

**FDA-American Society of Clinical Oncology-Friends of Cancer Research
Workshop on Development of Tissue-Agnostic, Biomarker-Based Indications
Presenters and Speakers Bio sketch Information (Submitted as of April 24)**

Workshop Coordinators and Moderators

**Suanna Steeby Bruinooge, MPH
Division Director, Research and Analysis
Center for Research and Analytics (CENTRA)
American Society of Clinical Oncology**

Suanna Bruinooge, MPH, is the Division Director of Research Strategy and Operations in ASCO's Center for Research and Analytics (CENTRA). CENTRA generates, integrates, analyzes, and shares oncology data to foster innovation in research and patient care and help develop and evaluate ASCO's policy positions. CENTRA develops and implements ASCO's research agenda, including the Targeted Agent Profiling and Utilization (TAPUR) clinical trial and projects to advance clinical trial design and methodology. CENTRA also staffs ASCO's Cancer Research Committee, Research Community Forum, and Workforce Advisory Group.

Prior to joining ASCO, Suanna worked for seven and a half years in the U.S. House of Representatives, working for Congresswoman Nancy Johnson (R-CT) and Congressman Vernon Ehlers (R-MI). Ms. Bruinooge earned a Master's of Public Health in Health Policy at The George Washington University's Milken Institute School of Public Health in 2015. Suanna also has a B.A. in political science from Calvin College in Grand Rapids, MI.

**Mark Stewart, PhD
Vice President, Science Policy
Friends of Cancer Research (Friends)**

Mark Stewart serves as a Vice President, Science Policy at Friends of Cancer Research (Friends). Friends is an advocacy organization based in Washington, DC that drives collaboration and has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. Mark leads the development and implementation of the organization's research and policy agenda as well as overseeing the conduct of research projects to inform ongoing policy discussions. Mark establishes unique partnerships to help develop innovative policy proposals and consensus-driven solutions to address challenges and accelerate cancer drug development. He regularly participates in policy discussions and meetings throughout the year to help catalyze meaningful change for oncology healthcare. Mark Stewart received his PhD in cancer biology from the University of Alabama at Birmingham and was a recipient of two Federal grants including the NCI's Ruth L. Kirschstein National Research Service Predoctoral Award.

**Gideon M. Blumenthal, M.D.
Deputy Office Director of the Oncology Center of Excellence, and Associate Director for Precision
Oncology
FDA**

Gideon M. Blumenthal, M.D. is Deputy Office Director of the Oncology Center of Excellence, and Associate Director for Precision Oncology, FDA. He earned a medical degree and completed internal medicine residency training from the University of Maryland School of Medicine and completed

hematology/oncology fellowship at the National Cancer Institute (NCI). At the NCI, his research focused on translational research of oncogene targeted therapy in lung cancer. Since joining the FDA in 2009, Dr. Blumenthal worked as a Medical Oncology reviewer in breast cancer, followed by an appointment as Clinical Team Leader in thoracic oncology and head and neck cancer. He was also an associate investigator on early phase clinical trials in the thoracic malignancy branch of the NCI, treating patients with lung cancer and other thoracic malignancies. Since 2017, he has been involved in the conception and implementation of the Oncology Center of Excellence and in advancing Precision Oncology initiatives for the Agency.

Tatiana M. Prowell, M.D.

**Breast Cancer Scientific Liaison, Assistant Professor of Oncology
Office of Hematology & Oncology Products, Breast Cancer Program
FDA and Johns Hopkins Kimmel Comprehensive Cancer Center**

Tatiana M. Prowell, MD is Breast Cancer Scientific Liaison in FDA's Office of Hematology & Oncology Products and Assistant Professor of Oncology in the Breast Cancer Program at the Johns Hopkins Kimmel Comprehensive Cancer Center. She was the principal architect of FDA's policy on accelerated approval using pathological complete response as a novel regulatory endpoint in the neoadjuvant high-risk breast cancer setting, and was a member of the Biden Cancer Moonshot Blue Ribbon Panel Cancer Immunology Working Group. She is a frequent public speaker and a three-time recipient of FDA's Excellence in Communication Award, as well as a Giants of Cancer Care Award finalist. A passionate medical educator and mentor, she is Chair-Elect of the 2020 ASCO Annual Meeting Education Committee and has served on the faculty of the Vail Methods in Clinical Cancer Research Workshop, the Society for Translational Oncology Fellows' Forum, the Dana Farber Clinical Investigator Seminar Series, and the FDA-ASCO Fellows' Day Workshop among several others. She sees patients in the Johns Hopkins Second Opinion Breast Cancer Clinic and teaches in the medical school and medical oncology fellowship training program. Dr. Prowell received her BA degree from Bard College in Languages and Literature and her MD degree from the Johns Hopkins School of Medicine with election to the Phi Beta Kappa and Alpha Omega Alpha honor societies. She completed her residency and fellowship at Johns Hopkins Hospital.

Steven Lemery, M.D.

**Associate Director
Division of Oncology Products 2
Office of Hematology and Oncology Products
CDER/FDA**

Dr. Lemery is the Associate Director of the Division of Oncology Products 2 within the Office of Hematology and Oncology Products in CDER/FDA. In addition to duties regarding general drug development for patients with cancer, Dr. Lemery has also focused on tissue-agnostic development and biosimilar development. Prior to assuming the role of Associate Director, he served as the Team Leader (Lead Medical Officer) for the gastrointestinal malignancies team. Dr. Lemery completed his clinical training in hematology and medical oncology at the National Institutes of Health in Bethesda, Maryland. Dr. Lemery also graduated with a Master of Health Sciences in Clinical Research degree awarded by the Duke University School of Medicine (joint NIH/Duke program).

