U.S. FOOD & DRUG ADMINISTRATION
Oncology Center of Excellence

10th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop

"Reflecting on a Decade of Progress"

October 8, 2025 (1:00 PM – 3:30 PM ET)

Participant Biographies

Session 1: FDA Oncology PRO Core Outcomes – Where have we come from?

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. He currently leads the OCE's Patient-Focused Drug Development program. Additionally, Dr. Bhatnagar has a strong clinical interest in multiple myeloma and was previously a clinical reviewer and team leader in the Division of Hematology Products. 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.

Melanie Calvert PhD, FMedSci
Professor of Outcomes Methodology, NIHR Senior Investigator
Director Centre for Patient Reported Outcomes Research, University of Birmingham, UK

Professor Melanie Calvert, PhD, FMedSci, is Professor of Outcomes Methodology at the University of Birmingham UK and National Institute for Health and Care Research Senior Investigator. She is Director of the Centre for Patient Reported Outcomes Research which aims to optimize the use of patient reported outcomes (PROs) in clinical trials and routine care, to improve service delivery, enhance patient care and outcomes and ensure that the patient perspective is at the heart of health research and healthcare decision-making.

Professor Calvert has >300 peer reviewed publications in journals including the NEJM, Nature Medicine, BMJ, JAMA and the Lancet. With international collaborators she led the development of international PRO guidance including the SPIRIT-PRO extension, CONSORT-PRO extension, PRO Ethics Guidelines and is a member of the SISAQOL-IMI initiative. Recent work includes publications on inclusive and equitable PRO data collection, use of PROs in early phase trials, reducing participant burden, AI studies and real-world evidence generation. Her highly cited work has informed clinical guidelines, NICE, EMA and FDA guidance and UK Government policy. Professor Calvert sits on a number of international committees leading national and international strategy for PROs research/implementation including the PROTEUS Consortium which promotes tools and resources to optimize the use of PROs in clinical trials to ensure that patients, clinicians, and other decision-makers can make the best decisions about treatment options.

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Sonya Eremenco, MA
Executive Director, Patient-Reported Outcome (PRO) Consortium
Critical Path Institute

Sonya Eremenco is Executive Director, Patient-Reported Outcome Consortium at Critical Path Institute, and has over 25 years of experience in the development and evaluation of patient-reported outcome (PRO) measures and other clinical outcome assessments (COAs), with a focus on multicultural development, linguistic validation, and electronic implementation. Prior to joining C-Path in 2016, Sonya served as Director of ePRO New Products at Evidera where she led Evidera's initiative to combine technology and PRO measurement expertise into a science-driven ePRO service. Prior to Evidera, she was Director of the Functional Assessment of Chronic Illness Therapy (FACIT) Translation and Formatting Services Department at the Center on Outcomes, Research and Education (CORE) at NorthShore Health System, which is now FACITtrans.org. Sonya has been active in advancing the science of PRO-based endpoint assessment through her service in scientific organizations, including chairing an ISPOR task force on the use of mixed modes of PRO data collection in clinical trials. Sonya received her undergraduate degree in cultural anthropology with a concentration in linguistics from Duke University and earned a Master of Arts in cross-cultural communication from DePaul University.

Patty Spears, BS, FASCO
Research Patient Advocate
University of North Carolina at Chapel Hill

Ms. Spears is a cancer research patient advocate bringing the experience as an over 20-year breast cancer and a 3-year liver cancer survivor. She has participated in two clinical trials including a HER2 vaccine clinical trial. She is currently working as a patient advocate at the University of North Carolina (UNC) at Chapel Hill, Lineberger Comprehensive Cancer Center (LCCC) where she leads the UNC Lineberger Patient Advocates for Research Council (PARC) and co-leads the Lineberger Excellence in Advocacy Program (LEAP). At UNC she focuses on communicating research to the public and facilitates the engagement of patient advocates with Lineberger researchers. She has been interested in patient reported outcome measures (PROMs) in drug development, clinical trials and clinical care for many years. She has been involved in many PRO projects including PRO-TECT and PRO-PM and is currently an advocate on the OncoPRO project.

