

## Published Articles - Translation

### **Multinational Trials—Recommendations on the Translations Required, Approaches to Using the Same Language in Different Countries, and the Approaches to Support Pooling the Data: The ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force Report**

Wild D, Eremenco S, Mear I, Martin M, Houchin C, Gawlicki M, Hareendran A, Wiklund I, Chong LY, von Maltzahn R, Cohen L, Molsen E.  
*Value in Health*, 2009, 12(4)

#### **ABSTRACT**

**Objectives:** With the internationalization of clinical trial programs, there is an increased need to translate and culturally adapt patient-reported outcome (PRO) measures. Although guidelines for good practices in translation and linguistic validation are available, the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Task Force identified a number of areas where they felt that further discussion around methods and best practices would be beneficial. The areas identified by the team were as follows: 1) the selection of the languages required for multinational trials; 2) the approaches suggested when the same language is required across two or more countries; and 3) the assessment of measurement equivalence to support the aggregation of data from different countries.

**Methods:** The task force addressed these three areas, reviewed the available literature, and had multiple discussions to develop this report.

**Results:** Decision aid tools have also been developed and presented for the selection of languages and the approaches suggested for the use of the same language in different countries.

**Conclusion:** It is hoped that this report and the decision tools proposed will assist those involved with multinational trials to 1) decide on the translations required for each country; 2) choose the approach to use when the same language is spoken in more than one country; and 3) choose methods to gather evidence to support the pooling of data collected using different language versions of the same tool.

### **Translation and psychometric evaluation of the Satisfaction with Oral Anti-Diabetic Agent Scale (SOADAS)**

C Donatti D Wild R Horblyuk K M Beusterien R T Anderson B Arondekar D B Dibenedetti

*Diabetes Research and Clinical Practice*, 2008, 80(1)

#### **ABSTRACT**

In 1999, ISPOR formed the Quality of Life Special Interest group (QoL-SIG)—Translation and Cultural Adaptation group (TCA group) to stimulate discussion on and create guidelines and standards for the translation and cultural adaptation of patient-reported outcome (PRO) measures. After identifying a general lack of consistency in current methods and published guidelines, the TCA group saw a need to develop a holistic perspective that synthesized the

full spectrum of published methods. This process resulted in the development of Translation and Cultural Adaptation of Patient Reported Outcomes Measures—Principles of Good Practice (PGP), a report on current methods, and an appraisal of their strengths and weaknesses. The TCA Group undertook a review of evidence from current practice, a review of the literature and existing guidelines, and consideration of the issues facing the pharmaceutical industry, regulators, and the broader outcomes research community. Each approach to translation and cultural adaptation was considered systematically in terms of rationale, components, key actors, and the potential benefits and risks associated with each approach and step. The results of this review were subjected to discussion and challenge within the TCA group, as well as consultation with the outcomes research community at large. Through this review, a consensus emerged on a broad approach, along with a detailed critique of the strengths and weaknesses of the differing methodologies. The results of this review are set out as “Translation and Cultural Adaptation of Patient Reported Outcomes Measures—Principles of Good Practice” and are reported in this document.

**Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation.**

Diane Wild, Alyson Grove, Mona Martin, Sonya Eremenco, Sandra McElroy, Aneesa Verjee-Lorenz, Pennifer Erikson  
*Value in Health*, 2005, 8(2)

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