Sasha Warren, BS, CCRC

Clinical Research Administrator, TAPUR Study

**Center for Research and Analytics (CENTRA)
American Society of Clinical Oncology**

Sasha Warren joined ASCO in November 2018 and serves as a Clinical Research Administrator for the Targeted Agent and Profiling Utilization Registry Study (TAPUR). The TAPUR Study, operating under ASCO's Center for Research and Analytics (CENTRA), offers a clinical trial opportunity for patients with advanced cancer who have not responded or are no longer responding to standard treatment, and who have genomic alterations in their tumors that can be targeted with a TAPUR Study drug. Sasha manages TAPUR Study clinical site relations and also serves as a representative for ASCO on the TAPUR Molecular Tumor Board. Her previous experience in clinical research originated at the NIH serviced Cancer Trials Support Unit (CTSU), where she served as a Cancer Trial Patient Registrar. In her work at CTSU, Sasha facilitated investigator and research staff participation in selected NCI multi-center programs and their clinical trials.

Prior to her role at ASCO, Sasha was a Clinical Trial Manager at the Georgetown University Department of Neurology. At Georgetown University, she led the administration of 16 Phase II-Phase IV clinical trials focused on Multiple Sclerosis, Parkinson's Disease, Lewy Body Dementia, Amyotrophic Lateral Sclerosis, Dystonia, Stroke, and Neuromyelitis Optica. Sasha is currently completing graduate courses in pursuit of a Master of Science degree in Clinical and Translational Research, at Georgetown University. Her primary research focus is patient navigator-supported care in patients with chronic migraine. Sasha received her Bachelor of Science degree in Biobehavioral Health at the Pennsylvania State University.

**Anna Jinkerson, MScM
Assistant to the Chief Medical Officer
American Society of Clinical Oncology**

Ms. Jinkerson is the assistant to the Chief Medical Officer at the American Society of Clinical Oncology. In her role, she provides operational support to Dr. Richard Schilsky and the Center for Research & Analytics (CENTRA). Prior to joining ASCO, she has worked in the Office of the CEO at The Pew Charitable Trusts shepherding contracts and grants through for final approval before being promoted to Program Administrator in Pew's Public Health Unit. During her time at Pew, she became keenly interested in research administration and the intersection of research, health equity, and public policy.

Ms. Jinkerson holds a Master of Science in Management with a Nonprofit and Association specialization from the University of Maryland-University College and Bachelor of Arts in Political Science from the University of Missouri-St. Louis. She began her career working in various capacities in the US House and US Senate before making a career change to nonprofit management.

Workshop Presenters

**Michael Berger
Associate Director, Center for Molecular Oncology
Memorial Sloan Kettering Cancer Center**

Michael Berger, PhD, is an Associate Director of the Marie-Josée and Henry R. Kravis Center for Molecular Oncology at Memorial Sloan Kettering Cancer Center, a multidisciplinary initiative to promote precision oncology through genomic analysis to guide the diagnosis and treatment of cancer patients. He is also an Associate Attending Geneticist in the Department of Pathology with expertise in cancer genomics, computational biology, and high-throughput DNA sequencing technology. His laboratory is developing experimental and computational methods to characterize the genetic makeup of individual

cancers and identify genomic biomarkers of drug response and resistance. As Scientific Director of Clinical NGS in the Molecular Diagnostics Service, he oversees the development and bioinformatics associated with clinical sequencing assays, and he helped lead the implementation and validation of MSK-IMPACT, a comprehensive FDA-authorized tumor sequencing panel that has been used to profile more than 38,000 tumors from advanced cancer patients at MSK. The resulting data have enabled the characterization of somatic and germline biomarkers across many cancer types and the identification of mutations associated with clonal hematopoiesis. Dr. Berger also led the development of a clinically validated plasma cell-free DNA assay, MSK-ACCESS, which his laboratory is using to explore tumor evolution, acquired drug resistance, and occult metastatic disease. He received his Bachelor's Degree in Physics from Princeton University and his Ph.D. in Biophysics from Harvard University.

Stacie Lindsey

Founder and President

Cholangiocarcinoma Foundation

Stacie Lindsey is the Founder and President of the Cholangiocarcinoma Foundation (CCF). Established in 2006, CCF is a global 501(c)(3) non-profit organization whose mission is to find a cure and improve the quality of life for those affected by cholangiocarcinoma (bile duct cancer) through advocacy, education, collaboration and research. Since 2006, she has engaged with members of the scientific, medical and academic communities; policymakers and regulators, industry, advocates, patients and caregivers to improve health outcomes for patients. Her efforts focus on increasing knowledge and understanding about key issues central to the prevention, diagnosis, treatment, and cure for this devastating disease by: 1) accelerating scientific and medical progress; 2) strengthening global collaborations; 3) nurturing a dedicated team of young investigators and 4) advocating for those affected by this rare and aggressive form of cancer.

Martha Donoghue

Clinical Team Leader, Gastrointestinal Cancer Team

Food and Drug Administration

Martha Donoghue is the Clinical Team Leader for the Gastrointestinal Cancer Team in the Division of Oncology Products 2, Office of Hematology and Oncology Products (OHOP), Center for Drug Evaluation and Research (CDER), United States Food and Drug Administration (FDA). Dr. Donoghue provides regulatory oversight, engages in clinical review activities, and advises stakeholders regarding strategies for clinical development of drugs and therapeutic biologics for the diagnosis, prevention, and treatment of cancer. Dr. Donoghue also serves on several FDA and external working groups aimed at expediting development of treatments for pediatric and adult patients with cancer. Areas of special interest include development of treatments for rare cancers and the use of innovative designs and clinical outcome assessments in clinical trials to optimize drug development. Prior to joining FDA in 2009, Dr. Donoghue completed a fellowship in Pediatric Hematology and Oncology at the Children's National Medical Center after working for several years as a general pediatrician in private practice. She received her medical degree from Emory University and completed a residency in general pediatrics at the Georgetown University Medical Center.

