# FDA-ASCO Clinical Outcome Assessment in Cancer Clinical Trials (COA-CCT)
## Fifth Annual Workshop

# Biographies

## 9:00 AM – 9:05 AM - Opening Remarks and Welcome

**Paul G. Kluetz, MD**
**Deputy Director, Oncology Center of Excellence, FDA**

Dr. Paul Kluetz is a medical oncologist and the Deputy Director of the Oncology Center of Excellence at the U.S. FDA. In addition to his broader role in OCE's strategic oversight and management, Dr. Kluetz founded the OCE's PFDD program and continues to support its strategic mission. He has engaged the global cancer drug development and health outcomes community in leading a sustained effort to advance patient reported outcomes (PRO) data, wearable technologies, and other methods to obtain rigorous patient experience data in both the clinical trial and "real-world" settings

**Heidi D. Klepin MD, MS**
**Professor, Hematology and Oncology, Wake Forest School of Medicine**

Dr. Heidi D. Klepin is a Professor in the Department of Internal Medicine, Section on Hematology and Oncology at the Wake Forest School of Medicine. She is a dually trained geriatrician and oncologist with a clinical and research focus on geriatric oncology. She also earned a master's degree in Health Sciences Research from Wake Forest University. Her clinical work focuses on a Geriatric Oncology Clinic, providing cancer care to adults 75 years of age or older. Her scholarly work is dedicated to improving the lives of older adults with cancer. Her research investigates the following themes among older adults with cancer: (1) patient-level characteristics as predictors of treatment outcomes; (2) the impact of chemotherapy on physical, cognitive and emotional health; and (3) interventions such as exercise to minimize treatment-associated disability and improve quality of life. She is a member of the Cancer and Aging Research Group, member of the Alliance for Clinical Trials in Oncology Cancer in the Older Adult and Health Outcomes Subcommittees, immediate past chair of the American Society of Clinical Oncology Cancer Research Committee and member of the American Society of Hematology Scientific Affairs Committee.

**Kathryn F. Mileham, MD, FACP**
**Chief of the Section of Thoracic Medical Oncology and Associate Professor at Atrium Health's Levine Cancer Institute**

Dr. Kathryn F. Mileham has been with Atrium Health in hematology/oncology since completing her fellowship at Vanderbilt eleven years ago. She is currently Chief of the Section of Thoracic Medical Oncology and Associate Professor at Atrium Health's Levine Cancer Institute. She has been awarded

Atrium Health's Provider of the Quarter and Patient Experience Top Care Provider as well as Charlotte Magazine's peer-selected Top Doctor for multiple years.
Dr. Mileham was selected for the 15th Workshop on Methods in Clinical Cancer Research. She is a graduate of the ASCO Leadership Development Program and is Chair of the ASCO Cancer Research Committee. She also serves on the Lung Cancer Initiative of North Carolina's Scientific Advisory Board. She is published in JCO, JAMA Oncology, and JOP and serves as the principal investigator for both sponsored and investigator-initiated protocols.

## 9:05 AM – 10:00 AM – Session 1: Identifying best methods for item selection to assess tolerability

**Vishal Bhatnagar, MD (Moderator)**
**Associate Director for Patient Outcomes, Oncology Center of Excellence, FDA**
Dr. Vishal Bhatnagar is a medical oncologist/hematologist and the Associate Director for Patient Outcomes in the OCE. His interests include patient reported outcomes, patient preference and incorporation of patient experience in oncology trials. His work focuses on the operational management of the OCE's Patient-Focused Drug Development, MD, is a medical oncologist/hematologist and the Associate Director for Patient Outcomes in the program. Additionally, Dr. Bhatnagar has a strong clinical interest in multiple myeloma and has previously served as an Office of Hematology and Oncology multiple myeloma scientific liaison. Dr. Bhatnagar received his BA in Political Science and his medical degree at the George Washington University. He completed his internal medicine residency and hematology/oncology fellowship at the University of Maryland.

### Panelists:

**Kathryn F. Mileham, MD, FACP**
**Chief of the Section of Thoracic Medical Oncology and Associate Professor at Atrium Health's Levine Cancer Institute**

Biography listed above

**Arlene E. Chung, MD, MHA, MMCi, FAMIA**
**Assistant Professor of Medicine and Pediatrics, University of North Carolina at Chapel Hill (UNC) School of Medicine and Associate Director of the Program on Health and Clinical Informatics at UNC**

Dr. Arlene E. Chung is Assistant Professor of Medicine and Pediatrics and the Associate Director of the Program on Health and Clinical Informatics at the University of North Carolina at Chapel Hill (UNC) School of Medicine. She is an informatician and physician scientist. She is triple board certified in the medical specialties of clinical informatics, general pediatrics, and general internal medicine. She serves as the Lead Informatics Physician for Patient Engagement at UNC Health, a system of 11 hospitals and over 350+ clinics across NC, where she leads digital health innovation projects to enable patient-centered care. She is the founding director of the UNC Clinical Informatics Subspecialty Fellowship Program and serves as an inaugural member of the NIH All of

Us Research Program's Institutional Review Board providing digital health and informatics expertise.

