Welcome and PRO Consortium Update

Stephen Joel Coons, PhD
Executive Director, PRO Consortium

THIRD ANNUAL
PATIENT-REPORTED OUTCOME (PRO) CONSORTIUM WORKSHOP

April 4, 2012 ■ Silver Spring, MD

Co-sponsored by

CRITICAL PATH INSTITUTE
FDA
Workshop Packet Contents

• Welcome Letter
• Workshop Agenda
• PRO Consortium Fact Sheet
• Critical Path Institute (C-Path) Overview
• PRO Consortium Mission Statement and Objectives
• Speaker Biographical Sketches
• Pre-Registrant List
• Workshop Feedback Form
• Press Release Regarding New C-Path CEO
Thank You!

Workshop Planning Subcommittee

- Rich Barron – Amgen (Co-Chair)
- Nick Greco – Abbott (Co-Chair)
- Laurie Burke – FDA
- Risa Hayes – Lilly
- Indira Hills – FDA
- Dianne (Dee) Kennedy – FDA
- Josephine Norquist – Merck
- Elektra Papadopoulos – FDA
- Jay D. Pearson – Merck
- Diana Rofail – Roche
- Juliana Setyawan – Shire
- Yun Su – Bristol-Myers Squibb
Thank You!

C-Path’s PRO Consortium Team

- J. Jason Lundy, PhD – Assistant Director
- Theresa (“T”) Griffey, PMP – Senior Project Manager
- Karla Lehmann, PMP – Senior Project Manager
- Elisabeth Piault-Louis, PharmD, MA – Clinical Outcome Assessments Qualification Specialist
- Theresa Flemming – Project Coordinator
- Alex Mutebi, MSc – Graduate Research Associate
PRO Consortium Member Firms

Abbott
AstraZeneca
Boehringer Ingelheim
Bristol-Myers Squibb
Daiichi-Sankyo
Eisai
Forest Laboratories, Inc.
GlaxoSmithKline
Ironwood
Johnson & Johnson
MERCK
Novartis
Novo Nordisk
Pfizer
Roche
Sanofi
Shire
Suneon
Takeda
UCB
PRO Consortium Working Groups

Asthma – 11 member firms
Cognition – 10 member firms
Depression – 7 member firms
Functional Dyspepsia – 3 member firms
Irritable Bowel Syndrome – 3 member firms
Lung Cancer (NSCLC) – 7 member firms
Rheumatoid Arthritis – 8 member firms
Participation by Member Firms

- Two firms are not participating in any current working groups
- Nine firms are in one working group
- Five firms are in two working groups
- Four firms are in three working groups
- Four firms are in four working groups
During breaks in today’s Workshop, please view the seven working group posters at the back of the room.
For more information on the PRO Consortium

• Coons SJ, Kothari S, Monz BU, Burke LB. The Patient-Reported Outcome (PRO) Consortium: filling measurement gaps for PRO endpoints to support labeling claims. *Clinical Pharmacology & Therapeutics* 2011;90:743-748.

• www.c-path.org/PRO.cfm
Please step to one of the microphones or let us bring a microphone to you before you speak.