Eric H. Rubin

SVP, Therapeutic Area Head, Oncology Early Development

Merck Research Laboratories

Dr. Rubin has focused on cancer drug development for over 25 years, initially as a faculty member at the Dana-Farber Cancer Institute, then as a senior leader of the Cancer Institute of New Jersey, where he served as the Director of the Investigational Therapeutics Division of that institution. His research efforts focused on mechanisms of resistance to DNA topoisomerase-targeting drugs and his laboratory cloned TOPORS, a novel topoisomerase I- and p53-interacting tumor suppressor gene. In 2008 he was recruited to Merck as Vice President, Oncology Clinical Research. Under his leadership, the clinical oncology group underwent a transformational change in an effort to realize the potential of cancer immunotherapy. He led the initial development of the anti-PD-1 antibody pembrolizumab, which was the first anti-PD-1 therapy approved in the U.S., and in the identification of the significant activity of this breakthrough therapeutic across several cancer types. In 2014 Dr. Rubin was asked to head up Oncology Early Development for Merck, and in this role he oversees development of a promising and expansive early pipeline, as well as translational oncology research activities.

Joshua Bilenker

Chief Executive Officer

Loxo Oncology, Inc., a wholly owned subsidiary of Eli Lilly and Company

Dr. Joshua H. Bilenker, founder of Loxo Oncology, Inc., a wholly owned subsidiary of Eli Lilly and Company, has served as Chief Executive Officer since July 2013. Dr. Bilenker joined Aisling Capital LLC, an investment firm, in April 2006 and has served as an Operating Partner since November 2013. From 2004 to 2006, Dr. Bilenker served as a Medical Officer at the FDA in the Office of Oncology. Dr. Bilenker trained at the University of Pennsylvania in internal medicine and medical oncology, earning board certification in these specialties. He received his M.D. from The Johns Hopkins School of Medicine and his A.B. degree in English from Princeton University.

Haleh Saber

Deputy Director; Division of Hematology Oncology Toxicology (DHOT)/ OHOP

FDA/ CDER/ OHOP/ DHOT

Dr. Saber is the Deputy Director in the Division of Hematology Oncology Toxicology (DHOT). In this role, she provides leadership for day-to-day activities, leads and coordinates scientific research, and participates in guidance development. Dr. Saber has extensive industry and regulatory experience. She served as a Subject Matter Expert assisting pharmaceutical companies worldwide in nonclinical drug development and served many roles at the FDA over 15 years. Dr. Saber is recognized for her efforts in establishing acceptable approaches in first-in-human dose selection for new classes of products. She has been the recipient of multiple CDER awards. Dr. Saber received her PhD in Biochemistry from Lehigh University and conducted her post-doctoral studies at Fox Chase Cancer Center, PA.

Alexia Iasonos

Attending Biostatistician

Memorial Sloan Kettering Cancer Center

Dr. Iasonos has been at MSKCC since 2005. She has collaborated primarily with investigators studying ovarian cancer and also with investigative teams studying bladder cancer, lymphoma, and health outcomes. Through her collaborations with investigators in gynecology (Departments of Surgery, Medicine and Pathology) she is exploring various biomarkers and assessing relationships to histology, metastasis and clinical outcome. She is also involved in vaccine trials as a second line therapy in ovarian cancer patients, and in identifying valid endpoints for these trials. Her methodological interests focus on

model-based designs that guide the dose escalation in phase I trials and in the past few years she has focused on the design of early phase trials that involve dose expansion cohorts or basket trials.

Julie Bullock

VP, Integrated Drug Development

Certara

Dr. Bullock is currently Vice President, Integrated Drug Development for Certara. Prior to her role at Certara, Dr. Bullock was at the FDA for 10-years and served for 7-years as the clinical pharmacology team leader in the Office of Hematology and Oncology Projects, CDER/FDA. Dr. Bullock is a recognized drug development scientist with clinical pharmacology and regulatory experience focused in the therapeutic areas of hematology/oncology and coagulation. She has unique insight in pediatric development, oncology dose-finding strategy and streamlining development for breakthrough therapies and accelerated approval. In her role with Certara, Dr. Bullock provides strategic clinical and regulatory development advice and where possible, leverages model-informed drug development tools to optimize productivity, commercial value and patient outcomes. Her clients include global biopharmaceutical companies, non-profit biotech, leading academic institutions, and key regulatory agencies. Dr. Bullock received her doctor of pharmacy from Drake University and completed a clinical pharmacology drug development fellowship with the State University of New York at Buffalo and Novartis Pharmaceuticals.

Leigh Marcus

Medical Officer (MD), Clinical Reviewer

FDA

Dr. Marcus received her medical degree from the Medical College of Virginia/Virginia Commonwealth University and a bachelor of science from the University of North Carolina at Chapel Hill. She did her pediatrics residency at Yale University followed by fellowship in pediatric hematology and oncology at the Johns Hopkins Hospital and the National Institutes of Health National Cancer Institute (NIH-NCI). She received additional training in clinical trials research at the Duke University-NIH Program. Dr. Marcus was assistant professor at the George Washington University School of Medicine, and attending physician at Children's National Medical Center before joining the U.S. Food and Drug Administration (FDA). She has board certification/subspecialty certification in pediatrics and pediatric hematology/oncology.

Vivian Yuan

Mathematical Statistician

FDA/CDER

Dr. Vivian joined the FDA after she received her PhD in Mathematical Statistics from the Johns Hopkins University. She is currently a senior statistical reviewer at the Division of Biometrics V, Office of Biostatistics in CDER, which supports Office of Hematology Oncology Products. Before joining the FDA she was a mathematical statistician at the National Institute of Child Health and Human Development.

