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)

Agenda

1:00 PM – 1:10 PM *(10 min)*	**Welcome and opening remarks** Vishal Bhatnagar – Medical Oncologist, FDA
1:10 PM – 2:10 PM *(1 hour)*	**Session 1: FDA Oncology Core Patient-Reported Outcomes (PRO) – Where have we come from?** **Panelists:** • Sonya Eremenco – Clinical Outcome Assessment Program, Critical Path Institute • Mel Calvert – Professor of Outcomes Methodology, University of Birmingham • Gita Thanarajasingam – Hematologist, Mayo Clinic • Patty Spears – Patient Advocate and Research Manager, UNC Lineberger Cancer Center **Objectives:** 1. *Examine the integration of patient-generated data into regulatory submissions over the past decade.* 2. *Discuss research that has advanced the science of analyzing PROs.* 3. *Analyze historical examples of how core PRO data have been incorporated into labeling for anti-cancer products.*
2:10 PM – 2:20 PM *(10 min)*	**Break + Fireside Chat** **Panelists** • Vishal Bhatnagar – Medical Oncologist, FDA • Ethan Basch – Physician-in-Chief, North Carolina Cancer Hospital and Chief of Oncology, University of North Carolina
2:20 PM – 3:20 PM *(1 hour)*	**Session 2: Advancing Use of Core PROs in Oncology – Where do we want to go?** **Panelists:** • Amylou Dueck – Biostatistician, Mayo Clinic • Selena Daniels – Deputy Director, DCOA, FDA • Jane Perlmutter – Patient Advocate • Ting-Yu (Jeff) Chen – Mathematical Statistician, CDER, FDA • Devin Peipert – Professor, Centre for Patient Reported Outcomes Research, University of Birmingham **Objectives:** 1. *Review how PRO core outcomes have been utilized in cancer drug development.* 2. *Explore future directions for the analysis and visualization of PRO data.* 3. *Identify key, achievable milestones for advancing PRO data science and its regulatory use over the next five years.*
3:20 PM – 3:30 PM *(10 min)*	**Workshop Conclusion and Adjourn** Vishal Bhatnagar – Medical Oncologist, FDA