies Challenge RT6153

## Molecularly Targeted Radionuclide Therapy via the Integrin avß6

GRANT TERM: November 2018 - June 2023, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Julie L. Sutcliffe, PhD, University of California, Davis

#### **Principal:**

- Cameron C. Foster, MD, University of California, Davis
- Sonal J. Desai, PhD, University of California, Davis, sjdesai@ucdavis.edu

**Project Manager:** 

## Team Richa Unive

#### **Team Co-leader:** Richard J. Bold, MD, MBA, University of California, Davis

#### Advocate:

• Lora Kelly, RN

#### **Specific Aims:**

AIM 1A. Establish that 68Ga-avb6-BP can detect lesions in patients with locally advanced or metastatic pancreas cancer. The ability of 68Ga-avb6-BP to detect lesions will be assessed by increased standard uptake values (SUVmax >2-fold above normal lung or liver) of 68Ga-avb6-BP in at least one lesion assessed by 68Ga-avb6-BP PET/CT.

AIM 1B. Establish the safety and tolerability of the theranostic pair 68Gaavb6-BP/177Lu-avb6BP. Safety and tolerability of 68Ga-avb6-BP and/or 177Lu-avb6-BP will be assessed by number of patients with treatment-related adverse events using CTCAE v5.0.

AIM 1C. Evaluate the maximum tolerated dose (MTD), and determine the recommended phase II dose (RP2D) of 177Lu-avb6-BP. Dose-limiting toxicities (DLT) of 177Lu-avb6-BP with activity levels starting from 25 mCi and increasing up to the "standard" PRRT level of 200 mCi will be assessed using SPECT/CT.

AIM 2. Establish an optimal dosing regimen in pre-clinical models. Fractionated dosing with the 177Lu-avb6-BP as well as combination with standard-of-care chemotherapy and novel avb6-BP drug conjugates will be explored in xenograft, orthotopic and metastatic mouse models.

#### **Clinical Trial:**

First-in-human Study of the Theranostic Pair (68Ga)Ga DOTA-5G and (177Lu) Lu DOTA-ABM-5G in Pancreatic Cancer; NCT04665947; Recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/ molecularly-targetedradionuclide-therapy/

#### RESEARCH TEAMS

Research > Research Portfolio > Research Teams > Molecularly Tar

PANCREATIC CANCER COLLE MOLECULARLY TARGETED RADIONU ALPHAVBETA6 NEW THER

## Immunotherapy Targeting Mutant KRAS

GRANT TERM: November 2018 - June 2023, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Principal:** 

**Team Leader:** Robert H. Vonderheide, MD, DPhil, University of Pennsylvania



## Team Co-leader:

Elizabeth M. Jaffee, MD, Johns Hopkins University

# CE

#### Team Co-leader:

Beatriz M. Carreno, PhD, University of Pennsylvania

#### **Project Manager:**

TBD

- Neeha Zaidi, MD, Johns Hopkins University
- Adham Bear, MD, PhD, University of Pennsylvania

**Early-Career Investigator:** 

#### **Specific Aims:**

AIM 1. Identify and validate mKRAS-specific TCRs in healthy individuals and cancer patients.

**AIM 2.** Identify KRAS-specific TCRs from PDA patients enrolled in two clinical vaccine trials, exploiting the platform in Aim 1.

#### **Clinical Trials:**

Pilot Study of Mature Dendritic Cell Vaccination Against Mutated KRAS in Patients With Resectable Pancreatic Cancer; NCT03592888; Recruiting

Pooled Mutant KRAS-Targeted Long Peptide Vaccine Combined With Nivolumab and Ipilimumab for Patients With Resected MMR-p Colorectal and Pancreatic Cancer; NCT04117087; Recruiting

#### Website:

https:// standuptocancer.org/ research/researchportfolio/researchteams/immunotherapytargeting-mutant-kras/



PANCREATIC CANCER COL IMMUNOTHERAPY TARC

## Developing Novel Approaches to Detect and Treat Early Pancreatic Cancer

GRANT TERM: January 2018 - December 2022, administered by the American Association for Cancer Re-

#### **KEY PERSONNEL:**



**Team Leader:** David P. Ryan, MD, Massachusetts General Hospital

#### **Principals:**

- Richard A. Burkhart, MD, Johns Hopkins University
- Daniel Laheru, MD, Johns Hopkins University
- Wells A. Messersmith, MD, University of Colorado, Denver
- Cullen M. Taniguchi, MD, PhD, The University of Texas MD Anderson Cancer Center



#### **Team Co-leader:** Alec C. Kimmelman, MD, PhD, New York University

#### **Project Manager:**

• Leilana Ly, Massachusetts General Hospital, LLY2@mgh.harvard.edu

#### Advocates:

- Robert A. Ettl, Harvard Management Co., Inc.
- Regina Pyle, Massachusetts General Hospital
- Carole Seigel, Massachusetts General Hospital

#### **Specific Aims:**

AIM 1. Evaluate novel neoadjuvant approaches in PDAC patients.

AIM 1A: Conduct neoadjuvant clinical trial to increase curability.

**AIM 1B:** Determine whether therapeutic screening of patient-derived organoids can identify an optimal clinical treatment.

AIM 1C: Conduct primary tumor molecular analysis.

**AIM 1D:** Determine the ctDNA, CTC, and exosomes at presentation, during treatment, and after surgery.

**AIM 1E**: Determine the changes in the tumor microenvironment (TME) between arms.

#### **Clinical Trial:**

Randomized Phase II Study of Losartan and Nivolumab in Combination With FOLFIRINOX and SBRT in Localized Pancreatic Cancer; NCT03563248; Recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/ pancreatic-cancerinterception-researchteam/

#### RESEARCH TEAMS

SU2C-LUSTGARTEN FOUNDATION F INTERCEPTION RESE DEVELOPING NOVEL APPROACHE

## SU2C-LUNGevity Foundation-American Lung Association Lung Cancer Interception Research Team RT6058

# **Blood-Based Early Interception of Lung Cancer**

GRANT TERM: December 2017 - February 2019, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

Lecia V. Sequist, MD, Massachusetts General Hospital

#### **Project Manager:**

Elaina PuiYee Chan, PhD, Massachusetts General Hospital



**Team Co-leader:** Maximilian Diehn, MD, PhD, Stanford University

#### Advocate:

Chris M. Draft, Chris Draft Family Foundation

#### Specific Aim:

Optimize CTC-derived RNA signature and plasma ctDNA signature for use in early-stage lung cancer detection.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/lungcancer-interceptionresearch-team/

RESEARCH TEAMS

Research > Research Portfolio > Research Teams > Long Cancer

SU2C-LUNGEVITY-AMERICAN LUNG INTERCEPTION RES BLOOD-BASED EARLY INTERCE

# Chimeric Antigen Receptor T-cell (CAR T) Therapy for Pancreatic Cancer

GRANT TERM: April 2017 - November 2022

#### **KEY PERSONNEL:**



**Team Leader:** Carl H. June, MD, University of Pennsylvania



**Team Co-leader:** Shelley L. Berger, PhD, University of Pennsylvania



Team Co-leader:

E. John Wherry, PhD, University of Pennsylvania

#### **Principals:**

- M. Angela Aznar, PhD, University of Pennsylvania
- Charly R. Good, PhD, University of Pennsylvania
- Mark H. O'Hara, MD, University of Pennsylvania
- Janos L. Tanyi, MD, PhD, University of Pennsylvania

#### **Project Manager:**

 Regina M. Young, PhD, University of Pennsylvania, ryoung@upenn.edu

#### Advocate:

James E. Prevor, Phoenix Media Network

#### **Specific Aims:**

AIM 1. Carry out clinical trials in cancer immunotherapy for metastatic pancreatic cancer and transcriptionally and epigenetically interrogate samples prior to and following therapy to compare CAR T cell signatures from responsive and resistant patients, with the objective of improving therapeutic response.

**AIM 2.** Define the epigenetic landscape and sensitivities of pancreatic cancer cells and therapeutic immune cells, with the goal of identifying baseline molecular differences in pancreatic patients that may impede optimal CAR T cell function.

#### **Clinical Trials:**

Phase I Study of Human Chimeric Antigen Receptor Modified T Cells in Patients With Mesothelin-Expressing Cancers; NCT03054298; Recruiting

Phase I Study of Human Chimeric Antigen Receptor Modified T Cells (CAR T Cells) in Patients With Pancreatic Cancer; NCT03323944; Active, not recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/car-ttherapy-for-pancreaticcancer-research-team/

**RESEARCH TEAMS** 

Research > Research Portfolio > Research Teams > CAR T The

SU2C-LUSTGARTEN FOUNDATIK CHIMERIC ANTIGEN RECEPTO FOR PANCREAT

# Phosphatidylinositol 3-kinase $\delta$ Inhibition to Treat Patients With Relapsed or Refractory Follicular Lymphoma

GRANT TERM: March 2016 - May 2020

#### **KEY PERSONNEL:**



#### Team Leader:

Siddhartha Mukherjee, MD, Columbia University

#### **Co-Investigators:**

- Changchun Deng, MD, PhD, Columbia University
- Owen A. O'Connor, MD, PhD, Columbia University

#### Fellow:

 Lorenzo Falchi, MD, Columbia University

## **Project Manager:**

• Alice Lustig, Stand Up To Cancer

#### Specific Aims:

AIM 1. Assess markers of responsiveness versus resistance to PI3K  $\delta$  inhibition in a population of patients with relapsed or refractory FL using genomic, epigenomic, and metabolomics profiling.

AIM 2. Use cell lines to determine how PI3K  $\delta$  inhibition affects growth and survival of lymphoma cells and their sensitivity to other drugs active in lymphoma.

**AIM 3.** Develop mouse models of FL and use these models to study the response of lymphoma to duvelisib in vivo.

#### **Clinical Trial:**

Study of the Phosphoinositide-3-Kinase-Delta Inhibitor TGR-1202 in Patients With Relapsed or Refractory Follicular Lymphoma; NCT03178201; Terminated

# Therapeutic CD8 Vaccines Against Conserved E7 HPV Epitopes Identified by MS

GRANT TERM: July 2014 - February 2020, administered by the American Association for Cancer Research

Advocate:

Mary-Jo Murphy

#### **KEY PERSONNEL:**



**Team Leader:** Ellis L. Reinherz, MD, Dana-Farber Cancer Institute

#### **Project Managers:**

- Joanie Lindstrom,
   Dana-Farber Cancer Institute
- Farzana Masood, PhD, Dana-Farber Cancer Institute

#### **Specific Aims:**

AIM 1. Perform a phase IB/II trial of adjuvant E711-19 nanomer vaccine DPX-E7 in 40 HLA-A\*0201-positive patients with HPV16+ squamous cancers of the cervix, anus, or oropharynx.

**AIM 2.** Define additional immunogenic HLA-bound tumor antigens on HPVdriven cancers of the cervix, anus, and head and neck.

**AIM 3.** Investigate clonal heterogeneity and molecular functional avidity of TCRs elicited by vaccination to engender those supporting the most sensitive tumor antigen recognition/tumor cell killing as well as future adoptive cell therapy.

#### **Clinical Trial:**

Phase Ib/II Trial to Test the Safety and Efficacy of Vaccination With HPV16-E711-19 Nanomer for the Treatment of Incurable HPV16-Related Oropharyngeal, Cervical, and Anal Cancer in HLA-A\*02-Positive Patients; NCT02865135; Active, not recruiting

#### Website:

Team Co-leader:

Robert I. Haddad, MD,

Dana-Farber Cancer Institute

https:// standuptocancer.org/ research/researchportfolio/researchteams/hpv-researchteam/

RESEARCH TEAMS

Research > Research Portfolio > Research Teams > I

SU2C-FARRAH FAWCETT FOI (HPV) R

# Prospective Use of DNA-Guided Personalized Cancer Treatment

GRANT TERM: January 2013 - December 2017, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

Emile E. Voest, MD, PhD, Netherlands Cancer Institute

#### **Principals:**

- Trey Ideker, PhD, University of California, San Diego
- Stefan Sleijfer, MD, PhD, Erasmus MC Rotterdam
- Laura J. van't Veer, PhD, University of California, San Francisco



**Team Co-leader:** René Bernards, PhD, Netherlands Cancer Institute

#### **Project Manager:**

Alice Tondeur,
 Netherlands Cancer Institute

#### **Specific Aims:**

**AIM 1.** Identify DNA-based biomarkers of response to neoadjuvant chemotherapy+/- neratinib in breast cancer through analyses of biopsies from the trial.