Ms. Spears has been an advocate for the National Clinical Trials Network (NCTN) since 2008 and is currently the Associate Group Chair for Advocacy for the Alliance for Clinical Trials in Oncology and Chair of the Alliance Patient Advocate Committee. She is also a member of NCI's Clinical Trials and Translational Research Advisory Committee (CTAC), the Investigational Drug Steering Committee (IDSC), and is currently Co-Chair of the Patient Advocate Steering Committee (PASC). Ms. Spears is the recipient of the AACR 2020 Distinguished Public Service Award for Advocacy, the ASCO 2022 Patient Advocate Award and the Susan G. Komen 2023 Research Advocacy Champion Award. In 2023 she became a Fellow of the American Society of Clinical Oncology (FASCO).

Gita Thanarajasingam, MD
Associate Professor of Medicine, Division of Hematology
Mayo Clinic

Dr. Gita Thanarajasingam is an Associate 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 residency at the Brigham and Women's Hospital at Harvard Medical School. After Hematology and Oncology Fellowship and Advanced Lymphoma Fellowship at Mayo Clinic, she joined the faculty of the Mayo Clinic Rochester Lymphoma disease-oriented group. Her clinical practice as an oncologist focuses 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 treatment tolerability 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 (PRO) 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 has received K and U01 grants from the U.S. National Institutes of Health. She leads the ongoing international multi-stakeholder Lancet Haematology Commission, "Beyond maximum grade: modernizing the assessment and reporting of adverse events in hematological malignancies." She is an ad-hoc member of the U.S. Food and Drug Administration (FDA) Oncology Drug Advisory Committee (ODAC) with expertise in toxicity assessment. 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.

Fireside Chat with Ethan Basch, MD

Ethan Basch, MD, MSC
Distinguished Professor, Chief of Oncology & Physician – in-Chief
Cancer Hospital at the University of North Carolina

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. He led a group under contract to the National Cancer Institute to create and test a system for collecting 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. Dr. Basch received his MD from Harvard Medical School, a Master's degree in Epidemiology from the Harvard School of Public Health, completed his Internal Medicine residency at Massachusetts General Hospital, and fellowships in Oncology and Health Services Research at Memorial Sloan Kettering Cancer Center. He has published over 350 manuscripts, and is deeply committed to advancing integration of patient perspectives in oncology clinical research and care.

Session 2: Advancing Use of Core PRO Outcomes – Where do we want to go?

Vishal Bhatnagar, MD (Moderator)
Associate Director for Patient Outcomes
Oncology Center of Excellence, FDA

See above entry

Ting-Yu (Jeff) Chen, PhD
Mathematical Statistician
Division of Biometrics V, CDER, FDA

Ting-Yu (Jeff) Chen, PhD, is a mathematical statistician in the Division of Biometrics V at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). His areas of expertise include patient-reported outcome (PRO) assessment, adaptive clinical trial design, and survival analysis. Dr. Chen earned his PhD in Biostatistics from the University of Texas Health Science Center at Houston and previously worked as a data analyst at MD Anderson Cancer Center, where he developed a strong interest in clinical trial design and PRO development in oncology. At the FDA, Dr. Chen reviews new drug applications in oncology and evaluates PRO instruments through CDER's Drug Development Tool (DDT) Qualification Program. He has also contributed to the development of FDA guidance documents, particularly those related to PRO assessments in oncology.

Amylou Dueck, PhD
Professor of Biostatistics
Mayo Clinic, Arizona

Dr. Amylou Dueck is a Professor of Biostatistics 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 version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) and Myeloproliferative Neoplasm Symptom Assessment Form (MPN-SAF). Dr. Dueck is the Co-chair of the Health Outcomes Committee of the Alliance for Clinical Trials in Oncology. In this role, Dr. Dueck partners with clinical investigators to integrate, monitor, analyze, and report PROs in a variety of cancer clinical trials. Dr. Dueck is also a funded biostatistician/investigator in the Yale University-Mayo Clinic Center of Excellence in Regulatory Science and Innovation (CERSI).

