
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)	<i>Welcome to the 12th Annual Patient-Reported Outcome Consortium Workshop</i> Event will begin at 11:01 am US ET April 14 - 15, 2021 
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11:20–12:30 pm	<u>Session 1: 2021 FDA Update</u> Overview: Provides an update on FDA’s Clinical Outcome Assessment (COA) Qualification Program and other initiatives Moderator: <i>Michelle Campbell, PhD</i> – 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: <i>Robyn Bent, RN, MS</i> – Director, Patient Focused Drug Development Program, CDER, FDA <i>Laura Lee Johnson, PhD</i> – Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA <i>Elektra Papadopoulos, MD, MPH</i> – Acting Deputy Director, Division of Clinical Outcome Assessment, Office of Drug Evaluation Sciences (ODES), OND, CDER, FDA <i>David S. Reasner, PhD</i> – Division Director, Division of Clinical Outcome Assessment, ODES, OND, CDER, FDA Q & A	 The banner features the FDA logo at the top right, followed by the text "2021 FDA Update" in blue. Below that, in smaller text, it says "12th Annual PRO Consortium Workshop" and "April 14, 2021". The banner is flanked by two vertical black bars.
12:30–12:50 pm	Break – 20 min	

12:50–2:20 pm	<u>Session 2: Migraine: A Tale of Two Paths to PRO-Based Product Labeling</u> Overview: Discusses the experience of two pharmaceutical firms’ different paths to obtaining FDA-approved PRO-based label claims for novel migraine drugs Moderator: <i>Stephen Joel Coons, PhD</i> – Executive Director, PRO Consortium and Senior Vice President, Clinical Outcome Assessment Program, C-Path Opening Remarks: <i>Billy Dunn, MD</i> – Director, ON, CDER, FDA Presenters: <i>Pooja Desai, PhD</i> – Director, US Health Economics, Therapeutic Area Lead – Inflammation, Nephrology and Bone, Amgen <i>Elizabeth (Nicki) Bush, MHS</i> – Senior Advisor and Head, Patient-Focused Outcomes Center of Expertise, Eli Lilly and Company Panelists: <i>Eric Bastings, MD</i> – Acting Director, Division of Neurology I; Deputy Director, ON, CDER, FDA <i>Nick Kozauer, MD</i> – Director, Division of Neurology II, ON, CDER, FDA <i>Elektra Papadopoulos, MD, MPH</i> – Acting Deputy Director, Division of Clinical Outcome Assessment, ODES, OND, CDER, FDA Q & A	<i>Migraine: A Tale of Two Paths to PRO-Based Product Labeling</i> Session will begin at 12:51 pm US ET 12th Annual Patient-Reported Outcome Consortium Workshop April 14-15, 2021 
2:20–2:30 pm	Day 1 Wrap Up	

Agenda – Day 2

11:00–11:20 am	<u>eCOA: Getting Better Together Initiative Update</u> Overview: Provides a brief update on the eCOA: Getting Better Together Initiative, an ongoing collaboration between the PRO Consortium and ePRO Consortium Presenter: <i>Sonya Eremenco, MA</i> –Director, PRO Consortium and Acting Director, Electronic Patient-Reported Outcome (ePRO) Consortium, C-Path	Welcome to the 12th Annual Patient-Reported Outcome Consortium Workshop Event will begin at 11:01 am US ET April 14 - 15, 2021 
11:20–12:50 pm	<u>Session 3: Where Are We Headed with Activity Monitors in Clinical Trials?</u> Overview: Discusses practical considerations associated with the use of activity monitors to measure efficacy endpoints in clinical trials Moderator: <i>Maria Mattera, MPH</i> – Assistant Director, PRO Consortium, C-Path Presenters: <i>Jennifer Goldsack, MChem, MA, MBA</i> – Executive Director, Digital Medicine Society <i>Bill Byrom, PhD</i> – Vice President, Product Intelligence and Positioning, Signant Health <i>Jiat Ling Poon, PhD</i> – Principal Research Scientist, Eli Lilly and Company <i>Milena Anatchkova, PhD</i> – Senior Research Leader, Evidera, Inc. Panelists: <i>Andrew Potter, PhD</i> – Mathematical Statistician, Division of Biometrics I, CDER, FDA <i>Steven Blum, MBA, MA</i> – Asset and Indication Lead, Patient Reported Outcomes Assessment, WWHEOR, Bristol Myers Squibb Q & A	Where Are We Headed with Activity Monitors in Clinical Trials? 12th Annual Patient-Reported Outcome Consortium Workshop April 14-15, 2021 
12:50–1:10 pm	Break – 20 min	

1:10–2:40 pm	<u>Session 4: Identifying COAs for Use in Rare Disease Treatment Trials</u> 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: <i>Lindsey Murray, PhD, MPH</i> – Associate Director, PRO Consortium, C-Path Presenters: <i>Tori Brooks, MPH</i> – Research Associate II, Mapi Research Trust <i>Lindsey Murray, PhD, MPH</i> – Associate Director, PRO Consortium, C-Path <i>Kiera Berggren, MA/CCC-SLP, MS</i> – Research Speech-Language Pathologist, Department of Neurology, Virginia Commonwealth University Panelists: <i>Naomi Knoble, PhD</i> – Reviewer, Division of Clinical Outcome Assessment, OND, CDER, FDA <i>Dawn Phillips, PT, MS, PhD</i> – Director, Clinical Scientist, Outcomes Research, REGENXBIO Inc. <i>Adam Shaywitz, MD, PhD</i> – Chief Medical Officer, BridgeBio Gene Therapy <i>Allison Seebald</i> – Senior Research Program Manager, National Organization for Rare Disorders Q & A	Identifying COAs for Use in Rare Disease Treatment Trials Session will begin at 1:10 pm US ET 12th Annual Patient-Reported Outcome Consortium Workshop April 14-15, 2021  CRITICAL PATH INSTITUTE
2:40–2:45 pm	<u>Workshop Wrap Up – Sonya Eremenco</u>	Thank You to our Workshop Session Planners, Presenters, and Panelists  Eleftra Papadopoulos – FDA, Michelle Campbell – FDA, Linda Nielsen – GlaxoSmithKline • Viktoria Ananthakrishnan – Evidera • Eric Beilings – FDA • Evelyn Bent – FDA • Kiera Berggren – Virginia Commonwealth University • Steven Blatt – JMS • Tori Brooks – Mapi Research Trust • Elizabeth (Nicki) Bush-Lilly • All Brown – Argene Health • Priya Desai – Argene • Mikha Kahan – FDA • Jennifer Goldsack – Digital Medicine Society • Laura Lee Johnson – FDA • Naomi Knoble – FDA • Nick Kozlowski – FDA • Eleftra Papadopoulos – FDA • Dawn Phillips – REGENXBIO • Jodi Ling Thom – FDA • Andrew Fother – FDA • David Resman – FDA • Allison Seebald – National Organization for Rare Disorders • Adam Shaywitz – BridgeBio Gene Therapy

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

Posters

<u>Chronic Heart Failure Working Group</u>	<u>Pediatric Asthma Working Group</u>
<u>Cognition Working Group</u>	<u>Rheumatoid Arthritis Working Group</u>
<u>Depression Working Group 2.0</u>	<u>Small Cell Lung Cancer Working Group</u>
<u>Functional Dyspepsia Working Group</u>	<u>Rare Disease Subcommittee</u>
<u>Irritable Bowel Syndrome Working Group</u>	<u>ePRO Consortium</u>
<u>Multiple Sclerosis Working Group</u>	