

14th Annual Patient-Reported Outcome Consortium Workshop

On April 19–20, 2023, the 14th Annual Patient-Reported Outcome Consortium Workshop was held in Silver Spring, MD.

The following Workshop Agenda provides an overview of the day-and-a-half-long meeting as well as links to the session recordings, slide decks, and posters presented.

<i>Agenda – April 19, 2023</i>	
7:30 – 8:30 am ET (60 min)	Registration and Breakfast
8:30 – 8:50 am (20 min)	<p>Welcome and Patient-Reported Outcome Consortium Update</p> <p>Provide a high-level summary of the recent accomplishments and ongoing activities within the Patient-Reported Outcome Consortium</p>
8:50 – 10:20 am ET (90 min)	<p>Session 1: FDA Update</p> <p>Provide an update on FDA’s Clinical Outcome Assessment Qualification Program and other FDA initiatives</p>
10:20 – 10:45 am ET (25 min)	Break
10:45 – 12:15 pm ET (90 min)	<p>Session 2: Patient Experience Data: Use in Regulatory Decision Making and Labeling</p> <p>Discuss patient experience data and its use in regulatory decision making</p>
12:15 – 1:15 pm ET (60 min)	Lunch
1:15 – 2:45 pm ET (90 min)	<p>Session 3: Qualitative Methods in Clinical Trials: Opportunities and Challenges</p> <p>Discuss methodological approaches to qualitative data collection in clinical trials, and the opportunities and challenges involved</p>
2:45 – 3:10 pm ET (25 min)	Break

3:10 – 5:00 pm ET (110 min)	<p>Session 4: Applying Methodologies for Estimating Meaningful Within-person Change Thresholds: Considerations and Alternative Approaches</p> <p>Examine four examples that advance the estimation and use of meaningful within-person change thresholds</p>
5:00 – 5:10 pm ET (10 min)	Day 1 Closing Remarks / Adjourn
5:30 – 7:00 pm ET (90 min)	Reception and Poster Session

<i>Agenda – April 20, 2023</i>	
7:30 – 8:30 am ET (60 min)	Registration and Breakfast
8:30 – 10:00 am ET (90 min)	<p>Session 5: Strategies for Use of COAs in Rare Disease Pediatric Populations</p> <p>Explore methodological challenges in research involving rare pediatric populations, especially in children less than 5 years of age</p>
10:00 – 10:25 am ET (25 min)	Break
10:25 – 11:55 am ET (90 min)	<p>Session 6: eCOA: COA Program Projects and Collaborations Update</p> <p>Explore two collaborative projects leveraging sensor-based measurement of activity and discuss the challenges involved in assessing algorithms for deriving interpretable metrics from raw sensor data</p>
11:55 – 12:15 pm ET (20 min)	Workshop Wrap Up / Adjourn

NOTE: Session presentations will be recorded and posted to the PRO Consortium’s web page by May 31, 2023. In addition, posters summarizing the status of the PRO Consortium’s working groups and highlighting the activity within the eCOA Consortium and the Rare Disease COA Consortium will also be available.