8th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop

Overall Side Effect Impact: A Core Oncology Patient-Reported Outcome

June 27, 2023 (11:00 AM – 3:00 PM ET)

AGENDA	
11:00 AM – 11:05 AM	**Workshop welcome and opening remarks** Paul Kluetz – Medical Oncologist, FDA
11:05 AM – 12:05 PM	**Session 1: Understanding Overall Side Effect Impact**

Moderator: Erica Horodniceanu – Health Scientist, FDA

Panelists:

- Selena Daniels - Social Science Analyst, FDA
- Cheryl Jernigan – Patient Research Advocate
- Madeline Pe - Head of Quality of Life Department, EORTC
- Devin Peipert - Assistant Professor, Northwestern University
- Gita Thanarajasingam - Lymphoma Hematologist, Mayo Clinic

Objectives:

1. *To discuss the value of measuring patient-reported overall side effect impact.*
2. *To describe existing patient-reported overall side effect impact items and their current use.*
3. *To discuss general areas of challenge and opportunity in measuring patient-reported overall side effect impact measurement in cancer trials.*

12:05 PM – 12:20 PM	**Break**
12:20 PM – 1:35 PM	**Session 2: Analysis and Communication of Overall Side Effect Impact**

Moderator: Vishal Bhatnagar - Medical Oncologist, FDA

Panelists:

- Amylou Dueck - Biostatistician, Mayo Clinic
- Mallorie Fiero - Statistician, FDA
- Steven Merlin - Patient Advocate, Pancreatic Cancer Action Network
- Jessica Roydhouse - Researcher, University of Tasmania
- Lynne Wagner - Professor, Wake Forest University

Objectives:

1. *To explore overall side effect impact as a PRO endpoint in cancer trials to inform tolerability.*
2. *To consider methodological ways to handle side effect impact prior to trial therapy initiation.*
3. *To discuss methods to clearly communicate overall side effect impact results.*

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AGENDA	
1:35 PM – 1:45 PM	**Break**
1:45 PM – 2:45 PM	**Session 3: Future Directions for Overall Side Effect Impact**

Moderator: Meena Murugappan – Visiting Scientist, FDA

Panelists:

- Mel Calvert – Professor, University of Birmingham
- Jan Geissler – Patient Advocate, Lancet Hematology Commission
- Lori Minasian – Medical Oncologist, National Cancer Institute
- Mirat Shah – Medical Oncologist and Clinical Reviewer, FDA
- Ashley Slagle – Principal, Scientific and Regulatory Advisor, Aspen Consulting, LLC

Objectives:

1. *To discuss the extent to which overall side effect impact measures are being recommended or utilized by drug development stakeholders.*
2. *To consider barriers to uptake and widespread integration of overall side effect impact measures in cancer trials.*
3. *To identify novel trial settings and methods to measure overall side effect impact.*
4. *To explore opportunities and unique considerations for development of novel side effect impact questions, particularly within existing PRO item libraries.*

2:45 PM – 3:00 PM	**Workshop conclusion and adjourn** Vishal Bhatnagar – Medical Oncologist, FDA