Dr. Chung has extensive experience with the design, implementation, and evaluation of patient-facing technologies, and the development of user-centered technologies, including chatbots, voice-assistant apps, and the highly successful PCORI-funded Crohn's and Colitis Foundation of America Partners Patient-Powered Research Network patient portal that integrates patient-reported outcomes, social media, electronic health records, and wearable device data (15,000+ patient members). Her research focuses on the integration of patient-reported outcomes (PROs) and other patient-generated health data (PGHD) from wearables/sensors into the electronic health record and patient portal, implementation of PGHD into clinical workflows, and on interactive data visualization at the point-of-care and for patients. Her recent research demonstrated that patient-authored free-text narratives of adverse events could be mapped to standard lexicons and provides insights beyond trial-specific assessments of the symptom experience. The overarching goal of Dr. Chung's research is to integrate the patient experience into routine clinical care with the ultimate goal of improving outcomes and care quality.

**Mary (Dicey) Jackson Scroggins**
**Patient Advocate (International Gynecologic Cancer Society &Pinkie Hugs, LLC)**

Mary (Dicey) Jackson Scroggins, a 23-year ovarian cancer survivor and health activist, is a writer, producer, and founding partner in Pinkie Hugs, LLC (www.pinkiehugs.com)—a mother-daughter writing and film production firm specializing in social justice-focused documentaries. She is also the Director of Global Outreach and Engagement for the International Gynecologic Cancer Society; chair of the Advocacy Special Interest Group for the African Organisation for Research and Training in Cancer; and a co-founder of In My Sister's Care, an organization focused on improving gynecologic cancer awareness and care for medically underserved women and on eliminating health disparities.
The recipient of the 2016 AACR Distinguished Public Service Award, Dicey is a member of the AACR Minorities in Cancer Research Council, the GOG Foundation Board of Directors, the NCI's Investigational Drug Steering Committee, and the "Community Engagement in Genomics" Working Group of NIH's National Human Genome Research Institute. She is also a member of the Program Steering Committee for the NCI-funded Florida-California Cancer Research, Education & Engagement ($CaRE^2$) Health Equity Center and the chair of the Advocate Advisory Board of the DOD-funded Consortium for Long-Term Ovarian Cancer Survival. Her activism is driven by a commitment to global health equity.

**Peter C. Trask, PhD, MPH**
**Director and Head of Oncology, Patient Centered Outcomes Research Group, Genentech**

Dr. Peter Trask is the Director and Head of Oncology in the Patient Centered Outcomes Research Group at Genentech. He is a clinical psychologist by training with a Master's in Public Health. He is recognized for his work on assessing health-related quality of life, disease and treatment-related symptoms, and emotional distress in cancer patients.

His early research at the University of Michigan focused on assessing and treating emotional distress and changes in HRQOL in individuals diagnosed with cancer; with his research studies

focusing on a variety of cancer diagnoses and treatments. He has evaluated the engagement of cancer patients in cancer screening and developed several measures to assess symptoms in cancer patients. Dr. Trask was one of the early adopters of the PRO-CTCAE when he started his industry career at Pfizer and has continued to include the measure in early and late phase oncology clinical trials during his time at Sanofi and now with Genentech. In 2016 he presented recommendations for the inclusion and item-selection of the PRO-CTCAE in industry-sponsored oncology clinical trials at ISOQOL; recommendations that were subsequently published in 2018 in *Clinical Trials*.

**Maxime Sasseville, PhD, MSc**
**Manager of Oncology Division 2, Health Canada**

Dr. Maxime Sasseville is the manager of Oncology Division 2 within Health Canada. He and his team of scientific and clinical evaluators are responsible for pre-market drug risk/benefit assessments. His division has regulatory responsibility for assessing non-clinical, pharmacology and clinical data for drugs for the treatment of haematological and oncological diseases. Dr. Sasseville has 10 years of experience in the regulatory and scientific evaluation of new drugs in different therapeutic areas including oncology, metabolism and reproduction. He is participates in a number of initiatives for Health Canada, including memberships in the SISAQOL Consortium (Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data for Cancer Clinical Trials) led by the EORTC (European Organization for the Research and Treatment of Cancer) and PROTEUS Consortium (Patient-Reported Outcomes Tools: Engaging Users and Stakeholders), which aim at setting and promoting the use of best practices in Patient-Reported Outcome Measures design, analysis and reporting.

