13th Annual Patient-Reported Outcome Consortium Workshop – Held Virtually

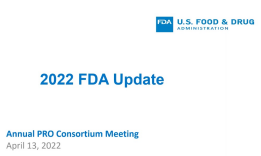
April 13–14, 2022

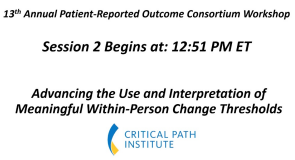
On April 13–14, 2022, the *13th Annual Patient-Reported Outcome Consortium Workshop* was held in a virtual format.

The following Workshop Agenda provides an overview of the two-day meeting as well as links to the session recordings and slide decks. Links to 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 are located after the agenda.

Agenda – Day 1

11:00–11:20 am	**Welcome and Patient-Reported Outcome Consortium Update** **Overview:** Provide a high-level summary of the recent accomplishments and ongoing activities within the Patient-Reported Outcome Consortium**Presenter:** *Sonya Eremenco, MA*– Director, Patient-Reported Outcome (PRO) Consortium, Critical Path Institute (C-Path)	

11:20–12:30 pm	**Session 1: FDA Update** **Overview:** Provide an update on FDA's Clinical Outcome Assessment Qualification Program and other FDA initiatives **Moderator:** *Michelle Campbell, PhD* – Senior Clinical Analyst for Stakeholder Engagement and Clinical Outcomes, Office of Neuroscience (ON), Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA) **Presenters:** *Robyn Bent, RN, MS* – Director, Patient Focused Drug Development Program, CDER, FDA *Selena Daniels, PharmD, PhD* – Clinical Outcome Assessment Team Leader, Division of Clinical Outcome Assessment, FDA *Laura Lee Johnson, PhD* – Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA *David S. Reasner, PhD* – Division Director, Division of Clinical Outcome Assessment, ODES, OND, CDER, FDA **Q & A**	
12:30–12:50 pm	**Break – 20 min**	

12:50–2:20 pm	**Session 2: Advancing the Use and Interpretation of Meaningful Within-Person Change Thresholds** **Overview:** Examine three examples that advance the use of meaningful within-person change thresholds**Moderator:** *Rebecca M. Speck, PhD, MPH* – Clinical Outcome Assessment Scientist, Clinical Outcome Assessment Program, C-Path **Presenters:** *Carla Mamolo, PhD* – Director, Health Economics & Outcomes Research, Pfizer, Inc. *Johannes Giesinger, PhD* – Assistant Professor, Medical University of Innsbruck Margaret Vernon, PhD – Senior Vice President, General Manager, Evidera, Inc. *Josephine Norquist, MS* – Executive Director, Patient-Centered Endpoints & Strategy Lead, Merck & Co., Inc. **Panelists:** *Selena Daniels, PharmD, PhD* – Clinical Outcome Assessment Team Leader, Division of Clinical Outcome Assessment, FDA *Lili Garrard, PhD* – Lead Mathematical Statistician, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA **Q & A**	
2:20–2:30 pm	**Day 1 Wrap Up**	

Agenda – Day 2

11:00–11:20 am	**eCOA: Getting Better Together Initiative Update** **Overview:** Provide a brief update on the eCOA: Getting Better Together Initiative, an ongoing collaboration between the PRO Consortium and eCOA Consortium**Presenter:** *Scottie Kern, BSc (Hons)* – Executive Director, Electronic Clinical Outcome Assessment (eCOA) Consortium, C-Path	

11:20–12:50 pm	**Session 3: Using Digital Health Technology to Measure What Matters** **Overview:** Discuss how digital health technology can be used to measure what is important**Moderator:** *Maria Mattera, MPH* – Scientific Director, PRO Consortium, C-Path **Presenters:** *Maria Mattera, MPH* – Scientific Director, PRO Consortium, C-Path *Rebecca M. Speck, PhD, MPH* – Clinical Outcome Assessment Scientist, Clinical Outcome Assessment Program, C-Path *Kai Langel* – Senior Director, Strategy and Innovation, Global Regulatory Policy and Intelligence, Janssen *Jessie P. Bakker, PhD, MS* – Executive Vice President of Medical Affairs, Signifier Medical Technologies (presenting on behalf of the Digital Medicine Society) **Panelists:** *Michelle Campbell, PhD* – Senior Clinical Analyst for Stakeholder Engagement and Clinical Outcomes, ON, OND, CDER, FDA *Anindita Saha, BSE* – Assistant Director, Digital Center of Excellence, Center for Devices and Radiological Health, FDA **Q & A**	
12:50–1:00 pm	**Workshop Wrap Up**	

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 are available below:

Posters	
Chronic Heart Failure Working Group Cognition Working Group Depression Working Group 2.0 Irritable Bowel Syndrome Working Group Multiple Sclerosis Working Group	Pediatric Asthma Working Group Rheumatoid Arthritis Working Group Small Cell Lung Cancer Working Group Rare Disease COA Consortium eCOA Consortium