Selena Daniels, PharmD, PhD
Deputy Division Director, Division of Clinical Outcome Assessment
CDER, FDA

Dr. Selena Daniels serves as the Deputy Division Director in the Division of Clinical Outcome Assessment at the FDA. She provides direction, oversight, and leadership to a team of expert analysts who provide consultation and advice on clinical outcome assessment (COA) endpoint development and validation, including considerations for clinical trial design, conduct, analysis, interpretation, and reporting for regulatory determinations of medical product benefit.

Prior to joining the FDA in 2015, Dr. Daniels worked in the Health Economic and Outcomes Research (HEOR) group at Allergan, Inc (now Abbvie), 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 Doctor of Pharmacy degree at Loma Linda University.

Devin Peipert, PhD
125th Anniversary Chair & Professor of Health Outcomes Measurement
Deputy Director, Birmingham Health Partners Centre for Regulatory Science and Innovation
Centre for Patient Reported Outcomes Research
Department of Applied Health Sciences
University of Birmingham, Edgbaston Birmingham

Devin Peipert, PhD is a 125th Anniversary Chair and Professor of Health Outcomes Measurement at the University of Birmingham in the United Kingdom, where he works within the Centre for Patient Reported Outcomes Research (CPROR) and is Deputy Director of the Birmingham Health Partners Centre for Regulatory Science and Innovation (BHP CRSI). Prof. Peipert's research focuses on amplifying the patient's voice in drug development. He focuses heavily on development and psychometric evaluation of patient-reported outcomes (PROs) to support regulatory decision-making. A central thread within this focus includes capturing treatment tolerability from the patient's perspective using PROs, wherein he has worked extensively on approaches to assess overall side effect impact of cancer treatment. Related to this activity, he is the ECOG-ACRIN PRO Workgroup Chair in the United States, and has taken on leadership roles within the National Cancer Institute's Tolerability Consortium. He also has a significant focus on patient-focused drug development in rare kidney diseases and solid organ transplantation, and he co-leads a project to develop a novel set of clinical outcome assessments and endpoints for patients with rare kidney disease across the lifespan who experience nephrotic syndrome-related swelling (Prepare-NS).

Jane Perlmutter, Ph.D., MBA
Patient Advocate

Jane Perlmutter is a long-term survivor of multiple cancers and an active advocate. Her advocacy is largely rooted in her own experiences and those of others with similar diagnoses. However, it is also informed by her formal training in cognitive psychology and experimental methods (Ph.D.), computer and information science (MS) and business (MBA), as well as her career experiences which included many years in academia, not-for-profit R&D, corporate senior management, and independent consulting.

During her early advocacy Jane was a peer counselor and board member for Y-ME, as well as a grant reviewer for ACS, CDMRP and PCORI. She has been involved in many research projects from early translational research to use of real-world data. Currently much of her advocacy focuses on clinical trials, ensuring that the patient voice is considered in the selection of research questions and that trial protocols are sensitive to patient issues. She is especially interested in innovative trial designs that can speed new treatments to patients who need them. Jane serves on the steering committees and is lead advocate on the I-SPY2 and TAPUR trials, two groundbreaking Master Protocol trials. She is also a long-term advocate member of the Alliance for Clinical Trials in Oncology and has been on multiple ASCO, National Academy of Medicine and NCI Committees.

Jane has also been involved in health advocacy beyond cancer and works with many government and not-for profit groups. For example, she is past chair of the Patient Centered Outcomes Research Institute's (PCORI) Patient Engagement Advisory Panel and a member of their Clinical Trials Advisory Committee as well as the Clinical Trials Transformation Initiative Steering Committee (CTTI). Jane is especially passionate about developing the next generation of advocates and fostering collaboration between advocates and researchers. She has developed and delivered training for many advocacy groups and been a long-term faculty member of the ASCO/AACR Methods in Clinical Research Workshop as well as SITC's SCION workshop. In 2023 Jane was honored with AACR's 2023 Distinguished Public Service Award for Exceptional Leadership in Cancer Advocacy as well as ASCO's 2023 Patient Advocate Award.