**Ethan Basch, MD, MSc**
**Physician-in-Chief, North Carolina Cancer Hospital**
**Professor and Chief, Oncology, University of North Carolina School, Chapel Hill**

Dr. Ethan Basch is Physician-in-Chief of the North Carolina Cancer Hospital and Chief of Oncology at the University North Carolina, where he is the Richard M. Goldberg Distinguished Professor in Medical Oncology and Professor of Public Health, Health Policy and Management, Gillings School of Global Public Health. His research group established that up to half of patients' symptomatic adverse events go undetected in clinical trials, and that patient-reported outcome questionnaires substantially improve detection. His team determined that integrating web-based patient-reported symptoms into oncology clinical practice improves clinical outcomes, including survival, and reduces health service utilization. His group created a system for the National Cancer Institute to collect patient-reported AEs during cancer trials called the 'PRO-CTCAE.'

Dr. Basch is involved in efforts to bring PROs into comparative effectiveness research, routine care, and quality improvement. He is a member of the Board of Directors of ASCO, an Associate Editor at JAMA, and a prior member of the Board of Scientific Advisors for the National Cancer Institute and the Methodology Committee of the Patient-Centered Outcomes Research Institute.

# Biographies

## 10:05 AM – 11 AM – Session 2: Considerations for assessment frequency and how it relates to the measurement of tolerability

**Bellinda King-Kallimanis, PhD (Moderator)**
**Senior Staff Fellow, Oncology Center of Excellence, FDA**
Bellinda King-Kallimanis is a Senior Staff Fellow in the Oncology Center of Excellence at the FDA. She has a PhD in psychometrics and works on patient-focused drug development initiatives that focus on using clinical outcome assessments (COAs) in cancer clinical trials. Her current projects involve looking at open label response bias, understanding responsiveness of physical function measures and investigating current COA strategies being submitted to the agency to learn how these can be improved. Bellinda has been working in the field of COAs for the past 11 years across both academia and industry. She has investigated how patients' responses to questionnaires can shift over time using structural equation modeling and worked on qualitative projects developing new patient-reported outcome instruments

### Panelists:

**Heidi D. Klepin MD, MS**
**Professor, Hematology and Oncology, Wake Forest School of Medicine**

Biography listed above

**Sundeep Agrawal, MD**
**Medical Oncologist, Office of Oncologic Diseases, CDER, FDA**

Sundeep Agrawal is a board-certified medical oncologist and current medical officer at the FDA's Center for Drug Evaluation and Research (CDER), Division of Oncology Products 1. He completed his residency training at Drexel University College of Medicine in 2012 and completed fellowship in hematology and oncology at Washington Hospital Center/Georgetown University Hospital in 2016. He joined the FDA in September 2016 and his area of focus is genitourinary cancers. Dr. Agrawal's interests include novel clinical trial designs, the use of real-world evidence for regulatory purposes, and the application of technology to promote advances in oncology clinical trials.

**Joyce Cheng, PhD**
**Mathematical Statistician, Office of Biostatistics, CDER, FDA**

Joyce Cheng has been a statistical reviewer in the Office of Biostatistics, Office of Translational Sciences in the Center for Drug Evaluation and Research since 2015. In addition to review work, Dr. Cheng has worked on projects involving small sample sizes in randomized oncology trials, assessment of benefit of CDK 4/6 inhibition in less common breast cancer subsets, and assessment frequency for patient reported outcomes. She received her PhD from Baylor University.

# Biographies

### Wendy R. Sanhai, PhD, MBA
### Patient Advocate

Dr. Wendy R. Sanhai has extensive experience across a broad spectrum of issues in the pharmaceutical, biotech and medical device industries and regulatory science. Over the course of her 25+ year career in healthcare and public health, she has held key leadership roles in academia, at federal research and regulatory organizations including the NIH, the Foundation for NIH (FNIH) and the FDA and within private industry. Among her many strengths is her ability to identify critical governance, strategic and scientific gaps, and leverage resources to create innovative approaches in support of large-scale, strategic, scientific, and public health initiatives, all directed to patient benefit.

Her experiences include developing strategies for governance, research, business development, as well as the design, implementation, and management of large-scale scientific programs at the NIH, FNIH, FDA, academia and industry. She has worked across multiple therapeutic and disease prevention areas as well as in medical product development, addressing specific product development issues, regulatory challenges as well as global health needs. Dr. Sanhai has a Ph.D. in clinical biochemistry, and an Executive MBA. She is on the faculty of Duke University, School of Medicine and a Senior Executive Education Fellow, University of Maryland, School of Business. Dr. Sanhai is a member of the Board of Directors, Medicines for Malaria Venture (MMV), Member of the Advisory Board, Univ. Maryland School of Business, and Member of the Advisory Committee for Innovation in Regulatory Science, Burroughs Wellcome Fund.

