Liquid Biopsies in Oncology Drug and Device Development Workshop

July 19, 2016

Walter E. Washington Convention Center, Washington, DC

Workshop Co-Chairs

Gideon Blumenthal, MD, Clinical Team Leader, Thoracic and Head/Neck Oncology, Office of Hematology and Oncology (OHOP), Center for Drug Evaluation and Research (CDER), FDA

Gideon Blumenthal, MD is Lead Medical Officer for Lung and Head and Neck cancer in the Office of Hematology Oncology Products, U.S. Food and Drug Administration. As part of professional development, Dr. Blumenthal is an attending in the thoracic malignancies clinic at the National Cancer Institute, National Institutes of Health.

Dr. Blumenthal received his Internal Medicine internship and residency training at the University of Maryland Medical Center. He received his Hematology and Medical Oncology fellowship training at the National Cancer Institute. In his fellowship and as an attending physician at the National Cancer Institute, Dr. Blumenthal served as lead associate investigator for multiple clinical trials, focusing mainly on targeting the pi3k/AKT/mTOR pathway in lung cancer and in other familial cancer predisposition syndromes. He joined the U.S. Food and Drug Administration as a Medical Officer in 2009. In 2013, he was appointed as the Clinical Team leader for lung cancer and head and neck cancer. As lung cancer scientific liaison, he performed outreach to other government agencies, patient advocacy groups, national organizations and steering committees, and assumes leadership roles in disease-specific activities and advisory committee meetings.

Dr. Blumenthal is a member of the American Society of Clinical Oncology and the International Association for the Study of Lung Cancer. He has numerous publications in peer reviewed journals, and has presented at international forums such as the ASCO annual meeting, the American Association for Clinical Research annual meeting, and the European Society for Medical Oncology- European Medicines Agency workshop on Single Arm Trials. He has served on the faculty for international meetings including the Accelerating Anticancer Agent Development and Validation workshop, and the ASCO Markers in Cancer Diagnostic Development tutorial. In 2014, he received the FDA Commissioner's Special Citation for his role in patient-focused drug development in lung cancer, and in 2016, he received the Center Director's Special Citation for outstanding performance in the support of novel clinical trial designs to maximize efficiency of drug development in rare lung cancer subtypes.

Pasi Jänne, MD, PhD, AACR Regulatory Science and Policy Subcommittee member; Director, Lowe Center for Thoracic Oncology; Scientific Director, Belfer Institute for Applied Cancer Science; Senior Physician, Dana-Farber Cancer Institute and Professor of Medicine, Harvard Medical School

Dr. Jänne is a translational thoracic medical oncologist at the Dana-Farber Cancer Institute and a Professor of Medicine at Harvard Medical School. He is the Director of the Lowe Center for Thoracic Oncology and the Scientific co-director of the Belfer Institute for Applied Cancer Sciences. After earning his MD and PhD from the School of Medicine at the University of Pennsylvania, Dr. Jänne completed his internship and residency in Medicine at Brigham and Women's Hospital, Boston. He subsequently completed fellowship training at the Dana-Farber Cancer Institute/Massachusetts General Hospital combined program in medical oncology in 2001. In 2002, he earned a Master's Degree in clinical investigation from Harvard University. Dr. Jänne's research combines laboratory based studies with translational research and clinical trials of novel therapeutic agents in patients with lung cancer. His main research interests center around understanding and translating the therapeutic importance of oncogenic alterations in lung cancer. He has made seminal therapeutic discoveries; including being one of the co-discoverers of *EGFR* mutations and findings from his work has led to the development of several clinical trials. Dr. Jänne has received several awards for his research from Uniting Against Lung Cancer, American Lung Association, and the Bonnie J. Addario Lung Cancer Foundation. In 2008, he was elected as a member to the American Society of Clinical Investigation. He is also the recipient of the 2010 American Association for Cancer Research (AACR) Richard and Hinda Rosenthal Memorial Award and a member of the 2010 AACR Team Science Award, and is an active member of the AACR's Regulatory Science and Policy subcommittee.

