2024 Clinical Outcome Assessment Program Annual Meeting

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April 17-18, 2024

Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Rd
Rockville, MD 20852
On April 17-18, 2024 the Clinical Outcome Assessment Program Annual Meeting was held in Rockville, MD.

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

Agenda – Day 1

7:30–8:30 am	**Registration and Breakfast – Veranda (Outside Salon E-H)**	
8:30–8:45 am	**Welcome** *Cheryl D. Coon, PhD* – Vice President, Clinical Outcome Assessment Program, Critical Path Institute	
8:45–9:15 am	**Rare Disease Clinical Outcome Assessment Consortium Update** *Lindsey Murray, PhD, MPH* – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute	

9:15–10:30 am	**FDA Update** **Moderator***:* *Michelle Campbell, PhD* –Associate Director, Stakeholder Engagement and Clinical Outcomes, Office of Neuroscience, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration **Presenters:** *Robyn Bent, RN, MS* – Director, Patient-Focused Drug Development Program, Center for Drug Evaluation and Research, U.S. Food and Drug Administration *Selena Daniels, PharmD, PhD* – Deputy Division Director, Division of Clinical Outcome Assessment, Office of Drug Evaluation Sciences, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration *Lili Garrad, PhD* – Master Scientist, Patient-Focused Statistical Scientists (PFSS), Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration *Jessica Mavadia-Shukla, PhD* – Director, Medical Device Development Tools Program, Center for Devices and Radiological Health, U.S. Food and Drug Administration *David S. Reasner, PhD* – Division Director, Division of Clinical Outcome Assessment, Office of Drug Evaluation Sciences, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration	
10:30–11:00 am	**Break**	
11:00–12:15 pm	**Session 1: Leveraging Digital Health Technology and Partnership Opportunities to Measure Clinical Outcomes That Matter** **Moderator:** *Maria Mattera, MPH* – Scientific Director, Patient-Reported Outcome Consortium, Critical Path Institute **Presenters:** *Katelyn Keyloun, PharmD, MS* – Director, R&D Digital and Data Strategy, AbbVie *Chad Gwaltney, PhD* – President, Gwaltney Consulting *Christine Guo, PhD* – Chief Scientific Officer, ActiGraph **Panelists:** *Jen Horonjeff, PhD* – Founder and CEO, Savvy Cooperative *Dilorom (Delia) Sass, PhD, RN, AGPCNP-BC* – Clinical Analyst, Division of Clinical Outcome Assessment, Office of Drug Evaluation Sciences, Office of New Drugs, Center for Drug Evaluation Research, U.S. Food and Drug Administration *Michelle Campbell, PhD* – Associate Director of Stakeholder Engagement and Clinical Outcomes, Division of Clinical Outcome Assessment, Office of Neuroscience, Office of New Drugs, Center for Drug Evaluation Research, U.S. Food and Drug Administration	
12:15–1:30 pm	**Lunch – Veranda (Outside Salon E-H)**	

1:30–2:00 pm	**Patient-Reported Outcome Consortium Update** *Sonya Eremenco, MA* – Executive Director, Patient-Reported Outcome Consortium, Critical Path Institute	
2:00–3:15 pm	**Session 2: eCOA and DHTs in Oncology: Realizing the Digital Dividend** **Moderator:** *Scottie Kern* – Executive Director, Electronic Clinical Outcome Assessment Consortium, Critical Path Institute **Presenters:** *Ari Gnanasakthy, MBA, MSc* – Principal Scientist, RTI Health Solutions *Jennifer Lord-Bessen, PhD* – Senior Director, Global HEOR Advanced Scientific Capabilities, Patient-Reported Outcomes Assessment (PROA), Hematology-Oncology, Bristol Myers Squibb *Florence Mowlem, PhD* – Vice President of Science, ObvioHealth; 2024 eCOA Consortium Industry Co-Director *Elena Izmailova, PhD* – Chief Scientific Officer, Koneksa Health *T. J. Sharpe* – Patient Engagement Program Manager, Medidata Solutions **Panelist:** *Vishal Bhatnagar, MD* – Associate Director for Patient Outcomes, Oncology Center of Excellence, Center for Drug Evaluation and Research, U.S. Food and Drug Administration	
3:15–3:45 pm	**Break**	
3:45-5:00 pm	**Session 3: Clinical Outcome Assessments Used in Trial Entry, Stratification, and Endpoints: Evidence and Implications to Ensure They're Fit For Their Purpose** **Moderator:** *Cheryl D. Coon, PhD* – Vice President, Clinical Outcome Assessment Program, Critical Path Institute **Presenters:** *Cole Ayasse, PhD* – Clinical Outcome Assessment Scientist, Critical Path Institute **Panelists:** *Katherine Bevans, PhD* – Director, Patient Reported Outcomes, Johnson & Johnson Innovative Medicine *Onyeka Illoh, OD, MPH* – Team Leader, Division of Clinical Outcome Assessment, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration *Gahan Pandina, PhD* – Senior Director, Compound Development Team Leader, Johnson & Johnson Innovative Medicine *Mitchell Psotka, MD, PhD* – Medical Officer, Division of Cardiology and Nephrology, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration *RJ Wirth, PhD* – CEO & Managing Partner, Vector Psychometric Group, LLC	
5:00–5:10 pm	**Day 1 Closing Remarks** *Cheryl D. Coon, PhD* – Vice President, Clinical Outcome Assessment Program, Critical Path Institute **Adjourn**	