### Diane Fairclough, DrPH
### Professor, Colorado School of Public Health, University of Colorado

Diane Fairclough, DrPH, is a Professor in the Colorado School of Public Health. She received her doctoral degree in Biostatistics from the University of North Carolina and has held appointments at St. Jude Children's Research Hospital, Harvard School of Public Health, AMC Cancer Research Center and the University of Colorado Denver. She is a Past President of the International Society for Quality of Life Research and the 2012 recipient of their President's Award for her contribution to the field and the society. Her primary research interest is Quality of Life, outcomes in palliative/hospice care, and psychosocial sequelae of cancer and its therapy in pediatric and adult patients. Dr. Fairclough's statistical research interests include the analysis of longitudinal studies with non-random missing data due to disease morbidity or mortality. She has over 200 peer-reviewed publications and is the author of Design and Analysis of Quality of Life Studies in Clinical Trials, 2nd edition (2010).

### James W. Shaw, PhD, PharmD, MPH
### Lead, Patient-Reported Outcomes Assessment, Bristol-Myers Squibb

James W. Shaw, PhD, PharmD, MPH is employed as Lead, Patient-Reported Outcomes Assessment (PROA) in Worldwide Health Economics and Outcomes Research (WWHEOR) at Bristol-Myers Squibb (BMS). He leads a team of research scientists specialized in the development, validation, and application of clinical outcome assessment (COA) tools. Members of the PROA team are responsible for driving COA strategies in BMS' clinical trial and real-world data generation

programs. As PROA Lead, Dr. Shaw ensures that endpoint strategies are aligned with product strategic plans from matrix teams to achieve BMS' vision of patient centricity. He also provides strategic leadership to therapeutic area teams regarding the development of COA strategies, fitness of assessment measures for intended uses, and regulatory efforts to maximize labeling opportunities.

Prior to assuming his current role, Dr. Shaw served as COA Lead for oncology indications and managed WWHEOR books of work for several OPDIVO lifecycle management (LCM) programs. Between 2011 and 2013, Dr. Shaw was employed in Global HEOR (GHEOR) at AbbVie where he supported HUMIRA's rheumatoid arthritis and juvenile idiopathic arthritis indications. Between 2005 and 2011, Dr. Shaw was employed as Assistant Professor in the Department of Pharmacy Systems, Outcomes, and Policy (PSOP) at the University of Illinois at Chicago (UIC) and the Department of Neurology at Thomas Jefferson University (TJU) where he drove research programs focusing on health preference assessment and issues in the analysis and application of health preference data. He maintains an adjunct faculty position at UIC. Dr. Shaw participates actively in numerous global external collaborations affecting policies, standards, and the use of COA measures, including the PRO Consortium, PRO Measurement Information System (PROMIS) Physical Function in Oncology COA Qualification Industry Partnership, and EuroQol Group. He is well known for his research involving the EQ-5D questionnaire and developed or co-developed US population utility indices the 3-level and 5-level versions of the EQ-5D. To date, Dr. Shaw has authored or co-authored more than 50 research papers and more than 100 published abstracts.

## 12:00 PM (Noon) – 1:00 PM – Session 3: An interactive panel discussion to explore how a global item capturing side effect bother complements the picture of tolerability

**Paul G. Kluetz, MD (Moderator)**
**Deputy Director, Oncology Center of Excellence, FDA**
Biography listed above

### Panelists:

**Laura Fernandes, PhD**
**Mathematical Statistician, Office of Biostatistics, CDER, FDA**
Dr. Laura Fernandes is a statistical reviewer in the Office of Biostatistics at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). She received her PhD in biostatistics from the University of Michigan, Ann Arbor. Prior to joining the FDA, she worked as a research analyst supporting the cancer center at University of Michigan. She also held positions as a statistical programmer at GlaxoSmithKline (GSK) prior to her PhD. At the FDA she has worked on numerous solid tumor applications and currently supports the division of hematology in the office of oncology products. Her research focusses on clinical trials, adaptive dose-finding designs, patient reported outcomes, and disparities in clinical trials in oncology.

# Biographies

**Preeti Narayan, MD**
**Medical Oncologist, Office of Oncologic Diseases, CDER, FDA**

Dr. Preeti Narayan is a medical oncologist and clinical reviewer on the breast cancer team in the Division of Oncology 1 (DO1) in the Office of Oncologic Diseases (OOD), Center for Drug Evaluation and Research at the FDA. She received her medical degree from St. George's University in the West Indies and completed her internal medicine residency at SUNY Downstate Medical Center in Brooklyn, NY. She completed her fellowship in Hematology and Oncology at the University of Florida in Gainesville, FL. Her professional interests include biomarker and liquid biopsy use in diagnosis, treatment and monitoring of solid tumors and treatment of high-risk breast cancer.

