

NIH-AACR Conference

CANCER, AUTOIMMUNITY, AND IMMUNOLOGY

April 15-16, 2019 | Masur Auditorium, National Institutes of Health | Bethesda, MD

Image courtesy of Andrea Radtke, PhD; CAT-I, LISB, NIAID

CONFERENCE COMMITTEE



Elizabeth M. Jaffee, MD

2018-2019 AACR President; Deputy
Director, Sidney Kimmel Comprehensive
Cancer Center



Elad Sharon, MD, MPH

Senior Investigator,
National Cancer Institute



Connie Sommers, PhD

Program Director, National
Cancer Institute



Howard Young, PhD

Senior Investigator, National
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Katarzyna (Kasia) Bourcier, PhD

Program Officer, National Institute of Allergy
and Infectious Diseases



Marie Mancini, PhD

Program Director, National Institute of Arthritis
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NIH-AACR Cancer, Autoimmunity, and Immunology Conference

April 15-16, 2019 | Bethesda, MD

Elizabeth M. Jaffee, MD, FAACR, AACR Past President; Deputy Director, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University

Elad Sharon, MD, MPH, Senior Investigator, National Cancer Institute

Connie Sommers, PhD, Program Director, National Cancer Institute

Howard Young, PhD, Senior Investigator, National Cancer Institute

Katarzyna (Kasia) Bourcier, PhD, Program Officer, National Institute of Allergy and Infectious Diseases

Marie Mancini, PhD, Program Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases

AGENDA: APRIL 15, 2019

9:00 AM Opening remarks and tribute to Stephen Katz
Dinah Singer, PhD, National Cancer Institute

KEYNOTE ADDRESS

9:15 AM T-cell co-stimulation in autoimmune diseases and cancer
Arlene H. Sharpe, MD, PhD, FAACR, Harvard Medical School

GASTROINTESTINAL TOXICITIES MODERATOR: MICHAEL DOUGAN, MD, PHD

9:50 AM GI toxicities of checkpoint blockade
Michael Dougan, MD, PhD, Massachusetts General Hospital

10:10 AM Pancreatic exocrine related diarrhea
Erez Baruch, MD, Sheba Medical Center

10:30 AM Gastrointestinal and hepatic complications of immune checkpoint inhibitors
Robert S. Bresalier, MD, MD Anderson Cancer Center

10:50 AM PANEL DISCUSSION

Moderator Michael Dougan, MD, PhD

Discussants Gastrointestinal Toxicities session speakers and additional panelist:
Mark Anderson, MD, PhD, University of California, San Francisco

MOONSHOT ADMINISTRATIVE SUPPLEMENT AWARDEE UPDATE

11:15 AM Disruption of T-cell tolerance in type 1 diabetes
Mark Anderson, MD, PhD, University of California, San Francisco

11:35 AM LUNCH BREAK



CYTOKINES, AUTOIMMUNITY, AND IMMUNE-RELATED ADVERSE EVENTS REFRACTORY TO INITIAL THERAPY

MODERATORS: JEFFREY A. SOSMAN, MD, & ELAD SHARON, MD, MPH

- 12:50 PM** **Steroid-refractory Pneumonitis and Prospective Studies for irAEs**
Jarushka Naidoo, MBBCh, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University
- 1:10 PM** **Multidisciplinary irAE models**
Kelly Walkovich, MD, C. S. Mott Children's Hospital
- 1:30 PM** **Balancing immune tolerance with low-dose IL-2**
David Klatzmann, MD, PhD, Hôpital Pitié-Salpêtrière, Sorbonne Université

1:50 PM **PANEL DISCUSSION**

- Moderators** Jeffrey A. Sosman, MD, & Elad Sharon, MD, MPH
- Discussants** Cytokines, Autoimmunity, and Immune Related Adverse Events session speakers.

NEUROLOGICAL AND OCULAR TOXICITIES

MODERATOR: DAVID HAFER, MD, FANA

- 2:15 PM** **Unleashing the immune system in the brain**
David Hafler, MD, FANA, Yale School of Medicine
- 2:35 PM** **Neurotoxicity associated with immune checkpoint inhibitor treatment**
Bianca D. Santomasso, MD, PhD, Memorial Sloan Kettering Cancer Center
- 2:55 PM** **Ocular toxicities**
Hatice Nida Sen, MD, MHS, National Eye Institute

3:15 PM **PANEL DISCUSSION**

- Moderator** David Hafler, MD, FANA
- Discussants** Neurological and Ocular Toxicities session speakers.

3:40 PM **BREAK**

KEYNOTE ADDRESS

- 4:00 PM** **Immuno-oncology combination clinical trials**
Elizabeth M. Jaffee, MD, FAACR, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University

COMBINATION THERAPIES

MODERATOR: ELIZABETH M. JAFFEE, MD, FAACR

- 4:30 PM** **Toxicities of radiation-immunotherapy combinations**
Jonathan D. Schoenfeld, MD, MPH, Dana-Farber Cancer Institute
- 4:50 PM** **Regulatory perspectives on combination immuno-oncology trials and approvals**
Nicole Drezner, MD, U.S. Food and Drug Administration

5:10 PM **PANEL DISCUSSION**

- Moderator** Elizabeth M. Jaffee, MD, FAACR
- Discussants** Combination Therapies session speakers.

5:35 PM **POSTER SESSION & RECEPTION**

Join us on the FAES Terrace for a Poster Session and Networking Reception

7:00 PM **ADJOURN**



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AGENDA: APRIL 16, 2019

9:00 AM Welcoming remarks

SKIN TOXICITIES AND RHEUMATOLOGY
MODERATOR: ROBERT H. CARTER, MD

9:05 AM Rheumatic adverse effects of immune checkpoint inhibitors
Xavier Mariette, MD, PhD, Hôpital Bicêtre, Université Paris-Sud

9:25 AM Sicca as a complication of immune checkpoint inhibition: Is it Sjögren's Syndrome?
Blake Warner, DDS, PhD, MPH, National Institute of Dental and Craniofacial Research

9:45 AM Skin toxicities from immune checkpoint inhibitors
Nicole LeBoeuf, MD, MPH, Dana-Farber Cancer Institute

10:05 AM Mechanisms of autoimmunity association with cancer
Antony Rosen, MBChB, BSc (Hon.), Johns Hopkins School of Medicine

10:25 AM **PANEL DISCUSSION**

Moderator Robert H. Carter, MD

Discussants Skin Toxicities and Rheumatology session speakers.

10:50 AM **BREAK**

MOONSHOT ADMINISTRATIVE SUPPLEMENT AWARDEE UPDATE

11:10 AM Assessing roles for dendritic cells in immune-related adverse events with checkpoint inhibitor therapy
Stephanie Watowich, PhD, MD Anderson Cancer Center

THE BIG PICTURE: APPROACHING IMMUNE-RELATED ADVERSE EVENTS FROM MULTIPLE DATA STREAMS
MODERATOR: GIORGIO TRINCHIERI, MD

11:35 AM Immune-related adverse events
Douglas B. Johnson, MD, Vanderbilt-Ingram Cancer Center

11:55 AM Alliance-NCI immune-related adverse events biorepository
David Kozono, MD, PhD, Dana-Farber Cancer Institute

12:15 PM Approaching irAEs from multiple data streams: Regulatory considerations
Meredith Chuk, MD, U.S. Food and Drug Administration

12:35 PM **LUNCH BREAK**

KEYNOTE ADDRESS

1:45 PM **The role of the microbiome in response and toxicity to therapy**
Jennifer Wargo, MD, MMSc, MD Anderson Cancer Center

2:15 PM PANEL DISCUSSION

Moderator **Giorgio Trinchieri, MD**
Discussants **Meredith Chuk, MD**
 Douglas B. Johnson, MD
 David Kozono, MD, PhD
 Jennifer Wargo, MD, MMSc

CELL-BASED IMMUNOTHERAPY

2:45 PM **Adverse events of CAR-T cell therapy for hematologic malignancies**
David L. Porter, MD, PhD, University of Pennsylvania Perelman School of Medicine

3:10 PM **CAAR-T for pemphigus vulgaris**
Michael Milone, MD, PhD, University of Pennsylvania Perelman School of Medicine