5:10–5:30 pm	**Open**
5:30–7:00 pm	**Reception – Foyer E-H and Veranda**

Agenda – Day 2

7:30–8:30 am	**Registration and Breakfast – Veranda (Outside Salon E-H)**	
8:30-9:00 am	**Welcome and Electronic Clinical Outcome Assessment Consortium Update** *Scottie Kern* – Executive Director, Electronic Clinical Outcome Assessment Consortium, Critical Path Institute	
9:00–10:15 am	**Session 4: Mitigating Challenges in Clinical Outcome Assessments With Multiple Respondents: Sharing Lessons Learned From Across the Clinical Outcome Assessment Program** **Moderator:** *Lindsey Murray, PhD, MPH* – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute **Presenters:** *Lindsey Murray, PhD, MPH* – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute *Adam Scheller, PhD* – Senior Scientist, Clinical Outcomes, Denali Therapeutics *Claire Trennery, MSc* – Associate Director, Patient-Centered Outcomes, Adelphi Values *Jill V. Platko, PhD* –Vice President, Scientific Services, Suvoda **Panelists:** *Sarita Edwards, MHA* – CEO & President, The E.WE Foundation *Marian M. Strazzeri, MS* – Mathematical Statistician, Patient-Focused Statistical Scientists, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration *Nicole Lyn, MPH* – Global Health Economics and Value Assessment Business Partner, Sanofi	
10:15–10:45 am	**Break**	

10:45–12:00 pm	**Session 5: Patient-Reported Outcome Measurement Now and Into the Future: Multi-Stakeholder Perspectives Regarding the Optimization of Patient-Reported Outcome Data in the Decision-Making Process Across the Healthcare Continuum** **Moderator:** *Adam Gater, MSc* – Senior Director, Adelphi Values **Presenters:** *Sharan Randhawa, MSc* – Senior Research Manager, Adelphi Values *Loriana Hernández-Aldama, BA* – 2x Survivor, Patient Advocate, ArmorUp for Life *John Powers, III, MD* – Professor of Clinical Medicine, George Washington University School of Medicine *Bellinda King-Kallimanis, PhD* – Senior Director of Patient-Focused Research, LUNGevity Foundation *Gary Rice, RPh, MS* – Senior Advisor of Specialty & Clinical Strategy, MedImpact Healthcare Systems, Inc. *Eleanor Perfetto, PhD* – Professor, University of Maryland *Claire Snyder, PhD* – Professor of Medicine, Oncology, and Health Policy & Management, Johns Hopkins University, PROTEUS Consortium (participating as a private consultant) **Panelist:** *Selena Daniels, PharmD, PhD* – Deputy Division Director, Division of Clinical Outcome Assessment, Office of Drug Evaluation Sciences, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration	
12:00–12:15 pm	**Annual Meeting Wrap Up** *Cheryl D. Coon, PhD* – Vice President, Clinical Outcome Assessment Program, Critical Path Institute	
12:15–1:30 pm	**Lunch – Veranda (Outside Salon E-H)**	

Posters summarizing the status of the PRO Consortium's working groups, the Rare Disease Subcommittee activities, and the ePRO Consortium are available below:

- 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