Reena Philip, PhD, Director, Division of Molecular Genetics and Pathology (DMGP), Office of In Vitro Diagnostics and Radiological Health (OIR), Center for Devices and Radiological Health (CDRH), FDA

Dr. Philip currently holds the position of Director in the Division of Molecular Genetics and Pathology in the Office of In Vitro Diagnostic Devices and Radiological Health, at Center for Devices and Radiologic Health at the FDA. 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 on In Vitro Companion Diagnostic Devices. In addition, she has been an ongoing participant in FDA multi-center reviews in companion diagnostics.

Workshop Speakers and Panelists

Julia Beaver, MD, Clinical Team Leader Breast and Gynecological Malignancies Group, OHOP/CDER/FDA

Dr. Julia A. Beaver is the Clinical Team Leader of the Breast and Gynecologic Malignancies Group 1 in the Office of Hematology Oncology Products at the U.S. Food and Drug Administration. She is also an Assistant Professor of Oncology, part-time, at Johns Hopkins University and practices medical oncology at Sibley Memorial Hospital where she sees breast cancer patients. Dr. Beaver earned her medical degree from the

University of Pennsylvania School of Medicine. She completed a residency in internal medicine at Johns Hopkins University School of Medicine, followed by a fellowship in medical oncology at The Johns Hopkins Sidney Kimmel Cancer Center.

Karen Bijwaard, MS, RAC, MB(ASCP)^{CM}, Scientific Master Reviewer, DMGP/OIR/CDRH/FDA

Karen Bijwaard, MS, RAC, MB(ASCP), joined the FDA's Office of In Vitro Diagnostics and Radiological Health (OIR) in April 2005 as a Scientific Reviewer in the Division of Immunology and Hematology Device evaluation (DIHD) and then in the Division of Molecular Genetics and Pathology when it was created in April 2014. In her current position, she reviews submissions for molecular pathology, genetics, instrumentation, and companion diagnostic In Vitro Devices (IVDs) and diagnostic software/instrumentation. She is a consultant for other divisions in OIR and the Centers for Biologics and Drugs. She is a member in a number of genetics/genomics committees and working groups in FDA. Ms Bijwaard is certified by ASCP as Technologist in Molecular Biology and received her Regulatory Affairs Certification from the Regulatory Affairs Professional Society in 2009. She has been an active member of the Assoc. for Molecular Pathology since 1996. In addition, she is active in CLSI and has served as a Subcommittee member and Advisor on several new and revised guidelines. Ms. Bijwaard received her undergraduate degrees in Animal Science and Biology from VA Tech in Blacksburg, VA and her Masters Degree in Pathology from Georgetown University in Washington, DC. Prior to joining OIR, she has extensive laboratory experiences in the area of molecular diagnostics. Previously she has worked as a medical technologist in the Molecular Diagnostics Laboratory (MDL) in the Dept. of Pathology at Georgetown University. In 1996, she joined the MDL at the Armed Forces Institute of Pathology as a medical technologist where she continued to perform and created new molecular assays until 2003, after which she worked in the Laboratory of Immunology at NIH/NIAID.

Tera Eerkes, PhD, Vice President of Strategy and Clinical Operations, Resolution Bioscience

Dr. Tera Eerkes has served at Resolution Bioscience as the Vice President of Strategy and Clinical Operations since 2015. Prior to joining Resolution Bio., she co-founded or contributed to multiple biotech startups, all focused on translating emergent genomic technologies into human clinical diagnostics. Her prior research efforts included the development of bioinformatics models for evolution of human genomic architecture and novel whole-genome structural variation analyses. She has published on these topics in peer-reviewed journals such as Cell and Nature. Dr. Eerkes received her B.S from the University of Colorado, in Computer Science, and her doctorate from the University of Washington, in Genome Sciences.