**AIM 2.** Generate genomic selection criteria for patients with KRAS wild-type colorectal tumors to improve the outcome of anti-EGFR antibody treatment using genomic analyses of metastases for a cancer mini-genome of genes.

**AIM 3.** Deliver systems biology tools to analyze alterations in our cancer mini-genome to refine patient selection criteria for individualized treatment.

**AIM 4.** Identify DNA- and RNA-based biomarkers of response to chemotherapy + atezolizumab in metastatic lobular breast cancer.

#### **Clinical Trials:**

I-SPY 2 Trial (Investigation of Serial Studies to Predict Your Therapeutic Response With Imaging and Molecular Analysis 2); NCT01042379; Recruiting

Assessing Efficacy of Carboplatin and Atezolizumab in Metastatic Lobular Breast Cancer GELATO Trial; NCT03147040; Recruiting

Development of a Platform for Next-Generation DNA Sequencing-Based Personalized Treatment for Cancer Patients: Protocol to Obtain Biopsies From Patients With Locally Advanced or Metastatic Cancer (CPCT-02 Biopsy Protocol); NCT01855477; Recruiting

Phase Ib/II Multicenter, Open-Label, Dose-Escalation Study of LGX818 and Cetuximab or LGX818, BYL719, and Cetuximab in Patients With BRAF Mutant Metastatic Colorectal Cancer; NCT01719380; Completed

#### Website:

https:// standuptocancer.org/ research/researchportfolio/researchteams/dna-guidedcare-research-team/

#### RESEARCH TEAMS

Research > Research Portfolio > Research Teams > DNA

SU2C-DUTCH TRANSLATIONA

# SU2C CONVERGENCE RESEARCH TEAMS

# Molecular and Biophysical Definition of Tumor-Host Interactions and Impact on Tumorigenesis and Therapeutic Response

GRANT TERM: January 2021 - December 2023

#### **KEY PERSONNEL:**



**Team Leader:** Ileana Cristea, PhD, Princeton University

#### **Team Members:**

- Shawn Davidson, PhD, Princeton University
- Scott Manalis, PhD, Massachusetts Institute of Technology
- Benjamin Neel, MD, PhD, New York University

## **Project Manager:**

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

#### Cristea Lab/Princeton University

**AIM 1.** Uncover molecular drivers of tumor-host interactions by developing methods for defining surface proteomes in 3D cell models in conjunction with secretome and intracellular proteome assays.

AIM 2. Define global protein complex dynamics underlying signaling and immune responses in organoids.

AIM 3. Determine how organelle contact sites link lipid metabolism and immune signaling in organoids.

#### Manalis Lab/Massachusetts Institute of Technology

AIM 1. Develop chemostat for organoid culture.

**AIM 2.** Study mechanisms by which microbiota affect tumor responses to anti-PD-1 therapy.

**AIM 3.** Understand how microbial peptides alter biophysical properties of mammalian cells.

**AIM 4.** Use genotype-defined syngeneic organoid models to study tumor/TME interactions and therapy.

**AIM 5.** Determine if single-cell biophysical measurements can optimize strategies to enhance immunotherapy.

#### Website:

https:// standuptocancer.org/ research/researchportfolio/researchteams/molecularand-biophysicaldefinition-of-tumorhost-interactionsand-impact-ontumorigenesis-andtherapeutic-response/

## RESEARCH TEAMS

SU2C CONVERGENCE 3.1416 RESEARCH TEAM: MOL BIOPHYSICAL DEFINITION OF TUMOR-HOST INTERAC IMPACT ON TUMORIGENESIS AND THERAPEUTIC I

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to SUSC Convergence Research Team is seeking to principle an understanding of the next
turno-most interaction interface and their effects on host interacting turnologinesis, and th
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#### Specific Aims (Cont'd):

#### Davidson Lab/Princeton University

**AIM 1.** Define the metabolic tumor microenvironment by integrating spatial-omics in mouse and organoid models of cancer.

**AIM 1A.** Define the metabolic and immunologic microenvironment of high-grade serous tuboovarian cancer (HGSC).

AIM 1B. Determine the functional metabolic interaction of commensal gut microbiota, T cells, and lung cancer.

AIM 2. Conduct high-throughput metabolic characterization of organoids based on biophysical separation.

AIM 2A: Perform metabolic screening of organoids from primary dissociated tumors separated by biophysical methods

AIM 3. Develop methods for MALDI (3D imaging and improved spatial resolution) and nanoflow-LCMS.

AIM 3A. Develop 3D MALDI for labeled metabolite distribution in tumors, organs, and organoids.

AIM 3B. Improve MALDI spatial resolution and metabolic pathway coverage.

AIM 3C. Investigate nanoflow metabolomics toward obtaining separation-based single-cell metabolism measurements.

#### Neel Lab/New York University

**AIM 1.** Use genotype-defined organoids to delineate cell autonomous/non-autonomous effects on HGSC evolution.

**AIM 2.** Further characterize tumor/TME interactions and optimize therapy for Ccne1OE and Nf-/- HGSC.

AIM 3. Develop more refined, TME-retaining human and mouse organoid models of HGSC.

# Integrating Gnotobiotic, Organoid, and Metabolomic Pipelines to Probe the Cancer-Microbiome Connection

GRANT TERM: January 2021 - December 2023

#### **KEY PERSONNEL:**



#### Team Leader:

Kenya Honda, MD, PhD, Keio University, Japan

#### **Team Members:**

- Hans Clevers, MD, PhD, Hubrecht Institute, Netherlands
- Josh Rabinowitz, MD, PhD, Princeton University
- Toshiro Sato, MD, PhD, Keio University, Japan

#### **Project Manager:**

Alice Lustig,
 Stand Up To Cancer,
 alustig@su2c.org

#### **Specific Aims:**

#### Honda Lab/Keio University

**AIM 1.** Establish an in vivo model appropriate for screening of CRCpromoting bacteria.

AIM 2. Search for bacterial strains that promote CRC development.

AIM 3. Model bacteria-induced colon carcinogenesis using an in vitro organoid co-culture system.

AIM 4. Search for bacterial strains that can prevent CRC development.

AIM 5. Elucidate diet-microbiome-immune connection.

#### **Clevers Lab/Hubrecht Institute**

**AIM 1.** Build on top of our identification of the first bacterially induced mutational signature by screening further bacterial toxins, strains, and species of potentially genotoxic bacteria.

AIM 2. Focus on the impact of colorectal cancer-associated bacteria on cellular behavior beyond mutation accumulation. This will be performed both on individual cancer-associated species and on microbial communities derived from healthy donors and colorectal cancer patients.

**AIM 3.** Study the role in tumorigenesis of bacteria from the Clostridium genus associated with CRC tumorigenesis by metagenomics studies.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/ integrating-gnotobioticorganoid-andmetabolomicpipelines-to-prove-thecancer-microbiomeconnection/

#### RESEARCH TEAMS

SU2C CONVERGINCE 3.1416 BESLARCH TEAM: IN GNIOTOBIONC, GROANDIA, AND METANOLOMIC P PROBETHE CANCER-MICROBIOME CONNEC Amany SID-fearmer Research and Analysiste ang The SIGC Compress Parsent Date of slids particulated independent memory and evaluations a large 1 and 1 and

#### Specific Aims (Cont'd):

#### Clevers Lab (Cont'd)

**AIM 4.** Obtain microbial communities derived from healthy donors and colorectal cancer patients, and expose healthy human colon and colorectal cancer organoids to microbial communities and the metabolites produced by these, to identify community-level effects on colorectal cancer cell behavior.

#### **Rabinowitz Lab/Princeton University**

AIM 1. Investigate diet-microbiome connection.

AIM 2. Study diet-microbiome-immune connection.

AIM 3. Explore diet-cancer therapy connection.

#### Sato Lab/Keio University

AIM 1. Study carcinogenic potential of gut microbes on colonic epithelium in vivo.

AIM 2. Develop new in vivo human CRC model.

AIM 3. Model bacteria-induced colon carcinogenesis using an in vitro organoid coculture system.

**AIM 4.** Understand the molecular determinants of invasiveness and metastatic capacity during colon carcinogenesis.

# Integrating Microbiome and Organoid Analyses of Patient Cohorts for Immunooncology Therapeutic Development

GRANT TERM: January 2021 - December 2023

#### **KEY PERSONNEL:**



## Team Leader:

Calvin Kuo, MD, PhD, Stanford University

#### **Team Members:**

- Ami Bhatt, MD, PhD, Stanford University
- Michael Fischbach, PhD, Stanford University
- Jennifer Wargo, MD, MMSc, The University of Texas MD Anderson Cancer Center

#### **Project Manager:**

 Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### Specific Aims:

#### Kuo Lab/Stanford University

AIM 1. Investigate ALI tumor organoid-based anoxic culture for obligate anaerobes.

AIM 1A. Flow-based anaerobic/aerobic transwell platform for organoid culture.

AIM 1B. Organoid and anaerobic bacterial interaction and growth.

AIM 2. Integrate microbiota into ALI tumor organoids from neoadjuvant anti-PD-1 patient cohorts.

- AIM 2A. Combination with candidate microbiota.
- AIM 2B. Addition of microbiota-derived small molecules and peptides.

AIM 2C. Effects on anti-PD-1 responses.

AIM 3. Incorporate peripheral immune components with ALI tumor organoids.

AIM 3A. Human ALI tumor organoid co-culture with autologous lymph node organoids.

AIM 3B. Murine ALI tumor organoid co-culture with autologous lymph node organoids.

#### Website:

https:// standuptocancer.org/ research/researchportfolio/researchteams/integratingmicrobiome-andorganoid-analyses-ofpatient-cohorts-forimmuno-oncologytherapeuticdevelopment

#### RESEARCH TEAMS

SU2C CONVERGENCE 3.1416 RESEARCH TEAM: MICROBIOME AND ORGANOID ANALYSES OF PATI FOR IMMUNOONCOLOGY THERAPEUTIC DEV

Tes SUSC Convergence Research Team is sensing to investigate the limitations of inveintmiss and acquired resistance. They plan to integrate microbiume and organist angaterit cohorts, in order to develop novel immunotherapeutic contor

r Term: Jenuary 2007-december 2003

#### Specific Aims (Cont'd):

#### Bhatt Lab/Stanford University

AIM 1. Leverage culture-free approaches to strain tracking in human microbiome studies.

AIM 1A. Culture-free genome assembly from microbiomes.

AIM 1B. Measuring genomic plasticity.

AIM 1C. Dissecting the role of translated microbial genes in immunotherapy response.

**AIM 2.** Identify bioactive microbial small peptides that may modulate cancer biology and therapy efficacy.

AIM 2A. Decoding microbial communication.

AIM 2B. Microbial microproteins and their impact on cellular biophysics.

AIM 2C. Mining microbial microprotein communication signals to transform drug discovery.

#### Fishbach Lab/Stanford University

AIM 1. Study the role of bacterially derived molecules in dictating the fate of an elicited T cell.

AIM 2. Determine whether tumor-specific T cells can be induced by expressing host antigens in bacterial colonists.

**AIM 3.** Investigate whether we can study the contribution of each strain in a complex community to immune modulation.

#### Wargo Lab/MD Anderson Cancer Center

**AIM 1.** Determine characteristics of the gut microbiome associated with optimal response to immunotherapy in a prospective cohort of immunotherapy-treated patients.

**AIM 2.** Identify optimal strategies to enhance response to immunotherapy via gut microbiota modulation by deep profiling and integrated analysis of data from existing cohorts.

