6th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop

Characterizing Physical Function

Day 1: July 21, 2021 1:00 - 4:00 PM ET

Biographies

Workshop Welcome and Opening Remarks

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 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.

Session 1: Physical Function – Defining the Appropriate Research Question

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 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:

Ethan Basch, MD, MSc
Chief of Oncology, University of North Carolina
Physician-in-Chief, North Carolina Cancer Hospital

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Dr. Ethan Basch is Physician-in-Chief of the North Carolina Cancer Hospital and Chief of Oncology at the University of North Carolina, where he is Distinguished Professor in Medical Oncology and Professor of Health Policy & Management. 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.

Mallorie Fiero, PhD
Lead Mathematical Statistician
Office of Biostatistics, CDER, FDA

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.

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

Dr. Lori Minasian, a medical oncologist, is the Deputy Director for the Division of Cancer Prevention at the NCI. For over 15 years, she led the NCI's Community Clinical Oncology Program, a community-based clinical trials network that conducted cancer prevention clinical trials and supportive care clinical trials. She participated in the restructuring of the NCI clinical trials programs, facilitated the incorporation of patient reported outcomes and consulted on the development of other NIH institutes clinical trials programs. She is one of the senior leaders in NCI-NHLBI cardiotoxicity team, facilitating the development of the NIH Cardiotoxicity Funding Opportunity Announcement and the development of NCI-supported cardio-oncology clinical trials.

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.

Patty Spears
Cancer Research Advocate

Ms. Spears is an over 20-year breast cancer survivor and cancer research patient advocate. She was diagnosed with locally advanced breast cancer at the age of 40 and after neoadjuvant chemotherapy, surgery and radiation therapy, she participated in a HER2 vaccine clinical trial. Ms. Spears has concentrated her advocacy on clinical trials and serves as an advocate on the Translational Breast Cancer Research Consortium (TBCRC). She has also been an advocate for the National Clinical Trials Network (NCTN) since 2008, and is currently an advocate for the Alliance for Clinical Trials in Oncology as Associate Group Chair for Advocacy, Chair of the Alliance Patient Advocate Committee and a member of the Breast Committee. She is also a member of several NCI Committees, including the Breast Cancer Steering Committee (BCSC), Investigational Drug Steering Committee (IDSC), and the Core Correlative Science Committee (CCSC).

Ms. Spears is currently working as a scientific research manager and patient advocate at the University of North Carolina at Chapel Hill, Lineberger Comprehensive Cancer Center where she leads the UNC Lineberger Patient Advocates for Research Council (PARC) and the UNC Breast SPORE Advocates. At UNC she focuses on communicating research to the public and facilitates the engagement of patient advocates with Lineberger researchers. She also has an interest in patient reported outcome measures (PROMs) in drug development and clinical trials.

Peter C. Trask, PhD, MPH
Senior Director, Head, Patient Centered Outcomes Research – Oncology
Genentech

Dr. Trask is a Senior 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 has a strong interest in the relation between physical functioning and cancer and its treatment in a variety of solid and hematological diseases. In particular, his recent work has focused on determining whether pre-treatment patient-reported physical functioning is prognostic of overall and progression free survival in DLBCL patients; and whether reducing bleed rates in hemophilia A patients results in meaningful improvements in patient-reported physical functioning.

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Session 2: Leveraging Existing Measures to Assess Patient-Reported Physical Function

Erica Horodniceanu, MPH (Moderator)
Health Scientist, Oncology Center of Excellence, FDA

Erica Horodniceanu is a health scientist within the FDA Oncology Center of Excellence (OCE) Patient-Focused Drug Development (PFDD) program. Over the past 18 years, Erica has provided healthcare research, health education, health communications, and project management services to pharmaceutical, biotech, and medical device companies. She has previously held positions in industry within consulting firms focused on outcomes research and has been working in the field of clinical outcome assessments (COAs) for the past 8 years. Erica holds a Bachelor of Science degree in Health Science Education, with a concentration in Health Promotion from the University of Florida and a Master's in Public Health degree in Public Health Practice and Policy from the University of Maryland.

Panelists:

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.

Cella developed and is continually refining the Functional Assessment of Chronic Illness Therapy (FACIT) Measurement System for outcome evaluation in patients with chronic medical conditions. He was steering committee chair and principal investigator of the statistical coordinating center for the NIH Roadmap Initiative to build a Patient Reported Outcome Measurement Information System (PROMIS). Currently, he is principal investigator of a cooperative agreement to curate and sustain PROMIS along with three other measurement systems, under the umbrella heading of HealthMeasures: A National Person Centered Assessment Resource.

Cella has served on numerous patient reported outcomes and person centered care advisory panels, and he consults, collaborates with, or advises the following entities on person-centered measurement and applications relevant to their mission: US Food and Drug Administration, Centers for Disease Control and Prevention, National Center for Health Statistics, Centers for Medicare and Medicaid Services, The National Quality Forum, The American Cancer Society, and Cancer Care Ontario.