**Janet Freeman-Daily, MS, ENG**
**Patient Advocate**

Janet Freeman-Daily, MS, Eng., is a retired aerospace system engineer (trained at MIT and Caltech), freelance writer, speaker, and metastatic lung cancer patient/activist. She was diagnosed with advanced non-small cell lung cancer in May 2011 and progressed to stage 4 despite two lines of chemo and radiation. Fortunately, she learned about biomarker testing and clinical trials from other patients in online lung cancer communities. Thanks to a targeted therapy clinical trial, she has had no sign of cancer on scans since January 2012. Her focus is now on translating the experience and science of cancer for others. She writes an award-winning blog, cofounded and co-manages The ROS1ders, serves on staff for the IASLC STARS program, collaborates with lung cancer patient and advocacy organizations, and speaks as a research advocate at international oncology conferences, cancer research centers, biomedical and pharmaceutical companies, and government agencies. Her advocacy work focuses on ROS1 cancer, lung cancer, patient-centered outcomes, access to biomarker testing, data sharing, shared decision making, and goals of care.

**Sandra Spivey**
**Patient Advocate**

Sandi began her advocacy efforts in breast cancer in 1995 after receiving a diagnosis of stage 2 breast cancer at the age of 42. She was a board member for the Y-ME Orange County Breast Cancer affiliate for five years. Her interest in research grew as she attended several National Breast Cancer Coalition's annual advocacy conferences where she also learned how to become a legislative advocate. In 1998, at the age of 45, Sandi was diagnosed with metastatic breast cancer to her bones. At that time, she redoubled her advocacy involvement.

She currently serves on the Komen Advocates in Science Steering Committee, the Breast Cancer Disease Orientation Team at University of California, Irvine, the MBC Alliance Patient Advocate Advisory Group, the Komen MBC Advisory Group and the Orange County Komen MBC program committee. She has participated in over 20 scientific funding reviews for breast cancer research for Komen, the Department of Defense and METAvivor.

As a peer helpline volunteer for SHARE, Living Beyond Breast Cancer and After Breast Cancer Diagnosis, Sandi has provided one-to-one support to nearly 100 metastatic breast cancer patients and caregivers. She has found that many callers want to feel like they are not alone and find it empowering they are fully understood.

Sandi lives in Laguna Niguel, CA and has been married to Bill since 1975. They have two grown children and three grandchildren. She enjoys writing (including her catsncancer.com blog), traveling and volunteering at a regional animal shelter. Contact Info: Sandra.spivey@pacbell.net

**Sandra A. Mitchell, PhD**
**Research Scientist and Program Director, Healthcare Delivery Program**
**National Cancer Institute**

Dr. Sandra A. Mitchell is a Research Scientist and Program Director in the Outcomes Research Branch in the Healthcare Delivery Research Program, National Cancer Institute (NCI) at National Institute of Health (NIH). Her primary research interests focus on the measurement of symptoms and impairments in physical functioning, and the testing of interventions to improve these outcomes, especially in vulnerable cancer populations, including older adults, patients with multimorbidity, and transplant survivors with chronic graft-versus-host disease. She has extensive experience in the collection, analysis, and interpretation of patient-generated health outcomes data in clinical trials and the use of performance-based measures of physical functioning. Her methodologic interests include latent variable mixture modeling and visual data analytics. Her program of research has an emphasis in cancer care delivery science, including dissemination and implementation of evidence-based interventions, and the use of health information technologies and decision support to improve care quality and strengthen patient self-management.
Dr. Mitchell serves as the NCI Scientific Director for the development and testing of the National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). PRO-CTCAE is a measurement system designed to integrate patient-reporting of symptomatic adverse events into cancer clinical trials.

A board-certified acute care nurse practitioner, Dr. Mitchell received undergraduate and master's degrees from the University of Toronto and the University of Rochester, and a PhD from the University of Utah, with a focus in quantitative methods. She is the author of numerous peer-reviewed publications in the areas of symptom management, cancer survivorship, measurement of symptoms and physical function, and the application of patient-reported outcomes to evaluate treatment effects, including treatment tolerability. A Fellow of the American Academy of Nursing, her work has been recognized with several awards, including the Leukemia and Lymphoma Society *Relentless for a Cure* award.

**David Cella, PhD**
**The Ralph Seal Paffenbarger Professor and Chair, Department of Social Sciences, Director, Institute for Public Health and Medicine, Center for Patient-Centered Outcomes, Northwestern University**

Dr. David Cella is The Ralph Seal Paffenbarger Professor and Chair of the Department of Medical Social Sciences, and an elected member of the National Academy of Medicine. Dr. Cella's research portfolio extends from health outcomes measurement and applications to clinical trials, comparative effectiveness, and learning health system implementation.