Pierre DEMOLIS, MD, PhD

EMA

Physician and clinical pharmacologist, regulator at the French Medicines Agency, involved in the European regulator network at the EMA for years. Former vice-chair of the main EMA committee (CHMP), now chairman of the Oncology Working Party and member of the Scientific Advice Working Party.

Ashley Ward**Lead Medical Officer****Food and Drug Administration**

Ashley Ward, MD leads the Melanoma/Sarcoma Team in the Office of Hematology and Oncology Products at the U.S. Food and Drug Administration. Previously, Dr. Ward was an assistant professor at the University of California, San Francisco. She also spent several years in the early clinical development group at Genentech, where she led the development teams for several small molecules and antibody-drug conjugates through early phase testing for hematologic malignancies and breast cancer. Dr. Ward received her B.A. in Biology from Swarthmore College and her medical degree from Washington University School of Medicine. She completed her residence and chief residency at St. Louis Children's Hospital, and her fellowship in pediatric hematology and oncology at the University of California, San Francisco.

Deb Schrag, MD, MPH, FASCO**Chief of the Division of Population Sciences, Department of Medical Oncology and Senior Physician, Center for Gastrointestinal Oncology****Dana-Farber Cancer Institute**

Deb Schrag, MD, MPH, FASCO is Chief of the Division of Population Sciences, Department of Medical Oncology, and a Senior Physician in the Center for Gastrointestinal Oncology at Dana-Farber Cancer Institute. She is also a Professor of Medicine at Harvard Medical School. Her research focuses on evaluating and improving the quality and effectiveness of cancer care delivery and, on the clinical side, she focuses on the care of patients with tumors of the lower gastrointestinal tract, particularly colorectal cancer. In her role as Division Chief of Population Sciences, she is responsible for fostering the career growth of faculty focused on population health, cancer prevention, control, dissemination and implementation and remediation of health disparities. Dr. Schrag is a leader in the development of systems to engage patients in evaluating the quality and outcomes of cancer care. She is one of the lead developers of the PRO-CTCAE which is a validated set of metrics that engages patients as active participants in cancer research and routine care through systematic reporting of treatment side effects. Dr. Schrag's research has demonstrated that patient engagement improves care quality, decreases the need for emergency care, burdensome symptoms and improves survival. She has championed the dissemination and implementation of these systems and strategies to accelerate the pace of cancer research by forging effective partnerships between researchers and study participants. In addition, she leads clinical informatics efforts to capture the outcomes of cancer treatment from electronic health records to realize the goals of precision medicine—linking genomic information about the molecular attributes of tumors to phenomic information about how patients respond to treatments. She is the developer of the PRISMM phenomic data standard which enables consistent curation of cancer treatment outcomes in a tumor site agnostic manner and labels unstructured clinical data to facilitate application of machine learning methods. Dr. Schrag has served as a Board Member of the American Society of Clinical Oncology, as a member of the NCI's study standing study section on Health Services Organization and Delivery and is a current member of the National Cancer Policy Forum. She is an Associate Editor of the Journal of the American Medical Association. Dr. Schrag earned her medical degree from Columbia University College of Physicians and Surgeons and her Master of Public Health from the Harvard School of Public Health. She completed her residency in internal medicine at Brigham and Women's Hospital and oncology fellowship at Dana-Farber. She started her career at Memorial

Sloan-Kettering Cancer Center and Weill Cornell Medical School, where she was a member of the Departments of Medicine, Epidemiology and Biostatistics.

Meg Mooney

**Acting Associate Director & Chief, Clinical Investigations Branch, CTEP, DCTD, NCI
National Cancer Institute**

Dr. Mooney is currently the Acting Associate Director of the Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis, at the National Cancer Institute (NCI), National Institutes of Health (NIH) and is also the Chief of the Clinical Investigations Branch in CTEP. She received her medical degree from the University of Chicago Pritzker School of Medicine in Chicago and her general surgical training at the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. She completed her Surgical Oncology fellowship training at the Roswell Park Cancer Institute in Buffalo, New York and also holds a Masters of Science degree in Management from the Massachusetts Institute of Technology in Cambridge, Massachusetts. Dr. Mooney joined the US National Cancer Institute in 2002 as Head of Gastrointestinal and Neuroendocrine Cancer Therapeutics in the Clinical Investigations Branch and was appointed Chief of the Clinical Investigations Branch in May 2009. As Chief of the Clinical Investigations Branch, she is responsible for the direction of the NCI National Clinical Trials Network (NCTN) Program. This program performs large phase 2 and phase 3 cancer treatment and advanced imaging trials and is the NCI's primary vehicle for conducting large, definitive, practice-changing clinical treatment and imaging trials in oncology. In April 2014, she was named the Deputy Associate Director of CTEP and she became the Acting Associate Director of CTEP in December 2018 with oversight and coordination responsibilities for the programmatic, financial, and administrative functions for CTEP covering a broad, multidisciplinary, clinical research effort to coordinate nationwide phase 1-3 clinical trials programs testing new treatment approaches for cancer.

Monica M. Bertagnolli, MD

**Richard E. Wilson Professor of Surgery in the Field of Surgical Oncology at Harvard Medical School,
Chief Executive Officer of Alliance Foundation Trials, LLC
President, American Society of Clinical Oncology
Dana-Farber/Brigham & Women's Cancer Center**

Dr. Bertagnolli is the Richard E. Wilson Professor of Surgery in the Field of Surgical Oncology at Harvard Medical School, and a member of the Gastrointestinal Cancer and Sarcoma Disease Centers at Dana-Farber/Brigham & Women's Cancer Center, where she collaborates with colleagues in medical oncology, radiation oncology, and pathology to treat cancer patients in a tertiary care setting.