Andrea Ferris, President and Chairman of the Board, LUNGevity Foundation

Andrea became involved with lung cancer advocacy following her mother's death from the disease in 2008. After receiving a diagnosis of stage IV lung cancer in 2006, Andrea's mother underwent numerous treatments and clinical trials at several major academic institutions to no avail. Together with her father, Andrea was her mother's primary caregiver during this time. Determined to drive more money into lung cancer research, Andrea left the successful software company that she helped launch, to found Protect Your Lungs, an organization focused 100% on funding early detection research. In 2010, Andrea merged Protect Your Lungs with LUNGevity, a Chicago based organization, to form the nation's leading lung cancer focused non-profit. Andrea's strong business background combined with her connections to the worlds of

research and advocacy have enabled her to build the preeminent patient advocacy organization in the lung cancer space. LUNGevity funds translational research into both early detection and more effective treatments of lung cancer as well as a highly coveted Career Development Awards program. LUNGevity also fills unmet needs for people diagnosed with lung cancer by providing education, support, and survivorship programs. Recognizing the need to build awareness and understanding about lung cancer, LUNGevity has built the largest grassroots network of events and advocates across the country.

Gary Kelloff, MD, Special Advisor, National Cancer Institute

Gary J. Kelloff, MD has had over 40 years in cancer research at the National Cancer Institute (NCI), authoring more than 400 publications. Dr. Kelloff is a graduate of the University of Colorado (BS and MD degrees). After post-graduate training in medicine at Emory University, he began his NCI career as an intramural scientist and section head in viral immunology working on retroviruses and oncogenes. After fifteen years in NCI's intramural program, he developed a basic science, translational research, and clinical development program in chemoprevention. Since 2001, he has been a special advisor for the NCI Division of Cancer Treatment and Diagnosis working on strategies for developing biomarkers for oncology drug development and cancer patient management. He previously led and currently leads several collaborations with FDA and the pharmaceutical industry on drug development strategies and since 2009 has co-chaired on-going efforts under the Foundation for the National Institutes for Health Biomarkers Consortium to create public-private partnerships (PPPs) to define biomarker use in cancer drug development and patient management. Past work has included establishment of a developmental pathway for approval of cancer prevention drugs as part of an AACR initiative and evaluation of tumor burden markers and precancerous histopathology as part of a C Change initiative. Current efforts under the Biomarkers Consortium include consideration of imaging based biomarkers (FDG-PET/CT, volumetric CT, DW-MRI, molecular probes) and new technologies for measuring circulating tumor cells and nucleic acids, minimal residual disease, novel trial designs for evaluating prognostic and predictive biomarkers, molecular signatures and new drugs, including gene expression and proteomic biomarkers. This work has involved collaboration with all stakeholders including leaders in industry, academia, government, foundations, and advocacy groups and has resulted in many publications addressing specific biomarkers and general drug development strategies.

Walter Koch, PhD, Vice President, Head of Global Research, Roche Molecular Systems, Inc.

Walter H. Koch, PhD is Vice President and Head of Global Research for Roche Molecular Systems. He is responsible for all research and early development activities, including biomarker discovery and validation, the development of new molecular technologies with diagnostics potential, and expanding the use of real time PCR for clinical applications in the areas of infectious diseases, genetics, oncology companion diagnostics and "liquid Biopsy" cancer monitoring tests.

Prior to joining Roche he held several positions at the U.S. FDA, including Acting Lab Chief of Immunochemistry in CBER's Division of Transfusion Transmitted Disease. He received a BS in Chemistry from Memphis State University, a PhD in Toxicology and Pharmacology from the University of Tennessee Health Science Center, and was a Postdoctoral Fellow at the Johns Hopkins University School of Public Health.

Erin Larkins, CDR, USPHS, Medical Officer, OHOP/CDER/FDA

Dr. Erin Larkins is a clinical reviewer on the Thoracic and Head/Neck Oncology team in the Office of Hematology Oncology Products at the U.S. Food and Drug Administration and an officer in the U.S. Public Health Service. She completed her fellowship in medical oncology and hematology at the National Cancer Institute. She served as a physician in the U.S. Navy for 14 years, including 8 years at major Navy medical centers as a staff medical oncologist. She continues to participate in clinical practice at Walter Reed National Military Medical Center, with a focus on head and neck and lung cancer patients.

