Mixing Methods and/or Modes of PRO Data Collection in Clinical Trials: Issues to Consider

Stephen Joel Coons, PhD
Patient-Reported Outcome (PRO) Consortium
Critical Path Institute
Tucson, Arizona, USA

It is clear from the FDA’s PRO Guidance that this situation is anticipated to occur within clinical trials. Specifically, the Guidance states: “We intend to review the comparability of data obtained when using multiple data collection methods or administration modes within a single clinical trial to determine whether the treatment effect varies by methods or modes.” (FDA, 2009)

The FDA’s PRO Guidance has focused increased attention on the scientifically sound measurement of PRO endpoints in clinical trials. As the focus on PRO measures as efficacy endpoints has increased, the use of electronic data capture devices/systems has expanded dramatically as well. This has led to the need to assure measurement equivalence across and among the various methods and modes of PRO measure administration.

It is important to consider the reasons why you may not want to vary PRO data capture modes and/or methods within a single clinical trial or between trials that seek to provide comparable data.

Clinical trial designs should avoid as many sources of error variance (i.e., noise) in the PRO data as possible.

Measurement error can be introduced into the trial design by different PRO data collection modes or methods that are not providing comparable data (i.e., the methods and/or modes lack sufficient measurement equivalence.)
Multiple sources of potential response bias (i.e., measurement error) exist in multinational clinical trials that could cumulatively impact the ability of the PRO data to demonstrate a treatment effect. To the extent possible, avoid mixing methods and/or modes. (The reality is that methods and/or modes are routinely mixed.) Seriously consider all potential sources of measurement error in your trial design and proactively minimize the potential impact by maximizing measurement equivalence across the data capture methods and/or modes.

**Upcoming Workshop**

ISPOR 13th Annual European Congress  
Workshops - Session IV  
Tuesday, November 9, 2010  
16:00-17:00  
W26: Good Research Practices for Assuring Measurement Equivalence Between Electronic and Paper-Based Patient-Reported Outcome Measures: How are They Applied In Clinical Trial Planning?