2025 Clinical Outcome Assessment Program Annual Meeting

2025 Clinical Outcome Assessment Program Annual Meeting

April 9-10, 2025

Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Rd
Rockville, MD 20852

C-Path's Clinical Outcome Assessment (COA) Program recently held its Annual Meeting in Rockville, MD. Roughly 300 attendees gathered for two days of sessions and discussions on the methodologies and strategies that will advance drug development and regulatory approaches in COAs across a wide range of therapeutic areas.

Agenda – Day 1

7:30–8:30 am	**Registration and Breakfast – Veranda (Outside Salon E-H)**	
8:30–8:40 am	**Welcome** *Cheryl D. Coon, PhD – Vice President, Clinical Outcome Assessment Program, Critical Path Institute*	
8:40–9:00 am	**FDA Update** **Presenters:** *Robyn Bent, RN, MS – Director, Patient-Focused Drug Development Program, Center for Drug Evaluation and Research, 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*	

9:00–10:15 am	**Session 1: Current thinking on the accessibility and burden of eCOA & DHT system use** **Moderator:** *Scottie Kern – Executive Director, Electronic Clinical Outcome Assessment Consortium, Critical Path Institute* **Presenters:** *Lee Aiyegubsu, MBChB, PhD – Associate Professor and Deputy Director, Centre for Patient-Reported Outcomes Research (CPROR), University of Birmingham, UK* *Alisa Heinzman, MFA – Senior Project Manager, Electronic Clinical Outcome Assessment Consortium, Critical Path Institute* **Panelists:** *Katy Benjamin, SM, PhD – Senior Principal Scientist, Patient Centered Endpoints and Strategies (PaCES), Merck & Co., Inc.* *Ian Pallett, BSc, HNC – Sensor Solutions Director, Parexel* **Q & A**	
10:15–10:45 am	**Break**	
10:45–12:15 pm	**Session 2: The potential of AI for COA development and deployment in clinical trials** **Moderator**: *Fraser Bocell, MEd, PhD – Senior Clinical Outcome Assessment Scientist, Clinical Outcome Assessment Program, Critical Path Institute* **Presenter:** *Cole Ayasse, PhD – Clinical Outcome Assessment Scientist, Clinical Outcome Assessment Program, Critical Path Institute* **Panelists:** *Lynn Brielmaier, BSEET – Person living with amyotrophic lateral sclerosis (PLWALS)* *Jarjieh Fang, MPH – Senior Manager, Senior Manager, Patient-Centered Outcomes Assessment (PCOA), Pfizer, Inc.* *Kelly McCarrier, PhD, MPH – Senior Director and Global Lead – Qualitative Research, OPEN Health Group* *Jonathan Norman, PGDip – Director, Localization Services, YPrime* **Q & A**	
12:15–1:30 pm	**Lunch – Veranda (Outside Salon E-H)**	
1:30–2:10 pm	**Patient-Focused Drug Development at the Center of C-Path's Solutions** *Cheryl D. Coon, PhD – Vice President, Clinical Outcome Assessment Program, Critical Path Institute* *Klaus Romero, MD – CEO, Critical Path Institute* *Diane Stephenson, PhD – Vice President, Neurology, Executive Director, Critical Path for Parkinson's, Critical Path Institute* *Collin Hovinga, PharmD, MS, FCCP – Vice President, Rare and Orphan Disease Programs, Critical Path Institute*	
2:10–2:30 pm	**Patient-Reported Outcome Consortium Update** *Sonya Eremenco, MA – Executive Director, Patient-Reported Outcome Consortium, Critical Path Institute*	

2:30–3:00 pm	**Break**	
3:00–4:30 pm	**Session 3: Regulatory pathways for using patient experience data: Navigating benefit risk assessment pre-approval and communications consistent with labeling post approval** ***Moderator:*** *Robyn Carson, MPH – Vice President & Head, Patient-Centered Outcomes Research and HEOR-Strategy Aesthetics, AbbVie* ***Presenters:*** *Niklas Karlsson, PhD – Senior Director, Patient Centered Science Respiratory & Immunology, AstraZeneca* *Denise Sánchez Palomo, JD, MS, MA – Principal Consultant, Opus Regulatory* *Jonathan Stokes, MBA – Senior Director, Patient-Centered Outcomes Research, AbbVie* ***Panelists:*** *Charu Gandotra, MD, MS, FACC, FASE – Acting Associate Director for Therapeutic Review, Division of Cardiology and Nephrology, Office of Cardiology, Hematology, Endocrinology and Nephrology, Office of New Drugs, Center for Drug Evaluation and Research, 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* *Tricha Shivas, MBe – Chief of Staff and Strategy, Foundation for Sarcoidosis Research* ***Q & A***	
4:30–4:35 pm	**Day 1 Closing Remarks** *Cheryl D. Coon, PhD – Vice President, Clinical Outcome Assessment Program, Critical Path Institute*	
4:35–5:00 pm	**Open**	
5:00–6:30 pm	**20th Anniversary Celebration/Reception – Foyer E-H and Veranda**	

Agenda – Day 2

7:30–8:30 am	**Registration and Breakfast – Veranda (Outside Salon E-H)**	
8:30–8:50 am	**Welcome and Electronic Clinical Outcome Assessment Consortium Update** *Scottie Kern – Executive Director, Electronic Clinical Outcome Assessment Consortium, Critical Path Institute*	

8:50–10:00 am	**Session 4: Implementation insights in rare disease clinical outcome assessment** **Moderator:** *Lindsey Murray, PhD, MPH – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute* **Panelists:** *Kayci Capps, MEd – Dravet Patient Advocate, Dravet Syndrome Foundation* *Lisa Dilworth, BS, MAS – Vice President, Disease Monitoring Program Strategy and Management, Ultragenyx* *Diana Rofail, PhD, CPsychol, MBA – Global Head of Patient-Centered Outcomes Research & Digital Health (PCOR-DH), Regeneron* *R.J. Wirth, PhD – CEO & Managing Partner, Vector Psychometric Group, LLC* **Q & A**	
10:00–10:30 am	**Break**	
10:30–10:45 am	**Rare Disease Clinical Outcome Assessment Consortium Update** *Lindsey Murray, PhD, MPH – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute*	
10:45–12:15 pm	**Session 5: Using patient-centered evidence to inform decision making across the drug development lifecycle: navigating a varied landscape** **Moderator:** *Sonya Eremenco, MA – Executive Director, Patient-Reported Outcome Consortium, Critical Path Institute* **Presenters:** *Chantal Quinten, PhD – Senior Expert in Health Analytics, European Medical Agency* *Benoit Arnould, PhD – Head, Clinical Outcomes Assessments, Sanofi* *Lynda Doward, MRes – Vice President & European Head Patient-Centered Outcomes Assessment, RTI Health Solutions* **Panelists:** *Cherié Butts, PhD – Senior Medical Director, Biogen* *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* *Jen Horonjeff, PhD – Founder and CEO, Savvy Cooperative* *Dan O'Connor, PhD – Director Regulatory and Early Access Policy, Association of the British Pharmaceutical Industry (ABPI)* *Matt Reaney, PhD, CPsychol, CSci – Head of Science and Analytics, Patient Centered Solutions (PCS); and Head of PCS Institute, IQVIA* ***Q & A***	
12:15–12:20 pm	**Annual Meeting Wrap Up** *Cheryl D. Coon, PhD – Vice President, Clinical Outcome Assessment Program, Critical Path Institute*	

12:20–1:30 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