Mark Lee, MD, PhD, Head of Clinical Development and Medical Affairs, GRAIL, Inc.

Mark Lee, MD, PhD is a medical oncologist and Head of Clinical Development and Medical Affairs at GRAIL, which is developing circulating cell-free nucleic acid technology for early cancer detection. Previously, Mark served as Lead for Oncology Clinical Sciences at Google Life Sciences, Chief Medical Officer at Boreal Genomics, and Vice President of Oncology Development at Genomic Health, where he led the successful development and validation of the Oncotype DX Colon and Prostate Cancer Assays. His prior work also includes design and conduct of clinical trials for tissue-based and molecular imaging biomarker discovery at Genentech. Mark holds a PhD in Biological Chemistry and Molecular Pharmacology from Harvard, and a MD from Stanford University, where he completed his internal medicine training and medical oncology fellowship and where he continues to serve as adjunct faculty.

Robert McDonough, MD, JD, Senior Director for Policy Research and Development, Aetna

Robert S. McDonough, MD is Senior Director for Clinical Policy Research and Development for Aetna, where he is responsible for developing Aetna's clinical policies. He is cochairman of Aetna's Pharmacy and Therapeutics Committee, is a member of the Medicare Evidence Development and Coverage Advisory Committee, and has served on several Institute of Medicine Committees. He is also a member of the governing board of the Systemic Review Data Repository. He has special interests in preventive health services, technology assessment, and outcomes research. He is former senior analyst and project director with the Health Program of the Congressional Office of Technology Assessment. He is a graduate of Duke University School of Medicine and School of Law (JD), and has a master's degree in policy analysis from Duke's Sanford Institute of Public Policy. He completed an internship in internal medicine at Stanford University School of Medicine, and is a Fellow of the American College of Legal Medicine.

Sumimasa Nagai, MD, PhD, Clinical expert advisor, Companion Diagnostics Working Group and Office of New Drug V, Pharmaceuticals and Medical Devices Agency, Japan

Sumimasa Nagai, MD, PhD is a clinical expert advisor at Companion Diagnostics Working Group and Office of New Drug V (Oncology), Pharmaceuticals and Medical Devices Agency (PMDA) and a senior assistant professor at the University of Tokyo as of June, 2016. He received his M. from Faculty of Medicine, the University of Tokyo in 2003 and his PhD from Graduate School of Medicine, the University of Tokyo in 2010. Before he joined PMDA as a clinical reviewer in 2011, he spent most of his career as a physician at Department of Hematology and Oncology, the University of Tokyo Hospital. In PMDA, he has been

involved in regulating oncologic drugs and companion diagnostics. He has worked also at the Institute of Medical Science, the University of Tokyo since November, 2014.

Geoffrey Oxnard, MD, Thoracic Oncologist, Dana-Farber Cancer Institute; Assistant Professor of Medicine, Harvard Medical School

Dr. Oxnard is a thoracic oncologist at the Dana-Farber Cancer Institute and an Assistant Professor of Medicine at Harvard Medical School. He is a clinic-based translational investigator whose research focuses on the development of biomarkers and targeted therapies for management of genotype-defined NSCLC populations and drug resistance. He was previously awarded with a Young Investigator Award and Career Development Award from the Conquer Cancer Foundation of ASCO, a Career Development Award from the U.S. Department of Defense, and has recently been named a Damon Runyon Clinical Investigator. He leads or co-leads a number of ongoing correlative studies including the NCI's ALCHEMIST study aiming to genomically characterize resected NSCLC, the INHERIT EGFR study of germline EGFR T790M mutations, and the FNIH VOL-PACT study of advanced imaging metrics for efficient clinical trial design.

