6th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop

Characterizing Physical Function

Day 2: July 23, 2021 9:00 AM - 12:00 PM ET

Biographies

Workshop Day 2 Opening Remarks

Vishal Bhatnagar, MD
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 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.

Session 3: Analytic Considerations when Measuring Physical Function

Paul Kluetz, MD (Moderator)
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 assisting in the strategic and operational oversight of the OCE, he has a broad interest in trial design and endpoint selection to expedite drug development and define clinical benefit in oncology trials. Some of his initiatives include creation of the OCE's patient-focused drug development program and expansion and direction of OCE's efforts to advance real-world evidence, decentralized trial design and digital health technology. He is also active in regulatory review of Oncology products and oversees important oncology drug labeling initiatives. Dr. Kluetz remains clinically active, caring for patients and supervising medical residents at the Georgetown University Hospital.

Panelists:

R. Angelo de Claro, MD
Director, Division of Hematologic Malignancies 1
CDER, FDA

Dr. de Claro is the Division Director for Division of Hematologic Malignancies I with Office of Oncologic Diseases. He provides leadership and scientific direction to staff engaged in the review and evaluation of applications for investigational new drugs and drug approvals. Dr. de Claro is also the Associate Director (Acting) for Global Clinical Sciences with US FDA Oncology Center of Excellence (OCE). In this role, he leads OCE efforts to advance cancer drug development and regulatory science across the globe, including direction of Project Orbis, a global collaborative review program started in 2019. He is board certified in Internal Medicine, Hematology, and Medical Oncology. He completed his Hematology-Oncology fellowship at University of Washington and Internal Medicine residency at Baylor College of Medicine. He has been with FDA since 2010.

Amylou Dueck, PhD
Associate Professor of Biostatistics
Mayo Clinic

Dr. Amylou Dueck is an Associate Professor of Biostatistics and Vice Chair of the Department of Quantitative Health Sciences at Mayo Clinic in Arizona. She is an expert in the statistical analysis of patient-reported outcomes (PROs) in cancer clinical trials and has contributed to the development of PRO measures, including the PRO-CTCAE and MPN-SAF. Dr. Dueck is the Chair of the Health Outcomes Committee of the Alliance for Clinical Trials in Oncology, which is an adult cancer cooperative group in the US. In this role, Dr. Dueck partners with clinical investigators to integrate, monitor, analyze, and report PROs in a wide variety of cancer clinical trials.

Bellinda King-Kallimanis, PhD
Director, Patient-Focused Research
LUNGevity Foundation Lori Minasian, MD, FACP

Dr. King-Kallimanis is responsible for overseeing LUNGevity's Patient-Focused Research Center (Patient FoRCe). Patient FoRCe serves as a bridge to connect the patient voice with healthcare professionals, regulators, policymakers, and drug developers to ensure that it is heard and incorporated into decisions.

Dr. King-Kallimanis has worked in patient-focused research for the past 17 years. Before joining LUNGevity as Director of Patient-Focused Research, she worked at the US Food and Drug Administration Oncology Center of Excellence on the Patient Focused Drug Development team. There, Dr. King-Kallimanis worked on the development and launch of Project Patient Voice, a resource for patients and caregivers along with their healthcare providers to look at patient-reported symptom data collected from cancer clinical trials.

Dr. King-Kallimanis also has experience in industry and academia where she worked on developing fit for purpose patient reported outcome measures from conducting the qualitative interviews of patients through to psychometric validation. She has published over 60 peer-reviewed papers that cover disease areas such as lung cancer, depression, cognitive impairment, and multiple sclerosis. She received her Bachelor of Social Science and her Master of Science in applied statistics from Swinburne University of Technology in Melbourne, Australia, and her PhD in psychometrics from the Academic Medical Center in Amsterdam, Netherlands.

Biographies

Pourab Roy, PhD
Biostatistician, Visiting Associate
CDER, FDA

Pourab Roy, PhD. is a statistician in the Division of Biometrics V, Office of Biostatistics which supports the Office of Oncology Drugs at the Center for Drug Evaluation and Research (CDER). His research interests include statistical methods for analyzing real world and patient-reported outcome data. He is also a member of the Pediatric Review Committee (PeRC) and conducts research on using Bayesian borrowing to analyze pediatric data. He has participated in several statistics and oncology workshops, conferences and working groups on these topics. Dr. Pourab Roy received his PhD in Biostatistics from the University of North Carolina at Chapel Hill and has been working at the FDA since 2018.

