SITC Crisis in Clinical Research Virtual Summit

Aug. 17, 2022 • 10:00 a.m.-3:30 p.m. EDT

Society for Immunotherapy of Cancer
# Table of Contents

## Welcome

Message from the Organizers ................................................................. 2

## Summit Information

Summit Information .................................................................................. 3
Schedule ...................................................................................................... 4
Organizers .................................................................................................. 6
Panelists ...................................................................................................... 9
Conflicts of Interest ................................................................................... 16

## Additional Resources

About SITC ............................................................................................... 19
Message from the Organizers

Dear Colleagues,

Welcome to the Society for Immunotherapy of Cancer (SITC) Crisis in Clinical Research Virtual Summit!

Thank you for attending this critical event. The SITC leadership group tasked with strategizing SITC’s response to the crisis in clinical research has worked rapidly to construct a program that leads to a national conversation on barriers that are limiting our ability to conduct clinical research.

While many of the barriers we will discuss today existed before the COVID-19 pandemic, the pandemic exacerbated these barriers and served as major disruption to staffing and standardized processes, severely limiting clinical trial accrual across the globe. Despite the evolution of the pandemic, clinical research continues to struggle and lag behind historical metrics. Through our exploratory and pre-summit conversations, it became clear this “crisis” is at a breaking point. If these issues are not addressed, we face a significant threat to advancement of new therapeutics, affecting both patients and early career researchers.

Today we will hear from site investigators, contract research organizations, industry and government, including the FDA and NCI, to begin a conversation on a multitude of clinical research barriers. Discussion topics include data collection and entry, regulatory processes, study inefficiencies, and current business models.

We want to be clear that this summit serves only as the first step in a long road toward increasing clinical research efficiency and enhancing patient access and outcomes. Our leadership group is committed to working with today’s participants on future efforts that will ensure implementation of real change. We look forward to interacting with you as these projects move forward, and encourage you to continue the discussion during and after the summit by using the hashtag #SITCresearchsolutions.

Again, thank you for your participation during today’s summit. We are grateful for all of our presenters and attendees who understand the importance of today’s topics. We hope you find today’s discussions enlightening and look forward to uniting over solutions with you in the future.

Sincerely,

Leisha Emens, MD, PhD
UPMC Hillman Cancer Center

Marc Ernstoff, MD
National Cancer Institute

David Feltquate, MD, PhD
Palleon Pharma

Michael S. Gordon, MD
Honor Health

Kristen Hege, MD
Bristol Myers Squibb

David Hong, MD
MD Anderson Cancer Center

Krystyna Kowalczyk
OncoBay

Mario Szol, MD
Yale University

Stephanie Terzulli, PhD
Memorial Sloan Kettering Cancer Center

Marc Theoret, MD
US Food and Drug Administration
Summit Information

Overview

The Society for Immunotherapy of Cancer (SITC) is holding a Crisis in Clinical Research Virtual Summit on Wednesday, Aug. 17, from 10 a.m.–3:30 p.m. EST. This free virtual summit will convene key oncology experts from academia, industry and government, including the FDA and NCI, to lead a conversation around what’s become a crisis in clinical research – limited patient access and slowed drug development due to staffing shortages, administrative burden, and current business models.

Through discussions with key stakeholders in academia, industry, and government, it has become apparent that this crisis is having a significant negative impact on cancer drug development and patient care, which threatens advancement of the field for years to come. Leveraging its convening powers, SITC is leading the national conversation around this crisis and is committed to finding collaborative solutions that ultimately reduce the administrative burden of clinical trials while increasing patient access to safe and effective clinical trials.

An initial step in addressing the crisis in clinical research is to host a multi-stakeholder virtual summit with oncologists, administrators, the NCI, the FDA, pharmaceutical companies, contract research organizations, and other major oncology professional organizations. The summit will further delineate the current staffing and administrative issues for oncology clinical trials, as well as consider alternative clinical trials administrative models to reduce the current burden.

Envisioned as a first step to address the nationwide crisis, the virtual summit will result in a whitepaper detailing the issues and potential solutions as well as work toward an actionable plan forward.

Program Organizers

Leisha Emens, MD, PhD – UPMC Hillman Cancer Center
Marc Ernstoff, MD – National Cancer Institute
David Feltquate, MD, PhD – Palleon Pharma
Michael S. Gordon, MD – Honor Health
Kristen Hege, MD – Bristol Myers Squibb
David Hong, MD – MD Anderson Cancer Center
Krystyna Kowalczyk – OncoBay
Mario Sznol, MD – Yale Cancer Center
Stephanie Terzulli, PhD – Memorial Sloan Kettering Cancer Center
Marc Theoret, MD – US Food and Drug Administration
### Schedule

Aug. 17, 2022: Crisis in Clinical Research Virtual Summit *EDT*

#### Setting the Stage and Defining the Problem

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| 10:00–11:00 a.m. | Welcome, Setting the Stage, and Defining the Problem  
Mary Dean, JD, CAE – Society for Immunotherapy of Cancer  
Mario Sznol, MD – Yale Cancer Center |
| 10:12–10:24 a.m. | Site Investigator Perspective on Crisis  
Patricia LoRusso, DO – Yale Cancer Center |
| 10:24–10:36 a.m. | Sponsor Perspective on Crisis  
David Feltquate, MD, PhD – Palleon Pharma |
| 10:36–10:48 a.m. | Clinical Research Organization Perspective on Crisis  
Krystyna Kowalczyk - OncoBay |
| 10:48–11:00 a.m. | Regulatory Perspective on Crisis  
Marc Theoret, MD – US Food and Drug Administration |
| 11:00–11:15 a.m. | Break |

#### Panel 1: Streamlining Data Collection and Entry

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| 11:15–11:55 a.m. | Chair: Stephanie Terzulli, PhD – Memorial Sloan Kettering Cancer Center  
Michael Buckley, MD – Memorial Sloan Kettering Cancer Center  
Edward Cha, MD, PhD – Genentech  
Tess Cummings, RN, DBA – UPMC Hillman Cancer Center  
Jason Luke, MD, FACP – UPMC Hillman Cancer Center  
Jeffrey Moscow, MD – National Cancer Institute  
Danelle Palmer, MBA – OncoBay  
Leonard Sacks, MD – US Food and Drug Administration |

#### Panel 2: Reducing the Burden of Scientific Review and Maximizing Efficiency in Meeting Regulatory Requirements

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| 11:55 a.m.–12:35 p.m. | Chair: Marc Ernstoff, MD – National Cancer Institute  
Chris A. Learn, PhD, PMP – Paraxel  
Lacey McQuinn Renard, MPH – MD Anderson Cancer Center  
Leonard Sacks, MD – US Food and Drug Administration  
Alex Spira, MD, PhD, FACP – US Oncology  
Charles Theuer, MD, PhD – Tracon Pharma |
| 12:35–12:40 p.m. | Break |
Schedule

Panel 3: Increasing Efficiency in Study Activation and Conduct

**Time:** 12:40–1:20 p.m.

Chair: David Hong, MD – *MD Anderson Cancer Center*
David Feltquate, MD, PhD – *Palleon Pharma*
Heidi D. Finnes, PharmD, BCOP, FHOPA – *Hematology/Oncology Pharmacy Association*
Jamie Harper, MHA, CCRP – *WCG*
Collette Houston – *Memorial Sloan Kettering Cancer Center*
Jeffrey Infante, MD – *Janssen*
Patricia LoRusso, DO – *Yale Cancer Center*
Jose Lutzky, MD – *University of Miami*
Leonard Sacks, MD – *US Food and Drug Administration*
Elad Sharon, MD, MPH – *National Cancer Institute*
James Yao, MD – *MD Anderson Cancer Center*