**AIM 3.** Optimize strategies to enhance immunotherapy response via gut microbiota/ functional interventions with testing in preclinical models.

# Multi-omic Analysis of Immune System and Microbiota Influence on Temporal and Spatial Evolution of Tumor Microenvironments

#### GRANT TERM: January 2021 - December 2023

#### **KEY PERSONNEL:**



#### Team Leader:

Dan Littman, MD, PhD, New York University Grossman School of Medicine

#### **Team Members:**

- Karuna Ganesh, MD, PhD, Memorial Sloan Kettering Cancer Center
- Tyler Jacks, PhD,
   Massachusetts Institute of Technology
- Raul Rabadan, PhD, Columbia University

#### **Project Manager:**

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

#### Littman Lab/New York University

**AIM 1.** Investigate mechanisms by which microbiota influence tumor responses to anti-PD-1 therapy.

AIM 1A: Examination of how gut microbiota exert functions at distal sites.

AIM 1B: Characterization of candidate microbiota/diet-derived metabolites in regulation of antitumor responses.

**AIM 2.** Study effects of microbiota on intratumoral T cells in mice and organoids.

AIM 2A: Mechanisms of microbiota-induced T-cell differentiation. AIM 2B: Screening of bacterial peptide libraries for effects on the tumor microenvironment and T-cell differentiation.

**AIM 3.** Analyze role of SAAs and effector T cells in tumor growth and checkpoint therapy.

AIM 3A: Role of SAAs in tumor growth, evolution, and metastasis.

AIM 3B: Elucidation of the SAA signaling pathway in Th17 cell differentiation.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/ multi-omic-analysisof-immune-systemand-microbiotainfluence-ontemporal-and-spatialevolution-of-tumormicroenvironments/

#### RESEARCH TEAMS

SU2C CONVERGENCE 3.1416 RESEARCH TEAM: ANALYSIS OF IMMUNE SYSTEM AND MICROBIOTA I TEMPORAL AND SPATIAL EVOLUTION OF TI INCOMPUTED ON MENTS

arm: January 2027-December 2022

This SUEC Convergence Research Team is seeking to advance understanding of tunifactors that contribute to the dynamic interactions between intruse epidem cells a covervicement. The Team aims to identify tunior extremabilities and new molecular at

#### Specific Aims (Cont'd):

#### Ganesh Lab/Memorial Sloan Kettering Cancer Center

**AIM 1.** Develop a prospective functional longitudinal biospecimen platform to dissect tumor, immune, and microbial determinants of metastasis.

**AIM 2.** Develop a novel fluidic platform for in vitro modeling of epithelial-immunemicrobial interactions.

**AIM 3.** Define molecular determinants of regenerative plasticity and innate immune activation during infection and cancer.

#### Jacks Lab/Massachusetts Institute of Technology

AIM 1. Investigate the tumor-immune contexture in immunogenic and immune refractory pancreas and colon cancers by single-cell mRNA sequencing (sc-mRNAseq) and spatial analysis of gene expression, protein expression, and metabolites.

AIM 2. Conduct ex vivo and in vivo organoid-based functional studies.

#### Rabadan Lab/Columbia University

AIM 1. Quantify host expression and microbial abundances for bulk and single-cell data analysis.

AIM 2. Quantify allele-specific HLA class I expression.

AIM 3. Random matrix theory (RMT) for single-cell denoising.

AIM 4. Topological data analysis (TDA) for dissecting dynamical single-cell data.

**AIM 5**. Gaussian random fields (GRF) approach for studying cell-cell interactions with special protein and transcriptomic data.

# Intra-team Collaboration: The Multi-organ Organoid Chemostat Group

GRANT TERM: January 2021 - December 2023

#### **KEY PERSONNEL:**



#### Team Leader:

Calvin Kuo, MD, PhD, Stanford University

#### **Team Members:**

- Michael Fischbach, PhD, Stanford University
- Karuna Ganesh, MD, PhD, Memorial Sloan Kettering Cancer Center
- Scott Manalis, PhD, Massachusetts Institute of Technology

#### **Collaborator:**

Man-Wah Tan, PhD, Genentech

#### **Project Manager:**

 Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

AIM 1. Build and populate a new device to culture gut organoids with stem cells, lymphoid tissue, and a microbiome.

**AIM 2.** Apply molecular, biochemical, and biophysical technologies to address additional fundamental questions in tumor-host interactions: tumor evolution, the effects of the immune system and the microbiome, and determinants of regenerative plasticity.

**AIM 3**. Use the chemostat platform to be developed to study various organoid types and explore their interactions with immune cells.

**AIM 4.** Use the blood exchange method to uncover soluble and cellular mediators of immune response.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ research-teams/themulti-organ-organoidchemostat-group/

#### RESEARCH TEAMS

SU2C 3.1416 CONVERGENCE RESEARCH TEL INTEA-TEAM COLLABORATION: THE MULTI-ORGAN ORGANOID CHEMOSTAT G

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# Correlating Immunological Health to Cancer Susceptibility

GRANT TERM: January 2018 - December 2021

#### **KEY PERSONNEL:**



#### **Team Leader:**

Mark M. Davis, PhD, Stanford University

#### **Team Members:**

- David Furman, PhD, Buck Institute
- Thomas Montine, MD, PhD, Stanford University
- Kari Nadeau, MD, PhD, Stanford University
- Stephen Quake, PhD, Stanford University

#### **Project Manager:**

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

- AIM 1. Correlates of cancer susceptibility in the Stanford-Ellison cohort.
- AIM 2. Complementary cohorts.
- AIM 3. Validation cohorts.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ cancer-susceptibilityconvergence-researchteam/

CONVERGENCE TEAMS

Research > Research Portfolio > Convergence Teams > Cancer I

SU2C CANCER SUSCEPTIBILITY CC CORRELATING IMMUNO CANCER SUSC

# Single-Cell Functional Multi-omics to Characterize and Monitor CAR T Therapy

GRANT TERM: January 2018 - November 2022

#### **KEY PERSONNEL:**



#### Team Leader:

Rong Fan, PhD, Yale University

#### **Team Members:**

- Pablo Gonzalez
   Camara, PhD,
   University of Pennsylvania
   Perelman School
   of Medicine
- Stephanie Halene, MD, PhD, Yale University
- Carl H. June, MD, University of Pennsylvania Perelman School of Medicine
- J. Joseph Melenhorst, PhD, University of Pennsylvania Perelman School of Medicine

#### **Project Manager:**

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### Specific Aims:

**AIM 1.** Measure the full spectrum of cytokine functions in pre-infusion CAR T cells upon antigen-specific stimulation, correlating to objective response and adverse effect.

**AIM 2.** Measure circulating and/or tumor-infiltrating CAR T cells ex vivo to monitor patient outcome and investigate the mechanism of efficacy versus immune-toxicity.

**AIM 3.** Develop computational models combining topological analysis and machine learning to unveil the molecular characteristics that underlie therapeutic efficacy and toxicity of CAR T therapy, and identify candidate biomarkers.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ single-cell-multi-omicsconvergence-researchteam/

#### CONVERGENCE TEAMS

Research > Research Portfolio > Convergence Teams > Single-

SU2C SINGLE-CELL MULTI-OMICS C SINGLE-CELL FUNCTIONAL MULTI-MONITOR CAI

# **Machine Learning for Cancer Immunotherapy**

GRANT TERM: January 2018 - November 2022

#### **KEY PERSONNEL:**



## Team Co-leader:

Ernest Fraenkel, PhD, Massachusetts Institute of Technology



 Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

AIM 1. Conduct integrative modeling of immune health and tumor biology.

AIM 2. Identify pathways conferring resistance to natural killer cells.

#### Website:

Massachusetts Institute of Technology

Team Co-leader:

Regina Barzilay, PhD,

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ machine-learningconvergence-researchteam/

## CONVERGENCE TEAMS

Research > Research Portfolio > Convergence Teams > Machine

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## SU2C-Lustgarten Foundation Convergence Research Team CV6122

# Computational Deconstruction of Neoantigen-TCR Degeneracy for Cancer Immunotherapy

GRANT TERM: January 2018 - November 2022

#### **KEY PERSONNEL:**



**Team Co-leader:** Benjamin Greenbaum, PhD, Memorial Sloan Kettering Cancer Center

#### **Team Members:**

- Marta Luksza, PhD, Icahn School of Medicine at Mount Sinai
- Eileen M. O'Reilly, MD, Memorial Sloan Kettering Cancer Center
- Jedd Wolchok, MD, PhD, Memorial Sloan Kettering Cancer Center



#### **Team Co-leader:** Vinod Balachandran, MD, Memorial Sloan Kettering

Cancer Center

#### Project Manager:

 Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

**AIM 1.** Define the rules of recognition of cancer neoantigens by human T cells.

**AIM 2.** Identify the role of the host microbiome in modulating neoantigen recognition.

AIM 3. Evaluate a neoantigen cancer vaccine as an adjuvant pancreatic cancer therapy.

#### **Clinical Trial:**

Phase I Clinical Trial of Personalized Neoantigen Tumor Vaccines and Programmed Death-Ligand 1 (PD-L1) Blockade in Patients With Surgically Resected Pancreatic Cancer; NCT04161755; Recruiting

#### Website:

#### <u>https://</u>

standuptocancer.org/ research/researchportfolio/convergenceteams/neoantigentcr-degeneracy-

<u>convergence-research-</u> team/



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SU2C-LUSTGARTEN FOUNDATION PJ CONVERGENCE RESEARC COMPUTATIONAL DECONSTRUCTION DEGENERACY FOR CANCER IM

# Integrating Experimental and Computational Pipelines to Develop Biomarkers of Tumor Cell Resistance to NK Cells

GRANT TERM: January 2018 - November 2022

#### **KEY PERSONNEL:**



#### Team Leader:

Constantine S. Mitsiades, MD, PhD, Dana-Farber Cancer Institute

#### **Team Members:**

- Aedin Culhane, PhD, Dana-Farber Cancer Institute
- Todd Golub, MD, Broad Institute of MIT and Harvard
- Ricardo de Matos Simoes, PhD, Dana-Farber Cancer Institute
- Jennifer Roth, MSc, MBA, Broad Institute of MIT and Harvard
- Michal Sheffer, PhD, Dana-Farber Cancer Institute
- Aviad Tshemiak, MSc, Broad Institute of MIT and Harvard

#### Project Manager:

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

**AIM 1.** Apply and develop next-level computational resources to optimize identification of biomarkers of tumor cell sensitivity versus resistance to NK cells.

AIM 2. Expand the spectrum of phenotypic data on NK cell responses.

AIM 3. Validate candidate markers in our in vitro and in vivo experimental platforms.

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ natural-killer-cellsconvergence-researchteam/

#### CONVERGENCE TEAMS

Research > Research Portfolio > Convergence Teams > Natur

SU2C NATURAL KILLER CELLS CO INTEGRATING EXPERIMENTAL ANI DEVELOP BIOMARKERS OF TUMO

# Responders and Non-responders to Endometrial Cancers With Mismatch Repair

GRANT TERM: January 2018 - December 2021

#### **KEY PERSONNEL:**



#### Team Leader:

Alessandro D. Santin, MD, Yale University

#### **Team Members:**

- Ludmil Alexandrov, PhD, University of California, San Diego
- Stephania Bellone, PhD, Yale University
- Akiko Iwasaki, PhD, Yale University

#### **Project Manager:**

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

**AIM 1.** How can we predict responders from non-responders to checkpoint inhibitors?

**AIM 2.** Can we predict which patients will develop side effects to these therapies? How can we relate the peptide sequence of antigens to the nucleic acid sequence of T-cell receptor variable regions?

AIM 3. Can we predict peptide antigens from T-cell receptor sequences? Can we determine with some confidence the neoantigens that are expressed by tumors that are recognized by the immune system in an HLA-dependent fashion?