3:35 PM BREAK

NON-CLINICAL MODELS

MODERATORS: JOHN LEIGHTON, PHD, & JULIE SCHNEIDER, PHD

3:55 PM **Autoimmunity following cancer treatment, more questions than answers**
Jeff Bluestone, PhD, Parker Institute for Cancer Immunotherapy

4:15 PM **Understanding IO toxicities using syngeneic immunocompetent mouse models: Lessons, opportunities, and challenges**
Gregory L. Beatty, MD, PhD, University of Pennsylvania Perelman School of Medicine

4:35 PM **Preventing immunotherapy related adverse events by targeting CD24-Siglec signaling pathway**
Pan Zheng, MD, PhD, University of Maryland, Baltimore

4:55 PM **Use of immune humanized mice in assessment of biological drug product adverse events and immunogenicity**
Kristina E. Howard, DVM, PhD, U.S. Food and Drug Administration

5:15 PM PANEL DISCUSSION

Moderators **John Leighton, PhD, & Julie Schneider, PhD**
Discussants **Non-clinical Models session speakers and additional panelist:**
 Stephanie Watowich, PhD

5:45 PM ADJOURN





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Conference Organizing Committee

Katarzyna (Kasia) Bourcier, PhD, *National Institute of Allergy and Infectious Diseases*



Dr. Kasia Bourcier obtained her PhD in Biomedical Sciences from the Medical University of Warsaw, Poland, investigating neuroimmune interactions in mouse models of neurological diseases. She then joined the Center for Neurologic Diseases at Brigham and Women's Hospital, Harvard Medical School, to study immune function in Multiple Sclerosis patients. She became an Associate Director of the Clinical Immunology Laboratory and managed development and implementation of mechanism of action studies for clinical trials. In 2004 she joined the Immune Tolerance Network, University of California, San Francisco to lead a group overseeing core facilities in efforts to introduce standardized assays for monitoring human immune responses and biomarker detection. In 2011 she joined the

Autoimmunity and Mucosal Immunology Branch at the Division of Allergy, Immunology and Transplantation at NIAID. Her programmatic interests include studies in autoimmune diseases, specifically in Type 1 Diabetes, immunotherapy, preclinical models, cancer-autoimmunity interactions, and development of new cutting-edge technologies.

Elizabeth M. Jaffee, MD, FAACR, *Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University*



An internationally heralded expert in cancer immunology, Dr. Jaffee is well-regarded for her clinical studies that have fueled the development of immunotherapies, specifically allogeneic cancer vaccines. She has led numerous efforts and clinical trials dedicated to establishing effective vaccines for the treatment of not only unresectable breast and pancreatic cancers, but also cancers that are eligible for surgical resection, but present with a high likelihood of recurrence. These vaccines have been designed to bypass immunotolerance exhibited by tumors and have proven effective in improving disease-free survival in patients.

Specifically, Dr. Jaffee has contributed to the testing and development of the GVAX cancer vaccine for pancreatic cancer, which is designed to include allogeneic pancreatic cancer cells capable of secreting the immunostimulatory cytokine, granulocyte-macrophage colony-stimulating factor (GM-CSF), normally produced by immune cells including T cells and natural killer cells. Dr. Jaffee has explored combinations involving GVAX and the CRS-207 vaccine, composed of recombinant live-attenuated, double-deleted *Listeria monocytogenes* that are genetically modified to secrete the tumor-associated antigen, mesothelin. These studies have demonstrated that GVAX administration in combination with CRS-207 effectively combats pancreatic cancer progression and increases overall survival with low toxicity.

More recently, her research has been dedicated to exploiting genomic and proteomic technologies to define biomarkers required for pancreatic cancer onset and progression. These studies have resulted in the identification of ANXA2 (Annexin A2) as a potential regulator of pancreatic cancer metastasis. Dr. Jaffee and her colleagues have demonstrated that ANXA2 is overexpressed in pancreatic cancers and that this overexpression is accompanied by changes in intracellular trafficking of ANXA2. Furthermore, changes in the cellular location of ANXA2 directly correlate with the ability of pancreatic cancer cells to proliferate and migrate into adjacent organs such as the liver. Dr. Jaffee's ongoing efforts are dedicated to understanding how to integrate immune modulating agents with vaccines in both patients and animal models.

Marie Mancini, PhD, *National Institute of Arthritis and Musculoskeletal and Skin Diseases*



Dr. Marie Mancini is the Program Director of the Systemic Autoimmune Diseases Biology Program in the Division of Extramural Research at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). Her programmatic interests include basic and translational studies on rheumatic autoimmune diseases, such as lupus and inflammatory myositis; intersection of cancer immunotherapies and autoimmune diseases; and training and career development of early-stage investigators and physician-scientists. Prior to joining the NIAMS in 2007, Dr. Mancini was a Research Scientist at MedImmune, Inc., where she focused on pre-clinical studies for several disease targets in the areas of autoimmunity, inflammation, and respiratory diseases. Dr. Mancini earned her doctorate in 2000 in Immunology and completed a post-doctoral fellowship at the Johns Hopkins University School of Medicine, where she studied the cell biology of programmed cell death. Prior to full-time graduate studies, Dr. Mancini worked as a Biologist at the Surgery Branch of the National Cancer Institute, after obtaining a B.S. in Biology from Georgetown University.

Elad Sharon, MD, MPH, *National Cancer Institute*



Elad Sharon, MD, MPH, joined the NCI Cancer Therapy Evaluation Program (CTEP) in December 2011 as a Senior Investigator in the Investigational Drug Branch, where he works with academia and industry to develop promising cancer therapies. His portfolio includes antibody-drug conjugates, immune checkpoint inhibitors and other agents. Dr. Sharon co-directs immunotherapy trials at CTEP and serves as an attending physician in NCI's Developmental Therapeutics Clinic (DTC). As part of his work for CTEP and the DTC, Dr. Sharon has assisted the NCI in planning major initiatives to study the intersection of the fields of cancer immunotherapy treatment and autoimmunity. Dr. Sharon is the co-Principal Investigator on a trial of nivolumab for patients with autoimmune diseases (NCI Trial 10204), and he is assisting the Alliance for Clinical Trials in Oncology in developing an immune-related Adverse Events (irAE) Biorepository to better characterize and learn from irAEs as they occur.

Dr. Sharon received his MD from Baylor College of Medicine in Houston, Texas in 2003. He completed his internal medicine residency at Emory University in 2006 and his Hematology/Oncology Fellowship at the NIH in 2011, while obtaining a Master of Public Health degree at the Harvard University in 2009. His fellowship research focused on clinical trials in mesothelioma. Dr. Sharon works on patterns of care projects with NCI's Healthcare Delivery Research Program using SEER data and with NCI's Surveillance Research Program to evaluate emerging practice patterns and the economics of cancer care. He previously worked as a guest at the Brookings Institution. He is as an associate editor of *JNCI Cancer Spectrum* and on the editorial board of *JCO Clinical Cancer Informatics*.

Connie Sommers, PhD, *National Cancer Institute*



Dr. Connie Sommers is a Program Director in the ImmunoOncology Branch, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis. She introduced the concept of EMT (epithelial-mesenchymal transition) in breast cancer during her time at the National Cancer Institute (NCI) Medicine Branch and at Georgetown University School of Medicine (PhD). She transitioned to studying developmental immunology during her postdoctoral studies at the National Institute of Child Health and Human Development and was a Staff Scientist at NCI for 17 years as an expert on genetic mouse modeling to study T cell signaling. She is happy to be able to utilize her backgrounds in cancer research and in basic immunology in her current position. Her programmatic research interests include: checkpoint inhibitor immunotherapy, adoptive cellular immunotherapies, preclinical models of immunotherapy, canine immunotherapy, the role of the microbiome in immunotherapy, and combination cancer therapies.

Howard Young, PhD, *National Cancer Institute*



Dr. Howard Young obtained his PhD in microbiology at the University of Washington and carried out postdoctoral research at the National Cancer Institute under Drs. Edward Scolnick and Wade Parks. He was a member of the Laboratory of Molecular Immunoregulation at NCI from 1983 to 1989 prior to joining the Laboratory of Experimental Immunology in 1989. He was President of the International Society for Interferon and Cytokine Research (2004-2005) and served as Chair of the Immunology Division of the American Society for Microbiology. He has also served as Chair of the NIH Cytokine Interest Group and Co-Chair and then Chair of the NIH Immunology Interest Group. He is a three-time recipient of the NIH Director's Award for Mentoring (2000, 2006, 2018) and in 2006 he received the National Public Service Award.