Panel 4: Changing the Clinical Trial Business Model

**Time:** 1:20–2:00 p.m.

Co-chair: Michael Gordon, MD – *Honor Health*
Co-chair: Krystyna Kowalcyz – *OncoBay*
Leisha Emens, MD, PhD – *UPMC Hillman Cancer Center*
David Hong, MD – *MD Anderson Cancer Center*
Shaheen Limbada – *Veristat*
John Powderly, MD – *Carolina BioOncology Institute*
Leonard Sacks, MD – *US Food and Drug Administration*
Sandy Smith, RN, MSN, AOCN – *WCG*
Howard Streicher, MD – *National Cancer Institute*
Charles Theuer, MD, PhD – *Tracon Pharma*

2:00–2:45 p.m. **Lunch Break**

Panel Presentations and Debrief on Future Directions

**Time:** 2:45–3:30 p.m.

**Panel Presentations and Debrief on Future Directions**
Leisha Emens, MD, PhD – *UPMC Hillman Cancer Center*
Marc Ernstoff, MD – *National Cancer Institute*
Michael S. Gordon, MD – *Honor Health*
David Hong, MD – *MD Anderson Cancer Center*
Krystyna Kowalcyz – *OncoBay*
Mario Sznol, MD – *Yale Cancer Center*
Stephanie Terzulli, PhD – *Memorial Sloan Kettering Cancer Center*
Marc Theoret, MD – *US Food and Drug Administration*
Organizers

Leisha Emens, MD, PhD

UPMC Hillman Cancer Center

Leisha A. Emens, M.D., Ph.D., is a Professor of Medicine at the UPMC Hillman Cancer Center. She received her MD/PhD in the Medical Scientist Training Program (MSTP) at Baylor College of Medicine, and completed postgraduate training at the National Cancer Institute, the University of Texas at Southwestern, and Johns Hopkins University. She joined the faculty at Johns Hopkins University in 2001, where she rose to the rank of Associate Professor of Oncology before joining the UPMC Hillman Cancer Center. She is a medical oncologist focused on breast cancer and is internationally recognized for her work in breast cancer immunotherapy. She developed a breast cancer vaccine, has most recently played a key role in the development of the anti-PD-L1 agent atezolizumab, resulting in accelerated FDA approval for advanced triple negative breast cancer. Dr. Emens was a member of the FDA Advisory Committee on Cellular, Tissue, and Gene Therapies (CTGTC) 2012-2016. She is an active member of ASCO, AACR, and SITC, and is a member of the Cancer Immunology (CIMM) Steering Committee of the AACR. Dr. Emens currently serves as Vice President of the Society for Immunotherapy of Cancer (SITC), and section editor for Journal for the Immunotherapy of Cancer (JITC). Dr. Emens has received the President’s Award by the YWCA of Greater Baltimore, the Maryland Governor’s Citation, the Sy Holzer Immunotherapy Research Award, and the Stand Up to Cancer Laura Ziskin Prize in Breast Cancer Translational Research.

David Feltquate, MD, PhD

Palleon Pharma

David Feltquate, M.D. Ph.D. has over 20 years’ experience in academia and industry including roles in biotech and big pharma companies. David is currently the Chief Medical Officer at Palleon Pharmaceuticals. Prior to this, David held a range of leadership roles in big pharma including in order of recency: Global Head of Hematology Development and Chair of the Precision Medicine Leadership Team at Novartis; Head of Oncology Early Clinical Development and Development Leader for Ipilimumab/Nivolumab Life Cycle Management at BMS; Nivolumab Clinical Head where David was responsible for the clinical development of nivolumab, the first PD1 inhibitor, from proof of concept through initial registrations in non-small cell lung cancer, melanoma, and renal cell carcinoma. David earned a B.S. in biology from MIT and an M.D./Ph.D. (Immunology) from UMass Medical School. He completed internal medicine training at Dartmouth Hitchcock Medical Center and medical oncology training at Memorial Sloan-Kettering Cancer Center.

Marc Ernstoff, MD

National Cancer Institute (NCI)

Dr. Marc Ernstoff joined the NCI Division of Cancer Treatment and Diagnosis, Developmental Therapy Program in 2020 as Medical Officer and the new Chief of the ImmunoOncology Branch. He has over 40 years experience in studying the immunobiology of human cancer and the development of new immune therapies. Dr. Ernstoff did his Medical Oncology and cancer immunology training at Yale University where he stayed as an Assistant Professor of Medicine prior to joining the medical oncology and translational immunotherapy program at the University of Pittsburgh Cancer Institute. Much of his career was spent at Dartmouth College’s Geisel School of Medicine where he was Section Chief of Hematology/Oncology and the Deputy Director of the Norris Cotton Cancer Center. He was also the Director of the Melanoma Program at the Cleveland Clinic. Prior to joining NCI, he was Professor and Chair, Department of Medicine, Senior Vice President for Clinical Investigation, The Katherine Anne Gioia Chair of Medicine at Roswell Park Comprehensive Cancer Center. He published over 250 original research manuscripts in the areas of renal cell cancer, melanoma and immune therapy strategies including cytokine therapies, dendritic cell vaccines, immune checkpoint inhibition, targeted therapies and ex vivo expanded effector cells for adoptive transfer.

Michael S. Gordon, MD

Honor Health

Dr. Michael S. Gordon specializes in medical oncology and hematology, and his principle interests have been in the development of new cancer therapies with a focus on targeted therapies as well as drugs that affect angiogenesis (tumor blood vessel supply). His disease focuses include kidney cancer, melanoma, prostate cancer, gastrointestinal stromal tumor (GIST) and ovarian cancer. Dr. Gordon currently serves as the Chief Medical Officer at HonorHealth Research & Innovation Institute.
Organizers

Kristen Hege, MD

*Bristol Myers Squibb*

Dr. Hege joined Celgene in September, 2010 as the San Francisco Site Head and Vice President, Translational Development, Hematology & Oncology. She has oversight of the translational development operations group and phase 1 cancer clinical programs focused on next generation kinase inhibitors, IMiDs, epigenetic therapies and immunotherapy. She participates in the management of Celgene alliances with companies focused on cancer immunotherapies and other early phase cancer programs. Prior to joining Celgene, Dr. Hege worked in a consulting capacity as Acting Chief Medical Officer for several West Coast biotechnology start ups including Aragon, Theraclone, Cellerant and the Cancer Vaccine Company, focused on small molecule, antibody and cell-based therapies for cancer and infectious diseases. In addition, Dr. Hege spent 14 years at Cell Genesys, ultimately as Vice President, Clinical Research and Development and a member of the executive team. At Cell Genesys she was responsible for early and late-stage clinical development, clinical operations, biometrics and drug safety. Programs focused on cancer immune and gene therapies, including engineered “CAR” T cells, cancer vaccines, and oncolytic viruses.

In addition to her biotechnology experience, Dr. Hege holds an active faculty appointment at the University of California, San Francisco (UCSF) where she is an Associate Clinical Professor of Medicine, Division of Hematology/Oncology. She served as attending physician on the inpatient leukemia/BMT service for 12 years and continues to see outpatients with benign and malignant hematologic disorders weekly.

Dr. Hege holds active board certification in Hematology and Medical Oncology. She received her MD from UCSF, Internal Medicine training at the Harvard-affiliated Brigham & Women's Hospital, and Hematology & Oncology fellowship training at UCSF. Academic honors include graduation from Dartmouth College summa cum laude and election to the Phi Beta Kappa and Alpha Omega Alpha Academic and Medical Honor Societies. She is an active member of the American Society of Hematology, American Society of Clinical Oncology, American Association of Cancer Research and Society for the Immunotherapy of Cancer. She is an Associate Editor of the Journal of Immunotherapy of Cancer, an active member of the PhRMA Translational Development Advisory Committee, BayBio Board of Directors, Flexus Biotechnology Board of Directors (Observer), Immune Design Clinical Advisory Board and immediate Past Chairperson of the Executive Leadership Committee for the Leukemia and Lymphoma Society San Francisco Light the Night event.