Theresa Coles, PhD
Assistant Professor, Population Health Sciences
Duke University School of Medicine

Dr. Theresa Coles is an Assistant Professor in the Center for Health Measurement in the Department of Population Health Sciences at Duke University. She specializes in the development and psychometric evaluation (reliability, validity, responsiveness, interpretation of scores) of patient-reported outcome (PRO) measures. Dr. Coles is particularly interested in measuring patient function, meaningful changes in function, and goals for function. She is also interested in integrating PRO measures as interventions in clinical care to support shared decision-making, and evaluating the PRO measures' influence on resource utilization, and patient outcomes.

Prior to joining the Duke faculty in 2018, Dr. Coles worked in the Patient-Centered Outcomes Assessment group at RTI Health Solutions for almost 10 years, where collaborated with colleagues to develop and evaluate PRO measures for use in clinical trials and clinical practice. Dr. Coles received her PhD in Health Policy and Management (Decision Sciences and Outcomes Research) from the University of North Carolina at Chapel Hill.

Selena Daniels, PharmD, PhD
Clinical Outcome Assessment Team Leader
CDER, FDA

Dr. Selena Daniels serves as a Team Leader in the Division of Clinical Outcome Assessment at the FDA. She leads a team of expert analysts who evaluate a variety of complex clinical outcome assessment (COA) endpoint issues related to the evaluation of clinical benefit in registration trials to support labeling claims.

Prior to joining the FDA in 2015, Dr. Daniels worked in the Health Economic and Outcomes Research (HEOR) group at Allergan, Inc for almost five years, where she developed and executed HEOR strategies, as well as developed and implemented innovative COA strategies and endpoints for clinical trials.

Dr. Daniels received her doctor of philosophy degree in Education at Nova Southeastern University and pharmacy degree at Loma Linda University.

Jill Feldman
Lung Cancer Patient Advocate

Jill Feldman is a lung cancer patient and advocate. When Jill was 13 years old, she lost her dad and two grandparents to lung cancer and then her mom and close aunt died of lung cancer when she was in her 20's. She became a volunteer, an advocate and past president of LUNGevity Foundation before the unthinkable happened. In 2009, at 39 years old with four small children, Jill herself was diagnosed with EGFR positive lung cancer.

Jill continues to be involved with LUNGevity. She is also Deputy Chair of IASLC's patient advisory board and a member of The Chicago Institute of Translational Medicine's patient advisory board. Jill is committed to understanding and promoting patient-centered research as a member of the programmatic panel for the Department of Defense Lung Cancer Research Program, as a planning committee member on IASLC's North America Conference on Lung cancer and as a member of the

the ECOG-ACRIN Research Group's patient advocate committee and thoracic committee. She is the patient advocate on the National Lung Cancer Round Table steering committee. She is a co-author of the ASTRO Guidelines for SBRT in early stage lung cancer that was published in an ASCO special article in the Journal of Clinical Oncology.

In 2017, Jill co-founded the EGFR Resisters, a grassroots, patient-driven community committed to accelerating research that will prolong and better the lives of people diagnosed with EGFRm lung cancer. Jill also continues to share her story in the media and at various events and participates in countless advocacy opportunities to shine a light on lung cancer and end the stigma associated with it.

Mogens Grønvold, MD, PhD, DMSc
Professor, Section of Health Services Research
University of Copenhagen & Bispebjerg and Frederiksberg Hospital

Dr. Mogens Grønvold is Professor of Palliative Care and Patient-Reported Outcomes at University of Copenhagen, Denmark, and Head of the Palliative Care Research Unit at Department of Geriatrics and Palliative Medicine, Bispebjerg University Hospital in Copenhagen.
Since 1989, his research has focused on the development and application of PRO's in palliative care and oncology. This includes several intervention studies, a national quality of care register including PRO, and international studies such the EU-funded trials ACTION (Advance Care Planning in oncology) and DIAdIC. He is the founder and chairman of the Danish Palliative Care Database and additional national networks and organisations aiming at improving palliative care across the country. At the University he leads the pre- and postgraduate courses in questionnaire development and application.

Mogens has been a member of the EORTC Quality of Life Group since 1989, was its chair 2011-2014, and is PI for the multinational EORTC CAT Project developing computer-adaptive testing for the 14 dimensions of the EORTC QLQ-C30. From 2015 to 2018 he was member of and represented the EORTC Quality of Life Group in the EORTC Board. He has been part of the SISAQOL initiative since its start.

Mogens was elected to the International Society of Quality of Life Research (ISOQOL) Board of Directors (2015-18) and was co-chair of the ISOQOL 2016 Conference in Copenhagen, Denmark.

Heidi Klepin, MD, MS, FASCO
Professor, Hematology &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 Co-Leader 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, past chair of the American Society of Clinical Oncology Cancer Research Committee and member of the American Society of Hematology Scientific Affairs Committee