As an expert in applied health status measurement, he has led the development and validation of the FACIT Measurement System, PROMIS, Neuro-QoL, and the emotional health domain of the NIH Toolbox. These measurement systems are used around the world by thousands, in clinical practice and research.

**Gita Thanarajasingam, MD**
**Assistant Professor of Medicine and Consultant, Hematology, Mayo Clinic**

Dr. Gita Thanarajasingam is an Assistant Professor of Medicine and consultant in the Division of Hematology at Mayo Clinic in Rochester, Minnesota. She is a graduate of Yale University and Mayo Clinic School of Medicine and completed her internal medicine residency at the Brigham and Women's Hospital at Harvard Medical School. She returned to Mayo Clinic Rochester to complete her Hematology/Oncology Fellowship and Advanced Lymphoma Fellowship before joining the faculty of the Mayo Clinic Lymphoma disease-oriented group in 2016.

Her clinical practice as an oncologist is focused on Hodgkin and non-Hodgkin lymphoma, and she performs health outcomes research in lymphoma and other cancers. As a clinical investigator, her work focuses on improving the evaluation of adverse events (AEs) of treatment and measuring their impact on cancer patients. She developed the Toxicity over Time (ToxT), a longitudinal patient-focused approach to AE evaluation. She is active in the implementation of patient-reported outcomes to better understand treatment toxicity and tolerability. She serves of as vice co-chair of the Alliance for Clinical Trials in Oncology Health Outcomes Committee and is the recipient of K and U01 grants from the U.S. National Institutes of Health in support of her work. She leads the ongoing international multi-stakeholder Lancet Haematology Commission, "Beyond maximum grade: modernizing the assessment and reporting of adverse events in haematological malignancies." Her research program overall endeavors to improve the accuracy and patient-centeredness of AE evaluation and better understand cancer treatment tolerability from the patient's perspective.

## 2:00 PM- 2:50 PM – Session 4: Project Patient Voice - Methodological Perspectives

**Janice Kim, Pharm.D., MS (Moderator)**
**Senior Regulatory Health Project Manager, Office of Oncologic Diseases, CDER, FDA**
Janice Kim is a Senior Regulatory Health Project Manager in the Office of Oncologic Diseases – Immediate Office and is a practicing pharmacist. She graduated from the University of Virginia with a Bachelor's degree in biomedical engineering. In addition, she received her Master's degree in biochemistry at Georgetown University before completing her pharmacy degree at the Medical College of Virginia. She completed her ambulatory care residency at a free clinic. She contributes to the policy development for the patient-focused drug development program in the Oncology Center of Excellence at the FDA. She enjoys working with patients and continues to work in the free clinic setting.

# Biographies

## Panelists:

**Paul G. Kluetz, MD**
**Deputy Director, Oncology Center of Excellence, FDA**

Biography listed above

**Vishal Bhatnagar, MD**
**Associate Director for Patient Outcomes, Oncology Center of Excellence, FDA**

Biography listed above

**Mallorie Fiero, PhD**
**Mathematical Statistician, Team Leader, Office of Biostatistics, CDER, FDA**

Dr. Mallorie Fiero has been at the FDA since 2016 and is a statistical team leader supporting the Division of Oncology 1 (DO1) in the Office of Oncologic Diseases (OOD). She received her BS in Statistics from UCLA and a PhD in Biostatistics from the University of Arizona where her research focused on missing data in cluster-randomized trials. Before her current role, she was a statistical reviewer in DO2 and DO3 covering gastrointestinal, thoracic head and neck, neuro-oncology, and other rare cancers. Mallorie has been heavily involved in patient-focused drug development (PFDD) in the Oncology Center of Excellence and CDER. Her research interests include estimands, missing data, and statistical analysis of patient-reported outcomes in cancer trials.

**Katarina Halling**
**Global Head, Patient Centered Science, AstraZeneca**

Katarina Halling is leading the Patient Centered Science group at AstraZeneca. Katarina is passionate about patient focused drug development and innovative ways to capture patient experience in a robust way that is meaningful to patients and other stakeholders. In her role, she and the PCS team collaborates with the broader organization to develop and implement relevant patient centered strategies and plans in support of global development programs. Katarina has more than 20 years of experience of incorporating the patient voice in drug development, both within AstraZeneca and as a consultant. As a consultant, Katarina was the European scientific and regulatory lead for COA and eCOA in Europe with PRO Consulting.

During her career, Katarina has developed several PRO instruments, to address efficacy, tolerability and impact of disease and treatments in several diseases as well as diagnostic PRO tools and communication tools to improve communication between patients and physicians. Katarina was the industry co-director in the C-Path PRO Consortia 2015 -2016. She has been involved in multiple pharma FDA collaborations, including Brookings and PFDD meetings. The last 7 years Katarina and members of the PCS and oncology R&D team has worked to develop innovative ways to optimally communicate patients' experience of tolerability symptoms and partnered with the FDA on Project Patient Voice.