David Hong, MD

*MD Anderson Cancer Center*

Dr. David S. Hong is a Professor, Deputy Chairman in the Department of Investigational Cancer Therapeutics (Phase I Program), Clinical Medical Director of the Clinical Translational Research Center (CTRC), and Associate Vice President of Clinical Research at The University of Texas MD Anderson Cancer Center.

Dr. Hong was instrumental in forming one of the largest and most innovative Phase 1 clinical trial units in the world, with over 1300 patients enrolled in clinical trials in FY2021 and over 400 active ongoing clinical trials.

Dr. Hong has been the Principal Investigator of over 120 research protocols that involve a wide range of sponsors, including the Cancer Therapy Evaluation Program (CTEP) at the National Cancer Institute. He has published over 374 publications in Peer-reviewed Journals such as NEJM, Lancet Oncology, JCO and Nature.

He has been involved in the early development of cabozantinib, siltuximab, dabrafenib, trametinib, regorafenib, lenvatinib, larotrectinib, tesotumab vendotin, and sotorasib the first drug to target KRAS that have led to FDA approval.

He has also helped found 2 companies OncoResponse and Telperian.

He is an expert on c-Met, NTRK, KRAS, and adoptive cellular therapy in solid tumors and has led several national trials such as the c-Met amplified, c-Met exon 14 deleted, and NTRK arms of the NCI-MATCH trial. He been awarded the ASCO Young Investigator Award, the Jesse Jones award, Best Boss award at MD Anderson, Irwin Krakoff Award for Clinical Research, and the Gerald P. Bodey award for education and Mentor of the year award in the Division of Cancer Medicine, MD Anderson.

Krystyna Kowalczyk

*OncoBay*

Krystyna has spent over 25 years in leadership roles in small and large CROs with extensive COO-level experience building operational teams and leading global trial execution. Throughout her career, she has focused on creating an environment of opportunity and hope for patients with cancer and other rare diseases. Now leading OncoBay Clinical, Krystyna continues her mission to change the paradigm of clinical trial operations and patient access through technology and innovation.
Organizers

Mario Sznol, MD  
Yale Cancer Center

Dr. Mario Sznol is a Professor of Medicine (Medical Oncology). Dr. Sznol, formerly with the National Cancer Institute, has an international reputation in cancer drug development. Dr. Sznol's expertise and experience is in cancer immunotherapy, drug development for cancer, and treatment of patients with melanoma and renal cell carcinoma. He is working to expand the opportunities for clinical trials at the Yale Cancer Center, particularly those focusing on immunotherapy and novel agents.

Stephanie Terzulli, PhD  
Memorial Sloan Kettering Cancer Center

Stephanie Terzulli serves as Vice President of Clinical Research Operations in Clinical Research Administration (CRA) at Memorial Sloan Kettering. In this role, she oversees clinical research operations, administration, education, and information and technology. Previously, Stephanie was CRA’s Director, Protocol Operations and Director, Protocol Core Services. In earlier roles at MSK, she served as Program Manager of the Center for Mechanism Based Therapy, and Clinical Research Manager of the Immunotherapeutics Core. Prior to joining MSK in 2006, Stephanie held scientific appointments at Pall Corporation, and the Institute for Scientific Research (Staten Island, NY). Stephanie received her PhD from St. John's University, where her thesis work focused on the role of DNA transcription factors and DNA supercoiling in the expression of acid-inducible genes in Escherichia coli.

Marc Theoret, MD  
US Food and Drug Administration

Marc Theoret Deputy Director Oncology Center of Excellence (OCE) US FDA Dr. Marc Theoret is a medical oncologist and serves as Deputy Director in the Oncology Center of Excellence (OCE), FDA, and Acting Supervisory Associate Director of Oncology Sciences in the Office of Oncologic Diseases (OOD), Center for Drug Evaluation and Research, FDA. Dr. Theoret earned his medical degree from the Penn State College of Medicine. He completed internship and residency training in Internal Medicine at the Beth Israel Deaconess Medical Center in Boston, and fellowship training in Hematology and Oncology at the National Cancer Institute (NCI) in Bethesda. While a medical student as a Howard Hughes Medical Institute-National Institutes of Health (NIH) Medical Student Research Fellow and subsequently during fellowship training, he performed basic and translational clinical research in the Surgery Branch, NCI, to investigate novel immunotherapeutic strategies to treat patients with melanoma and other advanced solid tumors.
Panelists

Michael Buckley, MD  
*Memorial Sloan Kettering Cancer Center*

Michael is the manager of enterprise innovation in the clinical research informatics and technology division of the clinical research administration. Michael’s focus is on technologically innovative projects to improve the efficiency of clinical trial conduct, refine processes to simplify clinical trial data acquisition, and reduce the time and effort required for the completion of all stages of clinical trial work ranging from aligning and consenting patients through data analysis.

Edward Cha, MD, PhD  
*Genentech*

Dr. Edward Cha is the Global Development Leader for GI cancers in Product Development Oncology at Genentech, South San Francisco. He leads the clinical development for Tecentriq and combination therapies in multiple GI cancers, including hepatocellular carcinoma, gastroesophageal, pancreatic and colorectal cancers. His additional areas of focus are the development of novel combinations, innovative clinical study designs, and clinical collaborations. He is the medical lead for the Morpheus combinations platform, a series of clinical studies exploring combination therapies in oncology.

Ed received his MD and PhD from Columbia University and an AB degree in Molecular Biology from Princeton University. Prior to his current position, he was an oncology and postdoctoral fellow at the University of California, San Francisco, where he focused on melanoma, combination therapies, and biologic markers of response to immune therapies.

Tess Cummings, RN, DBA  
*UPMC Hillman Cancer Center*

Dr. Theresa (Tess) Cummings is joining UPMC in the role of Vice President of Clinical Research for Hillman’s Comprehensive Cancer Center. She has previously served as the Director of Clinical Protocol Office at Lineberger Comprehensive Cancer Center at UNC and at the University of Maryland’s Greenebaum Comprehensive Cancer Center. During her 20+ career in clinical research she has also lead several Contract Research Organizations Phase 1 Healthy Normal Volunteer clinics as well as served as Vice Chairperson and Board Member at Advarra IRB. Tess holds a bachelor’s degree in nursing from Georgetown University, an MS in Nursing Education from University of Maryland School of Nursing and a Doctorate in Business Administration from University of Maryland Global Campus.

Heidi D. Finnes, PharmD, BCOP, FHOPA  
*Hematology/Oncology Pharmacy Association (HOPA)*

Heidi D. Finnes, PharmD, BCOP is the Senior Manager Pharmacy Cancer Center Research at the Mayo Clinic Comprehensive Cancer Center in Rochester, MN. Dr. Finnes obtained her Doctor of Pharmacy degree from Drake University and has obtained her Board Certification in Oncology Pharmacy. Dr. Finnes is the Director of the Mayo Clinic Cancer Center Pharmacy Shared Resource and provides input on oncology clinical trials during protocol development and offers recommendations for therapy and supportive care via a Medication Therapy Management Clinic. She is the Chair of the Alliance for Clinical Trials in Oncology Pharmacy Committee and is the 2022-2023 President of the Hematology Oncology Pharmacy Association (HOPA). She is a metastatic melanoma cancer survivor.

Jamie Harper, MHA, CCRP  
*WCG*

As Director, Site Engagement & Relations for WCG ThreeWire, Jamie Harper regularly develops and executes strategical solutions mitigating the challenges experienced at clinical research sites around the globe. Ms. Harper has 13 years of experience building successful clinical research programs at a large private oncology practice and developing appropriate study strategies that take into account the individual needs of each institution. As past president of the Society of Clinical Research Associates, she has well-rounded, real world knowledge of all aspects of a clinical trial with a focus on the site perspective.
Collette Houston

Memorial Sloan Kettering Cancer Center

My interests and dedication has been focused on the successful management of a Center-wide clinical research program ensuring the highest degree of quality while maintaining full compliance with the regulations. We optimize our efforts with strategic planning, dedicated resources, technology and an organizational structure focused on all critical aspects of human subjects research.

