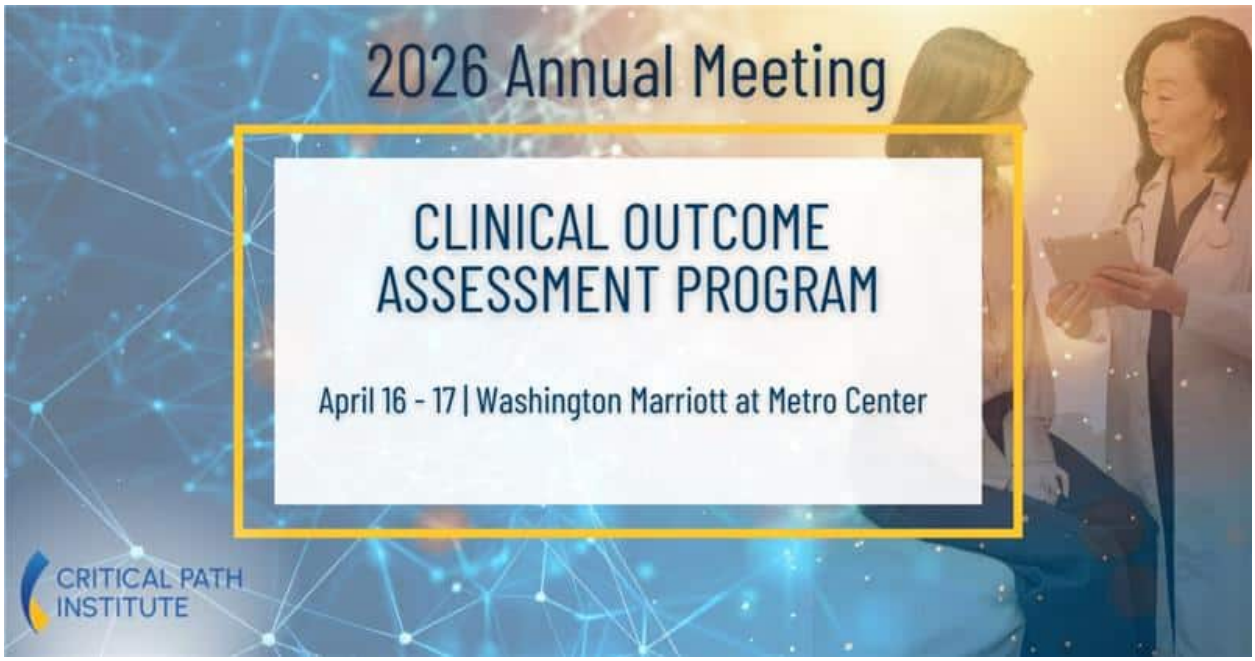
2026 Clinical Outcome Assessment Program Annual Meeting



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.

This year's meeting brought together leaders from across industry, regulatory agencies, academia, patient organizations, and technology and allied service partners to advance the science and application of COAs in medical product development. Building on the strong engagement and momentum from last year, the 2026 program featured deep-dive sessions, case studies, and multi-stakeholder discussions on pressing issues in the field, including:

- Using patient experience data to inform value assessment for access decision making
- Pulling back the curtain: Multi-stakeholder insights on electronic clinical outcome assessment implementation
- Incorporating the patient voice into clinical trial design: More than just checking the box
- From meaningful aspect of health to metric to endpoint: How multidisciplinary teams form a comprehensive approach to digitally-derived endpoints
- Revisiting meaningful change: Current thinking on establishing and applying benchmarks
- Addressing challenges in rare disease clinical trials: Methodological case studies

Please see the detailed recap, complete with session recordings and presentations below:

2026 Clinical Outcome Assessment Program Annual Meeting

Agenda – Day 1

8:00 – 9:00 a.m.	**Registration and Breakfast – Veranda (Outside Salon E-H)**	
9:00-9:15 a.m.	**Welcome** *Cheryl D. Coon, PhD – Vice President, Clinical Outcome Assessment Program, Critical Path Institute* *Klaus Romero, MD – Chief Executive Officer and Chief Science Officer, Critical Path Institute*	
9:15-10:15 a.m.	**Update on FDA's COA Qualification Program, ISTAND Program, and Patient-Focused Drug Development Initiatives** **Presenters:** *Robyn Bent, RN, MS – Director, Patient-Focused Drug Development Program, Center for Drug Evaluation and Research, U.S. Food and Drug Administration* *Michelle Campbell, PhD* – Associate Director for Stakeholder Engagement and Clinical Outcomes, Office of Neuroscience, Office of New Drugs, 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* *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* *Vanitha Sekar, MS, PhD – Division Director, Division of Biomedical Informatics, Research, and Biomarker Development, Office of Drug Evaluation Sciences, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*	
10:15-10:30 a.m.	**Spotlight: Best practice recommendations and considerations for designing and electronically implementing event-driven diaries in clinical trials** **Presenter:** *Florence Mowlem, PhD –* Chief Scientific Officer, uMotif **Q & A**	