#### **Clinical Trial:**

Phase II Evaluation of Pembrolizumab, a Humanized Antibody Against PD-1, in the Treatment of Persistent or Recurrent Hypermutated/ Ultramutated Endometrial Cancer Identified by Next-Generation Sequencing (NGS) and Comprehensive Genomic Profiling (CGP); NCT02899793; Active, not recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ endometrial-cancersconvergence-researchteam/

#### CONVERGENCE TEAMS

Research > Research Portfolio > Convergence Teams > Endometri

SU2C ENDOMETRIAL CANCERS COI RESPONDERS AND NONRESPONDER WITH MISMATCH REPA

# Connecting Immune Health and Tumor Biology in Gynecologic Cancers

GRANT TERM: January 2018 - November 2022

#### **KEY PERSONNEL:**



**Team Leader:** E. John Wherry, Ph

E. John Wherry, PhD, University of Pennsylvania

#### Team Members:

- Shelley Berger, PhD, University of Pennsylvania
- Robert Burger, MD, FACOG, FACS, Hospital of the University of Pennsylvania
- Erica Carpenter, MBA, PhD, University of Pennsylvania

- Travis Hollman, MD, Memorial Sloan Kettering Cancer Center
- Dana Pe'er, PhD, Memorial Sloan Kettering Cancer Center
- Daniel Powell, PhD, University of Pennsylvania
- Dmitriy Zamarin, MD, PhD, Memorial Sloan Kettering Cancer Center

#### Team Co-leader:

Claire Friedman, MD, Memorial Sloan Kettering Cancer Center

#### **Project Manager:**

 Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### Specific Aims:

**AIM 1.** Test how tumor-intrinsic factors predispose to response or resistance to checkpoint blockade.

**AIM 2.** Test how baseline immune function and quality affects response to checkpoint blockade.

**AIM 3.** Define how on-treatment blood markers may reflect the tumorimmune interaction.

#### **Clinical Trials:**

Pilot Study of Nivolumab in Combination With Front-Line Neoadjuvant Dose-Dense Paclitaxel and Carboplatin Chemotherapy and Postsurgical Dose-Dense Paclitaxel and Carboplatin Chemotherapy in Patients With High-Grade Serous Ovarian, Fallopian Tube, or Primary Peritoneal Cancer; NCT03245892; Recruiting

Phase II Trial of Single-Agent Nivolumab in Patients With Microsatellite Unstable/Mismatch Repair Deficient/Hypermutated Uterine Cancer; NCT03241745; Recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ gynecologic-cancersconvergence-researchteam/

#### CONVERGENCE TEAMS

Research > Research Portfolio > Convergence Teams > Gynecologic Ce

SU2C GYNECOLOGIC CANCERS CONV CONNECTING IMMUNE HEALTH AN GYNECOLOGIC CI

SU2C-Breast Cancer Research Foundation Convergence Research Team CV6004

Herbert Levine, PhD,

University of California, Irvine

**Rice University** 

Clare C. Yu, PhD,

# Ecology of the Tumor Microenvironment in Breast Cancer

GRANT TERM: June 2015 - December 2019

#### **KEY PERSONNEL:**



#### Team Leader:

Peter P. Lee, MD, City of Hope

#### **Team Members:**

- Gurinder S. "Mickey" Singh Atwal, PhD, Cold Spring Harbor Laboratory
- Darrell J. Irvine, PhD, Massachusetts Institute of Technology
- **Specific Aims:**

AIM 1. Study the breast cancer TME via deconstruction into key components and 3-D reconstruction.

**AIM 2.** Study the intact breast cancer TME and TDLN via quantitative, spatial tissue analysis.

**AIM 3.** Investigate combination therapy targeting multiple components of the TE.

#### **Project Manager:**

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ breast-cancer-tumormicroenvironment/

#### CONVERGENCE TEAMS

Research > Research Portfolio > Convergence Teams > Breast

SU2C-BREAST CANCER RESEARCI CONVERGENCE R ECOLOGY OF THE TUMOR SU2C-National Science Foundation Convergence Research Team CV6006

### Rational Design of Anticancer Drug Combinations with Dynamic Multi-Dimensional Input

GRANT TERM: September 2015 - August 2019

#### **KEY PERSONNEL:**



#### Team Leader:

Anthony G. Letai, MD, PhD, Dana-Farber Cancer Institute

#### **Team Members:**

- Reka Z. Albert, PhD, Pennsylvania State University
- Raul Rabadan, PhD, Columbia University
- Maurizio Scaltriti, PhD, Memorial Sloan Kettering Cancer Center
- Nikhil Wagle, MD, Dana-Farber Cancer Institute/ Harvard Cancer Center

#### **Specific Aims:**

**AIM 1.** Construct dynamic models for signal transduction in PIK3CAmutant, ER+ breast cancer cells.

**AIM 2.** Perform systematic gain-of-function screens to refine and iterate the dynamic models.

**AIM 3**. Dissect the evolutionary trajectories of acquired cancer drug resistance.

#### **Clinical Trials:**

Phase I Trial of BYL719 Plus Letrozole or Exemestane for Patients With Hormone Receptor- Positive, Locally Advanced, Unresectable or Metastatic Breast Cancer; NCT01870505; Active, not recruiting

Phase II, Randomized, Double-Blind Study of Neoadjuvant Letrozole Plus GDC-0032 Versus Letrozole Plus Placebo in Postmenopausal Women With ER-Positive/HER2-Negative, Early-Stage Breast Cancer; NCT02273973; Completed

Phase I, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, and Pharmacokinetics of GDC-0077 as a Single Agent in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Solid Tumors and in Combination With Endocrine and Targeted Therapies in Patients With Locally Advanced or Metastatic PIK3CA-Mutant Hormone Receptor–Positive Breast Cancer; NCT03006172; Recruiting

#### **Project Manager:**

Alice Lustig,
 Stand Up To Cancer,
 alustig@su2c.org

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ rational-design-ofanticancer-drugcombinationsconvergence-researchteam/

#### CONVERGENCE TEAMS

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### Genetic, Epigenetic, and Immunological Underpinnings of Cancer Evolution Through Treatment

GRANT TERM: September 2015 - December 2019

#### **KEY PERSONNEL:**



#### Team Leader:

Ross Levine, MD, Memorial Sloan Kettering Cancer Center

#### **Team Members:**

- Steven J. Altschuler, PhD, University of California, San Francisco
- Chang S. Chan, PhD, Rutgers Cancer Institute of New Jersey
- Daniel S. Fisher, PhD, Stanford University

- Aaron Hata, MD, PhD, Massachusetts General Hospital
- Harlan Robins, PhD, Fred Hutchinson Cancer Research Center
- Lecia VanDam Sequist, MD, MPH, Massachusetts General Hospital

#### Project Manager:

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

**AIM 1.** Investigate genetic, epigenetic, and phenotypic diversity in response to cancer therapies.

- AIM 2. Examine immune system dynamics in response to cancer therapies.
- AIM 3. Conduct functional interrogation of drug response/resistance.

#### **Clinical Trial:**

Phase II Study of EGF816 and Gefitinib in TKI-Naive EGFR-Mutant Non-small Cell Lung Cancer; NCT03292133; Recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ cancer-evolutionconvergence-team/

#### CONVERGENCE TEAMS

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#### SU2C-National Science Foundation-Lustgarten Foundation Convergence Research Team CV6005

### Liberating T-Cell Mediated Immunity to Pancreatic Cancer

GRANT TERM: September 2015 - January 2020

#### **KEY PERSONNEL:**



**Team Co-leader:** Peter O'Dwyer, MD, University of Pennsylvania



**Team Co-leader:** Jeffrey Drebin, MD, Memorial Sloan Kettering Cancer Center



- Curtis G. Callan, PhD, Princeton University
- Benjamin D.
   Greenbaum, PhD,
   Icahn Medical School at Mount Sinai

## Harlan Robins, PhD, Fred Hutchinson Cancer Research Center

 David T. Ting, MD, Massachusetts General Hospital/Harvard Medical School



**Team Co-leader:** Jedd Wolchok, MD, PhD, Memorial Sloan Kettering Cancer Center

#### **Project Manager:**

Alice Lustig, Stand Up To Cancer, alustig@su2c.org

#### **Specific Aims:**

**AIM 1.** Characterize neoadjuvant vitamin D effects on the T-cell repertoire and immunologic milieu in human pancreatic cancer.

AIM 1.1. Understand the interplay of TCR diversity and neoepitopes in PDAC.

AIM 1.2. Characterize pancreatic cancer transcriptional response to immunomodulatory signals.

AIM 2. Conduct exploratory study of neoadjuvant chemoimmunotherapy in pancreatic cancer.

AIM 2.1. Phase I trial of neoadjuvant gemcitabine/nab-paclitaxel/ paricalcitol/nivolumab. (Work on this Aim is continuing as an SU2C subproject)

**AIM 2.2.** Perform T-cell repertoire analysis and in vitro characterization of neoantigen reactivity.

#### **Clinical Trial:**

Phase Ib Pharmacodynamic Study of Neoadjuvant Paricalcitol in Resectable Pancreatic Cancer; NCT03300921; Active, not recruiting

#### Website:

https:// standuptocancer. org/research/ research-portfolio/ convergence-teams/ mediated-immunityin-pancreatic-cancerconvergence-team/

#### CONVERGENCE TEAMS

Research > Research Portfolio > Convergence Teams > Mediate

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# SU2C CATALYST® TEAMS

SU2C Catalyst® Research Team With Support From Jazz Pharmaceuticals CT6330

## The LiFFT Study (Lurbinectedin in FET-Fusion Tumors)

#### **GRANT TERM: TBD**

#### **KEY PERSONNEL:**



#### Team Leader:

Patrick Grohar, MD, PhD, Children's Hospital of Philadelphia

#### Principal:

• Brian D. Compton, MD, Dana-Farber Cancer Institute

#### **Project Managers:**

- Jennifer Baldi, Children's Hospital of Philadelphia, baldij@chop.edu
- Cecilia Carlowicz, CCRC, Children's Hospital of Philadelphia, CARLOWICZC@chop.edu

#### **Specific Aims:**

#### **Website:** TBD

Team Co-leader:

Advocates:

Carol R. Basso

Robert Maki, MD, PhD,

Laurie E. Karl, Sean Karl Foundation

University of Pennsylvania

AIM 1. Determine the safety, tolerability, and pharmacokinetic profile of lurbinectedin in patients with FET-fusion tumors.

**AIM 2.** Determine if lurbinectedin inhibits EWS-FLI1 and/or shows antitumor activity in Ewing's sarcoma.

### Identification of Combination Therapeutics Using JZP-815 for the Treatment of NSCLC

**GRANT TERM: TBD** 

#### **KEY PERSONNEL:**



**Team Leader:** Fred R. Hirsch, MD, PhD, Icahn School of Medicine at Mount Sinai

#### **Project Manager:**

 Benjamin Hopkins, PhD, Icahn School of Medicine at Mount Sinai, benjamin.hopkins@mssm.edu

#### **Specific Aims:**

AIM 1. Take functional genomics approach to identify JZP-815-based combinations for the treatment of KRAS mutant NSCLC.

**AIM 2.** Evaluate therapeutic potential of JZP-815-based combination in GEMM models of KRAS mutant NSCLC.

Website:

TBD

Team Co-leader:

School of Medicine

Kwok-Kin Wong, MD, PhD,

New York University, Grossman

### Technology-Enabled Immunotherapy Monitoring in NYC Minority NSCLC Patients

**GRANT TERM: TBD** 

#### **KEY PERSONNEL:**



#### Team Leader:

Vamsidhar Velcheti, MD, New York University Grossman School of Medicine

#### **Principals:**

- Balazs Halmos, MD, MS, Albert Einstein College of Medicine
- Brian Henick, MD, Columbia University

#### **Project Manager:**

 Kristen Labbe, MPH, New York University Grossman School of Medicine, Kristen.Labbe@nyulangone.org

#### **Specific Aims:**

**AIM 1.** Evaluate the barriers to adoption and optimal utilization of technology-enabled remote monitoring and adverse event management of underserved minority patients with non-small cell lung cancer (NSCLC) on immunotherapy.

AIM 2. Determine the impact of patient-reported outcome measures collected using ApricityRx<sup>™</sup> and CARE service on the management of NSCLC patients receiving immunotherapy in a highly diverse New York City community.