Ben Ho Park, MD, PhD, Professor of Oncology, Breast, and Ovarian Cancer Program, Johns Hopkins Sidney Kimmel Cancer Center

Dr. Park is a native of the Midwest and attended The University of Chicago for his AB degree, followed by dual training at The University of Pennsylvania School of Medicine where he received both his MD and PhD degrees in 1995. Dr. Park then trained in Internal Medicine and Hematology/Oncology at The Hospital of The University of Pennsylvania prior to coming to Johns Hopkins where he completed a post-doctoral fellowship in cancer genetics in the laboratory of Drs. Ken Kinzler and Bert Vogelstein. In 2002, Dr. Park joined the faculty as an Assistant Professor of Oncology at The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins where he is developing new therapeutics and diagnostics for breast cancer using genetic based approaches. He is currently Professor of Oncology in the Breast and Ovarian Cancer Program at Johns Hopkins and the Associate Director of the Hematology/Oncology Fellowship Training Program and Associate Director for Research Training and Education.

Girish Putcha, MD, PhD, Director, Laboratory Science, MolDX, Palmetto GBA

Girish Putcha is currently Director of Laboratory Science for Palmetto GBA's MolDX program, the founding Medical Director for Orion Genomics, and Managing Director at Personalized Medicine & Diagnostic Solutions.

Previously, Girish was the founding Laboratory Director and/or Chief Medical Officer at Ariosa Diagnostics, Crescendo Bioscience, Life Technologies, and VitaPath Genetics. Prior to this, he focused on investments across healthcare, from biopharmaceuticals and medical devices to diagnostics and services, at Panorama Capital and RiverVest Venture Partners, where he also served on the boards of several portfolio companies, including Presidio Pharmaceuticals, PowerVision, and Phenomix. He was also a founding team member at VeraCyte and a clinical development fellow at CardioDx, both venture-funded personalized medicine companies.

Girish received a bachelor's degree from Rice University and master's degrees from the University of London and the Welcome Institute as a Marshall Scholar. He holds medical and doctoral degrees from Washington University School of Medicine, where he also completed a postdoctoral fellowship in molecular neuroscience. Girish completed his postgraduate medical training at the Stanford University School of Medicine, where he also served as adjunct clinical faculty, specializing in molecular genetic pathology.

Mark Sausen, PhD, Vice President of Research and Development, Personal Genome Diagnostics

Dr. Mark Sausen joined Personal Genome Diagnostics in 2013 and currently serves as the Vice President of Research and Development. His prior research has focused on the development of novel tissue and cell free DNA-based genomic approaches for the detection and analysis of cancer. Dr. Sausen has authored and co-authored several peer-reviewed articles in journals such as Science, Nature Genetics, and Science Translational Medicine on these topics. He received his B.A. from the University of Delaware in Biological Sciences and PhD from Johns Hopkins University in Cellular and Molecular Medicine where he received the Hans J. Prochaska Young Investigator's Award.

Howard Scher, MD, Chief, Genitourinary Oncology Service; D. Wayne Calloway Chair in Urologic Oncology, Memorial Sloan Kettering Cancer Center

Howard I. Scher, MD is Chief of the Genitourinary Oncology Service at Memorial Sloan Kettering Cancer Center (MSKCC), Professor of Medicine at the Weill Cornell Medical College, and the D. Wayne Calloway Chair in Urologic Oncology. Dr. Scher's research is focused on the codevelopment of targeted therapies and biomarkers such as circulating tumor cells (CTCs) which can be used to guide individual patients' treatment selection and improve the way drugs are evaluated in the clinic, accelerating regulatory approvals. Accordingly, he has led international efforts to standardize the design and analysis of phase II prostate cancer trials (PCWG2, PCWG3) and helped elucidate key molecular and genetic features of prostate cancer, translating these insights into the clinic by leading early phase and phase III registration trials of abiraterone acetate and enzalutamide which are now FDA approved. Dr. Scher serves as the principal investigator of the NIH Specialized Program of Research Excellence (SPORE) in Prostate Cancer at MSKCC and the Department of Defense-sponsored Prostate Cancer Clinical Trials Consortium (PCCTC), and has received the 2015 AACR Team Science Award for his multidisciplinary work developing AR inhibitors.