# Biographies

### Claire Snyder, PhD
### Professor of Medicine and Oncology, Johns Hopkins School of Medicine

Dr. Claire Snyder is a Professor of Medicine, (Division of General Internal Medicine) and Oncology at the Johns Hopkins School of Medicine, with a joint appointment in Health Policy & Management in the Bloomberg School of Public Health. She is Director of the Johns Hopkins Program for Building Lifestyle, Outcomes, and Care Services Research in Cancer (BLOCS).

Dr. Snyder's research focuses on the quality of cancer care, and she has received competitive, peer-reviewed funding from the National Cancer Institute, American Cancer Society, and Patient-Centered Outcomes Research Institute. Dr. Snyder is a past president of the International Society for Quality of Life Research. For the American Society of Clinical Oncology (ASCO), she served on the Health Services Committee, Quality of Care Committee, Survivorship Care Planning Task Force, and Patient-Reported Outcomes Panel. Previously, Dr. Snyder worked at the U.S. National Cancer Institute and edited *Outcomes Assessment in Cancer: Measures, Methods, and Applications* (Cambridge University Press). She began her career in the private sector at Covance Health Economics and Outcomes Services Inc.

Dr. Snyder received a BA *cum laude* in Public Policy Studies with a certificate in Health Policy from Duke University. She received a Master of Health Science in Health Policy in 2000 and a PhD in Health Policy & Management in 2005 from the Johns Hopkins Bloomberg School of Public Health. She is originally from New Orleans, Louisiana, and currently resides in Baltimore, Maryland.

### Lori Minasian, MD, FACP
### Deputy Director, Division of Cancer Prevention, National Cancer Institute

Dr. Lori Minasian, a medical oncologist, is the Deputy Director for the Division of Cancer Prevention at the National Cancer Institute, NIH. She is a leader in NCI clinical trials, first leading the NCI's Community Clinical Oncology Program (a community trials program) for over 15 years, and then supporting a variety of the processes in the restructuring of the NCI's clinical trials programs. She has facilitated the development of cancer prevention and symptom management clinical trials and the incorporation of patient reported outcomes in cancer clinical trials. She is one of the senior leaders in the development of the Patient Reported Outcomes version of the CTCAE and leads the NCI's Community Cardiotoxicity Task Force.

In addition to her administrative position, she participates in the NCI's Women's Malignancy Clinic seeing patients, supervising fellows and participating in the development and implementation of clinical trials using novel agents. Dr. Minasian earned a Medical Degree from the George Washington University School of Medicine in Washington, D.C. She completed a fellowship in Medical Oncology at the Memorial Sloan-Kettering Cancer Center.

# Biographies

## 3:00 PM – 3:50 PM – Session 5: Project Patient Voice – Patient & Health Care Provider Perspective

**Bellinda King-Kallimanis, PhD (Moderator)**
**Senior Staff Fellow, Oncology Center of Excellence, FDA**
Biography listed above

### Panelists:

**Christine Hodgdon**
**Patient Advocate**

Christine Hodgdon has been a metastatic breast cancer (MBC) patient and advocate since her diagnosis in April 2015. Her goal as an advocate is to influence and improve research outcomes by 1) empowering patients through education and 2) helping the science community understand that research is most effective when the patient voice is represented.

Christine created her own search algorithm to capture ALL possible clinical trials for MBC patients and launched a website, TheStormRiders.org, which includes a searchable trial and drug database, a calendar of events, and research articles all specific to MBC. She also co-founded the program, Guiding Researchers & Advocates to Scientific Partnerships (GRASP) in order to bridge the gap that often exists between scientists and patient advocates. Important to any of the initiatives with which Christine is involved is ensuring that health disparities are addressed, especially in underserved and vulnerable populations that are disproportionately impacted by breast cancer

**Lee Jones, MBA**
**Patient Advocate**

Lee was diagnosed with Stage IV colon cancer in March 2004. Since undergoing a number of rounds of chemotherapy and a liver resection in July 2006, he has been cancer-free. Lee has a BA in Psychology and an MBA in Finance and had a successful executive career in government, banking, consulting and not-for-profit organizations.

To help others to survive and thrive after a cancer diagnosis, Lee became active with Fight Colorectal Cancer as a research advocate and became a member of the Georgetown Oncology Institutional Review Board (IRB). He is a patient advocate member of the SWOG Survivorship Committee and the PCORI Clinical Trials Advisory Panel (CTAP), and he is on the Boards of the Cancer Action Coalition of Virginia (CACV), the Ruesch Center (Georgetown University) and the Cancer Policy and Advocacy Team (CPAT) of the National Coalition for Cancer Survivorship. He has been a peer research proposal reviewer for ASCO, PCORI and the DOD, and he is a member of ASCO, the Colorectal Cancer Roundtable and the Alliance for Regenerative Medicine (ARM). Lee has collaborated on several projects sponsored by The Friends of Cancer Research, including defining tolerability, reporting adverse events and tightening exclusion criteria, and has been a speaker at Ruesch Center, AAADV, CPAT and NCCN conferences.

