NEWS FROM...

Critical Path Institute's Electronic Patient-Reported Outcome Consortium

J. Jason Lundy, PhD, Director, ePRO Consortium, Critical Path Institute, Tucson, Arizona, USA

Concurrent with the increased attention on patient-reported outcomes (PROs) as efficacy endpoints in clinical trials for new medical products, electronic data-collection technologies have emerged that enable the capture of high-quality patient-reported data. To facilitate the adoption of electronic data-collection technologies, the Critical Path Institute (C-Path) established the Electronic Patient-Reported Outcome (ePRO) Consortium in April 2011. C-Path is a private, non-profit organization that provides a pre-competitive space for cooperation among non-traditional collaborators. The ePRO Consortium's mission is to advance the quality, practicality, and acceptability of electronic data-collection modes for PRO endpoint assessment in clinical trials. The ePRO Consortium will generate evidence and provide methodological and operational guidance on ePRO applications. The overarching aim is to enhance public health by optimizing the value of PRO data in medical product evaluation and clinical decision-making. The ePRO Consortium has seven member firms that provide electronic data-collection technologies/services to the medical products industry for capturing PRO endpoints in clinical trials (http://c-path.org/ePRO.cfm).

In addition to providing recommendations and guidance regarding PRO instrument migration and adaptation, the ePRO Consortium will be working closely with C-Path's PRO Consortium to make newly developed and qualified PRO instruments available in multiple data-collection formats. Furthermore, the members of the ePRO Consortium are in a unique position to collectively document the extent of PRO instrument migration to electronic technologies and the amount of testing that has been conducted for these migrated instruments. One of the ePRO Consortium's objectives is to avoid unnecessary duplication by pursuing a coordinated approach to gathering evidence supporting the measurement equivalence of the various PRO instrument administration modes. The development of publicly available specification documents will facilitate the adaptation and migration of existing PRO instruments to all relevant electronic data-collection technologies. Advances in these technologies should greatly enhance the data-collection process for pharmaceutical sponsors, site investigators, and clinical-trial subjects.

For more information, please contact Jason Lundy at jlundy@c-path.org