Conference Speakers and Panelists

Mark Anderson, MD, PhD, *University of California, San Francisco*



Dr. Anderson is a Professor in the UCSF Diabetes Center and is a leading expert in the understanding of autoimmune diseases and their underpinnings. His major scientific contributions involve unraveling the mechanisms by which a key transcription factor called Aire promotes immune tolerance. He continues to make significant contributions in this area of research and even has developed translational approaches to his findings that involve manipulating this key tolerance mechanism. As a leader in the translation of Immunology to human health, Dr. Anderson is a co-founder of ImmunoX, a novel program to harness the immune system for human health at UCSF and he is also President Elect of the Federation of Clinical Immunology Societies (FOCIS). He is a practicing Diabetologist and serves in an advisory capacity for the translation of immunology to autoimmunity including service as a mechanistic investigator/advisor to Trialnet, a NIH-sponsored multi-center clinical trial consortium whose focus is on preventing and reversing type 1 diabetes. Dr. Anderson also serves as director of the UCSF MD/PhD training program and as Research Director of the UCSF Diabetes Center.

Erez Baruch, MD, *Sheba Medical Center*



Dr. Baruch is a physician-scientist at the Ella Lemelbaum Institute for Immune-Oncology at the Sheba Medical Center, Israel. His research focuses on understanding mechanisms of resistance, toxicity, and response to immune checkpoint inhibitors with particular interest on the gut microbiota-host interaction on clinical outcomes following anti-PD-1 therapy.

Dr. Baruch is currently leading a first-in-humans clinical trial of fecal transplantation to include clinical response in anti-OD-1 refractory patients.

Gregory L. Beatty, MD, PhD, *University of Pennsylvania Perelman School of Medicine*



Gregory Beatty, MD, PhD, is an Assistant Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania and in the Division of Hematology/Oncology within the Abramson Cancer Center at the Hospital of the University of Pennsylvania. Dr. Beatty directs the Translational Research Program in the Pancreatic Cancer Research Center at the University of Pennsylvania. He graduated from Bucknell University with a BS in chemical engineering and then received his PhD in Immunology followed by an MD from the University of Pennsylvania Perelman School of Medicine. He went on to complete a residency in Internal Medicine and a fellowship in Medical Oncology at the Hospital of the University of Pennsylvania. In 2012, Dr. Beatty joined the faculty at the University of Pennsylvania and since, has produced multiple advancements in our basic understanding of the immune reaction to cancer and novel clinical strategies for the treatment of cancer patients. Dr. Beatty's research interest is in understanding mechanisms that regulate immune-surveillance in cancer with a focus on immunologically “cold” tumors including pancreatic cancer, colon cancer, esophageal cancer and glioblastoma. Dr. Beatty directs a discovery laboratory that incorporates the analysis of human tissues and the study of mouse models to inform biology that regulates immunotherapy outcomes in cancer. Dr. Beatty has led several early Phase I clinical studies investigating novel immunotherapeutic approaches for the treatment of cancer. He is a member of the American Society for Clinical Investigation (ASCI) and a recipient of the Doris Duke Clinical Scientist Development Award, the Damon Runyon-Rachleff Innovator Award and the SU2C Innovation Research Grant. He is chair of the PANCAN Precision Promise Immunotherapy Working Group, and a member of the Pancreatic Cancer Action Network's Scientific and Medical Advisory Board.

Jeffrey Bluestone, PhD, *Parker Institute for Cancer Immunotherapy*



Jeffrey Bluestone, PhD, is president and CEO of the Parker Institute for Cancer Immunotherapy and the A.W. and Mary Margaret Clausen Distinguished Professor at UCSF. Dr. Bluestone is one of the leading immunologists in the field of T-cell activation and immune tolerance research that has led to the development of multiple immunotherapies, including the first FDA-approved drug targeting T-cell co-stimulation to treat autoimmune disease and organ transplantation and the first CTLA-4 antagonist drugs approved for the treatment of metastatic melanoma.

Dr. Bluestone is an academic leader on a national and international scale. He was the founding director of the Immune Tolerance Network, the largest NIH-funded multicenter clinical immunology research program, testing novel immunotherapies in transplantation, autoimmunity and asthma/allergy; executive vice chancellor and provost emeritus at UCSF and the former director of the UCSF Diabetes Center. Finally, Dr. Bluestone has authored more than 400 peer-reviewed publications and has received numerous awards, including election to the American Academy of Arts and Sciences and the National Academy of Medicine. He was also appointed a member of Vice President Joe Biden's Cancer Moonshot Blue Ribbon Panel.

Robert S. Bresalier, MD, *University of Texas MD Anderson Cancer Center*



Dr. Bresalier is Professor of Medicine and Birdie J and Lydia Resoft Distinguished Professor in Gastrointestinal Oncology at the University of Texas MD Anderson Cancer Center. Dr. Bresalier's research program focuses on the role of glycoproteins and carbohydrate binding proteins in tumor progression and metastasis as well as their role as diagnostic and prognostic biomarkers. This research group has been instrumental in establishing the roles of mucin-associated glycoproteins and the β -galactoside binding protein galectin-3 in progression of gastrointestinal neoplasia (colon, pancreas, esophagus), and as a target for therapy. He developed several animal models of colon cancer metastasis which are extensively used for research in this area. He has been a leader in cancer

prevention and biomarker development and translational applications which span the spectrum from laboratory studies to randomized clinical trials. As a longstanding member of the Polyp Prevention Study Group he successfully carried out numerous chemoprevention trials related to colorectal and esophageal neoplasia. He served as organ section Chair (colon) of the Steering Committee of the Prostate, Lung Colorectal and Ovarian Cancer Screening Trial (PLCO), is a longstanding funded investigator of NCI's Early Detection Research Network (EDRN), and pioneered methods for collection of clinical specimens for biomarker development, biomarker validation, and translation from the lab to clinical application.

Robert H. Carter, MD, *National Institute of Arthritis and Musculoskeletal and Skin Diseases*



Robert H. Carter, MD, became Acting Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in December 2018.

Dr. Carter received his bachelor's degree from Williams College in Williamstown, MA, in 1978, magna cum laude, in biology. He received his medical degree from Harvard Medical School in 1982. He trained in internal medicine at the University of Virginia Health Sciences Center. He was a fellow in rheumatology and immunology at Brigham and Women's Hospital, and in molecular and clinical rheumatology at the Johns Hopkins University School of Medicine. He is board certified in internal medicine and rheumatology.

Prior to joining NIAMS, Dr. Carter was professor of medicine at the University of Alabama at Birmingham (UAB) and served as director of the Division of Clinical Immunology and Rheumatology. He established a record of exemplary career achievements in the fields of rheumatology and immunology. He was the principal investigator (PI) of the NIAMS-supported UAB Rheumatic Disease Core Center and the PI of an Autoimmunity Center of Excellence supported by the National Institute of Allergy and Infectious Disease (NIAID). He also served as staff physician at the Birmingham Veterans Affairs Medical Center.

He has served as NIAMS Deputy Director since 2008. As Deputy Director, Dr. Carter led NIAMS policy initiatives and projects such as the NIAMS Centers Evaluation Working Group and Clinical Trials Working Group. He leads the Accelerating Medicines Partnership (AMP) in Rheumatoid Arthritis and Lupus, a public-private partnership between government, industry, advocacy organizations, and academic centers that has changed the landscape for research in these diseases by focusing on tissues with active disease from patients. Dr. Carter also led the development of the Back Pain Consortium (BACPAC), part of the NIH's Helping to End Addition Long-term (HEAL) Initiative.

As Deputy Director, Dr. Carter worked in close association with former NIAMS Director Dr. Steve Katz on all elements of the Institute, including all the major areas of research in the NIAMS' mission areas. This experience will serve him well as he takes on the interim title of Acting Director.