**AIM 3.** Utilize technology-enabled monitoring to enhance the overall quality of care and translational research in underserved minority patients with NSCLC.

#### Website:

#### TBD

Team Co-leader:

at Mount Sinai

Advocates:

Sulaiha Mastan

Rajwanth Veluswamy, MD,

Icahn School of Medicine

Catherine Paykin, New York University

Grossman School of Medicine

### Targeting Adaptive and Acquired Resistance to Direct KRAS Inhibition

GRANT TERM: February 2022 – January 2025

#### **KEY PERSONNEL:**



#### Team Leader:

Ryan B. Corcoran, MD, PhD, Massachusetts General Hospital



#### **Team Co-leader:** Scott Kopetz, MD, PhD, The University of Texas MD Anderson Cancer Center

#### Principals:

- Rebecca Heist, MD, Massachusetts General Hospital
- David Hong, MD, The University of Texas MD Anderson Cancer Center
- Pasi A. Jänne, MD, PhD, Harvard Medical School and Dana-Farber Cancer Institute

#### **Project Manager:**

 Stephanie McQueen, Massachusetts General Hospital, smcqueen1@partners.org

#### Advocates:

- Bonnie Addario, GO2 Foundation for Lung Cancer
- Anjee Davis, Fight CRC
- Manju George, Colontown

#### **Specific Aims:**

#### Website:

AIM 1. Elucidate mechanisms of adaptive resistance to direct KRAS inhibition and understand the drug-tolerant persister state.

**AIM 2.** Identify mechanisms of acquired resistance to KRASG12C inhibition and perform clinical trials to overcome resistance.

**AIM 3.** Define interactions between direct KRAS inhibition and the tumor immune response and perform preclinical prioritization of novel therapeutic strategies.

TBD

### Atezolizumab, Abiraterone, and SBRT in Hormone Sensitive Prostate Cancer

GRANT TERM: September 2019 - February 2023, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Sean M. McBride, MD, Memorial Sloan Kettering Cancer Center

#### **Principals:**

- Yingbei Chen, MD, PhD, Memorial Sloan Kettering Cancer Center
- Jessica E. Hawley, MD, Columbia University Medical Center
- Michael J. Morris, MD, Memorial Sloan Kettering Cancer Center
- Lawrence H. Schwartz, MD, Columbia University Medical Center



**Clinical Lead:** Dana E. Rathkopf, MD, Memorial Sloan Kettering Cancer Center

#### **Project Manager:**

 Kevin DeRudder, Memorial Sloan Kettering Cancer Center, deruddek@mskcc.org

#### Advocates:

- Jan Manarite, Prostate Cancer International
- Joel Nowark, Cancer ABCs

#### **Specific Aims:**

**AIM 1.** Determine if the addition of SBRT and atezolizumab to abiraterone + leuprolide improves failure-free survival (FFS) at two years relative to the FFS in the STAMPEDE trial.

AIM 2. Evaluate potential immunologic biomarkers of response.

**AIM 3.** Evaluate whether noninvasive blood-based and imaging-based biomarkers can be used to monitor and/or predict treatment response.

#### **Clinical Trial:**

SAABR: Single-Arm Phase II Study of Abiraterone + Atezolizumab + GnRH Analog and Stereotactic Body Radiotherapy (SBRT) to the Prostate in Men With Newly Diagnosed Hormone-Sensitive Metastatic Prostate Cancer; NCT04262154; Recruiting

#### Website:

https://progress. standuptocancer.org/ catalyst?team=prostatecancer



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### Combination Sacituzumab and Atezolizumab to Prevent Recurrence in Triple Negative Breast Cancer (TNBC)

GRANT TERM: July 2019 - December 2022, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



Team Leader:

Elizabeth A. Mittendorf, MD, PhD, Dana-Farber Cancer Institute

#### **Principals:**

- Vandana Abramson, MD, Vanderbilt University Medical Center
- Heather L. McArthur, MD, Cedars-Sinai Medical Center
- Rita Nanda, MD, University of Chicago
- Ben Ho Park, MD, PhD, Vanderbilt University Medical Center
- Hope S. Rugo, MD, University of California, San Francisco
- Sara M. Tolaney, MD, Dana-Farber Cancer Institute

#### **Specific Aims:**

**AIM 1.** Conduct a single-arm, phase II trial of sacituzumab govitecan in combination with atezolizumab, enrolling TNBC patients with residual disease and cfDNA following NACT.

**AIM 2.** Perform correlative studies to determine whether PD-L1 expression on CTCs has utility as a pharmacodynamic biomarker, and whether there is an association between molecular and immunobiological features in residual disease after NACT and response to sacituzumab govitecan plus atezolizumab.

#### **Clinical Trial:**

Single-Arm Phase II Trial of Atezolizumab With Sacituzumab Govitecan to Prevent Recurrence in Triple-Negative Breast Cancer (ASPRIA); NCT04434040; Recruiting



**Clinical Lead:** Angela M. DeMichele, MD, University of Pennsylvania

#### **Project Manager:**

 Michelle DeMeo, Dana-Farber Cancer Institute, Michelle\_DeMeo@dfci.harvard.edu

#### Advocates:

- Caroline Abi-Khattar, JD, University of Pennsylvania
- Elizabeth S. Frank, Dana-Farber Cancer Institute

#### Website:

https://progress. standuptocancer.org/ catalyst?team=triplenegative-breastcancer



### Clinical Translation of Novel Immune-Based Combination Therapies for Pediatric Hypermutant Cancers

GRANT TERM: June 2019- November 2023

#### **KEY PERSONNEL:**



**Team Leader and Clinical Lead:** Uri Tabori, MD, The Hospital for Sick Children

#### **Principals:**

- Crystal Mackall, MD, Stanford University
- John Maris, MD, Children's Hospital of Philadelphia

#### **Project Manager:**

 Vanessa Bianchi, PhD, The Hospital for Sick Children, vanessa.bianchi@sickkids.ca

#### **Specific Aims:**

**AIM 1.** Perform a phase lb clinical trial of combinational immune checkpoint inhibitor (ICI) therapies in childhood hypermutant cancers.

AIM 2. Determine the biological aspects and preclinical benefits of combined BMS lead compounds with ICI on replication repair deficiency (RRD) hypermutant immunocompetent mouse models.

**AIM 3.** Define immediately translatable tumor intrinsic molecular vulnerabilities in RRD hypermutant cancers.

#### **Clinical Trial:**

3Cl Study: Childhood Cancer Combination Immunotherapy. Phase Ib and Expansion Study of Nivolumab Combination Immunotherapy in Children, Adolescent, and Young Adult (CAYA) Patients With Relapsed/Refractory Hypermutant Cancers; NCT04500548; Recruiting

#### Website:

https://progress. standuptocancer.org/ pediatric-catalyst/ ?team=hypermutantcancers-ll





**Team Co-leader:** Daniel Morgenstern, MD, The Hospital for Sick Children

#### Advocates:

- Denise Bebenek, Meagan's Hug
- Karen Haas, The Hospital for Sick Children
- Jenell Holstead, PhD, University of Wisconsin
- Parvathy Krishnan, The Hospital for Sick Children

### Immunomodulation to Treat Poor-Prognosis Pediatric Brain Tumors

GRANT TERM: February 2019 - August 2021

#### **KEY PERSONNEL:**



#### Team Leader:

Maryam Fouladi, MD, Nationwide Children's Hospital

#### **Principals:**

- Rachid Drissi, PhD, Nationwide Children's Hospital
- Annie Huang, MD, PhD, The Hospital for Sick Children
- Nada Jabado, MD, PhD, McGill University Health Centre



#### **Team Co-leader:** James Olson, MD, PhD, Fred Hutchinson Cancer Research Center

#### **Project Manager:**

 Sara Lawellin, Cincinnati Children's Hospital Medical Center, Sara.Lawellin@cchmc.org

#### Advocate:

• Keith Desserich, Cure Starts Now

#### **Specific Aims:**

AIM 1. Determine the extent to which 5-aza, ribo, or other non-cytotoxic FDA-approved drugs enhance T-cell mediated PBT cell death in vitro.

AIM 1B. Assess the efficacy of 5-aza, ribo, or a superior candidate in vivo.

AIM 2. Establish a biomarker-based responder hypothesis.

#### Website:

https://progress. standuptocancer.org/ pediatric-catalyst? team=epigenetics



Pediatric SU2C Catalyst® Research Team With Support From Bristol Myers Squibb CT6143

### Targeting Epigenetic Dysregulation in Pediatric Cancer

GRANT TERM: January 2019 - June 2023

#### **KEY PERSONNEL:**



#### Team Leader:

Kimberly Stegmaier, MD, Dana-Farber Cancer Institute

#### **Principals:**

- Peter Dirks, MD, PhD, The Hospital for Sick Children
- David Kirsch, MD, PhD, Duke University
- Elizabeth Lawlor, MD, PhD,
   Seattle Children's Research Institute



**Team Co-leader and Clinical Lead:** Steven DuBois, MD, Dana-Farber Cancer Institute

#### **Project Manager:**

Jennifer Perry, PhD, Dana-Farber Cancer Institute, Jennifer\_perry@dfci.harvard.edu

#### Advocate:

Kathleen Malcolmson

#### **Specific Aims:**

**AIM 1.** Conduct a phase I clinical trial testing the BMS BETi BMS-986158 in children with cancer.

**AIM 2.** Test rational drug combinations with BMS-986158 in preclinical models of pediatric cancer.

**AIM 3.** Identify novel drug combinations with BMS-986158 through genomescale CRISPR-Cas9 synergy screens.

#### **Clinical Trial:**

Study of the Bromodomain (BRD) and Extra-Terminal Domain (BET) Inhibitors BMS-986158 and BMS-986378 in Pediatric Cancer; NCT03936465; Recruiting

#### Website:

https://progress. standuptocancer.org/ pediatric-catalyst? team=epigenetics



### Neoadjuvant Therapy for Patients With High-Risk Stage III Melanoma

GRANT TERM: June 2018 - November 2024, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Matthew S. Block, MD, PhD, Mayo Clinic

#### **Principals:**

- Jun Chen, PhD, Mayo Clinic
- Evidio Domingo-Musibay, MD, University of Minnesota
- Roxana S. Dronca, MD, Mayo Clinic
- Thomas J. Flotte, MD, Mayo Clinic
- Rachel L. Maus, PhD, Mayo Clinic
- Vera J. Suman, PhD, Mayo Clinic



**Clinical Lead:** Tina J. Hieken, MD, Mayo Clinic

#### **Project Manager:**

 Jill Schimke, Mayo Clinic, schimke.jill@mayo.edu

#### Advocates:

- Cynthia Chauhan
- Heidi Turner, Mayo Clinic
- Simone Veum, University of Minnesota

#### **Specific Aims:**

**AIM 1.** Test the safety and efficacy of the neoadjuvant combination of vemurafenib/cobimetinib/atezolizumab followed by surgery followed by adjuvant atezolizumab in patients with BRAFm high-risk stage III melanoma

AIM 2. Test the safety and efficacy of neoadjuvant combination of cobimetinib/atezolizumab followed by surgery followed by adjuvant atezolizumab in patients with BRAFwt high-risk stage III melanoma.

**AIM 3.** Test the safety and efficacy of the neoadjuvant combination of tiragolumab/atezolizumab followed by surgery and adjuvant atezolizumab in patients with high-risk stage III melanoma.

#### **Clinical Trial:**

Neoadjuvant Therapy for Patients With High-Risk Stage III Melanoma: A Pilot Clinical Trial; NCT03554083, Recruiting

#### Website:

https://progress. standuptocancer.org/ catalyst?team= neoadjuvantmelanoma



### Immunotherapy Combination Strategies in ER-Positive Metastatic Breast Cancer

GRANT TERM: May 2018 - December 2019, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Ingrid A. Mayer, MD, Vanderbilt University

#### **Principals:**

- Rita Nanda, MD, University of Chicago
- Hope S. Rugo, MD, University of California, San Francisco
- Melinda E. Sanders, MD, Vanderbilt University
- Yu Shyr, PhD, Vanderbilt University



#### **Team Co-leader:** Justin M. Balko, PharmD, PhD, Vanderbilt University

#### **Project Manager:**

Catherine Weir, Vanderbilt University

#### Advocates:

- Lynn Cargen
- Linda J. Horton

#### Specific Aims:

AIM 1. Perform preclinical assays to determine the functional effect of MDM2 inhibition on T cells.

