View Now: 12th Annual Patient-Reported Outcome Consortium Workshop – Held Virtually

April 14–15, 2021

On April 14–15, 2021, the *12th 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, the Rare Disease Subcommittee activities, and the ePRO Consortium are located after the agenda.

Agenda – Day 1

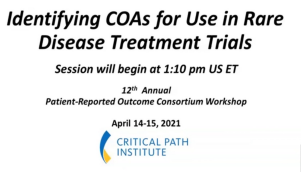
11:00–11:20 am	**Welcome and Patient-Reported Outcome Consortium Update** **Overview:** Provides a high-level summary of the recent accomplishments and ongoing activities within the Patient-Reported Outcome (PRO) Consortium **Presenter:** *Sonya Eremenco, MA* – Director, Patient-Reported Outcome (PRO)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

11:20–12:30 pm	**Session 1: 2021 FDA Update** **Overview:** Provides an update on FDA's Clinical Outcome Assessment (COA) Qualification Program and other 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 *Laura Lee Johnson, PhD* – Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA *Elektra Papadopoulos, MD, MPH* – Acting Deputy Director, Division of Clinical Outcome Assessment, Office of Drug Evaluation Sciences (ODES), OND, 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: Migraine: A Tale of Two Paths to PRO-Based Product Labeling** **Overview:** Discusses the experience of two pharmaceutical firms' different paths to obtaining FDA-approved PRO-based label claims for novel migraine drugs **Moderator:** *Stephen Joel Coons, PhD* – Executive Director, PRO Consortium and Senior Vice President, Clinical Outcome Assessment Program, C-Path **Opening Remarks:** *Billy Dunn, MD* – Director, ON, CDER, FDA **Presenters:** *Pooja Desai, PhD* – Director, US Health Economics, Therapeutic Area Lead – Inflammation, Nephrology and Bone, Amgen *Elizabeth (Nicki) Bush, MHS* – Senior Advisor and Head, Patient-Focused Outcomes Center of Expertise, Eli Lilly and Company **Panelists:** *Eric Bastings, MD* – Acting Director, Division of Neurology I; Deputy Director, ON, CDER, FDA *Nick Kozauer, MD* – Director, Division of Neurology II, ON, CDER, FDA *Elektra Papadopoulos, MD, MPH* – Acting Deputy Director, Division of Clinical Outcome Assessment, ODES, OND, 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:** Provides a brief update on the eCOA: Getting Better Together Initiative, an ongoing collaboration between the PRO Consortium and ePRO Consortium **Presenter:** *Sonya Eremenco, MA* –Director, PRO Consortium and Acting Director, Electronic Patient-Reported Outcome (ePRO) Consortium, C-Path	
11:20–12:50 pm	**Session 3: Where Are We Headed with Activity Monitors in Clinical Trials?** **Overview:** Discusses practical considerations associated with the use of activity monitors to measure efficacy endpoints in clinical trials **Moderator:** *Maria Mattera, MPH* – Assistant Director, PRO Consortium, C-Path **Presenters:** *Jennifer Goldsack, MChem, MA, MBA* – Executive Director, Digital Medicine Society *Bill Byrom, PhD* – Vice President, Product Intelligence and Positioning, Signant Health *Jiat Ling Poon, PhD* – Principal Research Scientist, Eli Lilly and Company *Milena Anatchkova, PhD* – Senior Research Leader, Evidera, Inc. **Panelists:** *Andrew Potter, PhD* – Mathematical Statistician, Division of Biometrics I, CDER, FDA *Steven Blum, MBA, MA* – Asset and Indication Lead, Patient Reported Outcomes Assessment, WWHEOR, Bristol Myers Squibb **Q & A**	
12:50–1:10 pm	**Break – 20 min**	

1:10–2:40 pm	**Session 4: Identifying COAs for Use in Rare Disease Treatment Trials** **Overview:** Provides an update regarding the establishment and goals of the Rare Disease COA Consortium and presents results of work accomplished by the PRO Consortium's Rare Disease Subcommittee **Moderator:** *Lindsey Murray, PhD, MPH* – Associate Director, PRO Consortium, C-Path **Presenters:** *Tori Brooks, MPH* – Research Associate II, Mapi Research Trust *Lindsey Murray, PhD, MPH* – Associate Director, PRO Consortium, C-Path *Kiera Berggren, MA/CCC-SLP, MS* – Research Speech-Language Pathologist, Department of Neurology, Virginia Commonwealth University **Panelists:** *Naomi Knoble, PhD* – Reviewer, Division of Clinical Outcome Assessment, OND, CDER, FDA *Dawn Phillips, PT, MS, PhD* – Director, Clinical Scientist, Outcomes Research, REGENXBIO Inc. *Adam Shaywitz, MD, PhD* – Chief Medical Officer, BridgeBio Gene Therapy *Allison Seebald* – Senior Research Program Manager, National Organization for Rare Disorders **Q & A**	
2:40–2:45 pm	**Workshop Wrap Up** – *Sonya Eremenco*	

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

Posters	
Chronic Heart Failure Working Group Cognition Working Group Depression Working Group 2.0 Functional Dyspepsia Working Group 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 Subcommittee ePRO Consortium