Meredith K. Chuk, MD, *U.S. Food and Drug Administration*



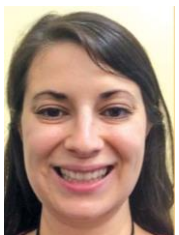
Dr. Meredith Chuk is the Acting Associate Director for Safety in the Office of Hematology and Oncology Products in CDER at the FDA. She completed her pediatric hematology/oncology fellowship at the Johns Hopkins/National Cancer Institute (NCI) fellowship program and was an instructor in the Pediatric Oncology Branch of the NCI while completing a Master's Degree in Clinical Research through Duke University. Dr. Chuk was an assistant professor of Pediatrics at the Children's Hospital of Pittsburgh in the Department of Hematology/Oncology before joining the FDA in 2013 as a medical officer. In her current role, Dr. Chuk works with the review divisions in ensuring the safety of oncology drugs from the IND through post-marketing stages with a focus on optimizing the collection, submission, and analysis of safety data.

Michael L. Dougan, MD, PhD, *Massachusetts General Hospital*



Dr. Dougan received his MD and PhD from Harvard Medical School, completing his dissertation work in Immunology with Dr. Glenn Dranoff at the Dana-Farber Cancer Institute where he studied the interplay between chronic inflammation, tumor promotion, and antitumor immunity. He completed Internal Medicine Residency and Gastroenterology Fellowship at Massachusetts General Hospital, where he has been on faculty since 2017. He is currently an Assistant Professor of Medicine and the Director of the Immunotherapy Mucosal Toxicities Program. His research focuses on understanding the immune mechanisms driving the gastrointestinal toxicities of checkpoint blockade, and on translating that information into novel treatment strategies for gastrointestinal immune-related adverse events.

Nicole Drezner, MD, *U.S. Food and Drug Administration*



Dr. Drezner is a medical officer on the thoracic team in the Division of Oncology Products 2 (DOP2) in the Office of Hematology and Oncology Products (OHOP) at the FDA. She completed a residency in pediatrics at Cohen Children's Medical Center in NY followed by a fellowship in pediatric hematology oncology at Children's National Medical Center in Washington, DC. She did a senior fellowship in pediatric neuro-oncology at CNMC after which she joined the FDA. As a medical officer, her primary responsibilities include reviewing the safety and efficacy of oncology drug products, managing investigational new drug applications, and evaluating all stages of drug development.

David Hafler, MD, FANA, *Yale School of Medicine*



Dr. Hafler is the William S. and Lois Stiles Edgerly Professor and Chairman Department of Neurology and Professor of Immunobiology, Yale School of Medicine, and is the Neurologist-in-Chief of the Yale-New Haven Hospital. He graduated magna cum laude in 1974 from Emory University with combined BS and MSc degrees in biochemistry, and the University of Miami School of Medicine in 1978. He then completed his internship in internal medicine at Johns Hopkins followed by a neurology residency at Cornell Medical Center-New York Hospital in New York. Dr. Hafler was trained in immunology at the Rockefeller University and then at Harvard where he joined the faculty in 1984 and later became the Breakstone Professorship of Neurology at Harvard and was a founding

Associated Member of the Broad Institute at MIT. In 2009 he moved to Yale as the Chair of the Department of Neurology. Dr. Hafler is a clinical scientist with a research interest in the mechanism of multiple sclerosis with over 400 publications in the field of MS, autoimmunity and immunology. He is a co-founder of the International MS Genetic Consortium a group that identified the genes causing MS. He has served as a member of the editorial boards for *Journal of Clinical Investigation* and the *Journal of Experimental Medicine*, and is co-founder of the Federation of Clinical Immunology Societies and leads the NIH Autoimmunity Prevention Center Grant at Yale. He was a Jacob Javits Merit Award Recipient from the NIH and has won many awards including Dystel Prize for MS research from the American Academy of Neurology, the University of Miami Annual Distinguished Alumni Award, the Raymond Adams Prize from the American Neurologic Association, and was the 2016 Frontier Lecturer at the AAN. Dr. Hafler has been elected to membership in the Alpha Omega Society, the American Society of Clinical Investigation, and the National Academy of Medicine.

Kristina Howard, DVM, PhD, *U.S. Food and Drug Administration*

Kristina Howard is a scientist who directs research studies in the Division of Applied Regulatory Science, Center for Drug Evaluation and Research of the United States Food and Drug Administration. Her research focuses on evaluating the ability of humanized mouse models to better predict the safety of small and large molecule drug products in humans. She received her veterinary degree from the Virginia-Maryland College of Veterinary Medicine and her doctorate degree in immunology from North Carolina State University. Prior to joining the FDA, she worked with a wide variety of animal models in research focused on immunotoxicity, viral pathogenesis and vaccine development.

Douglas B. Johnson, MD, *Vanderbilt-Ingram Cancer Center*



Douglas Johnson, MD, MSCI received his MD from the University of Alabama School of Medicine and completed internal medicine residency at Duke University before coming to Vanderbilt for hematology/oncology fellowship. He has been on faculty at Vanderbilt since 2014 as an Assistant Professor of Medicine and is now the director of the melanoma clinical and research program.

Dr. Johnson's research focuses on optimizing and extending the use of novel immune and targeted therapies in melanoma, to identify markers of response and resistance, to understand and more effectively manage the side effects of these new therapies, and to develop new treatment options for melanoma. He is the local and national principal investigator for numerous clinical trials and his research is funded by individual philanthropy, National Cancer Institute, the American Society of Clinical Oncology, the National Comprehensive Cancer Network, and the Melanoma Research Foundation. He also has national leadership positions, including membership in the NCCN Melanoma Guidelines Committee.

David Klatzmann, MD, PhD, *Hôpital Pitié-Salpêtrière, Sorbonne Université*



As a Professor of Immunology and Director of the Biotherapy Department at the Pitié-Salpêtrière hospital and Sorbonne Université medical school, Dr. Klatzmann's main activities have been to advance translational research in Immunology.

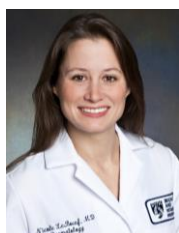
He built-up a global organization capable of developing biotherapies from bench to bedside. His current specific interests and research activities are studying the development, homeostasis and function of T cells, with a special focus on regulatory T cells (Treg) and systems immunology approaches and the role of Treg in cancer, inflammation and autoimmunity. Dr. Klatzmann also develops various Treg-based immunotherapies, notably the use of low dose IL-2.

David Kozono, MD, PhD, *Dana-Farber Cancer Institute*



David Kozono, MD, PhD, is a Senior Physician in Dana-Farber's Lowe Center for Thoracic Oncology and Assistant Professor of Radiation Oncology at Harvard Medical School. His clinical and research focus is on precision radiotherapy and combination therapies for lung cancer. He serves as the Executive Officer for the Respiratory Committee and Co-Chair of the Immuno-Oncology Committee in the Alliance for Clinical Trials in Oncology. He completed his undergraduate studies at the University of California Berkeley. He received his MD and PhD at Johns Hopkins University School of Medicine, where in the laboratory of Nobel laureate Dr. Peter Agre he and his colleagues characterized the molecular structure and function of the aquaporin water channels. He then completed his internship in internal medicine at Brigham and Women's Hospital and residency in the Harvard Radiation Oncology Program. His research in lung cancer has been supported by the American Society for Radiation Oncology (ASTRO) Junior Faculty Award, the LUNgevity Foundation Career Development Award and the National Cancer Institute (NCI) K08 Award.

Nicole R. LeBoeuf, MD, MPH, *Dana-Farber Cancer Institute*



Dr. LeBoeuf received her medical from the University of Massachusetts Medical School in 2006. She completed her residency in Dermatology at Columbia University followed by a fellowship in Cutaneous Oncology at Brigham and Women's/Dana-Farber Cancer Center at Harvard. Dr. LeBoeuf joined the faculty in the Department of Dermatology and Center for Cutaneous Oncology at Dana-Farber and Brigham and Women's in 2012 and earned a Masters in Public Health from the Harvard TH Chan School of Public Health in 2015. In addition to directing the Cutaneous Oncology and Medical Dermatology Fellowship programs, Dr. LeBoeuf established and directs the Program in Skin Toxicities from Anticancer Therapies at the Dana-Farber/Brigham and Women's Cancer Center. She leads clinical trials in cutaneous lymphoma and rare skin malignancies as well as interventional studies for the prevention or management of side effects from cancer treatment. Her research focuses on using novel imaging and computational methods to understand the immunologic mechanisms of side effects to cancer therapeutics and implementing therapies or other interventions to mitigate them.

