First Annual Patient-Reported Outcome Consortium Workshop

March 23, 2010

Sheraton Silver Spring Hotel
8777 Georgia Avenue – Silver Spring, MD 20910

SPONSORED BY:
Critical Path Institute
Food and Drug Administration (FDA)

The Patient-Reported Outcomes Consortium is a public-private partnership established by Critical Path Institute (C-Path) in cooperation with the U.S. Food and Drug Administration (FDA) and the medical products industry in 2008. The PRO Consortium brings together scientists from C-Path, industry, academia, and regulatory agencies in a pre-competitive environment for the purpose of developing, evaluating, and qualifying PRO instruments for use in clinical trials designed to evaluate the safety and efficacy of medical products.

On March 23, 2010 the **FIRST ANNUAL PATIENT-REPORTED OUTCOME CONSORTIUM WORKSHOP** was held in Silver Spring, Maryland. The overall Workshop objectives were to:

- Describe the genesis, purpose, and structure of the (1) Critical Path Institute and (2) PRO Consortium
- Explore the importance of PRO endpoints in the evaluation of medical products
- Discuss two FDA guidance documents relevant to PRO instrument development and use
- Describe the PRO Consortium's role from various stakeholders' perspectives
- review the progress made by the PRO Consortium's six working groups
- provide an open forum for further discussion of the PRO Consortium's function, processes, and deliverables

The following Workshop Agenda provides an overview of the day-and-a-half-long meeting as well as links to the slide sets and posters presented.

Workshop Agenda
March 23, 2010

Morning Session	**Moderator:** Stephen Joel Coons, PhD – Director, PRO Consortium, Critical Path Institute
9:00-9:05 am	**Welcome** Stephen Joel Coons, PhD

9:05-9:20 am	**Overview of Critical Path Institute** Raymond L. Woosley, MD, PhD – President and CEO, Critical Path Institute
9:20-9:30 am	**Overview of the PRO Consortium** Stephen Joel Coons, PhD
9:30-9:50 am	**The Importance of the PROs in the Evaluation of New Medical Products** Robert J. Temple, MD – Deputy Center Director for Clinical Science, Center for Drug Evaluation and Research (CDER), FDA
9:50-10:15 am	**Study Endpoint Considerations: Final PRO Guidance and Beyond** Laurie Beth Burke, RPh, MPH – Director, Study Endpoints and Labeling, Office of New Drugs, CDER, FDA
10:15-10:40 am	**Genesis of the PRO Consortium: Benefits of Collaboration** Wendy R. Sanhai, PhD – Senior Scientific Advisor, Office of Chief Scientist, Office of the Commissioner, FDA
10:40-11:00 am	**Break**
11:00-11:20 am	**FDA's Draft Drug Development Tools Qualification Guidance** ShaAvhrée Buckman, MD, PhD, FAAP – Director, Office of Translational Sciences, CDER, FDA
11:20-11:40 am	**EMA Perspective on PRO Instrument Qualification and Harmonization** Maria Isaac, MASc, MD, PhD – Scientific Administrator, Scientific Advice & Orphan Drugs Sector (SAOD), European Medicines Agency (EMA)
11:40-11:55 am	**PRO Consortium – Industry Perspective** Priti Jhingran, PhD – Director, US Health Outcomes, GlaxoSmithKline
11:55 am-Noon	**Morning Session Wrap-up** Stephen Joel Coons, PhD
Noon-1:00 pm	**Lunch**
Afternoon Session	**Moderator:** Priti Jhingran, PhD
1:00-1:05 pm	**Introduction to Afternoon Session** Priti Jhingran, PhD
1:05-1:25 pm	**The EXACT-PRO Expedition: Mapping the PRO Instrument Qualification Trail** Nancy Kline Leidy, PhD – Senior Vice President, Scientific Affairs and Senior Research Leader, United BioSource Corporation (UBC)

1:25-2:40 pm	**PRO Consortium Working Group Updates** **Irritable Bowel Syndrome (IBS)** – Charles Baum, MD, MS, FACG, Executive Medical Director, GI and Internal Medicine, Global Medical Affairs, Takeda Pharmaceuticals **Cognition** – Usha Mallya, PhD, Associate Director, Global Health Economics & Outcomes Research-Neuroscience and Ophthalmics, Novartis **Asthma** – Linda Nelsen, MHS, Associate Director, Epidemiology, Merck Sharp & Dohme Corp. **Depression** – Ken LaPensee, PhD, MPH, Director, Health Economics and Outcomes Research, Forest Research Institute **Non-Small Cell Lung Cancer** – Bhash Parasuraman, PhD, Senior Director, Health Economics and Outcomes Research, AstraZeneca **Advanced Breast Cancer** – Bonnie Teschendorf, PhD, Director, Patient Reported Outcomes, Johnson & Johnson Pharmaceutical Services
2:40-3:00 pm	**Break**
3:00-4:00 pm	**Open Panel Discussion** ShaAvhrée Buckman, MD, PhD Laurie Beth Burke, RPh, MPH Stephen Joel Coons, PhD Priti Jhingran, PhD Maria Isaac, MASc, MD, PhD Wendy R. Sanhai, PhD
4:00-4:30 pm	**Closing Remarks** Laurie Beth Burke, RPh, MPH and Stephen Joel Coons, PhD
4:30 pm	**Adjourn**