I have focused a significant portion of my career in the oversight and management of cancer clinical trials most recently focusing on all aspects of clinical research compliance including but not limited to protocol activation, Institutional Review Board and Privacy Board, adherence and management of federal regulatory compliance, IND/IDE management, multisite compliance including our Alliance Partners and quality assurance. My areas of expertise include federal regulations, process improvements, clinical trial management, quality management and the protection of human subjects.

Jeffrey Infante, MD

Janssen

Dr. Infante serves as the Global Head, Early Clinical Development and Translational Research at Janssen Oncology, leading the scientific strategy for clinical trials and translational research in Oncology early and late development.

Dr. Infante leads a team of physicians and scientists that design and conduct all the early phase cancer trials, spanning solid tumor and hematologic malignancies and ranging from first-in-human through proof-of-relevance. The early development team is also responsible for combination dose finding trials and all the clinical pharmacology studies that accompany our approved assets and those in registration.

Since joining Janssen Oncology in 2017 as Vice President, Oncology Early Development, Jeff has led a team that has delivered a robust portfolio, bringing nearly 20 new therapies to the clinic with more than 30 early phase clinical programs ongoing. Each of these programs have the potential to dramatically change clinical practice, bringing Janssen Oncology closer to its goal of the elimination of cancer.

Prior to joining Janssen, Dr. Infante spent over a decade at the Sarah Cannon Research Institute as a clinical investigator and board-certified medical oncologist. During his tenure, he served many roles, including Director, Drug Development Program where he provided physician leadership to the Drug Development Units in Nashville, Florida, Oklahoma, Denver, and London. He has expertise with multiple novel treatment platforms and has helped design and conduct many clinical studies ranging from first-in-human dosing through phase 3 registration trials.

Dr. Infante received his undergraduate and medical degrees from the University of Florida in 1994 and 1999, respectively, and finished his internal medicine residency at Parkland Memorial Hospital, University of Texas Southwestern Medical Center. He completed his fellowship in medical oncology at Johns Hopkins University School of Medicine in 2006. Concurrent with his fellowship, he undertook formal training in patient-oriented research and received a Master of Health Science degree in epidemiology at Johns Hopkins University’s Bloomberg School of Public Health.

Chris A. Learn, PhD, PMP

Parexel

MBA, North Carolina State University (ongoing), Industry Fellowship, The Hamner Institutes for Health Sciences, Post-doctoral Training, Division of Neurosurgery, Duke University, PhD, Microbiology and Immunology, Wake Forest University Graduate School of Arts and Sciences, B.S., Biology, Chemistry, Virginia Tech

Educated and trained in patient-oriented research and received a Master of Health Science degree in epidemiology at Johns Hopkins University School of Public Health.

Shaheen Limbada

Veristat

Shaheen Limbada is the Executive Vice President of Global Clinical Operations at Veristat. In this role, Shaheen oversees project management, clinical monitoring, site management, medical affairs, patient recruitment and post marketing pharmacovigilance. With over 20 years of experience running clinical trials, he excels in the areas of project delivery, clinical trial innovation, patient recruitment and retention, clinical study conduct and governance, drug safety monitoring, and decentralized trial solutions.

Panelists
Panelists

He joined Veristat through the acquisition of Topstone Research, a Canadian-based CRO that he co-founded and held the position of Managing Director. Prior to Topstone, he worked in clinical operations, project management and leadership roles at various clinical research organizations (CROs) and pharmaceutical firms including Leo Pharma, Cetero Research and AstraZeneca.

Mr. Limbada graduated from the University of Toronto and quickly began his career in clinical trials with AstraZeneca Canada Inc.

Patricia LoRusso, DO

Yale Cancer Center

Pat LoRusso brings more than 25 years of expertise in medical oncology, drug development, and early phase clinical trials. Prior to her Yale appointment, she served in numerous leadership roles at Wayne State University’s Barbara Karmanos Cancer Institute, most recently as director of the Phase I Clinical Trials Program and of the Eisenberg Center for Experimental Therapeutics.

Jason Luke, MD, FACP

UPMC Hillman Cancer Center

Jason J. Luke, M.D., F.A.C.P. is an Associate Professor of Medicine at the University of Pittsburgh and UPMC Hillman Cancer Center where he is the Director of the Immunotherapy and Drug Development Center and co-PI for the Pittsburgh UM1 LAO. Dr. Luke specializes in early phase drug development for solid tumors (particularly novel immunotherapeutics and biomarkers of immunotherapy activity) as well as the management of melanoma. Dr. Luke is one of the foremost international investigators in the realm of immuno-oncology, having led clinical trials of immunotherapies including but not limited to anti-PD1/L1, CTLA4, many secondary checkpoints, bispecific approaches (checkpoint, CD3 and cytokine), metabolism modifiers (IDO, A2Ar/CD73/CD39 and arginase), innate agonists of STING, TLRs and oncolytic virus as well as solid tumor cellular therapies (TCRs and CART). In melanoma, Dr. Luke has designed and led two practice changing trials determining the role of anti-PD1 + CTLA4 after initial anti-PD1 failure (compendium listed in the NCCN) and altering the landscape of melanoma oncology practice across dermatology, surgery and medical oncology via establishment of modern adjuvant therapy with anti-PD1 for node negative stage IIB/C disease (leading to FDA approval). Dr. Luke has been a major contributor toward the investigation of radiation and the microbiome in relation to cancer immunotherapy. Dr. Luke’s major translational research focus leverages large scale informatics to advance cancer immunotherapy. Dr. Luke received his M.D. from Rosalind Franklin University of Medicine and Science in Chicago. He then pursued internship and residency at the Boston University Medical Center followed by medicine and medical oncology fellowships at Weill Cornell Medical College and Memorial Sloan-Kettering Cancer Center in New York City. Following fellowship, Dr. Luke was a tenure-track, Type 1 Instructor in Medicine at Harvard Medical School as well as Staff Physician at the Dana-Farber Cancer Institute and Brigham and Women’s Hospital in Boston. Thereafter Dr. Luke was an Assistant Professor at the University of Chicago. Dr. Luke is currently Senior Editor at Clinical Cancer Research, Associate Editor at the Journal for Immunotherapy of Cancer and Skin Cancer Section Editor for the American Cancer Society journal Cancer. Dr. Luke is actively involved in several professional societies including SITC (where he sits on the Board of Directors), AACR, ASCO, and the Society for Melanoma Research, having served on the scientific program committees for each. Beyond the UM1, Dr. Luke has active funding as project 3 clinical co-leader of the Pittsburgh Skin Cancer P50 SPORE as well as multiple private and state awards with previous funding from NIH, DOD, ASCO, NCCN and other industry and private foundations. Dr. Luke has received several awards for research and clinical care including the Melanoma Research Foundation Humanitarian Award, Crain’s 40 under 40, DOD Career Development Award, Paul Calabresi Career Development in Clinical Oncology Award (K12), ASCO Merit Award as well as Young Investigator Awards from the Melanoma Research Alliance, the Cancer Research Foundation and the Conquer Cancer Foundation of ASCO.