John K. Leighton, PhD, *U.S. Food and Drug Administration*



Dr. Leighton received his PhD from the Department of Physiology and Biophysics at the University of Illinois, Urbana-Champaign. Dr. Leighton first came to FDA as a pharmacology and toxicology reviewer in the Center for Veterinary Medicine and moved to the Division of Oncology Drug Products (DODP) in CDER as a reviewing pharmacologist, later serving as a supervisory pharmacologist. Dr. Leighton is currently the Director for the Division of Hematology Oncology Toxicology in the Office of Hematology and Oncology Products, where his primary responsibility is providing policy direction and review oversight of nonclinical studies submitted to support IND, NDA and BLA applications for oncology and hematology indications. Dr. Leighton serves as co-chair of the PTCC Computational Toxicology Subcommittee. He served as Rapporteur for the ICH S9 Q&A guidance for anticancer pharmaceuticals which was approved by the ICH Assembly in April 2018, and is Deputy Topic Lead for FDA for ICH Q3D, Elemental Impurities.

Xavier Mariette, MD, PhD, *Hôpital Bicêtre, Université Paris-Sud*



Professor Xavier Mariette has served as the Head of the Rheumatology Department of Hôpital Bicêtre, Université Paris-Sud since 1999, a role he took following 10 years of practice of clinical immunology. Dr. Mariette, as the president of the “Club Rheumatism and Inflammation” (CRI) from 2001 to 2007, initiated numbers of clinical research on biotherapies in autoimmune diseases. He is the head of the French RATIO (Research Axed on Tolerance of Biotherapy) observatory, collecting specific rare serious adverse events in patients treated with anti-TNF. He initiated the French AIR (Autoimmunity and Rituximab) and ORA (Orencia and Rheumatoid arthritis) registries of patients with autoimmune diseases treated with rituximab and abatacept. He initiated clinical trials in Sjögren’s syndrome with infliximab, hydroxychloroquine and belimumab. Recently, he set-up a collaboration with the Gustave Roussy institute, anti-cancer center from the same Paris-Sud university about rheumatic immune-related adverse effects induced by immune check-point therapy. Dr. Mariette is also involved in basic research, leading a group working on pathogeny of Sjögren’s syndrome and rheumatoid arthritis, relationships between innate immunity and the BAFF (B-cell activating factor) cytokine, B cells in autoimmunity and the relationships between autoimmunity, immunosuppressant treatment and lymphoma. He is part of the Executive committee of EULAR as the past-chair of the Investigative Rheumatology committee, after having served as the president of the scientific committee for the 2012 EULAR congress.

Michael C. Milone, MD, PhD, *University of Pennsylvania Perelman School of Medicine*



Michael Milone is an Associate Professor of Pathology and Laboratory Medicine at the Hospital of the University of Pennsylvania and the School of Medicine. He earned his MD and PhD in 1999 from the University of Medicine and Dentistry of New Jersey. His doctoral work focused upon the unique interactions between plasmacytoid dendritic cells and viruses that stimulate abundant type I interferon production by this dendritic cell subset. He went on to post-graduate medical training in internal medicine, laboratory medicine and transfusion medicine at the University of Pennsylvania. Dr. Milone continued his scientific research studies during a post-doctoral fellowship pursuing adoptive immunotherapy of cancer with Dr. Carl June at the University of Pennsylvania. This work has lead to an open Phase I study of artificial antigen receptors in patients with B cell leukemia and lymphoma. Joining the faculty in 2007, Dr. Milone's laboratory continues to focus upon genetic engineering and adoptive immunotherapy of cancer with new approaches based upon work within the NCMDIR that began in 2008 when he joined the nanomedicine initiative as the center's clinical collaborator.

Jaruska Naidoo, MBBCh, *Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University*



Dr. Jarushka Naidoo is an Assistant Professor of Oncology at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, in Baltimore, MD. She completed Internal Medicine and Medical Oncology training through the Royal College of Physicians of Ireland, after which she was awarded an advanced fellowship at Memorial Sloan Kettering Cancer Center (New York), from the Irish Society of Medical Oncology. Her research interests include: immunotherapy, novel immunotherapeutic combinations, toxicities of immunotherapy and lung cancer. In the field of immune-related toxicity, she has published a number of seminal studies, including the first comprehensive analysis of pneumonitis with anti-PD-1/PD-L1 agents (J Clin Oncol 2016), the first analysis of patients with autoimmune bullous pemphigoid (Cancer Immunol Res 2017) and inflammatory arthritis (Oncologist 2018) from anti-PD-1/PD-L1. She serves on national immune-toxicity guidelines for NCCN and SITC, is the chair of the Johns Hopkins Immune-related Toxicity Team, and the Chair of the NRG Immunotherapy subcommittee.

David L. Porter, MD, *University of Pennsylvania Perelman School of Medicine*



Dr. Porter is the Jodi Fisher-Horowitz Professor of Leukemia Care Excellence at the Perelman School of Medicine and Abramson Cancer Center, and Director of the Cell Therapy and Transplant program at the University of Pennsylvania. He is a graduate of the University of Rochester and earned a medical degree at Brown University. He completed internship and residency at Boston University Hospital, and fellowship training at Brigham and Women's Hospital and Harvard Medical School in Boston.

He chairs or serves on numerous local, national and international committees focused on hematologic malignancies, hematopoietic stem cell transplantation and cell therapy. He is the Chair of the Board of Directors of the National Marrow Donor Program and a member of the American Board of Internal Medicine Hematology Exam Committee. Dr. Porter is a member of the American Society of Hematology, the American Society of Clinical Oncology, and the American Society of Blood and Marrow Transplantation. He has authored more than 170 research articles and book chapters, is an Associate Editor for the American Journal of Hematology and has served as a manuscript reviewer for numerous high impact medical journals. He serves on cell therapy advisory boards and steering committees for a number of organizations including the Foundation for the Accreditation of Cell Therapy (FACT), Association of American Cancer Institutes (AACI), Society for Immunotherapy of Cancer (SITC) and Center for International Blood and Marrow Transplant Research (CIBMTR). He is the recipient of several prestigious awards at the University of Pennsylvania including recognition for Professionalism and Mentorship. He is annually recognized as a "Top Doc" in Philadelphia Magazine and by Castle Connolly, and has been the recipient of the Leukemia and Lymphoma Society Service to Mankind Award.

Dr. Porter has expertise in development of novel cellular therapies, in the care of patients with hematologic malignancies including acute and chronic leukemia, and in all aspects of hematopoietic SCT. He leads numerous local and national research activities. He is an accomplished clinical investigator with principal research interests in development of novel methods of cellular therapy, stem cell transplantation and allogeneic adoptive immunotherapy. Dr. Porter has worked with colleagues at the University of Pennsylvania to pioneer successful development of CAR T cells (genetically modified T cells) to treat B cell cancers such as ALL, NHL and CLL; other research highlights include development of novel trials designed to prevent GVHD after allogeneic SCT by blocking lymphocyte trafficking, and studies to enhance graft-vs-tumor activity at the time of transplant, after non-myeloablative therapy, and for relapse after SCT.

Antony Rosen, MB ChB, BSc (Hon.), *Johns Hopkins School of Medicine*



Dr. Rosen is the Mary Betty Stevens Professor of Medicine, Pathology and Cell Biology, Director of the Division of Rheumatology, Vice Dean for Research at the Johns Hopkins School of Medicine, and Director of inHealth, the Johns Hopkins program in precision medicine and individualized health. Dr. Rosen received his medical degree from the University of Cape Town in South Africa in 1984. After completing his internship in Medicine and Surgery, he pursued postdoctoral studies in Immunology at the Rockefeller University in New York (1987-1990). Drawn by a desire for a deeper understanding of human inflammatory diseases, he returned to clinical medicine, and was an Osler resident and rheumatology fellow at Johns Hopkins Hospital (1990-1994). He subsequently joined the faculty at

Johns Hopkins in 1995, and rose to the rank of Professor in 2002. He has been Director of the Division of Rheumatology since then, overseeing a substantial expansion of the Division. His research focuses on autoimmunity in the rheumatic diseases, using subgroups of patients with distinct phenotypes, trajectories and specific autoimmune responses to define molecular mechanisms.

