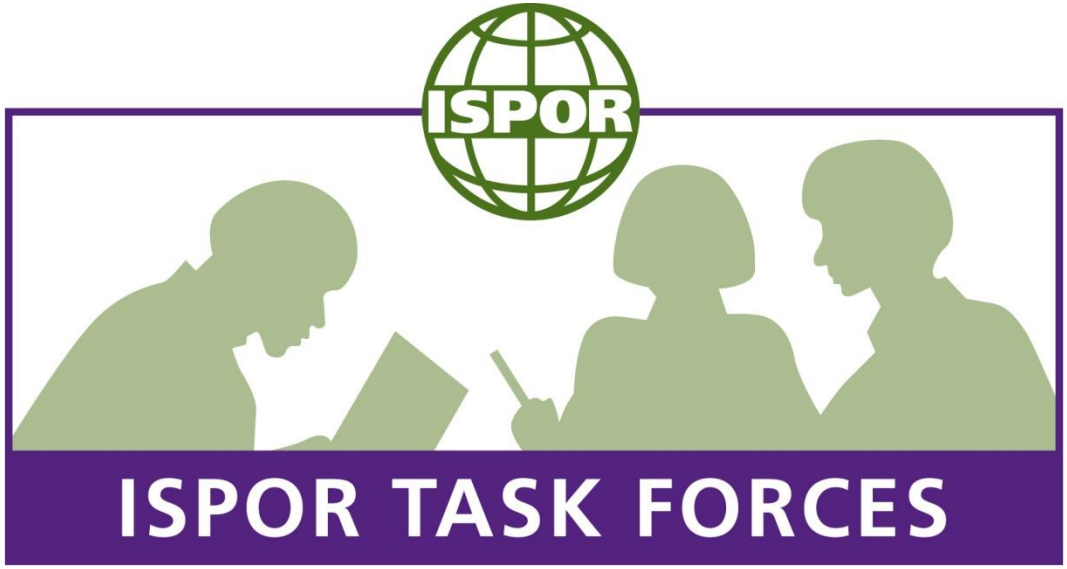
WORKSHOP



ISPOR PRO Mixed Modes Task Force

(www.ispor.org/sigs/mixedmodes.asp)

WORKSHOP

Mixing Modes of Patient-Reported Outcomes Data Collection in Clinical Trials: Recommendations

Moderator

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

Workshop Objectives

To discuss the Task Force's preliminary findings regarding

- mixing modes of PRO data collection in clinical trials used for regulatory purposes

and

- issues related to the analysis of data from trials involving mixed modes

Workshop Faculty

Study Design Issues

Sonya Eremenco, MA, ePRO Manager, United BioSource Corporation, Bethesda, MD, USA
Chair, ISPOR PRO Mixed Modes Task Force

Operational Issues

Jean Paty, PhD, Founder & Senior Vice President, Scientific, Quality & Regulatory Affairs, invivodata, inc., Pittsburgh, PA, USA

Statistical Issues

Andrew Lloyd, DPhil, Vice President & Practice Lead, Oxford Outcomes Ltd., an ICON PLC company, Oxford, UK

Background

- ISPOR ePRO Task Force Report (Coons et al. 2009)
  - Migrating from paper to electronic data capture
  - Mixing modes not explicitly addressed
- FDA PRO Guidance
  - "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)
- In this workshop, "mode" refers to all means of administration and methods of data capture
- Mixing modes is most challenging when one of the modes is paper

Issues to Consider

Technology makes mixed modes data collection feasible operationally, however…

- Clinical trial designs should avoid as many sources of error variance in the PRO data as possible.
- Measurement error can be introduced into the trial design by different PRO data capture modes that are not providing comparable data (i.e., the modes lack sufficient measurement equivalence.)
- Measurement error reduces statistical power and attenuates the ability of the trial to detect real change (i.e., treatment effect) in the PRO-based trial endpoint.

Important Note about "Validation"

- *Measurement equivalence* should not be equated with "validation."
- In fact, the term "validation" should be avoided in most cases in which it is used in the context of PRO measurement instruments.
- The term is best used with a qualifier, such as in "systems validation," which is the focus of an ISPOR ePRO Systems Validation Task Force report that is nearing completion.