Jose Lutzky, MD

University of Miami

Dr. Jose Lutzky is Director of Cutaneous Oncology, Cutaneous Site Disease Group Lead and Medical Director of the Clinical Trials Coordination Office at the University of Miami Sylvester Comprehensive Cancer Center in Miami, Florida. Dr. Lutzky graduated from Universidade Federal do Rio Grande do Sul Medical School, Brazil in 1980, completed his residency in Internal Medicine at Mount Sinai Medical Center in Miami and fellowship in Hematology/Oncology at Columbia University in New York. His main interest is the search for new treatments for melanoma and other cutaneous malignancies.
## Panelists

### Jeffrey Moscow, MD

**National Cancer Institute (NCI)**

Jeffrey A. Moscow, MD, joined the Investigational Drug Branch (IDB) in 2014 after serving part time since 2012, and became chief of IDB in 2018. He is a graduate of Harvard University and the Geisel School of Medicine at Dartmouth. He completed his pediatric residency at the University of Texas Southwestern in Dallas and a fellowship in pediatric hematology-oncology in the Pediatric Oncology Branch, NCI. Prior to joining CTEP, he was Children’s Miracle Network Professor of Pediatrics, Chief of Pediatric Hematology-Oncology, Vice Chair of Pediatrics, and co-leader of the Experimental Therapeutics Program of the Markey Cancer Center, all at the University of Kentucky. In addition to his role in IDB, Dr. Moscow serves as the program director of PDXNet, a Cancer Moonshot initiative to incorporate pre-clinical evidence developed with patient-derived models into NCI’s clinical drug development efforts; and as the NCI co-lead on the ComboMATCH Precision Medicine Initiative, a platform trial that will test promising targeted drug combinations in multiple clinical trials with a unified design.

### Danelle Palmer, MBA

**OncoBay**

Dannelle has 20 years of experience in Clinical Research, including Executive Leadership, project and portfolio management, and clinical monitoring, with the last 15 years focused on oncology research. Dannelle has experience with assets from first dose through marketing approval that drives unique insight into the critical impact of proper operations execution at each stage of development. Expertise and experience ranges from clinical development planning and regulatory consulting to leading studies from first in human through FDA and EMA approval. For the past 13 years, she has held executive level positions focused on portfolio leadership, strategic leadership, and customer relationship development.

### John Powderly, MD

**Carolina BioOncology Institute**

In 2005, Dr. John Powderly founded Carolina BioOncology Institute (CBOI), an independent community-based research clinic. It’s mission is to bring early phase clinical trials to cancer patients in Charlotte NC, the largest city in the US without a medical school. In 2005, he also founded BioCytics Inc. Human Applications Laboratory (HAL) incubated within CBOI. BioCytics mission is perform translational research to develop autologous cellular immunotherapies for point of care manufacturing. CBOI-BioCytics have grown to 40+ employees, with 31,000 sq ft with multiple large clean rooms, and built custom digital informatics solutions for its research operations. It is the only US based independent (privately held) phase I cancer clinic combined with a HAL cGMP IS07 clean room to enable leukapheresis, cellular manufacturing and phase 1 dosing “under 1 roof”. CBOI-BioCytics also offers CRO, CDMO, and IND enabling translational lab services to help small biotech companies develop their cell therapies. Under Dr. Powderly’s leadership, CBOI has opened > 160 early phase clinical trials, and led to 134 publications, including the New England Journal of Medicine, Journal of Clinical Oncology, Journal of Immunotherapy, Nature, Clinical Cancer Research, Clinical Chemistry, Investigational New Drugs, Science Translational Medicine. He is an adjunct Clinical Assistant Professor of Medicine at both Duke and UNC. In 2014 he was awarded the David King Community Scientist Award by the Association of Community Cancer Centers (ACCC). Some of his articles and presentations have been recognized as “top 50 most cited articles by JCO” and “top 10 most downloaded ASCO Video Presentations”, and “2015 Herbert Pardes Clinical Research Excellence Award.” Dr. Powderly’s research publications have been cited by >23,000 references in the scientific literature. He is currently also developing an autologous T cellular immunotherapy platform with BioCytics Inc, using autologous circulating tumor cells as the antigen source.

### Lacey McQuinn Renard, MPH

**MD Anderson Cancer Center**

Protocol Research Admin Director at The University of Texas MD Anderson Cancer Center within the Department of Investigational Cancer Therapeutics. Lacey has 15 years of clinical research experience specializing in Phase I regulatory operations and protocol administration.
Panelists

Leonard Sacks, MD

**US Food and Drug Administration**

Leonard Sacks received his medical education in South Africa, moving to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa and he joined the FDA in 1998 as medical reviewer in the Office of New Drugs. Subsequent positions included acting director of the Office of Critical Path Programs and associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research. In this capacity he has led efforts to support novel approaches to clinical trials including the use of electronic technology. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented on these topics. He holds academic appointments as Associate Clinical Professor of Medicine at George Washington University, and at the Uniformed Services University of the Health Sciences.

Elad Sharon, MD, MPH

**National Cancer Institute (NCI)**

Dr. Sharon oversees a large and productive portfolio of immunotherapy trials at CTEP. On a daily basis, he manages far-reaching clinical trials that encompass dozens of active Investigational New Drugs (INDs) and ongoing trials from Phase I through III. This clinical trial oversight directly impacts patient care, ranging from managing serious adverse events, patient eligibility, drug dosages and schedules. He has managed or co-managed one of the most active areas in the CTEP portfolio of trials, with an increasing proportion of CTEP trials including his agents or those of his close colleagues. Dr. Sharon has been extremely collaborative with his colleagues and assisted in boosting accrual to trials throughout his section and also assisting in drug development efforts in his section.

Dr. Sharon also serves as an attending physician in the Developmental Therapeutics Clinic (DTC), providing direct patient care for intramural NCI trials. He has also helped develop an immunotherapy trial (CTEP Trial 10204) to help serve as a platform to evaluate the use of immune checkpoint inhibitors in patients with pre-existing autoimmune diseases and a diagnosis of cancer. This large, multicenter effort in the Experimental Therapeutics Clinical Trials Network (ETCTN) is a multi-disciplinary clinical effort aimed at learning the effects of this new class of immunotherapy on patients with autoimmune conditions. Dr. Sharon is the national co-principal investigator for that effort along with Dr. Hussein Tawbi and Dr. Cathy Dumbrava of M.D. Anderson. Dr. Sharon, as both a CTEP and DTC physician, has overseen the trial of atezolizumab for patients with a rare sarcoma known as alveolar soft part sarcoma.

Since 2017, Dr. Sharon has served on the NCI Cancer Moonshot Adult Immunotherapy Implementation Team as co-chair of the committee. As part of this role, Dr. Sharon helped plan the initiatives that were endorsed before the NCI Board of Scientific Advisors. Much of this culminated in the Immuno-Oncology Translational Network (IOTN), whose grants were submitted in 2018, 2019, and 2020. These efforts are intended to accelerate immunotherapy research and eventually assist with drug development efforts for the NCI and the broader oncology community. In addition, Dr. Sharon has served as an advisor for several CTEP initiatives that have utilized Cancer Moonshot funds, including the Cancer Immune Monitoring and Analysis Centers (CIMACs) and the Cancer Immunologic Data Commons (CIDC). In addition, Dr. Sharon initiated the immune-related Adverse Event Biorepository initiative, which is now being implemented within the National Clinical Trials Network by the Alliance, led by Dr. David Kozono of Dana-Farber Cancer Institute. Dr. Sharon remains heavily engaged in that effort and other related projects evaluating immune-related adverse events. Both efforts reflect important initiatives in the field which the NCI is attempting to help advance.

Dr. Sharon is a nationally recognized expert in cancer treatment clinical trials, particularly in the emerging field of cancer immunotherapy clinical trial design. Since his arrival at the NCI, he has been a key participant in the design of clinical trials, including cancer immunotherapy trials, for agents in his portfolio. His NCI career has been devoted to the development of important early and late phase clinical trials designed to broaden access and bring new treatments to cancer patients.