Bianca D. Santomaso, MD, PhD, *Memorial Sloan Kettering Cancer Center*



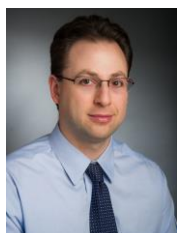
Bianca Santomaso is a neuro-oncologist at the Memorial Sloan Kettering Cancer Center who cares for patients with brain tumors and neurologic complications due to cancer. She is especially interested in immunotherapy and is currently conducting basic research to understand how the immune system can be optimally harnessed to treat brain tumors. She has additional research interest in the neurologic complications of cancer immunotherapies including CAR T cell therapies and immune checkpoint inhibitors. Santomaso's clinical expertise is in Neuro-Oncology, Adult Primary Brain Tumors, Central Nervous System Lymphoma, Brain Metastases, Leptomeningeal Metastases, neurologic complications of cancer, and management of neurotoxicity from immunotherapy.

Julie Schneider, PhD, *U.S. Food and Drug Administration*



Julie Schneider, PhD is Associate Director for Research Strategy and Partnerships at the FDA Oncology Center of Excellence. She previously ran the HHS Entrepreneurs-in-Residence Program within the HHS IDEA Lab and worked in several roles at the National Cancer Institute (NCI) focused on developing new research funding opportunities, including a \$20 million US-China Program for Biomedical Research Cooperation co-funded by five NIH institutes at the National Natural Science Foundation of China. Julie initially joined the NCI as an AAAS Science and Technology Policy Fellow and obtained her doctoral degree in genetics from the University of Oxford and her bachelor's degree in biology from Yale.

Jonathan D. Schoenfeld, MD, MPhil, MPH, *Dana-Farber Cancer Institute*



Dr. Jonathan Schoenfeld is a radiation oncologist at the Brigham and Women/Dana-Farber Cancer Center and Associate Professor of Radiation Oncology at Harvard Medical School. He serves as the Radiation Oncology Director of the Melanoma Disease Center at the Dana-Farber Cancer Institute and Director of Clinical Trial Development within the department of radiation oncology. He received his medical degree from the Harvard-MIT Division of Health Sciences and Technology at Harvard Medical School after completing a research fellowship as a Gates Scholar at the University of Cambridge in the UK. He performed his residency in radiation oncology in the Harvard Radiation Program and received a Master of Public Health in Clinical Effectiveness from the Harvard T.H. Chan School of Public Health.

He has served on the NCI Radiation and Immune Modulation Working Group and the Developmental Therapeutics Subcommittee for NRG oncology. He leads multicenter and national trials testing the combination of radiation and immune therapy and translational studies evaluating the effect of highly targeted radiation and novel therapies on the immune microenvironment. His work has helped establish the expected toxicity profile from combined radiation/immunotherapy treatments.

Hatice Nida Sen, MD, MHS, *National Eye Institute*



Hatice Nida Sen, M.D., MHS is the Head of Clinical and Translational Immunology Unit at the NEI. She is also the Director of the Uveitis Clinic and the Uveitis and Ocular Immunology Fellowship Program at the National Eye Institute (NEI), National Institutes of Health (NIH). Dr. Sen obtained her M.D. from Hacettepe University of Turkey and MHS from Duke University. She completed her ophthalmology residency at George Washington University and her uveitis and ocular immunology fellowship at the National Eye Institute.

The focus of Dr. Sen's research is to develop disease biomarkers through clinical and transcriptional profiling of patients with ocular inflammatory diseases and developing targeted therapies. She also investigates the role of gut microbiome in uveitis patients from both a mechanistic and biomarker perspective. She is interested in developing novel approaches of ocular image processing and analysis to be utilized as outcomes in clinical trials of inflammatory eye diseases. She is the principal investigator on several clinical trials on new treatment methods for uveitis.

Dr. Sen is actively involved several international multicenter trials and research networks including the MUST (Multicenter Uveitis Systemic Treatment) trial and the SUN (Standardization of Uveitis Nomenclature) working group. Dr. Sen also helps develop treatment guidelines for childhood uveitis as a member of the Childhood Arthritis and Rheumatism Registry Alliance's (CARRA) JIA-uveitis workgroup and the American College of Rheumatology (ACR). She is actively involved in educational and academic activities of American Academy of Ophthalmology. She is the president elect of American Uveitis Society. She has authored over 100 peer-reviewed articles and many book chapters and received many awards for her research, most recently, Lasker Clinical Research Scholar award.

Arlene H. Sharpe, MD, PhD, FAACR, *Harvard Medical School*



Dr. Sharpe earned her MD and PhD degrees from Harvard Medical School and completed her residency in Pathology at Brigham and Women's Hospital. Dr. Sharpe is a leader in the field of T cell costimulation. Her laboratory has discovered and elucidated the functions of T cell costimulatory pathways, including the immunoinhibitory functions of the CTLA-4 and PD-1 pathways, which have become exceptionally promising targets for cancer immunotherapy. Her laboratory currently focuses on the roles of T cell costimulatory pathways in regulating T cell tolerance and effective antimicrobial and antitumor immunity and translating fundamental understanding of T cell costimulation into new therapies for autoimmune diseases and cancer. Dr. Sharpe has published over 300 papers and was listed by Thomas Reuters as one of the most Highly Cited Researchers (top 1%) in 2014-2018 and a 2016 Citation Laureate. She received the William B. Coley Award for Distinguished Research in Tumor immunology in 2014 and the Warren Alpert Foundation Prize in 2017 for her contributions to the discovery of PD-1 pathway. Dr. Sharpe is an elected member of the National Academy of Sciences and National Academy of Medicine and a Fellow of the American Association for Cancer Research.

Dinah S. Singer, PhD, *National Cancer Institute*



Dinah Singer, PhD, is acting deputy director of the National Cancer Institute (NCI), National Institutes of Health (NIH) and director of the NCI Division of Cancer Biology. She currently serves as a co-chair of the Cancer Moonshot Blue Ribbon Panel. After receiving her BS degree from the Massachusetts Institute of Technology and her PhD from Columbia University, Dr. Singer was a postdoctoral fellow in the Laboratory of Biochemistry, NCI, and a senior investigator in the Experimental Immunology Branch, NCI. Dr. Singer serves on a number of scientific and advisory boards, is a member of the American Association of Immunologists and the American Association of Cancer Researchers, and has served as a senior science officer at the Howard Hughes Medical Institute. Her research interests are in the areas of regulation of transcription, gene expression and molecular immunology. Dr. Singer serves in leadership positions on a variety of trans-NIH scientific and administrative committees, including NIH Common Fund initiatives. She has trained a large number of post-doctoral fellows, post-baccalaureate students and high school students who have gone on to successful scientific careers.

Jeffery A. Sosman, MD, *Robert H. Lurie Comprehensive Cancer Center of Northwestern University*



Dr. Sosman has been an active clinical investigator vested in the immune-based therapy of melanoma. This has led to his role in the clinical development of initially Interleukin-2 and more recently anti-CTLA-4 and anti-PD1/PDL-1. Efforts to identify mechanisms of resistance to checkpoint inhibitors and approaches to overcome de novo and acquired resistance are one of his major interests. In addition, he has ongoing efforts in the personalized therapy of melanoma with well-defined targets (BRAF v600, NRAS mutations, CKIT mutations). Sosman co-leads the Northwestern Cancer Center Translational Research in Solid Tumors (TRIST) program which is critical to the success of the Cancer Center. In this role, he is working to bring translational studies including immunotherapy based trials to all solid tumors. The development of translational studies that will provide a better understanding to sensitivity and resistance to both immune checkpoint therapy and targeted therapy is his highest priority. As Co-Leader of TRIST program, Sosman is determined to bring creative immune based trials to cancers.

Giorgio Trinchieri, MD, *National Cancer Institute*



Dr. Trinchieri was most recently the Director of the Schering Plough Laboratory for Immunological Research in Dardilly, France, and an NIH Fogarty Scholar at the Laboratory for Parasitic Diseases, NIAID. Since August 2006, he has been the Director of the Cancer and Inflammation Program, and Chief of the Laboratory of Experimental Immunology. His research at the CCR focuses on the interplay between inflammation/innate resistance and adaptive immunity, and the role of pro-inflammatory cytokines in the regulation of hematopoiesis, innate resistance, and immunity. He discovered interleukin-12 while at the Wistar Institute in 1989 and for many years has been characterizing the molecular mechanisms of interleukin-12 production and action, and the role of this molecule in tumor immunity, infections, and autoimmunity.