Lecia Sequist, MD, MPH, Associate Professor of Medicine, Harvard Medical School, Massachusetts General Hospital Cancer Center

Dr. Sequist is originally from Michigan and studied chemistry at Cornell University. She received her MD from Harvard Medical School and trained in internal medicine at the Brigham and Women's Hospital and in hematology/oncology at the Dana-Farber Cancer Institute, where she also received an MPH from the Harvard School of Public Health. She joined the faculty of the Center for Thoracic Cancers at the Massachusetts General Hospital Cancer Center in 2005 and has an active clinical and translational research career, as well as a busy practice caring for patients with lung cancer. She is currently an Associate Professor of Medicine at Harvard Medical School and the Mary B. Saltonstall Endowed Chair in Medical Oncology at Massachusetts General Hospital. She has held grants from the NIH, the DOD, and many private foundations. Dr. Sequist's research focuses on studying novel targets for lung cancer treatment, especially in patients with EGFR mutations and other driver oncogenes. She also studies the changes that

occur in cancers at the time of acquired drug resistance through tumor biopsies and non-invasive tests like CTC's and ctDNA. She aims to develop personalized treatment algorithms for lung cancer, utilizing targeted therapies specific to the patients' cancer genotypes, and understanding how this may change over the courses of the disease. In her free time, she likes to spend time with her husband and two sons, and is a hockey mom.

David Shames, PhD, Principal Scientist, Department of Oncology Biomarker Development, Genentech Inc.

David Shames is a Principal Scientist in the Oncology Biomarker Development group at Genentech where he leads a translational cancer biology lab focused on understanding the etiology and pathogenesis of lung cancer with a goal of using novel approaches to identify and develop predictive biomarkers for pipeline molecules targeting lung cancer and other solid tumors. In addition, David leads the biomarker group for US Medical Affairs BioOncology at Genentech and supports several late stage and post-marketed products in the lung cancer space including Tarceva, Avastin, Tecentriq, and Alecensa David also led the development of the recently-approved COBAS EGFR mutation plasma assay from the Genentech side.

Phil Stephens, PhD, Chief Scientific Officer, Foundation Medicine, Inc.

Dr. Stephens leads research and development at Foundation Medicine. Dr. Stephens is a world-renowned expert in next-generation sequencing and cancer genome analysis and has authored numerous publications in Nature, Nature Genetics, Nature Medicine, Cell and other high-profile journals. Since joining Foundation Medicine in early 2011 Dr Stephens has overseen the development of multiple comprehensive next generation sequencing diagnostic assays that accurately profiles cancer-related genes for targeted treatment options for patients with cancer in the CLIA setting.

AmirAli Talasaz, PhD, Co-Founder, President, and Chief Operating Officer, Guardant Health

AmirAli is an entrepreneur in the sample preparation and clinical research fields. Prior to co-founding Guardant, he was Senior Director of Diagnostics Research at Illumina and led the research efforts for emerging clinical applications of next-generation genomic analysis. During that time, he developed different sample preparation technologies suitable for clinical applications. Before Illumina, he founded Auriphex Biosciences, which focused on purification and genetic analysis of circulating tumor cells for cancer management. The technology was acquired by Illumina in 2009. He led the Technology Development group at Stanford Genome Technology Center. AmirAli received his PhD in electrical engineering and MSc in management science from Stanford University.

Muneesh Tewari, MD, PhD, Associate Professor, University of Michigan

Dr. Tewari earned an MD and PhD from the University of Michigan in 1997, where he worked with Dr. Vishva Dixit on mechanisms of apoptosis for his thesis research. He then completed an internship and residency in Internal Medicine at the University of Michigan Hospitals and a Medical Oncology clinical fellowship at Dana-Farber Cancer Institute. He subsequently trained in systems biology and genetics at Dana-Farber Cancer Institute/Harvard Medical School, as a postdoctoral fellow bridging the labs of Dr. Marc Vidal and Dr. Gary Ruvkun.