# Biographies

**Ashley J. Housten, OTD, MSCI**
**Assistant Professor, Public Health Sciences, Washington University School of Medicine**

Ashley J. Housten, OTD, MSCI, is an Assistant Professor in the Division of Public Health Sciences at Washington University School of Medicine (WUSM). Her research program focuses on investigating the role of health literacy in decision-making among diverse and under-served populations. Specifically, she is interested in the dissemination and implementation of decision support strategies to improve health behaviors and outcomes, particularly in populations that experience health inequity. With a focus on how people evaluate and apply health information, her research uses qualitative and mixed-methods to identify challenges and opportunities to strengthen patient-provider engagement in decision-making across the cancer care continuum.

Dr. Housten has ongoing projects investigating decision support strategies for the initiation, frequency, and discontinuation of breast cancer screening mammography among racially/ethnically diverse women; breast cancer treatment decision-making among older women; and delays to breast cancer chemotherapy treatment among low resource populations. Dr. Housten earned her Doctoral Degree in Occupational Therapy and Master of Science in Clinical Investigation at WUSM. She completed her postdoctoral training at WUSM in the Division of Public Health Sciences and at The University of Texas MD Anderson Cancer Center in the Department of Health Services Research.

**Karen L. Smith, MD, MPH**
**Assistant Professor, Oncology, Johns Hopkins University School of Medicine**

Dr. Karen Smith is an Assistant Professor of Oncology at the Johns Hopkins University School of Medicine and a member of the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center Women's Malignancies Program. Her clinical practice is based at Sibley Memorial Hospital in Washington D.C. and focuses on breast cancer care with an emphasis on young women. Her primary research areas of interest include: patient-reported outcomes, reducing the toxicities of cancer therapies, improving care delivery and reproductive health in breast cancer patients. In addition, Dr. Smith is the Director of Breast Medical Oncology at Sibley Memorial Hospital and Co-Director of the Young Women with Breast Cancer Program at the Kimmel Cancer Center at Johns Hopkins.

She received a B.A. in Anthropology at Washington University in St. Louis and then attended medical school at Rush Medical College. She completed her internship and residency in internal medicine at the Hospital of the University of Pennsylvania and then received a M.P.H. at the Johns Hopkins Bloomberg School of Public Health followed by fellowship in in medical oncology at Memorial Sloan Kettering Cancer Center in New York.

**Adedayo A. Onitilo, MD, PhD, MSCR, FACP**
**Director of Cancer Care and Research Center, Marshfield Clinic Health System**
Dr. Adedayo Onitilo is the Director of Cancer Care and Research Center at Marshfield Clinic Health System (MCHS). He is a principal investigator of WiNCORP, which provides access to NCI-sponsored clinical trials to more than 680,000 people in Wisconsin, and parts of Michigan, Iowa and Minnesota. Dr. Onitilo is a principal investigator for various pharmaceutical clinical trials at

MCHS. He is editor-in-chief for Clinical Medicine and Research, a publication of original scientific medical research. He also holds a clinical faculty position at the University of Wisconsin. Dr. Onitilo enjoys working in the Health System because it allows him to practice exceptional medicine and conduct landmark research.

In his spare time, you'll find Dr. Onitilo displaying his ping-pong skills or working on his golf game. As a physician who has lived and practiced throughout the world, he loves to travel and meet new people. He is happily married with children.

Dr. Onitilo is a board certified in internal medicine, hematology, medical oncology, and hospice and palliative medicine. He earned his medical degree at Ogun State University in Nigeria. He did his residency at Columbia University, College of Physicians and Surgeons - Harlem Hospital in New York. Dr. Onitilo completed a fellowship in oncology/hematology and earned a Master of Science degree in clinical research at the Medical University of South Carolina. He earned a doctorate degree in epidemiology from The University of Queensland, Australia. Dr. Onitilo is a member of the Wisconsin chapter of the American Cancer Society and Wisconsin Cancer Council steering committee.

## 3:50 PM – 4:00 PM - Workshop Wrap-Up and Closing Remarks

Paul G. Kluetz, MD
Deputy Director, Oncology Center of Excellence, FDA

Heidi D. Klepin MD, MS
Professor, Hematology and Oncology, Wake Forest School of Medicine

Kathryn F. Mileham, MD, FACP
Chief of the Section of Thoracic Medical Oncology and Associate Professor at Atrium Health's Levine Cancer Institute

## 4:00 PM – Adjourn