AIM 2. Perform preclinical studies to model the molecular and therapeutic effects of MDM2 inhibition with anti-PD-L1 therapy in breast cancer.

AIM 3. Perform a multicenter, open-label, two-arm phase lb/ll clinical trial that will evaluate the antitumor effect of atezolizumab (ATEZ, an anti-PD-L1 mAb) in combination with cobimetinib (COBI, a MEK inhibitor) in patients with TP53-mutated ER+ mBC (metastatic breast cancer), or idasanutlin (IDASA, an MDM2 antagonist) in patients with TP53-wt ER+ mBC.

**AIM 4.** Determine whether IDASA or COBI enhances T-cell infiltration and activation in ER+ breast tumors, and whether this effect is associated with patient-specific clinical response to ATEZ. In addition, molecular correlates both intra-tumoral and in the peripheral blood of patients will be tested as correlative analyses.

**AIM 5.** Perform active monitoring of T-cell populations in PBMCs from IDASAtreated patients. To ensure that treatment for two weeks with IDASA does not eliminate peripheral effector T-cell populations, we will perform CyTOF to identify expanded or eliminated T-cell populations in the peripheral blood in the phase I portion of the IDASA arm.

#### Website:

https://progress. standuptocancer.org/ catalyst/?team= metastatic-breastcancer



#### SU2C Catalyst® Research Team With Support From Genentech CT6053

#### **Clinical Trial:**

BRE 17107: Phase Ib/II Trial of Atezolizumab (an Anti-PD-L1 Monoclonal Antibody) With Cobimetinib (a MEK1/2 Inhibitor) or Idasanutlin (an MDM2 Antagonist) in Metastatic ER+ Breast Cancer; NCT03566485; Terminated

### Overcoming Urothelial Cancer Atezolizumab Resistance by Epigenetic Therapy

GRANT TERM: November 2017 - April 2021, administered by the American Association for Cancer Research

**Project Managers:** 

Penny Berger,

Ryan Burgos,

Van Andel Institute,

Van Andel Institute,

Ryan.Burgos@vai.org

Revathi Penumatsa, Van Andel Institute,

Revathi.Penumatsa@vai.org

Penny.Berger@vai.org

#### **KEY PERSONNEL:**



**Team Leader:** Peter A. Jones, PhD, DSc, Van Andel Institute

#### **Principals:**

- Stephen B. Baylin, MD, Johns Hopkins University
- Noah M. Hahn, MD, Johns Hopkins University
- Jean-Pierre J. Issa, MD, Coriell Institute for Medical Research
- David I. Quinn, MD, USC Norris Comprehensive Cancer Center



**Team Co-leader:** Elizabeth R. Plimack, MD, Fox Chase Cancer Center

#### Advocates:

- Rick Bangs
- Beth Flory

#### Specific Aims:

**AIM 1.** Dose selection: Identify a safe, biologically active dose of concurrent guadecitabine and atezolizumab for patients with advanced UC in the safety run-in portion of our phase II study.

**AIM 2.** Dose expansion: Determine the efficacy (ORR) of the combination in patients with advanced UC who progressed after immune checkpoint therapy in a single-arm phase II expansion cohort.

**AIM 3.** Correlative science: Use paired pre- and post-treatment biopsies and peripheral blood to explore genomes, genome-wide expression, pathway alterations, and epigenomes in tumor and immune cells.

#### **Clinical Trial:**

GU-114: Overcoming Checkpoint Inhibitor Resistance With Epigenetic Therapy in Urothelial Cancer; NCT03179943; Active, not recruiting

#### Website:

https://progress. standuptocancer.org/ catalyst/?team= urothelial-bladdercancer



### Tumor Infiltrating Lymphocyte Adoptive T-Cell Therapy for Non-small Cell Lung Cancer (NSCLC)

GRANT TERM: June 2017 - May 2020, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Co-leader:** Eric B. Haura, MD, H. Lee Moffitt Cancer Center & Research Institute



**Team Co-leader:** Scott J. Antonia, MD, PhD, Duke University



Clinical Lead:

Benjamin C. Creelan, MD, H. Lee Moffitt Cancer Center & Research Institute

#### Investigators:

- Frederic J. Kaye, MD, University of Florida
- John M. Koomen, PhD,
   H. Lee Moffitt Cancer
   Center& Research Institute

#### **Project Manager:**

Carol Ulge,
 H. Lee Moffitt Cancer Center
 & Research Institute,
 Carol.Ulge@moffitt.org

#### Advocates:

- Rosalynne I. Miller
- Joan Tashbar

#### **Specific Aims:**

AIM 1. Conduct a trial of TIL ACT and  $\alpha$ -PD-1 in advanced-stage NSCLC patients.

**AIM 2.** Characterize tumor and TIL features associated with response using proteogenomics.

#### **Clinical Trial:**

A Phase I Clinical Trial Combining Nivolumab and Tumor Infiltrating Lymphocytes (TIL) for Patients With Advanced Non-small Cell Lung Cancer; NCT03215810; Recruiting

#### Website:

https://progress. standuptocancer.org/ catalyst/?team=lungimmunotherapy



### Immunotherapy to Prevent Progression in Multiple Myeloma

GRANT TERM: May 2017 - October 2021, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### **Team Leader and Clinical Lead:** Irene M. Ghobrial, MD, Dana-Farber Cancer Institute

#### **Principals:**

- Viktor A. Adalsteinsson, PhD, Broad Institute
- Mark W. Bustoros, MD, Weill Cornell Medical College
- Marzia Capelletti, PhD, Dana-Farber Cancer Institute
- Jihye Park, PhD, Dana-Farber Cancer Institute
- Romanos Sklavenitis Pistofidis, MD, Dana-Farber Cancer Institute
- Yujia Shen, PhD, Dana-Farber Cancer Institute
- Oksana Zavidij, PhD, Dana-Farber Cancer Institute

#### **Specific Aims:**

**AIM 1.** Define the immune-oncogenomic landscape of smoldering multiple myeloma (SMM) in response to immunotherapy.

AIM 2. Characterize somatic aberrations present in cell-free DNA (cfDNA) and circulating tumor cells (CTCs) as biomarkers of response/resistance in SMM enrolled in the trial.

**AIM 3.** Define markers of the permissive bone marrow microenvironment that characterize risks of progression in SMM patients enrolled in the trial.

#### **Clinical Trial:**

Phase II Trial of Combination of Elotuzumab, Lenalidomide, and Dexamethasone in High-Risk Smoldering Multiple Myeloma; NCT02279394; Active, not recruiting

#### **Project Manager:**

 Alexandra Savell, Dana-Farber Cancer Institute, asavell@partners.org

#### Advocate:

• Jenny Ahlstrom, Myeloma Crowd

#### Website:

https://progress. standuptocancer.org/ catalyst/?team=multiplemyeloma\_



### Pembrolizumab and Radiation Therapy to Improve Outcome in High-Risk Sarcoma

GRANT TERM: May 2017 - October 2022, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### **Team Leader and Clinical Lead:** David G. Kirsch, MD, PhD, Duke University Medical School

#### **Principals:**

- Karla V. Ballman, PhD, Weill Cornell Medical College
- Brian E. Brigman, MD, Duke Cancer Institute
- George D. Demetri, MD, Dana-Farber Cancer Institute
- Richard F. Riedel, MD, Duke Cancer Institute
- Matt van de Rijn, MD, PhD, Stanford University

- Andrew J. Wagner, MD, PhD, Dana-Farber Cancer Institute
- Kent J. Weinhold, PhD, Duke University Medical Center
- Steven Young, Sarcoma Alliance for Research Through Collaboration

#### **Early Career Investigators:**

- Everett Moding, MD, PhD, Stanford University
- Yvonne Mowery, MD, PhD, Duke Cancer Institute

#### **Project Managers:**

- Erin Kozlowski, Sarcoma Alliance for Research Through Collaboration, ekozlowski@sarctrials.org
- Lindsay Overman, Sarcoma Alliance for Research Through Collaboration, leoverman@sarctrials.org

#### Advocate:

• Corrie A. Painter, PhD, Broad Institute

#### **Specific Aims:**

**AIM 1.** Test the safety and efficacy of pembrolizumab combined with preoperative radiotherapy to reduce the development of metastatic disease in sarcoma patients.

**AIM 2.** Characterize immune response to radiotherapy with or without pembrolizumab and identify predictors of pembrolizumab response in patients with soft-tissue sarcoma.

#### **Clinical Trial:**

SU2C-SARC032: Phase II Randomized Controlled Trial of Neoadjuvant Pembrolizumab With Radiotherapy and Adjuvant Pembrolizumab in Patients With High-Risk, Localized Soft-Tissue Sarcoma of the Extremity; NCT03092323; Recruiting

#### Website:

https://progress. standuptocancer.org/ catalyst/?team= sarcoma



SU2C Catalyst® Research Team With Support From Bristol Myers Squibb CT6050

## Reversing Primary Anti-PD-1 Resistance with Ipilimumab and Nivolumab

GRANT TERM: May 2017 - October 2022, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Antoni Ribas, MD, PhD, University of California, Los Angeles

#### **Principals:**

- Kenneth F. Grossmann, MD, PhD, Huntsman Cancer Institute, University of Utah
- Siwen Hu-Lieskovan, MD, PhD, Huntsman Cancer Institute, University of Utah
- Jeffrey A. Sosman, MD, Northwestern University



#### **Clinical Lead:** Ari M. Vanderwalde, MD, West Cancer Center and Research Institute

#### **Project Manager:**

Jia M. Chen, PhD,
 University of California, Los Angeles,
 JiaChen@mednet.ucla.edu

#### Advocate:

• Samantha Guild, AIM at Melanoma Foundation

#### **Specific Aims:**

**AIM 1.** Conduct a phase II study of ipilimumab and nivolumab in patients with metastatic melanoma progressing on prior anti-PD-1 therapy.

AIM 2. Investigate cellular and genomic changes in biopsies when adding ipilimumab to continued PD-1 inhibition.

#### **Clinical Trial:**

Phase II Randomized Study of Nivolumab (NSC-748726) With Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent; NCT03033576; Active, not recruiting

#### Website:

https://progress. standuptocancer.org/ catalyst/?team= reversing-resistancemelanoma\_



### Targeting VDR to Make Pancreatic Cancer Competent for Immunotherapy

GRANT TERM: May 2017 - June 2020, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### **Team Leader and Clinical Lead:** Daniel D. Von Hoff, MD, Translational Genomics Research Institute

#### **Principals:**

- Angela T. Alistar, MD, Atlantic Health System
- Michael T. Barrett, PhD, Mayo Clinic Arizona
- Carlos H. Becerra, MD, Baylor University Medical Center
- Erkut H. Borazanci, MD, Honor Health Research Institute
- Vincent Chung, MD, City of Hope
- Michael R. Downes, PhD, Salk Institute for Biological Studies
- Ronald M. Evans, PhD, Salk Institute for Biological Studies

- Haiyong Han, PhD, Translational Genomics Research Institute
- Anup Kasi, MD, University of Kansas Medical Center
- Ronald L. Korn, MD, PhD, Imaging Endpoints, LLC
- Winnie Liang, PhD, Translational Genomics Research Institute
- Andrew M. Lowy, MD, University of California, San Diego
- Hitendra P. Patel, MBBS, UCSD Moores Cancer Center
- Paul S. Ritch, MD, Medical College of Wisconsin

#### **Project Manager:**

 Jatan Clark, Translational Genomics Research Institute, jclark@tgen.org

#### Advocates:

- Roger E. Magowitz, Seena Magowitz Foundation
- Howard E. Young, General
   Wholesale Beer Company

#### Specific Aims:

**AIM 1.** Determine the synergy between the VDR agonist paricalcitol and the PD-1 inhibitor pembrolizumab in effecting an antitumor immune response in clinical trials.