Dr. Bertagnolli graduated from Princeton University, and attended medical school at the University of Utah. She trained in surgery at Brigham and Women's Hospital, and was a research fellow at the Dana Farber Cancer Institute (DF/BWCC). Dr. Bertagnolli has a background in laboratory work focusing upon understanding the role of the inflammatory response in epithelial tumor formation. From 1994-2011, she led gastrointestinal correlative science initiatives within the National Cancer Institute (NCI)-funded Cancer Cooperative Groups, where she facilitated integration of tumor-specific molecular markers of treatment outcome into nation-wide clinical cancer treatment protocols. From 2007-2018, Dr. Bertagnolli served as the Chief of the Division of Surgical Oncology at DF/BWCC. Dr. Bertagnolli has also had numerous leadership roles in multi-institutional cancer clinical research consortia, and currently serves as the Group Chair of the Alliance for Clinical Trials in Oncology, a nation-wide NCI-funded clinical trials group. She is also the Chief Executive Officer of Alliance Foundation Trials, LLC, a not-for-profit

corporation that conducts international cancer clinical trials. In addition, Dr. Bertagnolli is the 2018-2019 President of the American Society of Clinical Oncology, a 45,000 member organization serving the needs of physicians and other clinicians who care for patients with cancer.

Workshop Panelists

Ann Ramer

Patient Advocate

Teen Cancer America

Ann Ramer is a parent of four children, two who have Li-Fraumeni Syndrome, a condition which predisposes them to all forms of cancer. She has easily logged more hospital hours than is required to complete a residency program. Her children have been diagnosed with cancer a combined 8 times, spanning developmental ages (17 months to 18 years) and tumor type (adrenal cortical cancer, osteosarcoma times three, brain tumor times two, metastatic melanoma, and t-AML). Since 2011, she has advocated for her children continuously through nearly every type of cancer treatment: surgery, chemotherapy, radiation, BMT, immunotherapy, cellular therapy and demonstrated creativity in problem solving for difficult complications like GVHD and necrotizing fasciitis. She has managed the care for both her children, often simultaneously, with separate specialty teams and between institutions. She has experience from the patient perspective with both expanded access (Gemtuzimab and Ibrutinib) and clinical trials (CAR T). Because of her children's particularly virulent mutation in p53, Ann is conversant in the latest cancer research, even with those approaches and malignancies that she does not have direct experience with yet. In the midst of pediatric cancer, she served as founding board member of Living LFS, a non-profit focusing on psychosocial support for this isolating genetic condition. She advocated locally for hospital improvements on Family Advisory Council, provided testimony at the state level for restructuring of the BCMH program, and lobbied nationally for the STAR Act (Survivorship, Research, Treatment and Access) which is the most comprehensive piece of pediatric cancer legislation ever passed and funded by congress. She has attended nearly a dozen medical conferences, across tumor type and will begin her MPH program in the fall.

Antoine Yver, MD

Executive Vice President, Global Head Oncology R&D

Daiichi Sankyo, Inc.

Antoine Yver, MD, MSc currently serves as Executive Vice President and Global Head, Oncology Research and Development, and Chair, Daiichi Sankyo Cancer Enterprise. In this role, Dr. Yver is responsible for leading all of the global research and development across the oncology therapeutic area including external investments, internal pipeline decisions, and resourcing requirements. Dr. Yver joined Daiichi Sankyo in April 2016 with more than 25 years of scientific leadership in global pharmaceutical research and development. He has worked across the entire research and development spectrum from compound selection through registration including biologics, gene transfer agents and small molecules. He has been the global clinical lead for multiple new and supplemental drug applications worldwide. Prior to joining Daiichi Sankyo, Dr. Yver was Senior Vice President and Head of Oncology, Global Medicines Development and the Global Medicines Development China Lead across all therapeutic areas for AstraZeneca. In this position, he was responsible for the development of the oncology pipeline of AstraZeneca including input into the business development strategy that led to the acquisition of several important assets. Before joining AstraZeneca in 2009, he spent several years at Schering-Plough then

Merck, where he led the US approval of peg-interferon alfa-2b as adjuvant treatment for malignant melanoma as well as supplemental indications for Caelyx combinations in multiple myeloma. Before Schering-Plough, he was at Johnson & Johnson Pharmaceutical Research & Development as a Global Clinical Leader in Oncology leading the ex-USA approval of Yondelis. Dr. Yver began his career in the pharmaceutical industry with Rhône-Poulenc Rorer/Aventis as the Head of Clinical Research for a Joint Venture with Chugai. He spent 15 years in Europe, including two in the UK, and then moved to the United States in 1998, advancing to Senior Director Global Clinical Oncology, delivering Granocyte in 1993 (Chugai's G-CSF) and all but the first indication for Taxotere. Prior to the completion of his masters in Pediatric Oncology and Immunology, Dr. Yver received his medical education at Paris XI University with honors. He also is a French Board Certified Pediatrician.

John Simmons

VP, Translational Medicine

PGDx

John Simmons, PhD is the VP of Translational Medicine at Personal Genome Diagnostics (PGDx), a cutting-edge NGS cancer diagnostic company empowering the fight against cancer by developing a portfolio of regulated tissue-based and liquid biopsy genomic products for laboratories worldwide. John leads PGDx's scientific strategy and biomarker discovery and diagnostics development partnerships with pharma/biotech. John joined PGDx from the National Cancer Institute where his research using chemical genomic approaches to develop systems-level approaches for drug combination identification and prioritization was supported by the Multiple Myeloma Research Foundation. John received his Ph.D. in Tumor Biology from Georgetown University.

Adnan A. Jaigirdar

Medical Officer

CBER/FDA

Adnan Jaigirdar is a medical officer in Oncology in the Office of Tissues and Advanced Therapies (OTAT), in the Center for Biologics Evaluation and Review (CBER) at FDA. This office evaluates and approves innovative cancer therapeutics with curative potential. Dr. Jaigirdar focuses in the review of investigational biologic and combination advanced therapies involving cell and gene therapy in solid tumors. Examples include chimeric antigen receptor (CAR) T-cells, dendritic cells, adoptive T-cell therapies, tumor neoantigen-based personalized medicine (vaccine or cell therapy), natural killer cells, oncolytic viruses, therapeutic cancer vaccines, and combinations of these immune-oncologic therapeutics with checkpoint inhibitors and other agents.