Kelly J. Walkovich, MD, *C.S. Mott Children's Hospital*



Kelly Walkovich, MD is an Associate Professor in Pediatric Hematology/Oncology at the University of Michigan, C.S. Mott Children's hospital. She graduated with a BS in Molecular Biology and Biochemistry from Penn State University prior to completing her medical school training at the University of Michigan. She went on to complete her pediatric residency at Children's Hospital of Philadelphia and her hematology/oncology fellowship at the University of Michigan. Under the mentorship of the late Laurence Boxer, MD, she has cultivated clinical expertise in immuno-hematology, particularly phagocyte disorders. At the University of Michigan, she serves as the director of the Immuno-Hematology Comprehensive Program, a multidisciplinary clinical care and research team dedicated to the optimizing the diagnosis, management and understanding of primary immunodeficiency disorders and rare hematologic diseases. She also serves as the executive chair of the North American Immuno-Hematology Clinical Education and Research (NICER) Consortium, a multidisciplinary, multi-institutional collaborative clinical-education and research platform for understanding cytopenias and malignancy in primary immunodeficiency disorders as well immune-related adverse events.

Jennifer Wargo, MD, MMSc, *University of Texas MD Anderson Cancer Center*



Dr. Wargo's career commitment is to advance the understanding and treatment of disease through science. After completing her medical degree, she entered surgical residency training at the Massachusetts General Hospital/Harvard Medical School where she became interested in the biology and treatment of cancer. During her training, she completed two fellowships in surgical oncology and immunotherapy for cancer (with Dr. Toni Ribas and Dr. Steve Rosenberg). Dr. Wargo was recruited to the Division of Surgical Oncology at the Massachusetts General Hospital in July 2008, and ran an active research laboratory focusing on the interface between oncogenic mutations and anti-tumor immunity. There, she made the critical observation that targeting oncogenic mutations could make tumors more immunogenic, providing the rationale for combining targeted therapy and immunotherapy in the treatment of cancer. In September 2013, Dr. Wargo was recruited by University of Texas MD Anderson Cancer Center to help lead the Melanoma Moon Shot program. She is currently an Associate Professor of Surgical Oncology and Genomic Medicine, and has continued her critical research to better understand responses to therapy and to develop novel strategies to combat resistance. This includes her groundbreaking recent work elucidating the role of the gut microbiome in shaping responses to immunotherapy in patients with melanoma – with a manuscript describing this work published in *Science*.

Dr. Wargo has contributed significantly to the world literature with her impactful research on melanoma tumorigenesis/immunotherapy for cancer and the gut microbiome having published over 140 peer-reviewed manuscripts and extensive grant funding (including R01 funding). She is also the recipient of numerous awards, including the Rising STARS and Regents Health Scholars Award, Outstanding Young Investigator Award, Stand up to Cancer/AACR Innovative Research Award, Society for Melanoma Research Outstanding Investigator Award, Best Boss Award, among others. She is recognized internationally as a leader in cancer research, and is leading innovative efforts globally.

Blake M. Warner, DDS, PhD, MPH, *National Institute of Dental and Craniofacial Research*



Dr. Warner received his DDS-PhD from The Ohio State University and his certificate in Oral and Maxillofacial Pathology from the University of Pittsburgh Medical Center. Dr. Warner in the final year of his postdoctoral Clinical Research Fellowship at the National Institute of Dental and Craniofacial Research in the Laboratory of Dr. Jay Chiorini. Presently, he serves as the Acting Chief of the NIDCR Salivary Disorders Program and Principle Investigator of the Characterization of Salivary Gland Diseases and the Pathogenesis and Natural History of Sjögren's Syndrome protocols. Dr. Warner is specifically interested in several clinical conditions that affect the salivary complex including Sjögren's Syndrome (SS) and irreversible iatrogenic damage from targeted oncologic therapies. These clinically similar but biologically distinct disease states offer the opportunity to dissect differential mechanisms of salivary gland dysfunction including the role of immune dysregulation and the consequence on salivary gland function. These conditions remain important unmet healthcare needs and the development of novel preventative strategies and therapies are of critical clinical importance.

Stephanie S. Watowich, PhD, *University of Texas MD Anderson Cancer Center*



Dr. Stephanie S. Watowich is a Professor of Immunology and Co-Director of the Center for Inflammation and Cancer at The University of Texas MD Anderson Cancer Center. Dr. Watowich obtained her BA in Biology at Carleton College and her PhD in Molecular and Cellular Biology at Northwestern University, where she trained with Dr. Richard I. Morimoto. Dr. Watowich performed her postdoctoral fellowship at the Whitehead Institute of Biomedical Research with Dr. Harvey F. Lodish. Her studies uncovered the importance of cytokine receptor dimerization in receptor signaling and activation. Since joining MD Anderson, Dr. Watowich's research has focused on transcriptional control of innate immunity, with specific interest in the actions of the cytokine-activated STAT transcriptional regulators. Dr. Watowich has served as chair or member of NIH and AHA research grant and fellowship study sections. She has been the recipient of several grants and awards, including research funding from NIH, CPRIT, and biotech. Dr. Watowich has also led or co-directed the CPRIT Research Training program at MD Anderson since 2010, in collaboration with Dr. Khandan Keyomarsi. Dr. Watowich has been recognized with the MD Anderson Faculty Achievement Award in Education, the John P. McGovern Outstanding Teacher Award and induction into the UT Kenneth I. Shine Academy of Health Science Education.

Pan Zheng, MD, PhD, *University of Maryland, Baltimore*



Dr. Pan Zheng is a Professor of Surgery and a senior member at the Division of Immunotherapy, Institute of Human Virology in University of Maryland Baltimore. Dr. Zheng received her MD from Peking Union Medical College and PhD in Immunobiology from Yale University. She had Internal Medicine and Endocrinology residency training in Peking Union Medical College Hospital and completed Pathology residency in New York University Medical Center. She has been a faculty member in the Ohio State University, University of Michigan, and Children's National Medical Center. Her lab works on CTLA-4, CD24 and mTOR. Dr. Zheng established a humanized mouse model that full recapitulates immunotherapy-related adverse events observed in clinical use of immune-oncology antibodies. She co-founded Oncolimmune, Inc. and serves as its Chief Medical Officer, overseeing the Phase 1 and Phase 2 clinical trials sponsored by the company.

Continuing Medical Education (CME)

Accreditation Statement



The American Association for Cancer Research (AACR) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education activities for physicians.

Credit Designation Statement

AACR has designated this live activity for a maximum of 13.0 *AMA PRA Category 1 Credit(s)*[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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Physicians and other health care professionals seeking *AMA PRA Category 1 Credit(s)*[™] for this live continuing medical education activity must complete the online CME Request for Credit Survey by **May 28, 2019**. Certificates will only be issued to those who complete the survey. The Request for Credit Survey will be available via a link on the conference website and via email. *Your CME certificate will be sent to you via email after the completion of the activity.*

Statement of Educational Need, Target Audience, and Learning Objectives

The incredible clinical success of cancer immunotherapies, particularly immune checkpoint inhibitors, has resulted in widespread use across many cancers. As utilization has increased, so too have observations and reports of toxicities, sometimes severe, in nearly every organ system. These immune-related adverse events (irAEs) manifest differently depending on the pathway targeted by the therapy (i.e., CTLA-4 or PD-1/PD-L1), and the emerging use of combination therapies has only increased the frequency of events.

In order to better understand, predict, and treat immunotoxicities in cancer patients, clinicians need to first understand the mechanisms underlying irAEs. Recognizing the similarities to and associations

with autoimmune diseases—which share many biologic underpinnings with irAEs—will also be beneficial, as will increased awareness of how irAEs present across multiple organ systems.