Sandy Smith, RN, MSN, AOCN

**WCG**

Sandy works with research sites, sponsors, and patient advocacy groups in support of WCG's mission to accelerate the development of new medical therapies by improving the conduct and quality of clinical trials. She provides consultation to research sites by strategically aligning clinical solutions to improve and create efficient processes in the areas of ethical review, biosafety, trial initiation, research financial services, staffing augmentation, and support for investigator-initiated trials with DSMBs, clinical endpoints, and statistical consulting. Prior to joining WCG, Sandy was Vice-President of US Oncology Research, an oncology site management organization of independent practices and hospital research programs with approximately 1,000 investigators and 175 research sites.
Panelists

Alex Spira, MD, PhD, FACP

**US Oncology**

Dr. Alexander Spira earned his medical degree from the New York University School of Medicine. He then went on to complete his internship and residency at the Hospital of the University of Pennsylvania, and his medical oncology fellowship at Johns Hopkins Hospital. During his training, Dr. Spira was granted many awards and honors, and he completed several specialized fellowship programs. Among these honors were the National Institutes of Health Medical Scientist Training Program Fellowship (1990-1997), Merck Corporation Scholarship (1995-1995), Pediatric AIDS Foundation Fellowship (1993-1995) and Harvard University Scholarship (1987-1990). Dr. Spira has also received his PhD from the New York School of Arts and Sciences.

As Director of the Virginia Cancer Specialists (VCS) Research Institute and the Phase I Trial Program, Dr. Spira is actively involved in advancing medicine and offering targeted treatment options for patients. Although his research interests are numerous, Dr. Spira particularly enjoys studying immunotherapy, personalized medicine, GI, thoracic and lung cancer and sarcomas. Dr. Spira is also Co-Chair of the US Oncology Thoracic Oncology Committee, Chair of the US Oncology Research Executive Committee, and member of the US Oncology National Policy Board Executive Committee. Dr. Spira is a faculty member at Johns Hopkins School of Medicine, and serves as Assistant Professor of Oncology.

Howard Streicher, MD

**National Cancer Institute (NCI)**

Dr. Streicher received AB in physics from Cornell University and his medical degree from New York University. He completed an internship and residency training in Internal Medicine at the New York University-Bellevue Medical Center and New York Veterans Hospital. He was on active duty with the United States Naval Reserve and a faculty member at the John Burns School of Medicine. He completed training in immunology at the University of Colorado and the Metabolism Branch of the National Cancer Institute before joining the Laboratory of Tumor Immunology National Cancer Institute. As a member of the Investigational Drug Branch of CTEP his portfolio centers on immunotherapeutic agents including immune modulating agents, cytokines, vaccines, and IMIDs for the treatment of cancer.

Charles Theuer, MD, PhD

**Tracon Pharma**

Dr. Theuer has been CEO and President and a Director of TRACON Pharmaceuticals (NASDAQ: TCON) since 2006. Prior thereto, from October 2004 to July 2006, Dr. Theuer was Chief Medical Officer at TargeGen Inc., where he initiated the development of small molecule kinase inhibitors in oncology (including Inrebic® (fedratinib), a JAK2 inhibitor approved for myelofibrosis), ophthalmology and cardiovascular disease. From October 2003 to October 2004, Dr. Theuer was the Director, Clinical Oncology at Pfizer, where he led the clinical development of Sutent® (sunitinib) in kidney cancer; Sutent® was approved by the U.S. Food and Drug Administration in January 2006 for treating advanced kidney cancer. Prior thereto, Dr. Theuer held senior positions at IDEC Pharmaceuticals, from June 2002 to October 2003, and the National Cancer Institute developing other agents, including small molecules and monoclonal antibody therapies. Dr. Theuer holds a B.S. degree from the Massachusetts Institute of Technology, an M.D. degree from the University of California, San Francisco and a Ph.D. degree from the University of California, Irvine. He completed a residency in general surgery at Harbor-UCLA Medical Center and was Board Certified in general surgery in 1997. Dr. Theuer held academic positions at the National Cancer Institute and at the University of California, Irvine, where he was a member of the Division of Surgical Oncology and Department of Medicine. He serves as a Board member of TRACON Pharmaceuticals, 4D Molecular Therapeutics (NASDAQ: FDMT), and Oncternal Therapeutics (NASDAQ: ONCT) and the non-profit San Diego Squared which promotes STEM careers for underrepresented youth.

James Yao, MD

**MD Anderson Cancer Center**

James Yao, MD, is professor and chair of the Department of Gastrointestinal Medical Oncology at the University of Texas MD Anderson Cancer Center, Houston. He earned his medical degree from Baylor College of Medicine in Houston and completed a clinical fellowship in medical oncology at the University of Texas MD Anderson Cancer Center.

Dr. Yao’s clinical and translational research interests are focused on the development of novel clinical trials and the identification of biomarkers for patients with neuroendocrine tumors (NETs). As a clinical investigator, he has served as principal investigator on numerous national and international
Panelists

clinical trials for patients with gastrointestinal malignancies, including the phase III RADIANT-3 and RADIANT-4 studies, which advanced the standard of care for patients with advanced lung, pancreatic and gastrointestinal NETs. Dr. Yao leads the NCI funded Clinical Trial Rapid Activation Consortium (CTRAC) dedicated to accelerating clinical trial builds in EHR.

Dr. Yao serves on the National Cancer Institute (NCI) Investigational Drug Steering Committee and is a founding member and past Chairman of the North American Neuroendocrine Tumor Society. He is past chairman of the NCI Neuroendocrine Task Force and previously chaired the NCI Clinical Trial Planning Meeting for NETs.
Conflicts of Interest

The Society for Immunotherapy of Cancer requires instructors, planners, managers and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflicts of interest (COI) they may have as related to the content of this activity. All identified conflicts of interest are thoroughly vetted and resolved according to SITC policy.

Leisha Emens, MD, PhD

Consulting Fees: Genentech, F Hoffmann La Roche, Chugai, GPCR, Gilead, Immune Onc, Immutep, Shionogi, Mersana

Contracted Research: AbbVie, AstraZeneca, Bolt Therapeutics, Bristol Myers Squibb, Compugen, Corvus, CytomX, EMD Serono, Genentech, F Hoffmann La Roche, Immune Onc, Maxcyte, Merck, Next Cure, Silverback, Takeda, Tempest

Other: These are grants from non-industry entities, HeritX Incorporated, NSABP Foundation, Translational Breast Cancer Research Consortium, Breast Cancer Research Foundation, National Cancer Institute, Department of Defense, Johns Hopkins University, University of California San Francisco, Cornell University, Dana Farber Cancer Institute

Marc Ernstoff, MD

Nothing to disclose

David Feltquate, MD, PhD

Employed by: Palleon Pharma

Michael Gordon, MD

IP Rights: Caremission

Consulting Fees: Qualigen, MorphicTx, OnQuality, Viracta, Imaging Endpoints

Fees for Non CE Services: FirstThought

Contracted Research: Agenus, Arcus, Celldex, Corcept, Daiichi, Deciphera, Dynamicure, EMD Serono, Endocyte, Fore, Genentech, I-Mab Bio, IGM Biosciences, ImaginAB, Jubilant, Medimmune, Nektar, Nikang, Pfizer, Pionyr, Plexxicon, Revolution Medicine, Riboscience, Roche, Salarius, SQZ, Theseus, Tracon, Trishula, Vedanta, Veru, Redhill, Syndax, Fujifilm

Kristen Hege, MD

Employed by: Bristol Myers Squibb

IP Rights: Bristol Myers Squibb

David Hong, MD

Research[Inst]/Grant Funding (Inst) : AbbVie, Adaptimmune, Adlai-Nortye, Amgen, AstraZeneca, Bayer, Bristol Myers Squibb, Daiichi-Sankyo, Deciphera, Endeavor, Erasca, F. Hoffmann-La Roche, Fate Therapeutics, Genentech, Genmab, Immunogen, Infinity, Merck, Mirati, Navier, NCI-CTEP, Novartis, Numab, Pfizer, Pyramid Bio, Revolution Medicine, SeaGen, ST-Cube, Takeda, TCR2, Turning Point Therapeutics, VM Oncology