Marian Strazzeri, PhD
Mathematical Statistician
CDER, FDA

Marian is a reviewer on the PFSS Team in FDA/CDER/OB and is also pursuing a PhD in Measurement, Statistics, and Evaluation (EDMS) at the University of Maryland (UMD) College Park. Both her work and research interests center around the use of clinical outcome assessments (COAs) in clinical research (e.g., drug development) and health care settings. She earned her BAs in Mathematical Statistics and Sociology from the University of Virginia (UVA) in 2008 and then went on to earn a M.S. in Statistics from UVA in 2009. After graduating with her master's degree, she worked as a research analyst in the Office of Surveillance and Epidemiology (OSE) at FDA/CDER.

In OSE, among other things, she helped conduct observational, epidemiologic post-market safety studies to investigate potential safety signals generated from adverse event reports. Subsequently, she worked as a Mathematical Statistician at the National Center for Health Statistics (NCHS) from 2013 to 2015. At NCHS, she gained experience with survey design and sampling methods, small area estimation, multiple imputation techniques, and methods for evaluating the impact of imputed data on design effects and variance estimates. In July 2015, she transferred to FDA/CDER/OB and joined the PFSS Team, where her work has centered around the use of COAs in medical product development and regulatory review, with a particular focus on quantitative measurement issues.

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Session 4: Envisioning Physical Function Moving Forward

Paul Kluetz, MD (Moderator)
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 assisting in the strategic and operational oversight of the OCE, he has a broad interest in trial design and endpoint selection to expedite drug development and define clinical benefit in oncology trials. Some of his initiatives include creation of the OCE's patient-focused drug development program and expansion and direction of OCE's efforts to advance real-world evidence, decentralized trial design and digital health technology. He is also active in regulatory review of Oncology products and oversees important oncology drug labeling initiatives. Dr. Kluetz remains clinically active, caring for patients and supervising medical residents at the Georgetown University Hospital.

Panelists:

Alicyn Campbell, MPH
Head of Digital Health, Oncology R&D
Astra Zeneca

Alicyn Campbell is currently Head of Digital Health Oncology R&D at AstraZeneca, where she leads on the development of strategies designed to increase their evidence base and improve care, through intelligent use of emerging technologies. Alicyn has over 12 years of experience in Health Outcomes Research. Prior to joining AstraZeneca, she served as the Global Head of Patient Centered Outcomes Research at Genentech/Roche. In that capacity, she was responsible for leadership in the assessment of the patient experience and consulted widely with the FDA and international regulators.

She achieved the first ever novel FDA patient reported outcome data approved in label for Hycela and was also responsible for novel patient-reported efficacy data for Hemlibra. She is the Founder, Executive Sponsor and Co-chair of Industry PRO-CTCAE Working Group, recognized as part of the 'Cancer Moonshot' initiative by President Biden and is a frequent research collaborator to Friends of Cancer Research and LUNGevity.
She has also authored several significant scientific publications and presentations, the latest of which was published in The Lancet Oncology.

James Gulley, MD, PhD, FACP
Director, Medical Oncology Service
National Cancer Institute, NIH

Dr. James Gulley is an internationally recognized expert in immunotherapy for cancer. He graduated from Loma Linda University in California with a PhD in microbiology in 1994 and an MD in 1995. As part of this eight-year MD/PhD Medical Scientist Training Program, he completed a dissertation on tumor immunology. He completed his residency in Internal Medicine at Emory

University in 1998, followed by a Medical Oncology fellowship at the National Cancer Institute (NCI).

Dr. Gulley serves within the Center for Cancer Research (CCR) of the National Cancer Institute as Chief of the Genitourinary Malignancies Branch (GMB), the Director of the Medical Oncology Service (CCR), Deputy Director of the CCR and also Head of the Immunotherapy Section within the GMB. He has been instrumental in the clinical development multiple immunotherapeutic agents and has led multiple first-in-human immunotherapy studies through phase 3 clinical trials. He was the coordinating PI of an international trial of avelumab that led to regulatory approval. He serves as the coordinating PI of the international bintrafusp alfa, a bifunctional agent targeting PDL1 and TGF-beta. He also leads a number of rationally designed, cutting edge combination immunotherapy studies.

In collaboration with the FDA, he has created the intelligent health (iHealth) clinic at the CCR. He leads 2 ongoing and 1 planned digital health studies there and works with others in a portfolio that currently spans 5 trials.

