

Second Annual Workshop on Clinical Outcome Assessments in Cancer Clinical Trials

Event: Second Annual Workshop on Clinical Outcome Assessments in Cancer Clinical Trials

Date: April 25, 2017

Location: Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814

Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium, in collaboration with the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), is planning a public meeting titled *Second Annual Workshop on Clinical Outcome Assessments (COAs) in Cancer Clinical Trials*. The purpose of the workshop is to provide a forum for collaborative multidisciplinary discussion to identify opportunities and address challenges for clinical outcome assessments (COAs), particularly patient-reported outcome assessments, in oncology drug development.

During this year's workshop, a broad array of international stakeholders involved in oncology drug development and patient-reported outcome measurement will provide perspectives on the role of patient-reported symptomatic adverse events in evaluating and describing the tolerability and safety of anti-cancer agents. Speakers and panelists will explore the utility of information derived from existing and emerging patient-reported measures and discuss potential ways to improve the collection, analysis, and presentation of the data to support drug development and better inform treatment decisions. In addition, discussion of possible ways to assess an investigational drug's overall side effect burden as a clinical trial endpoint will be initiated. This workshop will include panelists and speakers from regulatory agencies, academia, patient advocacy groups, and the medical product industry.

This public workshop is intended for stakeholders interested in advancing COAs in cancer drug development including, but not limited to, academia, industry, regulatory agencies, consulting firms, HTA groups and patient groups.

To register for this workshop please click <u>here</u>. Government, non-profit or academic registrants should contact <u>Theresa Hall</u> for registration assistance.