Travel, Accommodations, Expenses: Bayer, Genmab, AACR, ASCO, SITC, Telperian

Consulting, Speaker or Advisory Role: Adaptimmune, Alpha Insights, Acuta, Alkermes, Amgen, Aumbiosciences, Axiom, Baxter, Bayer, Boxer Capital, BridgeBio, COR2ed, COG, Cowen, Ecor1, F. Hoffmann-La Roche, Gennao Bio, Genentech, Gilead, GLG, Group H, Guidepoint, HCW Precision, Immunogen, Janssen, Libeirum, MedaCorp, Medscape, Numab, Oncologia Brasil, Orbi Captal, Pfizer, Pharma Intelligence, POET Congress, Prime Oncology, RAIN, Seattle Genetics, ST Cube, Takeda, Tavistock, Treizera Therapeutics, Turning Point, WebMD, YingLing Pharma, Ziopharm

Other ownership interests: Molecular Match (Advisor), OncoResponse (Founder, Advisor), Telperian (Founder, Advisor)

Krystyna Kowalcyk

Employed by: OncoBay

Mario Sznol, MD

Consulting Fees: Adaptimmune, Pfizer, Kadmon, Pierre-Fabre, Biond, Nextcure, Incyte, Alligator, Bristol Myers Squibb, Ocellaris, Simcha, Rootpath, Numab, Evolveimmune, Biontech, Immunocore, Glastra Smith Kline, Adagene, Asher, Kanaph, iTEOS, Genocea, Trillium, Sapience, Targovax, Molecular Partners, Ontario Institute for Cancer Research, Jazz Pharmaceuticals, Gilead, Innate Pharma, Tessa, Stcube, Oncosec, Regeneron, AstraZeneca, Agenus, Idera, Apexigen, Verastem, Rubius, Genentech-Roche, Boston Pharmaceuticals, Servier, Dragonfly, Boehringer Ingelheim, Nektar, Pieris, AbbVie, Zelluna, Seattle Genetics

Stephanie Terzulli, PhD

Nothing to disclose
## Conflicts of Interest

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<td><strong>Marc Theoret, MD</strong></td>
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<td><strong>Michael Buckley, MD</strong></td>
<td>Nothing to disclose</td>
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<td><strong>Edward Cha, MD, PhD</strong></td>
<td>Employed by: Roche/Genentech</td>
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<td><strong>Tess Cummings, RN, DBA</strong></td>
<td>Nothing to disclose</td>
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<td><strong>Heidi D. Finnes, PharmD, BCOP, FHOPA</strong></td>
<td>Nothing to disclose</td>
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<td><strong>Jamie Harper, MHA, CCRP</strong></td>
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<td><strong>Jeffrey Infante, MD</strong></td>
<td>Employed by: Janssen</td>
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<td><strong>Chris A. Learn, PhD, PMP</strong></td>
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<td><strong>Shaheen Limbada</strong></td>
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<td><strong>Patricia LoRusso, DO</strong></td>
<td>Consulting Fees: AbbVie, Agios, Five Prime, GenMab, Halozyme, Genentech, CytomX, Takeda, SOTIO, Cybrexa, Agenus, Tyme, IQVIA, TRIGR, Pfizer, ImmunoMet, Black Diamond, Glaxo-Smith Kline, QED Therapeutics, AstraZeneca, EMD Serono, Shattuck, Astellas, Salarius, Silverback, MacroGenics, Kyowa Kirin, Kineta, Zentalis, Molecular Templates, ABL Bio, SK Life Science, STCube, Bayer, I-Mab, Seagen, imCheck, Relay, Stemline, Compass BADX, Mekanist, Merseana, BAKK Therapeutics, Scenic Biotech, Qualigen, Roivant, NeuroTrials</td>
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**Jason Luke, MD, FACP**
- IP Rights: Serial #15/612,657 (Cancer Immunotherapy), PCT/US18/36052 (Microbiome Biomarkers for Anti-PD-1/PD-L1 Responsiveness: Diagnostic, Prognostic and Therapeutic Uses Thereof)
- Consulting Fees: Fstar, RefleXion, Xilio AbbVie, Alnylam, Bayer, Bristol Myers Squibb, Checkmate, Crown, Cstone, Eisai, EMD Serono, Flame, Genentech, Gilead, Kadmon, KSQ, Janssen, Immunocore, Inzen, Macrogenics, Merck, Mersana, Nektar, Novartis, Pfizer, Regeneron, Ribon, Rubius, Silicon, Synlogic, TRex, Werewolf, Xencor
- Contracted Research: AbbVie, Agios (IIT), Array (IIT), Astellas, Bristol Myers Squibb (IIT & industry), Corvus, EMD Serono, Fstar, Genmab, Ikona, Immatics, Incyte, Kadmon, KAHR, Macrogenics, Merck, Moderna, Nektar, Numab, Replimmune, Rubius, Spring bank, Synlogic, Takeda, Trishula, Tizona, Xencor

**Jose Lutzky, MD**
- Consulting Fees: Castle, Regeneron, Replimune, Iovance, Sapience
- Contracted Research: Bristol Myers Squibb, Replimune, Novartis, Regeneron, Immunocore, Iovance, InstilBio, Takeda, Dragonfly, Agenus, Vyriad

**Jeffrey Moscow, MD**
- Nothing to disclose

**Danelle Palmer, MBA**
- Employed by: OncoBay
Conflicts of Interest

John Powderly, MD
Employed by: Carolina BioOncology Institute, PLLC
IP Rights: BioCytics Inc.
Consulting Fees: Macrogenics, Aavocyte, Affinant, Phanes Therapeutics, AbbVie, Top Alliance, TBP Therapeutics, Boxer Capital, ModernaTX
Contracted Research: Aavocyte, AbbVie, Adagene, Alkermes, Apros, Arcus BioSciences, AstraZeneca-Medimmune, Atreca, BJ BioScience, Bristol Myers Squibb, Calico Life Sciences, Conjupro BioTherapeutics, Cullinan, EMD Serono, FLX Bio/ RAPT Therapeutics, Genentech/Roche, I-MAB Pharma, Immune-Onc, InCyte, Jounce Therapeutics, Macrogenics, Merck, Molecular Templates, MT Group, NexCure, Nuvation, PIOMA, Precision for Medicine, Repertoire Immune Medicines, Replimmune, Seattle Genetics, Sequenom, StemCell Technologies, Tempest Therapeutics, Top Alliance BioScience, Trethera, Xilis Therapeutics, Xilis, Zenshine Pharma, Moderna TX, RiboScience, Pieris, CUE BioPharma, PEEL Therapeutics,
Other: BioCytics is developing intellectual property for point of care cell therapies.

