6th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop
Characterizing Physical Function

AGENDA	
Day 1: July 21, 2021 (1pm – 4pm ET)	
1:00 PM – 1:15 PM	**Workshop Welcome and Opening Remarks**
Paul Kluetz – FDA, Medical Oncologist Dr. Kluetz will provide an overview of how physical function in cancer clinical trials has been used and future directions for assessing physical function to inform risks and benefits of cancer drugs.	
1:15 – 2:30 PM	**Session 1: Physical function - Defining the Appropriate Research Question**
Moderator: Vishal Bhatnagar - FDA, Medical Oncologist **Panelists:** • Ethan Basch – University of North Carolina • Mallorie Fiero – FDA, Statistician • Lori Minasian – National Cancer Institute • Patty Spears – Patient Advocate • Peter Trask – Genentech **Objectives:** 1. Identify various research objectives for physical function in interventional cancer trials. 2. Revisit how to align physical function research questions and endpoints with the estimand framework. 3. Identify commonly used physical function endpoints and potential limitations. 4. Identify challenges and propose solutions for including physical function as part of clinical trial assessments.	
2:30 – 2:45 PM	**Break**
2:45 – 3:45 PM	**Session 2: Leveraging Existing Measures to Assess Patient-Reported Physical Function**
Moderator: Erica Horodniceanu – FDA, Health Scientist **Panelists:** • David Cella – Northwestern University • Theresa Coles – Duke University • Selena Daniels – FDA, Clinical Outcome Assessment Team Leader • Jill Feldman – Patient Advocate • Mogens Grønvold – European Organisation for Research and Treatment of Cancer • Heidi Klepin – Wake Forest **Objectives:** 1. Consider which physical function concepts are most relevant during cancer treatment, from a patient and clinician perspective. 2. Review examples of existing PRO tools used to measure physical function concepts and discuss what is considered to be a "well-defined" measure. 3. Discuss the practicality of using existing instruments, including use of item libraries, and Computer Adaptive Testing.	
3:45 – 4:00 PM	**Day 1 Wrap-up**
Erica Horodniceanu – FDA, Health Scientist Erica Horodniceanu will provide an overview of Day 1 sessions and introduce how the concepts discussed relate to Day 2 topics.	

AGENDA	
Day 2: July 23, 2021 (9am – 12pm ET)	
9:00 – 9:05 AM	**Day 2 Opening Remarks**
Vishal Bhatnagar – FDA, Medical Oncologist Dr. Bhatnagar will summarize Day 1 and introduce topics to be discussed on Day 2.	
9:05 – 10:10 AM	**Session 3: Analytic Considerations when Measuring Physical Function**
Moderator: Paul Kluetz – FDA, Medical Oncologist **Panelists:** • Angelo de Claro – FDA, Medical Oncologist • Amylou Dueck – Mayo Clinic • Bellinda King-Kallimanis – LUNGevity Foundation • Pourab Roy – FDA, Statistician • Marian Strazzeri – FDA, Statistician **Objectives:** 1. Explore the objective of describing physical function of cancer patients while they are achieving tumor control from anticancer agents. 2. Consider various analysis methods for physical function data. 3. Visualize longitudinal physical function data using a single question with categorical responses.	
10:10 – 10:20 AM	**Break**
10:20 – 11:45 AM	**Session 4: Envisioning Physical Function Moving Forward**
Moderator: Paul Kluetz – FDA, Medical Oncologist **Panelists:** • Alicyn Campbell – AstraZeneca • James Gulley – National Cancer Institute • Lee Jones – Patient Advocate • Bakul Patel – FDA, Director, Digital Health Center of Excellence • Lara Strawbridge – Center for Medicare and Medicaid Innovation • Gita Thanarajasingam – Mayo Clinic **Objectives:** 1. Explore novel methods to collect patient generated physical function data in cancer clinical trials. 2. Discuss optimal methods to analyze data from wearable devices in the context of patient-reported physical function data. 3. Consider methods to assess the "whole patient environment," which includes patient-report and sensor data, to improve physical function data collection. 4. Envision how physical function data will be collected and analyzed in 2025.	
11:45 AM – 12:00 PM	**Workshop Conclusion and Adjourn**
Paul Kluetz – FDA, Medical Oncologist Dr. Kluetz will provide a summary of Day 1 and Day 2 and provide closing comments.	