Dr. Gulley serves on many national and NIH boards and committees. He has been an investigator on more than 190 clinical trials, authored over 350 scientific papers or chapters which have been cited over 9,500 times, serves on a number of editorial boards and has made hundreds of scientific presentations at universities or national / international meetings. He has had multiple awards including the 2010 Presidential Early Career Award for Scientists and Engineers, the highest award bestowed by the US President on investigators early in their careers. He also was awarded the 2018 Hubert H. Humphrey Award for Service to America for contributing to the health, safety, and well-being of the nation by helping to get FDA approval for avelumab for Merkel cell carcinoma and urothelial carcinoma and has received 8 NCI or NIH Director's Awards.

Lee Jones, MBA
Patient Advocate

Lee was diagnosed with Stage IV colon cancer in March 2004, and since undergoing 18 rounds of chemotherapy and a liver resection in July 2006 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). Also, he is a research advocate member of the SWOG Survivorship Committee and completed a 3-year term as a patient member of the PCORI Clinical Trials Advisory Panel (CTAP), 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, has been a peer research proposal reviewer for ASCO, PCORI and the DOD, and is a member of ASCO, the National 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, FDA and NCCN conferences. Lee has been appointed as a patient representative on the NCI's Early Phase Emphasis Central IRB and is an advocate member of a Cancer Grand Challenges multi-national team studying the relationship of the human microbiome and colorectal cancer (OPTIMISTICC).

As a cancer patient and survivor, Lee is committed to promoting the patient voice in cancer research, treatments, medical care and the health care system in general.

Bakul Patel, MSc, MBA
Director, Digital Health Center of Excellence, CDRH, FDA

Bakul Patel is the Director for Digital Health Center of Excellence, at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies.

Mr. Patel, in 2013, created the term "software as a medical device" (SaMD) and under his leadership the International Medical Device Regulators Forum (IMDRF) established the globally harmonized definition of SaMD. Mr. Patel subsequently led global regulators at IMDRF to create and author the globally harmonized regulatory framework for SaMD. The concepts, principles and vocabulary created in harmonized regulatory framework has been used as a foundation and adopted by medical device regulatory bodies in the European union, Japan, Canada, Brazil, Australia and in the USA by US-FDA.

Mr. Patel is currently leading the effort for the agency in developing an innovative software precertification program to reimagine a pragmatic regulatory approach for Digital health that that aims for patients and providers to have timely access to safe and effective digital health products.

Prior to joining FDA, Mr. Patel held key leadership positions in several sectors including telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations. Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.

Lara Strawbridge, MPH
Director, Division of Ambulatory Payment Models
Center for Medicare and Medicaid

Lara Strawbridge is the Director of the Division of Ambulatory Payment Models in the Patient Care Models Group in the Center for Medicare and Medicaid Innovation (CMMI). In this role, Ms. Strawbridge leads CMS's efforts on physician specialty models, such as the Oncology Care Model and the Radiation Oncology Model, and Part B drug issues.

Prior to taking on the Division Director role, Ms. Strawbridge led the Oncology Care Model and previously worked in CMMI's Research and Rapid-Cycle Evaluation Group. Ms. Strawbridge began her career in health policy and research at the Institute of Medicine and previously was a teacher in Hertfordshire, England, and Washington, DC. Ms. Strawbridge earned her MPH from Johns Hopkins Bloomberg School of Public Health.

Gita Thanarajasingam, MD
Assistant Professor of Medicine/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 Alix 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 health outcomes clinical investigator, Dr. Thanarajasingam's work focuses on improving the evaluation of adverse events (AEs) of treatment and measuring their impact on treatment tolerability in cancer patients. She is committed to transforming the way AEs are assessed on three fronts: (1) displaying toxicity data in a more comprehensive, precise way that reflects the time profile of AEs and (2) using patient-reported outcomes and technology to more accurately and efficiently capture AE and treatment tolerability data directly from patients and (3) ultimately harnessing this information to guide patient education and symptom control. She developed the Toxicity over Time (ToxT), a longitudinal patient-focused approach to AE evaluation which she published in *The Lancet Oncology*, among multiple additional peer-reviewed high impact publications relating to toxicity and tolerability assessment. She has presented her work at the American Society for Clinical Oncology (ASCO), American Society of Hematology (ASH), European Haematology Association (EHA) International Society for Quality of Life (ISOQOL), and Multinational Association for Symptom Control (MASCC), National Cancer Institute Clinical Trials and Translational Research Advisory Committee (NCI CTAC), and several other forums.

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 is currently the lead principal investigator of a multi-site study in collaboration with the United States Food and Drug Administration evaluating physical functioning in cancer patients with clinician-reports, patient-reported outcomes and wearable device data. Additionally, 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.