NEWS FROM...

The Patient-Reported Outcome (PRO) Consortium at the Critical Path Institute (C-Path)

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On August 28, 2012, the PRO Consortium's Rheumatoid Arthritis (RA) Working Group held a consensus development workshop. The objective of the workshop was to identify RA-related symptoms and sub-domains of RA-defining decrements in physical function that could be explored as potential PRO endpoints in clinical trials (CTs) to support label claims for RA drugs. Along with RA Working Group members and C-Path personnel, participants included RA patients and representatives from the US Food and Drug Administration, National Institute for Arthritis and Musculoskeletal and Skin Diseases, American College of Rheumatology (ACR), Outcome Measures in Rheumatology (OMERACT), and European League Against Rheumatism.

A fundamental premise of the workshop was that new PRO measures would be secondary endpoints and would need to provide information over and above what is currently captured by traditional primary endpoints. The ACR response criteria serve as a well-established primary efficacy endpoint for CTs in RA. It is a composite endpoint comprised of clinician-reported outcomes (tender and swollen joint count, global assessment of disease activity), patient-reported outcomes (global assessment of disease activity, pain, and physical function), and a biomarker (C-reactive protein [CRP] level or erythrocyte sedimentation rate [ESR]).

Over the course of the workshop, a consensus emerged that the RA Working Group would not focus on decrements in physical function because of other ongoing efforts to address this measurement gap. However, other outcomes important to RA patients not explicitly assessed by the ACR response criteria (i.e., fatigue, stiffness, and participation) were deemed measurement targets that merited consideration. At the end of the day, consensus was reached that the RA Working Group would focus on FDA qualification of a PRO measure of fatigue for use as a secondary endpoint in documenting treatment benefit in RA CTs. The RA Working Group is initiating a collaboration with OMERACT aimed at developing an operational definition of fatigue and developing a conceptual framework for assessing this concept.

For more information, please visit c-path.org/PRO.cfm.