The NIH-AACR Cancer, Autoimmunity, and Immunology Conference will bring together world-renowned oncologists, immunologists, rheumatologists, and basic researchers to address these gaps. Attendees will hear about cutting-edge research on immunologic toxicities in the gastrointestinal and neurologic/ocular systems and skin. They will learn how animal models are being used to interrogate the mechanistic bases for irAEs and conventional autoimmunities, and how meta-analyses are being harnessed to determine prevalence of and predict outcomes following irAEs. Emerging topics in autoimmunity and immunotherapy, such as the role of the gut microbiome and potential uses and dangers of cell-based therapies, will also be presented.

With invited speakers presenting case studies and/or recent research on immune-related adverse events across multiple organ systems, this conference will be of interest to oncologists of all subspecialties, as well as immunologists and rheumatologists.

After participating in this CME activity, physicians should be able to:

1. Explain how manipulation of T-cell costimulatory pathways can play therapeutic roles in both cancers and autoimmune diseases.
2. Articulate the influence of the gut microbiome on patients' response to immunotherapy.
3. Incorporate immuno-oncology therapy combinations into personalized treatment strategies.
4. Recognize presentation of symptoms of immunotherapy toxicity across multiple organ systems.
5. Extrapolate the relevance of research and clinical findings on immune-related adverse events (irAEs) to the study and treatment of autoimmune diseases, and vice versa.
6. Explain how preclinical models are being used to investigate mechanisms underlying irAEs following immunotherapy.

Disclosure Statement

It is the policy of the AACR that the information presented at AACR CME activities will be unbiased and based on scientific evidence. To help participants make judgments about the presence of bias, AACR will provide information that Scientific Program Committee members and speakers have disclosed about financial relationships they have with commercial entities that produce or market products or services related to the content of this CME activity. This disclosure information will be made available in the *Program/Proceedings* of this conference.

Questions about CME?

Please contact the Office of CME at (215) 440-9300 or cme@aacr.org.

Disclosure of Financial Relationships

In compliance with the standards set by the Accreditation Council for Continuing Medical Education (ACCME), it is the policy of the American Association for Cancer Research (AACR) that the information presented at CME activities will be unbiased and based on scientific evidence. To help participants make judgments about the presence of bias, the AACR has provided information that planning committee members, speakers, and abstract presenters have disclosed about financial relationships they have with commercial entities that produce or market products or services related to the content of this CME activity.

Relationships are abbreviated as follows: E, Employee of listed company, G, Grant/research support recipient, A, Advisor or review panel member, C, Consultant, S, Stock Shareholder, SB, Speakers' Bureau, H, Honoraria, O, Other.

Last Name	First Name	Company	Relationships	Type	Role
Anderson	Mark	UCSF	Merck, Medtronic, Inc	S	Speaker
Arthur	Ronald	American Association for Cancer Research	No Relationships		Staff
Barksdale	Elizabeth	American Association for Cancer Research	No Relationships		Staff
Baruch	Erez	Sheba Medical Ctr. Ella Inst.	No Relationships		Speaker
Beatty	Gregory	Univ. of Pennsylvania	Janssen, Verastem, Biothera, Halozyme, BMS	A, G	Speaker
Bluestone	Jeffrey	Parker Institute for Cancer Immunotherapy	Juno/Celgene, Vir Therapeutics, Rheos, Pfizer, Celcius, Arcus, Macrogenics, Quantis, Solid	A, S	Speaker
Bourcier	Katarzyna	National Institute of Allergy and Infectious Diseases	No Relationships		Program Committee
Bresalier	Robert	UT MD Anderson Cancer Ctr.	No Relationships		Speaker
Carter	Robert	NIH	No Relationships		Speaker
Chuk	Meredith	FDA	No Relationships		Speaker
Dougan	Michael	Massachusetts General Hospital	Genentech, Novartis	C, G	Speaker
Drezner	Nicole	FDA	No Relationships		Speaker
Hafler	David	Yale Univ. School of Medicine	No Relationships		Speaker
Howard	Kristina	FDA	No Relationships		Speaker
Jaffee	Elizabeth	Johns Hopkins Sidney Kimmel Comp. Cancer Ctr.	Aduro Biotech, Amgen, BMS, Genocoea, Adaptive Biotech, DragonFly, Medimmune, CSTONE, Hertix, Corvus	A, G, O	Program Committee, Speaker
Johnson	Douglas	Vanderbilt-Ingram Cancer Ctr.	BMS, Array Biopharma, Incyte, Merck, Novartis	A, G	Speaker
Klatzmann	David	Sorbonne University	No Relationships		Speaker

Kozono	David	Dana-Farber Cancer Institute	ILTOO pharma	A,G,S	Speaker
Leboeuf	Nicole	Dana-Farber Cancer Institute	No Relationships		Speaker
Leighton	John	FDA	No Relationships		Speaker
Mancini	Marie	National Institute of Arthritis and Musculoskeletal and Skin Diseases	No Relationships		Program Committee
Marriette	Xavier	Bicetre Hospital, Paris-Sud University	BMS	H	Speaker
Martin	Sarah	American Association for Cancer Research	No Relationships		Staff
Milone	Michael	Univ. of Pennsylvania School of Medicine	Cabaletta Bio, Novartis	A,G,S	Speaker
Naidoo	Jarushka	Johns Hopkins University	No Relationships		Speaker
Porter	David	Univ. of Pennsylvania School of Medicine	Novartis, Genentech, Kite Pharma, Incyte	A,G,O	Speaker
Rosen	Antony	Johns Hopkins Medicine	No Relationships		Speaker
Santomasso	Bianca	Mem. Sloan Kettering Cancer Ctr.	Juno/Cellgene, Kite/Gilead, Novartis	C	Speaker
Schneider	Julie	FDA	No Relationships		Speaker
Schoenfeld	Jonathan	Dana-Farber Cancer Institute	Merck, BMS, Tilos	C,G	Speaker
Sen	Hatice Nida	NIH	No Relationships		Speaker
Sharon	Elad	National Cancer Institute	No Relationships		Program Committee
Sharpe	Arlene	Harvard Medical School	Merck, Boehringer Ingelheim, BMS, Bethyl Labs, Medarex, MedImmune, Amplimmune, EMD Serono, Becton Dickinson and Co., BioXcell, Cell Signaling Technology, Inc., Ventana Medical Systems, Inc., Exbio, Antibody Diagnostics, Biolegend, eBioscience, Inc., Miltenyi Biotec, Inc., Life Sciences Advanced Technologies, Novartis, Genentech, Roche, SQZ Biotech, Surface Oncology, Pfizer, Inc, Adapimmune, Ipsen, Seattle Genetics	A,C,G, H,S,O	Speaker
Sommers	Connie	National Cancer Institute	No Relationships		Program Committee
Trinchieri	Giorgio	National Cancer Institute	No Relationships		Speaker
Walkovich	Kelly	C.S. Mott Children's Hospital	No Relationships		Speaker

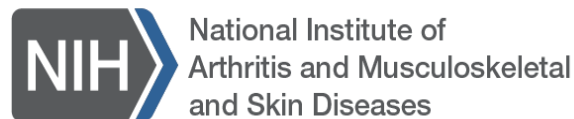
Wargo	Jennifer	UT MD Anderson Cancer Ctr.	Roche/Genentech, Novartis, AstraZeneca, GSK, BMS, Merck, Microbiome DX, Biothera Pharmaceuticals, Imedex, Dava Oncology, Omniprex, Illumina, Gilead, MedImmune, Patent Application	A, C, G, S B, O	Speaker
Warner	Blake	National Institute of Dental and Craniofacial Research	No Relationships		Speaker
Watowich	Stephanie	UT MD Anderson Cancer Ctr.	No Relationships		Speaker
Young	Howard	NCI-Frederick	No Relationships		Program Committee
Zheng	Pan	OncImmune & Univ. of Maryland, Baltimore	OncImmune, Inc.	E, G, S	Speaker



The National Cancer Institute leads, conducts, and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives.



The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.



The mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; the training of basic and clinical scientists to carry out this research; and the dissemination of information on research progress in these diseases.



The mission of the American Association for Cancer Research is to prevent and cure cancer through research, education, communication, collaboration, funding, and advocacy. Through its programs and services, the AACR fosters research in cancer and related biomedical science; accelerates the dissemination of new research findings among scientists and others dedicated to the conquest of cancer; promotes science education and training; and advances the understanding of cancer etiology, prevention, diagnosis, and treatment throughout the world.