NEWS FROM...

Critical Path Institute's Patient-Reported Outcome Consortium

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Critical Path Institute (C-Path) is a private, non-profit organization created in 2005 by the University of Arizona and the US Food and Drug Administration (FDA) to support the FDA's Critical Path Initiative, which is a strategy for transforming the way FDA-regulated medical products are developed, evaluated, manufactured, and used. The Patient-Reported Outcome (PRO) Consortium was established in late 2008 by C-Path, in cooperation with the FDA and the medical products industry, to collect the necessary evidence to support FDA "qualification" of new or existing PRO instruments for use in clinical trials where PRO endpoints can be used to support product-labeling claims.[1]

PRO instrument qualification, via the FDA's drug development tool qualification process, is a formal conclusion by the FDA that the results obtained from the PRO instrument within a stated context of use can be relied upon to measure important aspects of clinical benefit and can be used as the basis of medical product approval and labeling claims.[2] Qualification has the potential to: increase the number of accepted PRO measures used to support claims in product labeling; enhance comparability/consistency of endpoints across clinical trials; improve efficiency for sponsors in endpoint selection; and facilitate the FDA's review of medical products by standardizing PRO endpoints.

The PRO Consortium has 25 member firms (http://www.c-path.org/PRO.cfm). Its goals include enabling pre-competitive collaboration that includes FDA input and expertise, avoiding development of multiple PRO instruments for the same purpose, sharing costs of qualifying new or existing PRO instruments, and advancing the science of PRO measurement. The PRO Consortium has working groups in the following therapeutic areas: asthma, depression, functional dyspepsia, irritable bowel syndrome, mild cognitive impairment, non-small-cell lung cancer, and rheumatoid arthritis. The working groups are at different points on the path to PRO instrument qualification. The PRO Consortium is committed to sharing the procedural and scientific insights that emerge along the way.

1. Coons SJ, Kothari S, Monz BU, Burke LB. The Patient-Reported Outcome (PRO) Consortium: filling measurement gaps for PRO end points to support labeling claims. *Clinical Pharmacology and Therapeutics* 2011;90(5):743-8.
2. US Food and Drug Administration. Guidance for Industry: Qualification Process for Drug Development Tools (Draft). 2010; http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM230597.pdf. Accessed August 3, 2012.