**AIM 2.** Define the impact of paricalcitol and pembrolizumab combination therapy on the mutational landscapes and transcriptional programs of pancreatic tumors.

**AIM 3.** Identify cellular and molecular VDR targets in the immune microenvironment that synergize with PD-1 blockade.

#### Website:

https://progress. standuptocancer.org/ catalyst/?team= pancreatic



CATALYST® TEAMS

#### SU2C Catalyst® Research Team With Support From Merck CT6031

#### **Clinical Trial:**

SU2C Catalyst® Randomized Phase II Trial of the PD1 Inhibitor Pembrolizumab With or Without Vitamin D Receptor Agonist Paricalcitol in Patients With Stage IV Pancreatic Cancer Who Have Been Placed in Best Possible Response; NCT03331562; Completed

### Combined Epigenetic Therapy and Pembrolizumab for Advanced Non-small Cell Lung Cancer (NSCLC)

GRANT TERM: April 2017 - June 2022, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



**Team Leader:** Stephen B. Baylin, MD, Johns Hopkins University



**Team Co-leader:** Kathryn C. Arbour, MD, Memorial Sloan Kettering Cancer Center

#### **Principals:**

- Hossein Borghaei, DO, Fox Chase Cancer Center
- Peter A. Jones, PhD, DSc, Van Andel Institute
- Kristen A. Marrone, MD, Johns Hopkins University
- Jarushka Naidoo, MBBCh, Johns Hopkins University
- Charles M. Rudin, MD, Memorial Sloan Kettering Cancer Center
- Hui Shen, PhD, Van Andel Institute
- E. John Wherry, PhD, University of Pennsylvania

#### **Project Managers:**

- Penny Berger,
   Van Andel Institute,
   Penny.Berger@vai.org
- Ryan Burgos, Van Andel Institute, Ryan.Burgos@vai.org
- Kerri Muenkel Calderone, Memorial Sloan Kettering Cancer Center, muenkelk@mskcc.org
- Revathi Penumatsa, Van Andel Institute, Revathi.Penumatsa@vai.org

#### Advocate:

Beth Flory, Van Andel
Institute

#### Specific Aims:

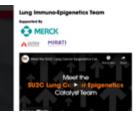
AIM 1. Dose selection: Identify a safe, biologically active dose of concurrent combination pembrolizumab, guadecitabine, and mocetinostat for patients with advanced NSCLC in a Phase I study.

AIM 2. Dose expansion: Determine the efficacy of this triplet combination in patients with advanced NSCLC as part of a Phase Ib dose expansion, in the context of tumor PD-L1 expression.

AIM 3. Use paired pre-and post-treatment biopsies and serial peripheral blood to explore (in collaboration with Merck) the attraction of immune cells to the tumor microenvironment and genome-wide changes in expression, pathway alterations, and epigenome in tumor and host immune cells.

#### Website:

https://progress. standuptocancer.org/ catalyst/?team=lungimmuno-epigenetics



#### SU2C Catalyst® Research Team With Support From Merck CT6030

#### **Clinical Trial:**

Phase I/Ib Study of Combined Pembrolizumab Plus Guadecitabine and Mocetinostat for Patients With Advanced NSCLC (dose selection); NCT03220477; Active, not recruiting

### Combined Approaches by Immune Checkpoint Inhibition for Hypermutant Cancers

GRANT TERM: April 2017 - March 2020, administered by the American Association for Cancer Research

**Project Manager:** 

Melissa Edwards, PhD,

The Hospital for Sick Children,

melissa.edwards@sickkids.ca

#### **KEY PERSONNEL:**



**Team Leader:** Uri Y. Tabori, MD, The Hospital for Sick Children

#### **Principals:**

- Eric Bouffet, MD, The Hospital for Sick Children
- Michael J. Fisher, MD, Children's Hospital of Philadelphia



**Investigator:** John M. Maris, MD,

Children's Hospital of Philadelphia

#### Advocate:

 Denise Bebenek, Meagan's Walk: Creating a Circle of Hope

#### **Specific Aims:**

**AIM 1.** Determine the prevalence and type of hypermutant human cancers.

**AIM 2.** Test three types of combinational ICI therapies using hypermutant cancer mouse models.

**AIM 3.** Perform pilot case studies of ICI combinational therapies on recurrent hypermutant human cancers.

#### **Clinical Trial:**

Pilot Study of Nivolumab in Pediatric Patients With Hypermutant Cancers; NCT02992964; Active, not recruiting

#### Website:

https://progress. standuptocancer.org/ pediatric-catalyst?team= hypermutant-cancers-l



### **DNA Repair Therapies for Ovarian Cancer**

GRANT TERM: July 2016 - December 2020, administered by the American Association for Cancer Research

#### **KEY PERSONNEL:**



#### Team Leader:

Alan D. D'Andrea, MD, Dana-Farber Cancer Institute

#### Principal:

Panagiotis (Panos) A.
 Konstantinopoulos, MD, PhD,
 Dana-Farber Cancer Institute

#### **Project Manager:**

Donald R. Watson, Dana-Farber Cancer Institute, donald\_watson@dfci.harvard.edu



**Team Co-leader:** Elizabeth M. Swisher, MD, University of Washington

#### Advocates:

- Jamie Crase, University of Washington
- Sue Friedman, FORCE: Facing Our Risk of Cancer Empowered
- Kathleen Gavin, Minnesota Ovarian Cancer Alliance
- Deborah Polinsky, FORCE: Facing Our Risk of Cancer Empowered (deceased)

#### **Specific Aims:**

**AIM 1.** Collect and distribute tumor samples and blood samples from TNBC (triple-negative breast cancer) and HGSOC (high-grade serous ovarian cancer) patients enrolled in this joint Tesaro/Merck/SU2C clinical trial.

**AIM 2.** Complete the indicated biomarker studies, from multiple industry-sponsored and academic laboratories, and analyze the collected data.

#### **Clinical Trial:**

Phase I/II Clinical Study of Niraparib in Combination With Pembrolizumab (MK-3475) in Patients With Advanced or Metastatic Triple-Negative Breast Cancer and in Patients With Recurrent Ovarian Cancer; NCT02657889; Active, not recruiting

#### Websites:

https://progress. standuptocancer.org/ catalyst/?team=ovarian



# INNOVATIVE RESEARCH GRANTS

#### INNOVATIVE RESEARCH GRANTS

### **CLASS OF 2017**

The 2017 class is specifically focused on immuno-oncology, supported by a grant from Bristol Myers Squibb.

### Harnessing Dipeptidyl Peptidase Inhibition for Cancer Immunotherapy

Daniel A. Bachovchin, PhD, Memorial Sloan Kettering Cancer Center

### Rescuing T-Cell Function for Immunotherapy of Pediatric Malignancies

David M. Barrett, MD, PhD, Children's Hospital of Philadelphia

#### Targeting the Pro-Metastatic Niche in the Liver for Cancer Immunotherapy

Gregory L. Beatty, MD, PhD, University of Pennsylvania

#### T-Cell Immunotherapy for Core Binding Factor Acute Myeloid Leukemia

Marie E. Bleakley, MD, PhD, Fred Hutchinson Cancer Research Center

### Imaging CAR T Cells With a Dual-Function PET Reporter Gene

Michael D. Farwell, MD, University of Pennsylvania

### Identifying and Targeting Mechanisms of Resistance to Immunotherapy

Rizwan Haq, MD, PhD, Dana-Farber Cancer Institute

### Reworking Negative Receptor Signals for Improved Anti-glioma T-Cell Therapy

Meenakshi G. Hegde, MD, Baylor College of Medicine

#### Potentiating Novel Engineered Cellular Therapies for Solid Tumors

Marcela V. Maus, MD, PhD, Massachusetts General Hospital

#### Delineating the Role of the Microbiome in Modulating Tumor and Host Immunity

Jennifer A. Wargo, MD, The University of Texas MD Anderson Cancer Center

#### Reprogramming Tumor Immunogenicity with STING-Activating Nanoparticles

John T. Wilson, PhD, Vanderbilt University



### **CLASS OF 2016**

#### Targeting Cellular Plasticity in Individual Basal-Type Breast Cancer Cells

John G. Albeck, PhD, University of California, Davis

#### Uncovering How RAD51 Paralog Mutations Contribute to Cancer Predisposition

Kara A. Bernstein, PhD, University of Pittsburgh

### Phospholipid Messengers as Drivers of Dendritic Cell Dysfunction in Cancer

Juan R. Cubillos-Ruiz, PhD, Weill Cornell Medicine

#### Metabolic Reprogramming Using Oncolytic Viruses to Improve Immunotherapy

Greg M. Delgoffe, PhD, University of Pittsburgh

#### "Weak Links" in Cancer Proteostasis Networks as New Therapeutic Targets

Martin Kampmann, PhD, University of California, San Francisco

#### Algorithmically Driven Quantitative Combination Cancer Therapy Engineering

Dan A. Landau, MD, PhD, Weill Cornell Medicine

#### Deubiquitinating Enzymes as Novel Anticancer Targets

Li Ma, PhD, The University of Texas MD Anderson Cancer Center

#### Imaging Cell-Level Heterogeneity in Solid Tumors for Personalized Treatment

Melissa C. Skala, PhD, Morgridge Institute for Research

### Defining the Metabolic Dependencies of Tumors

Matthew Vander Heiden, MD, PhD, Massachusetts Institute of Technology

#### **Defining the Mechanistic Connections Between Injury, Regeneration, and Cancer** Hao Zhu, MD, The University of Texas Southwestern Medical Center



#### **INNOVATIVE RESEARCH GRANTS**

### **CLASS OF 2011**

#### **Targeting MLL in Acute Myeloid Leukemia** Yali Dou, PhD, University of Michigan

#### Targeting Genetic and Metabolic Networks in T-ALL

Adolfo A. Ferrando, MD, PhD, Columbia University

#### Targeting Protein Quality Control for Cancer Therapy

Estela Jacinto, PhD, Rutgers University

#### Targeting PP2A and the Glutamine-Sensing Pathway as Cancer Treatment

Mei Kong, PhD, Beckman Research Institute, City of Hope

Chimeric RNAs Generated by Trans-splicing and Their Implications in Cancer Hui Li, PhD, University of Virginia

#### Allan H. (Bud) and Sue Selig Stand Up To Cancer Melanoma Innovative Research Grant: Exome Sequencing of Melanomas With Acquired Resistance to BRAF Inhibitors

Roger S. Lo, MD, PhD, University of California, Los Angeles

#### Identification and Targeting of Novel Rearrangements in High-Risk ALL

Charles G. Mullighan, MD, St. Jude Children's Research Hospital

#### A Systems Approach to Understanding Tumor-Specific Drug Response

Dana Pe'er, PhD, Columbia University

#### **Targeting Sleeping Cancer Cells**

Sridhar Ramaswamy, MD, Massachusetts General Hospital

#### Inhibiting Innate Resistance to Chemotherapy in Lung Cancer Stem Cells Eric Alejandro Sweet-Cordero, MD,

Stanford University

#### **Developing New Therapeutic Strategies for Soft-Tissue Sarcoma** Amy J. Wagers, PhD, Joslin Diabetes Center

#### Framing Therapeutic Opportunities in Tumor-Activated Gametogenic Programs

Angelique W. Whitehurst, PhD, UT Southwestern Simmons Comprehensive Cancer Center