Alex Spira, MD, PhD, FACP
Employed by: NEXT Oncology-Virginia
Consulting Fees: Incyte, Amgen, Novartis, Mirati Therapeutics, Gritstone Oncology, Jazz Pharmaceuticals, Takeda, Janssen Research & Development, Mersana, Gritstone Bio, Daiichi Sankyo/AstraZeneca, Regeneron, Array Biopharma, AstraZeneca/MedImmune, Merck, Bristol Myers Squibb, Blueprint Medicines
Contracted Research: LAM Therapeutics, Regeneron, Roche, AstraZeneca, Boehringer Ingelheim, Astellas Pharma, Medimmune, Novartis, Newlink Genetics, Incyte, AbbVie, Ignyta, Trovagene, Takeda, Macrogenics, CytomX Therapeutics, Astex Pharmaceuticals, Bristol Myers Squibb, Loxo, Acer Therapeutics, Gritstone, Plexxicon, Amgen, Daiichi Sankyo, ADCT, Janssen Oncology, Mirati Therapeutics, Rubius, Synthekine, Mersana, Blueprint Medicines, Alkermes, Revolution Medicines
Other: Honorarium, CytomX Therapeutics, AstraZeneca/ Medimmune, Merck, Takeda, Amgen, Janssen Oncology, Novartis, Bristol-Myers Squibb, Bayer

Howard Streicher, MD
Nothing to disclose

Charles Theuer, MD, PhD
Employed by: TRACON Pharmaceuticals
IP Rights: TRACON Pharmaceuticals
Consulting Fees: TRACON Pharmaceuticals, 4D Molecular Therapeutics, Oncternal Therapeutics

James Yao, MD
Consulting Fees: Hutchison Medi Pharma, Crinetics Pharmaceuticals, Ipsen Biopharmaceuticals Inc, Amgen Inc, Chiasma Pharma
Fees for Non CE Services: Medscape
Other: Board of Directors, North American NeuroEndocrine Tumor Society
About SITC

The Society for Immunotherapy of Cancer (SITC) is the world’s leading member-driven organization specifically dedicated to professionals working in the field of cancer immunology and immunotherapy. Established in 1984, SITC is a 501(c)(3) not-for-profit medical professional society comprised of over 4,300 influential research scientists, physician scientists, clinicians, patients, patient advocates, government representatives and industry leaders dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy.

Through emphasis on high-caliber scientific meetings; dedication to education and outreach activities; focus on initiatives of major importance in the field; and commitment to collaborations with like-minded domestic and international organizations, government and regulatory agencies, associations and patient advocacy groups, SITC brings together all aspects of the cancer immunology and immunotherapy community. SITC aims to make cancer immunotherapy a standard of care and the word “cure” a reality for cancer patients everywhere.

Mission Statement

It is the mission of the society to improve cancer patient outcomes by advancing the science, development and application of cancer immunology and immunotherapy through our core values of interaction/integration, innovation, translation and leadership in the field.

Core Values

- Interaction/Integration: Facilitate the exchange of information and education among basic and translational researchers, clinicians, young investigators, patients, societies and groups sharing the mission of SITC
- Innovation: Challenge the thinking and seek the best research in the development of cancer immunotherapy
- Translation: Facilitate the transfer of cancer immunology and immunotherapy research from the bench to the clinic and back
- Leadership: Define what is new and important and effectively communicate it to all relevant stakeholders

Goals

- Education and Scientific Exchange: Serve as the leading resource for information and education on cancer immunotherapy
- Professional Standards: Set industry standards for the field of cancer immunotherapy in order to position SITC as the authority on immunotherapy of cancer
- Global Access and Impact: Advance the science and application of cancer immunotherapy worldwide
- Policy and Advocacy: Inform and influence the science and research, regulation, as well as quality of care and quality of access impacted by public policy, ensuring the patient voice is heard and recognized
- Science and Research: Challenge the thinking and seek the best research in the exploration and development of tumor immunology and cancer immunotherapy
- Leadership Development: Cultivate the next generation of leaders and innovators in tumor immunology and cancer immunotherapy
About SITC

**Disease States Represented by SITC Constituents**

SITC covers the full spectrum of both solid tumors and hematologic malignancies including:

- Bladder
- Brain/Central Nervous System
- Breast
- Colon/Rectum
- Genitourinary
- Glioblastoma
- Gynecological
- Head and Neck
- Leukemia
- Liver
- Lung
- Lymphoma
- Melanoma
- Mesothelioma
- Myeloma
- Neuroblastoma
- Pan-tumor
- Pancreas
- Prostate
- Renal

**Sample of Medical Specialties Represented by SITC Constituents**

- Antibody-Based Therapies
- Biochemistry
- Bioinformatics
- Biostatistician
- Cellular Biology
- Cellular Therapies
- Clinical Investigations/Clinical Trials
- Computational Biology
- Cytokines
- Dermatology
- Drug Development
- Endocrinology
- Gastroenterology
- Genetics and Genomics
- Gynecologic Oncology
- Hematology
- Immunology
- Immuno-Oncology
- Immunotherapy
- Internal Medicine
- Medical Oncology
- Microbiology and Infectious Diseases
- Molecular Biology
- Neuro-oncology
- Oncolytic Virus/Vaccines
- Pathology
- Pediatric Oncology
- Pharmacology/Toxicology
- Proteomics
- Radiation Biology/Radiation Oncology
- Research Administration
- Stem Cell Biology
- Surgical Oncology
- Transplantation
- Urology
Experience the Best of SITC
SITC 2022 is the premiere immuno-oncology conference, featuring the latest research from early career scientists and luminaries in the field.

SITC 2022 Keynote Speaker and Richard V. Smalley Memorial Award and Lectureship
SITC welcomes Padmanee Sharma, MD, PhD from The University of Texas MD Anderson Cancer Center as the Keynote Speaker. Her focus is on the mechanisms of response and resistance to immune checkpoint therapy.

SITC is also hosting a special panel to honor the work of Zelig Eshhar, PhD, the 2022 recipient of the Richard V. Smalley Memorial Award. Panel members include luminaries Carl June, MD, Crystal Mackall, MD, Steven Rosenberg, MD, PhD, and Michel Sadelain, MD, PhD.

Early Registration
Members and non-members can save on fees by registering early. Early Registration ends on Oct. 5, 2022 at 11:59 p.m. PT.

REGISTRATION NOW AT SITCANCER.ORG/2022
Members receive a discount on registration rates for both the Annual Meeting and Pre-Conference Programs. Not a member? Join today at sitcancer.com/join.

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#SITC22
Nov. 8-Nov. 12 | Boston, MA or Virtual
Apply to attend the SITC Clinical Immuno-Oncology Network (SCION) Workshop

JAN. 17-21, 2023, IN AUSTIN, TEXAS
AT&T HOTEL AND CONFERENCE CENTER

FEATURING EXPERT ORGANIZERS

• Elizabeth Garrett-Mayer, PhD – American Society of Clinical Oncology
• Isabella C. Glitza Oliva, MD, PhD – The University of Texas MD Anderson Cancer Center
• Michael Lotze, MD, FACS – Nurix Therapeutics
• Chris Takimoto, MD, PhD – IGM Biosciences

The Society for Immunotherapy of Cancer (SITC) Clinical Immuno-Oncology Network (SCION) Workshop is an intimate immunotherapy clinical trial development program, led by experts in the field who are equipped to help their assigned students navigate through the unique considerations that accompany immunotherapy treatments.

Designed to address the unique considerations for designing clinical trial protocols focused on cancer immunotherapy, the SCION Workshop connects participants with experienced faculty in the field and dedicated patient advocates to advise on clinical trial protocol development.

WHO SHOULD ATTEND?

• Eligible applicants are those working in the field of cancer immunotherapy who want to develop their own immunotherapy clinical trial protocol synopsis (resulting in an approved protocol and consent).
• This includes, but is not limited to, clinical fellows and junior faculty/attendings with medical, surgical, radiation, urologic, gynecologic, or pediatric oncology training and advanced degree scientists (e.g., Masters, PhD, PharmD, DNP) with research experience and interest in clinical and translational immuno-oncology.
• Applicants can be from academic, non-profit, or for-profit organizations, including the pharmaceutical industry/biotechnology.
• Those with other related professional degrees are also encouraged to apply.

This year, SITC will award one attendee the Dr. Martin “Mac” Cheever Excellence in Clinical Trial Design Travel Award. One awardee will be selected from the SCION participants for developing the most simple and elegant protocol. The awardee will receive travel reimbursement to the SITC 38th Annual Meeting & Pre-Conference Programs (SITC 2023).

Learn more and apply by Sept. 7, 2022, for the opportunity to attend. Learn more at sitcancer.org/SCION
YOUR FUTURE IS BRIGHT AT SITC!

Member benefits include:

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- Networking and Award opportunities
- Discounted article processing fees accepted to the *Journal for ImmunoTherapy of Cancer (JITC)*
- Scientific coverage of industry meetings

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