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

# 9th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop

***Modernizing tolerability assessment in cancer clinical trials***

**June 25, 2024 (11:00 AM – 2:30 PM ET) Virtual**

| AGENDA | |
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| **11:00 AM – 11:10 AM**<br>*(10 min)* | **Welcome and opening remarks**<br>Vishal Bhatnagar – Medical Oncologist, FDA<br>Paul Kluetz – Medical Oncologist, FDA |
| **11:10 AM – 12:25 PM**<br>*(1 hr. 15 min)* | **Session 1: Revisiting Core Item Sets in Oncology Trials – Where are we and where do we want to go?**<br>Moderator: Terri Armstrong - Outcomes Researcher, NCI |
| **Panelists:**<br>• Yelak Biru – Patient Advocate, International Myeloma Foundation<br>• Erica Horodniceanu – Senior Health Scientist, FDA<br>• Tito Mendoza – Senior Scientist, NCI<br>• Bryce Reeve – Professor, Duke University School of Medicine<br>• Gita Thanarajasingam – Lymphoma Hematologist, Mayo Clinic<br>• Lynne Wagner – Professor, University of North Carolina<br>**Objectives:**<br>1. *Provide contextual background for patient-reported symptom assessment – an overview of existing "core" symptom sets.*<br>2. *Review how current clinical trials require novel methods to select symptoms, including use of PRO item libraries.*<br>3. *Emphasize how early phase trials, pediatric trials, and use of novel agents require parsimonious symptom assessment.* | |
| **12:25 PM – 12:40 PM**<br>*(15 min)* | **Break** |
| **12:40 PM – 1:55 PM**<br>*(1 hr 15 min)* | **Session 2: Revisiting Core Item Sets in Oncology Trials – How do we get there?**<br>Moderator: Vishal Bhatnagar – Medical Oncologist, FDA |
| **Panelists:**<br>• Ethan Basch – Professor and Chief of Oncology, University of North Carolina<br>• Cheryl Coon – Vice President, Clinical Outcome Assessment Program, Critical Path Institute<br>• Amylou Dueck – Biostatistician, Mayo Clinic<br>• Megan Fitter – Clinical Outcomes Assessment Reviewer, FDA<br>• Jan Geissler – Patient Advocate, Patvocates<br>• Madeline Pe – Head of the Quality-of-Life Department, EORTC<br>• Ashley Wilder Smith – Chief, Outcomes Research Branch, NCI<br>**Objectives:**<br>1. *Consider actionable methods to modernize existing PRO item libraries.*<br>2. *Discuss a framework for selecting treatment-related symptoms across many therapeutic contexts.*<br>3. *Review analysis and visualization techniques for treatment related symptoms assessed during cancer trials.* | |
| **1:55 PM – 2:25 PM**<br>*(30 min)* | **Panel Discussion Q & A**<br>Moderator: Vishal Bhatnagar – Medical Oncologist, FDA |
| **Panelists:** All available panelists from Sessions 1 & 2 | |
| **2:25 PM – 2:30 PM**<br>*(5 min)* | **Workshop conclusion and adjournment**<br>Paul Kluetz - Medical Oncologist, FDA<br>Terri Armstrong – Outcomes Researcher, NCI<br>Vishal Bhatnagar – Medical Oncologist, FDA |