Dr. Tewari joined the faculty of Fred Hutchinson Cancer Research Center in 2005 where he began an independent research program studying microRNAs and cancer. In 2008, Dr. Tewari's laboratory reported that microRNAs are released from cancer cells into the bloodstream where they circulate in a highly stable form. This has led to burgeoning interest in circulating microRNAs as biomarkers for cancer and other diseases. His laboratory has gone on to study the biochemistry of extracellular microRNAs -- including mechanisms that stabilize them such as protein complexes and exosomes and other types of extracellular vesicles. His team has also advanced fundamental understanding pertinent to developing microRNA-based disease biomarker approaches, and advanced methodology for highly sensitive and reproducible measurement of extracellular microRNAs. He also currently leads an NIH-funded U01 team focused on performing discovery and establishing reference profiles of extracellular RNAs using next generation sequencing methods.

In the course of this research, Dr. Tewari has become inspired to develop a next generation of biomarker approaches that will involve serial monitoring at high time resolution at drastically lower cost than is currently possible. This will require both fundamental research on biomarkers and their relationship to physiology, as well as technology development grounded in advances in engineering and the physical sciences. In 2014, Dr. Tewari moved to the University of Michigan, where he is pursuing this inspiration as a tenured faculty member in the Departments of Internal Medicine and Biomedical Engineering, in the Center for Computational Medicine and Bioinformatics, and in the inter-disciplinary Biointerfaces Institute.

Kenneth Thress, PhD, Oncology Translational Scientist, AstraZeneca R&D

Kenneth Thress received his PhD in 2000 from the department of Pharmacology and Cancer Biology at Duke University, focusing on the mechanisms of apoptotic regulation. Following Duke, Ken joined the preclinical Oncology R&D unit of AstraZeneca based outside of Boston where he led several preclinical small molecule and immunotherapeutic drug discovery projects, including a Trk kinase inhibitor which progressed into Phase I trials. Ken then re-located to the UK for 2 years to lead a group of 10 translational scientists in AstraZeneca's Discovery Medicine. In 2009, Ken returned to the Boston area and soon joined the Oncology Biomarker group at Novartis where he was responsible for the biomarker strategy of three projects within Phase I clinical development. In 2011, Ken re-joined AstraZeneca's R&D group in their newly formed Translational Sciences department and, for the past 5 years, has been accountable for the scientific strategy to support the clinical translation of patient selection, response, and pharmacodynamic biomarkers on several high profile AstraZeneca pipeline projects. Most recently, Ken has led the biomarker efforts on Osimertinib (Tagrisso), the 3rd generation T790M-directed EGFR inhibitor recently approved in the US, Japan, and Europe for a subset of lung cancer patients. In his capacity on the Osimertinib program, Ken has become a leader in the use of circulating tumor DNA (ctDNA) to both select patients for targeted therapy and to explore for mechanisms of acquired resistance, co-authoring several high impact manuscripts.

Abraham Tzou, MD, Medical Officer, DMGP/OIR/CDRH/FDA

Abraham Tzou received his medical degree from Northwestern and trained in clinical pathology at Yale. He is a Medical Officer in the Division of Molecular Genetics and Pathology, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health. His work includes evaluation of in vitro diagnostic devices for cancer screening, companion diagnostics, cancer prognosis, genetic disorders, and other emerging diagnostics.

Victoria Zazulina, MD, Global Clinical Programme Team Leader, Boehringer Ingelheim

Victoria Zazulina, MD is a Global Team Leader in Clinical Development Oncology at Boehringer Ingelheim, currently leading the global pivotal development program. Dr. Zazulina is a pharmaceutical physician with experience across all phases of oncology clinical development and extensive regulatory experience as clinical lead for afatinib through successful global filing in two indications in lung cancer. Dr. Zazulina received her medical and specialist training in internal medicine at the Maimonid Classical State Academy in Russia. Prior to joining Boehringer Ingelheim in 2011, Dr Zazulina held the position of a Project Physician in Oncology at AstraZeneca working on Phase I – III clinical development of anti-cancer compounds. In this role Dr. Zazulina was a medical lead for in-house and external collaborative clinical trials investigating targeted therapies and their combinations in patients with various solid tumours. Dr Zazulina has presented the results of clinical research at international oncology congresses and has been published in a range of peer-reviewed journals.