
2024 Clinical Outcome Assessment Program Annual Meeting

2024 Clinical Outcome Assessment Program Annual Meeting

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	<u>Welcome</u> <i>Cheryl D. Coon, PhD</i> – Vice President, Clinical Outcome Assessment Program, Critical Path Institute	
8:45–9:15 am	<u>Rare Disease Clinical Outcome Assessment Consortium Update</u> <i>Lindsey Murray, PhD, MPH</i> – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute	

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

1:30–2:00 pm	<u>Patient-Reported Outcome Consortium Update</u> Sonya Eremenco, MA – Executive Director, Patient-Reported Outcome Consortium, Critical Path Institute	
2:00–3:15 pm	<u>Session 2: eCOA and DHTs in Oncology: Realizing the Digital Dividend</u> 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	<u>Session 3: Clinical Outcome Assessments Used in Trial Entry, Stratification, and Endpoints: Evidence and Implications to Ensure They're Fit For Their Purpose</u> 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	<u>Welcome and Electronic Clinical Outcome Assessment Consortium Update</u> <i>Scottie Kern</i> – Executive Director, Electronic Clinical Outcome Assessment Consortium, Critical Path Institute	
9:00–10:15 am	<u>Session 4: Mitigating Challenges in Clinical Outcome Assessments With Multiple Respondents: Sharing Lessons Learned From Across the Clinical Outcome Assessment Program</u> Moderator: <i>Lindsey Murray, PhD, MPH</i> – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute Presenters: <i>Lindsey Murray, PhD, MPH</i> – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute <i>Adam Scheller, PhD</i> – Senior Scientist, Clinical Outcomes, Denali Therapeutics <i>Claire Trennery, MSc</i> – Associate Director, Patient-Centered Outcomes, Adelphi Values <i>Jill V. Platko, PhD</i> – Vice President, Scientific Services, Suvoda Panelists: <i>Sarita Edwards, MHA</i> – CEO & President, The E.WE Foundation <i>Marian M. Strazzeri, MS</i> – Mathematical Statistician, Patient-Focused Statistical Scientists, Office of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration <i>Nicole Lyn, MPH</i> – Global Health Economics and Value Assessment Business Partner, Sanofi	
10:15–10:45 am	Break	

10:45–12:00 pm	<p><u>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</u></p> <p>Moderator: Adam Gater, MSc – Senior Director, Adelphi Values</p> <p>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)</p> <p>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</p>	
12:00–12:15 pm	<p><u>Annual Meeting Wrap Up</u></p> <p>Cheryl D. Coon, PhD – Vice President, Clinical Outcome Assessment Program, Critical Path Institute</p>	
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](#)