Josh Mailman

Patient Advocate

Patient Advocate diagnosed with Pancreatic Neuroendocrine Tumor in 2007. Josh has an MBA from the Anderson School of Management at UCLA and has been a technology entrepreneur for over 20 years having co created eFax.com. Currently Josh is the President of the NorCal CarciNET Community and Past Chairperson of the Patient Advocacy Advisory Board for the Society of Nuclear Medicine and Molecular Imaging. Josh is a former executive board member of the Society for Integrative Oncology (SIO) and was named SIO Patient Advocate of Year in 2010. He is a member of the National Cancer Institute's Steering Committee on GI Cancers. Josh serves on the following boards, World Association of Radiopharmaceutical Molecular Therapy (WARMTH), the NeuroEndocrine Tumor Research Foundation (NETRF), the Education and Research Foundation for Nuclear Medicine and Molecular Imaging and the

North America Neuroendocrine Tumor Society's (NANETS) Advisory Board. In 2015 Josh was honored for his work in the NETs and nuclear medicine with the SNNMI President's award for distinguished service and the Warner Advocacy Award for NETs. In 2018 Josh was selected to be one of six patient advocates to join the faculty of ASCO/AACR's "Methods in Clinical Cancer Research" at the Vail Workshop

Vivek Subbiah, MD

Associate professor, Cancer Medicine , Clinical Medical Director

Clinical Center for Targeted Therapy, Department of Investigational Cancer Therapeutics (Phase 1 clinical trials program)

Vivek Subbiah, MD Associate professor, Cancer Medicine Clinical Medical Director, Clinical Center for Targeted Therapy, Department of Investigational Cancer Therapeutics (Phase 1 clinical trials program). Dr. Vivek Subbiah is an Associate Professor in the Department of Investigational Cancer Therapeutics, Division of Cancer Medicine and also the Center Clinical Medical Director of the Clinical Center for Targeted Therapy. He serves as the Principal Investigator in over 50 Phase 1/2 trials. He has led several first-in-human and practice changing novel basket trials. He was one of the co-leaders on the international Vemurafenib Basket Trial in non-melanoma BRAF V600-mutated cancers, which pioneered a novel histology-independent clinical trial design. Vemurafenib was US FDA approved in Erdheim-Chester disease based on this trial. He also serve as the lead investigator for the global Rare Oncology Agnostic Research (ROAR) trial. Dabrafenib and trametinib was US FDA approved in the treatment of BRAF V600-mutant anaplastic thyroid cancer (ATC) based on practice changing data from this trial in 2018. Furthermore, his novel investigator-initiated trials have also laid the foundation for therapeutic breakthroughs for additional rare cancers. Specifically, his clinical trial for Radium-223 as a treatment for relapsed osteosarcoma was singularly responsible for the inclusion of this radiopharmaceutical in the treatment algorithm of osteosarcoma in the guidelines of the National Comprehensive Cancer Network (NCCN). He is a major advocate for precision oncology. His national leadership role continues to expand as the National PI for the BRAF non-V600 alteration arm of the NCI-MATCH Precision Medicine Clinical Trial and as a member of the NCI-CTEP PTMA for glutaminase inhibitor basket trial. His trial portfolio includes trials that target BRAF,MEK,RET,CDK,WNT,VEGF,mTOR,EZH2-EED pathways, novel immunotherapy combination trials G1TR,TLR7/9,PD1,WT1, several first in human antibody drug conjugates and radiopharmaceuticals. He is currently leading two selective RET inhibitor trials, LOXO-292 and BLU-667 for RET dependant cancers both of which are on track as registration trials directly from Phase 1 trial. He has published over 150 peer-reviewed in several prestigious journals such as The New England Journal of Medicine, Journal of Clinical Oncology, JAMA Oncology, Cancer Discovery, Clinical Cancer Research, and Lancet Oncology.

Theodore Laetsch, MD

Associate Professor of Pediatrics, the Norma and Jim Smith Professor of Clinical Excellence, and a Eugene P. Frenkel, M.D. Scholar in Clinical Medicine

University of Texas Southwestern Medical Center

Theodore Laetsch, MD is an Associate Professor of Pediatrics, the Norma and Jim Smith Professor of Clinical Excellence, and a Eugene P. Frenkel, M.D. Scholar in Clinical Medicine at the University of Texas Southwestern Medical Center. Dr. Laetsch earned his medical degree at the University of California San Francisco School of Medicine. He completed his residency and a chief residency in pediatrics at the University of Colorado/Children's Hospital of Colorado, and then fellowship in pediatric hematology/oncology at the Children's Hospital of Philadelphia. Dr. Laetsch directs of the Experimental Therapeutics Program at Children's Health/Children's Medical Center in Dallas, Texas where he conducts

clinical and translational research on molecularly targeted therapy and immunotherapy for pediatric cancers. Dr. Laetsch is one of the lead investigators on the pediatric phase 1/2 study of larotrectinib.

Adnan A. Jaigirdar

Medical Officer

CBER/FDA

Adnan Jaigirdar is a medical officer in Oncology in the Office of Tissues and Advanced Therapies (OTAT), in the Center for Biologics Evaluation and Review (CBER) at FDA. This office evaluates and approves innovative cancer therapeutics with curative potential. Dr. Jaigirdar focuses in the review of investigational biologic and combination advanced therapies involving cell and gene therapy in solid tumors. Examples include chimeric antigen receptor (CAR) T-cells, dendritic cells, adoptive T-cell therapies, tumor neoantigen-based personalized medicine (vaccine or cell therapy), natural killer cells, oncolytic viruses, therapeutic cancer vaccines, and combinations of these immune-oncologic therapeutics with checkpoint inhibitors and other agents.