11:00 a.m.–12:15 p.m.	***Incorporating the Patient Voice into Clinical Trial Design: More Than Just Checking the Box*** **Moderator:** *Nicki Bush, MHS* – Global Head, Endpoint Strategy and COA Measurement, Patient-Centered Outcomes, OPEN Health **Presenters:** *Pujita Vaidya, MPH* – Director, Regulatory Science and Policy, North America, Sanofi *Amanda Decoker, MA* – Sr. Director, Head of Patient Engagement, Experience and Recruitment, Takeda **Panelists:** *Cynthia Grossman, PhD* – Division Director, Division of Patient-Centered Development, Center for Devices and Radiological Health, US Food and Drug Administration *Samantha Parker, MBA* – Patient Engagement Lead, Italfarmaco & Vice-Chair International Rare Disease Research Consortium *Dominique Pichard, MD, MS* – Chief Science Officer, International Rett Syndrome Foundation **Q & A**	
1:30–1:45 pm	**Patient-Centered Evidence Consortium Update** *Sonya Eremenco, MA* – Executive Director, Patient-Reported Outcome Consortium, Critical Path Institute	
1:45–3:00 p.m.	**Pulling Back the Curtain: Multi-stakeholder Insights on Electronic Clinical Outcome Assessment Implementation** **Moderator:** *Scottie Kern* – Executive Director, Electronic Clinical Outcome Assessment Consortium, Critical Path Institute **Panelists:** *Caroline Anfray* – Principal, Head of COA Author Collaborations and Licensing Services, IQVIA *Jennifer Cook* – Senior Project Manager, Accellacare Site Network *Lynn Germscheid* – Associate Director, eCOA Management GDM, Bristol Myers Squibb *Paul O'Donohoe* – Senior Director, eCOA Product and Science, Medidata Solutions *Alexandros Rokotas* – Expert eCOA Project Manager, Bayer **Q & A**	
3:30–3:45 p.m.	**Rare Disease Clinical Outcome Assessment Consortium Update** *Lindsey Murray, PhD, MPH* – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute	
3:00–4:30 pm	**Expanding the Toolbox to Interpret the Meaningfulness of Treatment Effects** **Moderator:** *Fraser Bocell, MEd, PhD* – Senior Clinical Outcome Assessment Scientist, Clinical Outcome Assessment Program, Critical Path Institute **Panelists:** *Kim Cocks, PhD* – Senior Director, Patient-Centered Outcomes, Adelphi Values *Andrew Trigg, MSc* – Statistical Innovation Lead, Bayer *Kevin P. Weinfurt, PhD* – James B. Duke Distinguished Professor of Population Health Sciences, Duke University School of Medicine ***Q & A***	

Agenda – Day 2

7:30–8:30 am	**Registration and Breakfast – Veranda (Outside Salon E-H)**	
8:30–8:45 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 a.m.	**Using Patient Experience Data to Inform Value Assessment for Access Decision Making** **Moderator:** *Ebony Dasheill-Aje* – Executive Director & Head, Patient Centered Outcomes Science (PCOS), BioMarin **Presenters:** *Jessica Abel, MPH* – Director, Patient Experience Data Policy and Best Practices, AbbVie *Iyar Mazar, PhD* – Director of Patient-Centered Outcomes Assessment, Pfizer *Leah Howard, JD* – Chief Executive Officer, National Psoriasis Foundation **Panelists:** *Dana McCormick* – Senior Director, Practice Strategy & Innovation, AMCP **Q & A**	
10:30–11:30 a.m.	**Navigating Methodological Challenges in Rare Disease Clinical Trials: Lessons from Real-World Case Studies** **Moderator:** *Lindsey Murray, PhD, MPH* – Executive Director, Rare Disease Clinical Outcome Assessment Consortium, Critical Path Institute **Presenters:** *Nicola Williamson, MSc* –Patient Centered Outcomes Research Lead, UCB *Bryce Reeve, PhD* – Professor, Population Health Science and Pediatrics, Duke University School of Medicine **Panelists:** *Michelle Campbell, PhD* – Associate Director for Stakeholder Engagement and Clinical Outcomes, Office of Neuroscience, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration *Sue Vallow, MBD, MA* – Senior Director Patient Centered Evidence, Agios *Terry Jo Bichell, PhD* – Chief Executive Officer, COMBINEDBrain	

11:30 a.m.-12:30 p.m .	**How Multidisciplinary Teams Form a Comprehensive Approach to Digitally-derived Endpoints** **Moderator** : *Cheryl D. Coon, PhD* – Vice President, Clinical Outcome Assessment Program, Critical Path Institute **Presenters:** *Tom Willgoss, PhD* – Immunology Lead, Roch Products, Ltd *Marie McCarthy* – Digital Endpoint Lead Director, Novartis **Panelists:** *Andrew Potter, PhD* – Associate Director, Biostatistics, BMS *Abigail Newell, PhD* – Senior Director, Research, Cancer Support Community *Liam Kaufman, MS* – Executive VP, Partnerships and Strategic Projects, Cambridge Cognition **Q & A**	