### Coupled Genetic and Functional Dissection of Chronic Lymphocytic Leukemia

Catherine J. Wu, MD, Dana-Farber Cancer Institute



#### **INNOVATIVE RESEARCH GRANTS**

### **CLASS OF 2009**

### An Emerging Tumor Suppressor Pathway in Human Cancer

Fernando D. Camargo, PhD, Boston Children's Hospital

#### Modeling Ewing Tumor Initiation in Human Neural Crest Stem Cells

Elizabeth R. Lawlor, MD, PhD, University of Michigan

#### Cancer Cell-Specific, Self-Delivering Prodrugs

**RESEARCH GRAN** 

Matthew Levy, PhD, Albert Einstein College of Medicine of Yeshiva University

#### Targeted Inhibition of BCL6 for Leukemia Stem Cell Eradication

Markus Müschen, MD, PhD, Children's Hospital Los Angeles

### Identifying Solid Tumor Kinase Fusions via Exon Capture and 454 Sequencing

William Pao, MD, PhD, Vanderbilt University

### Therapeutically Targeting the Epigenome in Aggressive Pediatric Cancers

Charles M. Roberts, MD, PhD, Dana-Farber Cancer Institute

#### Endogenous Small Molecules That Regulate Signaling Pathways in Cancer Cells

Rajat Rohatgi, MD, PhD, Stanford University

#### Genetic Approaches for Next Generation of Breast Cancer Tailored Therapies

Jose M. Silva, PhD, Columbia University

#### Modulating Transcription Factor Abnormalities in Pediatric Cancer

Kimberly Stegmaier, MD, Dana-Farber Cancer Institute

### Noninvasive Molecular Profiling of Cancer via Tumor-Derived Microparticles

Muneesh Tewari, MD, PhD, Fred Hutchinson Cancer Research Center

#### A Transformative Technology to Capture and Drug New Cancer Targets

Loren D. Walensky, MD, PhD, Dana-Farber Cancer Institute

#### **Functional Oncogene Identification**

David M. Weinstock, MD, Dana-Farber Cancer Institute

#### Probing EBV-LMP-1's Transmembrane Activation Domain With Synthetic Peptide

Hang Hubert Yin, PhD, University of Colorado



# THE PHILLIP A. SHARP INNOVATION IN COLLABORATION AWARDS

### **CLASS OF 2020**

Genomic and Therapeutic Implications of Selective Bacterial and Fungal Colonization of Gastrointestinal Malignancies

Luis A. Diaz Jr., MD, and Florencia McAllister, MD

#### Utilizing Tumor Organoids to Facilitate the Development of Effective Strategies to Target Pancreatic Cancer with Engineered T Cells

Philip D. Greenberg, MD, Tyler E. Jacks, PhD, and William A. Freed-Pastor, MD, PhD

Harnessing NK Cells to Treat Pediatric Cancers David G. Kirsch, MD, PhD, and Michal Sheffer, PhD

#### Can scRNAseq-Derived Gene Programs Predict Anti-PD-1 Response in High TMB CRC and NSCLC Patients?

Karin Pelka, PhD, and Matthew D. Hellmann, MD

#### Enhancing Ferroptosis to Block Ewing Sarcoma Metastatic Capacity

Poul H. B. Sorenson, MD, PhD, and Elizabeth Lawlor, MD, PhD

### **CLASS OF 2019**

#### Resistance to PARP Inhibitor Plus Anti-PD1 Therapy Driven by ER Stress and Bioactive Lipids in Ovarian Cancer

Juan R. Cubillos-Ruiz, PhD, and Alan D. D'Andrea, MD

#### Uncovering Mutant TP53 Dependencies in Spontaneously Arising Triple-Negative Breast Cancer

Denada Dibra, PhD, and Peter P. Lee, MD

#### Noninvasive Monitoring of Tumor Phenotype by Interrogation of Plasma Cell Free RNA

Maximilian Diehn, MD, PhD, and Aaron N. Hata, MD, PhD Precision Combinatorial Immunotherapeutic Targeting of Thymic Stromal Lymphopoietin Receptor (TSLPR) Signaling in Pediatric and Young Adult CRLF2-Rearranged ALL

Sarah K. Tasian, MD, and Kimberly Stegmaier, MD

#### Antigenicity of Mutant KRAS and Impact on Cancer Evolution

Robert H. Vonderheide, D Phil, MD, and Vinod P. Balachandran, MD

### **CLASS OF 2018**

#### Defining Effective T-Cell Response in Viral and Nonviral Gynecologic Cancers

Claire F. Friedman, MD, and Marta J. Luksza, PhD

Cupid-Seq-High Throughput Transcriptomic Spatial Mapping of Immune-Tumor Interactions in the Microenvironment Dan Landau, MD, PhD, and Raul Rabadan, PhD

#### Characterizing Immune Variability in Children Following Standard-of-Care Treatment to Enable Precision

Trevor J. Pugh, PhD, and David M. Barrett, MD, PhD

Studies of Colorectal Cancer Patient-Derived Organoids to Validate Candidate Biomarkers of Resistance to Natural Killer Cells Michal Sheffer, PhD, and Hugo J. Snippert, PhD

#### Interrogating Impact of Epigenetic Modifiers on Durable Reprogramming of Exhausted CD8 T Cells in Patients With NSCLC Treated With PD-1 Blockade

E. John Wherry, PhD, and Matthew D. Hellmann, MD



**JUNE 2022** 

### **CLASS OF 2017**

Interrogation of Resistance Mechanisms to Checkpoint Inhibitors Using Functional Genomics

Siwen Hu-Lieskovan, MD, PhD, and René Bernards, PhD

Dissecting the Epigenetic Mechanisms of Repeat RNA Regulation in Cancer David T. Ting, MD, and Shelley L. Berger, PhD

**Probing the Metabolic Interactions Between Tumor and Stroma in Pancreatic Cancer** Matthew G. Vander Heiden, MD, PhD, and Melissa C, Skala, PhD

### Aptamer-Based Detection and Binding of Peptide-MHC Complexes

Cassian Yee, MD, and Bruce A. Sullenger, PhD

### **CLASS OF 2016**

#### Defining the Role of Epigenetics in Chimeric Antigen Receptor T-cell Therapy for CLL

Shelley L. Berger, PhD, Carl H. June, MD, and Junwei Shi, PhD

#### Towards Predictive Models of Immunotherapy Response

Benjamin D. Greenbaum, PhD and Jedd D. Wolchok, MD, PhD

#### Checkpoint Inhibition in Children With Ultra-Mutated Cancer Due to Biallelic Mismatch Repair Deficiency (bMMRD)

Crystal L. Mackall, MD, and Patrick M. Forde, MD

#### Fingerprinting the Systemic Microbiome in Plasma to Predict Immunotherapy Outcomes in Melanoma

Muhammed Murtaza, MBBS, PhD, and Antoni Ribas, MD, PhD

#### **Functional Verification of DNA Repair Mutations in Prostate and Ovary Tumors** Eliezer M. Van Allen, MD, and Maria Jasin, PhD

### **CLASS OF 2015**

#### **Development of a High-Throughput Method to Screen Drugs With Organoids** Hans Clevers, MD, PhD, and David A, Tuveson, MD, PhD

Cross-talk Between Histone H3K4 Mono-Methylation and Cancer Metabolism to Explore New Therapeutic Strategies Yali Dou, PhD and Mei Kong, PhD

**Targeting Epigenetic Plasticity and Drug Resistance in Pediatric Cancer** Adolfo Ferrando, MD, PhD, and Kimberly Stegmaier, MD

#### Identification and Analysis of Prostate Reactive TCRs for T-cell Mediated Adoptive Cellular Immunotherapy of Metastatic Prostate Cancer

Owen N. Witte, MD, and Padmanee Sharma, MD, PhD

### **CLASS OF 2014**

#### The Intersection of Epigenetic and Immune Checkpoint Therapy Stephen B. Baylin, MD, and James P. Allison, PhD

#### Determinants of Sensitivity and Resistance to MEK-Based Targeted Therapies in NRAS Mutant Melanomas Roger S. Lo, MD, PhD, and Jeffrey A. Sosman, MD

Analysis of High-Dimension Single-Cell Data From Cancer Immunotherapy Clinical Trials

Dana Pe'er, PhD, and Padmanee Sharma, MD, PhD

Clinical Development of CFI-400945, a PLK4 Inhibitor, in Breast Cancer Dennis J. Slamon, MD, PhD, and Tak W. Mak, PhD

**cBioPortal for Stand Up To Cancer** David B. Solit, MD, and Nikolaus Schultz, PhD



# ADDITIONAL AWARDS AND PRIZES

#### ADDITIONAL AWARDS AND PRIZES

## **ZISKIN PRIZE**

The Ziskin Prize is named for Laura Ziskin, legendary Hollywood producer, who cofounded SU2C and lived with breast cancer for seven years before she died in 2011.

- The prize provides a one-year, \$250,000 grant.
- The grant is shared by two scientists at different institutions.
- Funds are used to collaborate on high-risk, high reward breast cancer research.

#### **Recipients:**

- 2012 Stephen B. Baylin, MD, and Feyruz V. Rassool, PhD
- 2014 Taru E. Muranen, PhD, and Gordon B. Mills, MD, PhD
- 2015 Matthew J. Ellis, PhD, and Charles Swanton, PhD
- 2018 Jos Jonkers, PhD, and Helen Piwnica-Worms, PhD
- 2019 Silvia C. Formenti, MD, and Heather L. McArthur, MD, MOH
- 2020 Leisha A. Emens, MD, PhD, and Xiang Zhang, PhD
- 2022 Jane E. Visvader, PhD, and Geoffrey J. Lindeman, MBBS (Hon.), PhD

## THE JIM TOTH SR. BREAKTHROUGH LUNG CANCER RESEARCH AWARD

This award is named in honor of Jim Toth Sr., who passed away from lung cancer. It provides funding for highly innovative, clinically focused lung cancer research.

Two awards, covering the period 2014 - 2017

Leaders: Stephen B. Baylin, MD, and Peter A. Jones, PhD

## PEGGY PRESCOTT EARLY CAREER SCIENTIST AWARD

The SU2C-Peggy Prescott Early Career Scientist Award in Colorectal Cancer Research supports a novel cancer research project with significant potential for advancing key questions in colorectal cancer research.

Recipient: 2019 - Karin Pelka, PhD

#### ADDITIONAL AWARDS AND PRIZES

## GOLDEN ARROW EARLY CAREER SCIENTIST AWARD

The SU2C Golden Arrow Early Career Scientist Award supports a novel cancer research project that, through collaboration with a current SU2C project, has significant potential for advancing key questions in cancer research.

Recipient: 2019 - William Freed-Pastor, MD, PhD

## SU2C SHARP TANK EARLY CAREER SCIENTIST AWARD

The SU2C Sharp Tank Early Career Scientist Award supports an early-career investigator with a novel cancer research proposal incorporating cutting-edge, high-risk ideas and offering the greatest potential impact for cancer patients.

Recipient: 2020 - Catherine Marinac, PhD

## PHILLIP A. SHARP CHALLENGE AWARD

The Pancreatic Cancer Collective Phillip A. Sharp Challenge Award supports a novel cancer research project that explores synergistic and innovative collaborations exploring pancreatic cancer interception.

Recipients: 2021 - Alec Kimmelman, MD, PhD, and Benjamin Greenbaum, PhD

## **SU2C MAVERICK AWARD**

The SU2C Maverick Award supports an early-career investigator with a novel cancer research proposal incorporating cutting-edge, high-risk ideas and offering the greatest potential impact for cancer patients.

Recipient: 2022 - Anirban Das, MD

#### ADDITIONAL AWARDS AND PRIZES

## **EMPEROR SCIENCE AWARDS**

From 2016 to 2018 the Emperor Science Award program encouraged high school students to explore careers in cancer research through a unique mentoring opportunity. This education initiative was inspired by the Ken Burns documentary Cancer: The Emperor of All Maladies and supported with grants from Genentech, Bristol-Myers Squibb, and Novartis. Three hundred students were selected in national competitions and received a \$1,500 stipend, a laptop computer, and the opportunity to work alongside an esteemed scientist on a multi-week cancer research project.

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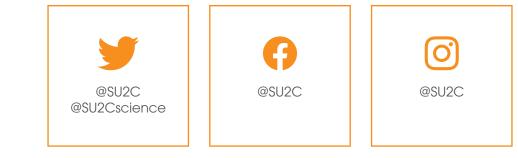
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