**Howard A. "Skip" Burris III, MD, FASCO, FACP
President and Chief Medical Officer**

Sarah Cannon

Howard A. "Skip" Burris III, MD, FASCO, FACP serves as president and chief medical officer of Sarah Cannon, as well as the executive director, drug development for the research institute. He is an associate of Tennessee Oncology, PLLC, where he practices medical oncology. Dr. Burris' clinical research career has focused on the development of new cancer agents with an emphasis on first in human therapies, having led the trials of many novel antibodies, small molecules, and chemotherapies now FDA approved, including ado-trastuzumab emtansine, everolimus, and gemcitabine. In 1997, he established in Nashville the first community based early phase drug development program, which grew into the Sarah Cannon Research Institute. He has authored over 400 publications and 700 abstracts. Sarah Cannon has now dosed over 350 first in human anticancer therapies and enrolls more than 3000 patients per year into clinical trials.

**Richard L. Schilsky, M.D., FACP, FSCT, FASCO
Senior Vice President and Chief Medical Officer
American Society of Clinical Oncology**

Dr. Schilsky is the Senior Vice President and Chief Medical Officer (CMO) of ASCO. Formerly the Chief of Hematology/Oncology in the Department of Medicine and Deputy Director of the University of Chicago Comprehensive Cancer Center, he is a highly respected leader in the field of clinical oncology. He specializes in new drug development and treatment of gastrointestinal cancers. Dr. Schilsky is a Past President of ASCO, having served in the role during 2008-2009, and also a Past Chair of one of the National Cancer Institute's Cooperative Groups, Cancer and Leukemia Group B (CALGB). Dr. Schilsky's impressive experience and many accomplishments in both clinical medicine and clinical research reflect his deep passion for cancer medicine. He has spent the majority of his career at the University of Chicago where he joined the faculty in 1984, subsequently rising to the rank of Professor of Medicine and serving in many roles, including Associate Dean for Clinical Research in the Biological Sciences Division and Director of the University of Chicago Cancer Research Center.

From 1995 to 2010, Dr. Schilsky served as chair of the Cancer and Leukemia Group B, a national cooperative clinical research group funded by the National Cancer Institute (NCI). He has extensive experience working with both the NCI and the Food and Drug Administration (FDA) having served as a member and chair of the NCI Board of Scientific Advisors, as a member of the NCI Clinical and Translational Research Committee, and as a member and chair of the Oncologic Drugs Advisory Committee of the FDA. Presently, he serves as a member of the board of directors of Friends of Cancer Research and of the Reagan-Udall Foundation for the FDA. Dr. Schilsky has served on the editorial boards of many cancer journals, including the Journal of Clinical Oncology. He presently serves on the editorial board of the New England Journal of Medicine. Dr. Schilsky is the author of nearly 400 original research articles, reviews and commentaries. Early in his career, he worked in the Clinical Pharmacology Branch of the Division of Cancer Treatment at the NCI and was an Assistant Professor in the Department of Internal Medicine, Division of Hematology and Oncology at the University of Missouri-Columbia School of Medicine. He was also the head of the hematology/medical oncology unit at the Harry S. Truman Veterans' Administration Hospital in Columbia, Missouri.

**Alex Spira
MD PhD FACP**

Virginia Cancer Specialists Research Institute, US Oncology

Dr Spira has been a medical oncologist for 16 years after completing his fellowship at Johns Hopkins in 2003. Since then he has focused on thoracic malignancies, with an interest in clinical trials, drug development. Dr Spira leads the research program at Virginia Cancer Specialists, including its Early Drug Development (Phase I) program. In addition, he is Co Director of the USOncology Thoracic Oncology Research program and chair of the USOncology Research Executive Committee, and a member of the USOncology National Policy Board Executive Committee. In addition, he is involved in several ASCO committees focusing on clinical research and improving access of patients to clinical studies.

Mary Beattie**Principal Medical Director, US Medical Affairs****Genentech**

Mary S. Beattie, MD, MAS is a Principal Medical Director at Genentech in BioOncology, US Medical Affairs. She works in Precision Medicine, and has expertise in innovative study designs, including basket studies, cohort studies, and trials. Mary joined Genentech in April 2012 after 15 years on faculty at the University of California, San Francisco (UCSF) where her clinical and research interests were in Hereditary Breast and Ovarian Cancer and observational research. At Genentech, Mary has led medical teams, launched drugs for new indications, filed Investigative New Drug reports with the FDA, written protocols, and served as a study medical monitor. Mary has a Bachelors in Science (Chemistry) from Duke University, a Medical Degree from the Ohio State University, and a Masters in Advanced Studies, Clinical Research, from UCSF. Her internship training was at the University of California, Davis, and her residency training and fellowship were at UCSF. Mary lives in San Francisco, where she enjoys running, hiking, and attending theater productions

Dana Deighton**Project Manager****Inspire**

Dana is a marketing professional with decades of experience in corporate marketing and publishing, membership, and partner/project management. After 25 years at National Geographic, she is now in a new career in the health and wellness arena at Inspire, the leading social network for health, whose mission is to accelerate medical progress through a world of connected patients. Outside of work, she is also focused on healthcare advocacy and policy. In addition to serving as an Executive Board Member of ECAN, she is a Patient Representative on the Locally Advanced Esophageal Cancer Guideline Panel for the American Society of Clinical Oncology (ASCO) and serves on the GastroEsophageal Project Patient Advisory Committee, a project led by the Broad Institute of MIT and Harvard (a nonprofit academic research institution whose mission is to dramatically accelerate the understanding and treatment of disease). A very grateful survivor of Stage IV Esophageal Cancer who continues to receive immunotherapy, Dana lives in Alexandria, VA, with her husband and three teenagers, and enjoys travel and walking and running outdoors.

