

Workshop on Patient Reported Outcomes (PROs) and Vision-Related Quality of Life (QoL) Questionnaires

Friday, September 29, 2023
10:00 AM – 4:00 PM ET – Virtual Meeting

Tentative Agenda
All times in ET

10:00 – 10:05 am	Welcome and Purpose of the Workshop Malvina B. Eydelman, MD <i>US Food and Drug Administration</i>
10:05 – 10:10 am	National Eye Institute (NEI) Strategic Plan and Quality of Life Michael F. Chiang, MD <i>National Eye Institute</i>
10:10 – 10:20 am	PCORI's Perspective on PROs and QoL Questionnaires Nakela L. Cook, MD <i>Patient-Centered Outcomes Research Institute (PCORI)</i>
10:20 – 10:30 am	AAO's Perspective on PROs and QoL Questionnaires Stephen D. McLeod, MD <i>American Academy of Ophthalmology</i> Flora Lum, MD <i>American Academy of Ophthalmology</i>
10:30 – 10:40 am	Introduction to the Importance of PROs and QoL Questionnaires Michelle E. Tarver, MD, PhD <i>US Food and Drug Administration</i>
10:40 – 11:05 am	The Current State of PROs and QoL Questionnaires for Eye & Vision Conditions Ron D. Hays, PhD <i>University of California, Los Angeles</i>
11:05 – 11:20 am	Moderated Q&A Moderated by Emily Chew, MD
11:20 – 11:30 am	Break

11:30 – 12:15 pm	What are the gaps? Researchers’ and Clinicians’ Perspectives Panel Moderated by Emily Chew, MD <p>Robert Finger, MD, PhD <i>University of Bonn</i></p> <p>Judy E. Goldstein, OD <i>Johns Hopkins University</i></p> <p>Emily Grattan, PhD <i>University of Pittsburgh</i></p> <p>Carol L. Shields, MD <i>Wills Eye Hospital</i></p> <p>Pradeep Ramulu, MD, PhD <i>Johns Hopkins University</i></p> <p>Kuldev Singh, MD <i>Stanford University</i></p> <p>S. Robert Levine, MD <i>Mary Tyler Moore Vision Initiative</i></p>
12:15 – 12:55 pm	What are the gaps? Patients’ Perspectives Panel Moderated by Michelle E. Tarver, MD, PhD <p>Alessio, Andrea, and Fabio</p> <p>Barbara</p> <p>Edlyn</p> <p>John</p> <p>Judy</p> <p>Jaime</p>
12:55 pm – 1:15 pm	Industry’s Perspectives Panel Moderated by Malvina B. Eydelman, MD <p>Kendra Hileman, PhD <i>Alcon</i></p> <p>Mark S. Humayun, MD, PhD <i>University of Southern California</i></p> <p>Steven Schallhorn, MD <i>Carl Zeiss Meditec</i></p>
1:15 – 1:45 pm	Lunch

1:45 – 2:00 pm	Considerations to Ensure Relevancy Across Populations Beverly Weidmer, MA <i>RAND Corporation</i>
2:00 – 2:15 pm	Development of the NEI VFQ Carol M. Mangione, MD <i>University of California, Los Angeles</i> Paul P. Lee, MD, JD <i>University of Michigan Medical Group</i>
2:15 – 2:30 pm	Introductions to Techniques and Approaches for Questionnaire Development R.J. Wirth, PhD <i>Vector Psychometric Group, LLC</i>
2:30 – 3:10 pm	Discussion on Techniques and Approaches for Questionnaire Development Panel Moderated by Fraser Bocell, PhD Cheryl D. Coon, PhD <i>Critical Path Institute</i> Rikki Mangrum, MLS <i>Vector Psychometric Group, LLC</i> Lori McLeod, PhD <i>RTI Health Solutions</i> R.J. Wirth, PhD <i>Vector Psychometric Group, LLC</i>
3:10 – 3:20 pm	Break
3:20 – 3:35 pm	Using the FDA Frameworks for Developing PROs and QoL Questionnaires Fraser Bocell, PhD US Food and Drug Administration
3:35 – 4:00 pm	General Discussion and Synthesis Jimmy T. Le, ScD, MA <i>National Eye Institute</i> Emily Y. Chew, MD <i>National Eye Institute</i>
4:00 pm	Adjournment

Abbreviations: AAO = American Academy of Ophthalmology; FDA = United States Food and Drug Administration; NEI = National Eye Institute; PROs = Patient-reported outcomes; PCORI = Patient-Centered Outcomes Research Institute; QoL = quality of life; Q&A = Question and Answer