Rajeshwari Sridhara, Ph.D**Division Director of Division of Biometrics V, Office of Biostatistics****Center for Drug Evaluation and Research (CDER)**

Rajeshwari Sridhara, Ph.D. is the Division Director of Division of Biometrics V, Office of Biostatistics which supports Office of Hematology Oncology Products at the Center for Drug Evaluation and Research (CDER). She joined the Food and Drug Administration (FDA) in 1999. Dr. Sridhara has contributed in the

understanding and addressing the statistical issues that are unique to the oncology disease area such as evaluation and analysis of time to disease progression. Her research interests also include evaluation of surrogate markers and design of clinical trials. She has organized, chaired and given invited presentations at several workshops. She has worked on many regulatory guidance documents across multiple disciplines. She has extensively published in refereed journals and presented at national and international conferences. She is an elected fellow of the American Statistical Association. Prior to joining FDA, Dr. Sridhara was a project statistician for the AIDS vaccine evaluation group at EMMES Corporation, and she was an assistant professor at the University of Maryland Cancer Center.

Reena Philip, Ph.D.

**Director, Division of Molecular Genetics and Pathology
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration**

Dr. Philip currently holds the position of Director in the Division of Molecular Genetics and Pathology in the Office of In Vitro Diagnostics and Radiological Health, at Center for Devices and Radiologic Health at the FDA. Division of Molecular Genetics and Pathology provides regulatory oversight of in vitro diagnostic tests of a variety of product areas including Oncology molecular tests, Pathology and cytology, Companion diagnostic tests, and Genetic disorder molecular tests. At the FDA, she has been involved in many diverse activities including premarket clearance/approval, manufacturer assistance, post market regulatory compliance actions, and the development of FDA Guidance documents. In addition, she has been an ongoing participant in FDA's activities in the area of liquid biopsy. Dr. Philip received her Ph.D. from University of Illinois at Urbana-Champaign.

Shivaani Kummar, MD, FACP

**Professor of Medicine and Radiology, Co-Director, Translational Oncology Program at Stanford,
Director of the Phase I Clinical Research Program, Associate Division Chief, Medical Oncology,
Stanford University, Palo Alto, CA, USA**

Upon completing her medical degree from Lady Hardinge Medical College in New Delhi, India, Shivaani Kummar moved to the United States to train in Internal Medicine at Emory University in Atlanta, Georgia. Following this Dr. Kummar was selected to pursue fellowship training at the National Institute of Health (NIH) in Medical Oncology and Hematology, which culminated in being offered a faculty position at Yale University, New Haven CT. After spending four years as Assistant Professor of Medicine at Yale Cancer Center, she moved back to the National Cancer Institute (NCI), NIH, where she developed a clinical research program in novel cancer therapeutics. In 2011 she became Head of Early Clinical Trials Development in the Office of the Director, Division of Cancer Treatment and Diagnosis, NCI. Dr. Kummar moved to Stanford University in 2015 as Professor of Medicine and Director of the Phase I Clinical Research Program. Her research interests focus on developing novel therapies for cancer. She specializes in conducting pharmacokinetic and pharmacodynamic driven first-in-human trials tailored to make early, informed decisions regarding the suitability of novel molecular agents for further clinical investigation. Dr. Kummar is the principal investigator of numerous early phase trials, and serves on multiple national and international scientific committees.

Joon Rhee, PhD

**Global Clinical Lead for Lynparza New Opportunities and Novel Combinations
AstraZeneca LLP**

Dr. Rhee joined AstraZeneca in 2016 where he oversees clinical development of new opportunities and novel combinations for Lynparza (PARPi). Prior to joining AstraZeneca Dr. Rhee held multiple roles at Roche-Genentech where he served as medical lead for Biosimilar Strategy, combination lead of development for the Cotellic (MEKi) program and supported development and submission of Avastin in Gynecological cancers. Dr. Rhee's career in industry began at Exelixis Inc., where we was involved in drug discovery and early clinical development of multiple targeted therapies including Cometriq/Cabometyx (TKI). Dr. Rhee received his PhD Immunology at Stanford University and BA in Molecular Biology at the University of California at Berkeley.

David Fabrizio

Vice President, Product Development

Foundation Medicine, Inc.

Cambridge, MA

David Fabrizio serves as the Vice President of Product Development at Foundation Medicine in Cambridge, MA. Prior to joining Foundation Medicine, David held senior scientific positions at Adnexus Therapeutics and subsequently Bristol-Myers Squibb post acquisition of Adnexus, where he co-lead the pre-clinical development of their PD1/PDL1 inhibitor program. Subsequently, David served in a senior scientific role at Abvitro, where he helped develop a novel neo-antigen discovery platform which was acquired by Juno Therapeutics in 2013 to advance the development of their CAR-T platform. Under David's leadership, Foundation Medicine has pioneered new genomic biomarkers for immunotherapy, including tumor mutational burden (TMB), and launched the first comprehensive genomic profiling test approved by the FDA, FoundationOne CDx

Suparna Wedam

Medical Officer

FDA

Suparna Wedam, MD, is a Medical Officer and Breast Cancer Scientific Liaison at the FDA, CDER, Office of Hematology and Oncology Products. Dr. Wedam graduated magna cum laude from Northwestern University with a BA in economics and then earned her medical degree from Georgetown University with election to the Alpha Omega Alpha honor society. She completed her internal medicine residency at Georgetown University Medical Center, where she was also a chief medical resident. Subsequently, she completed her medical oncology and hematology fellowship at the National Cancer Institute (NCI) in Bethesda, MD. Dr. Wedam remains clinically active, treating breast cancer patients at Walter Reed National Military Medical Center in Bethesda, MD.