

# ePRO TRANSLATIONS: ACHIEVING A SUCCESSFUL END-PRODUCT

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Developing translated instruments for use on ePRO devices requires early collaboration among the sponsor, ePRO vendor, and language service provider (LSP) in order to achieve a successful end-product. This important step can eliminate many technical problems and instrument administration issues. It is imperative for the LSP to communicate directly with the ePRO vendor at project start, establishing milestones within the confines of the delivery timeline to meet study requirements, and continuing a high level of communication throughout the endeavor.

When translating for ePRO, important considerations must be made to ensure a successful collaboration between the ePRO vendor and LSP, accurate translations, and timely delivery of the end-product. The LSP should confirm with the ePRO vendor any ePRO software font requirements and the format in which the translation should be provided. Font-testing should be performed to ensure that the required languages are compatible with the ePRO software platform. Many instruments place emphasis on certain terms, using underlining, boldface, italics, and capitalization. If the ePRO software does not support the mode of emphasis in the source, then the LSP and ePRO vendor should work to achieve a solution that maintains the source's intent. Anticipating ePRO-

specific translation modifications such as these saves time and unnecessary expense.

If electronic administration of a paper PRO is desired, adaptations are necessary for ePRO. Per the ISPOR ePRO Task Force recommendations, the extent of modification is an important consideration. When only minor changes are needed for paper PRO to ePRO migration, a large body of evidence suggests that the psychometric properties of the original measurement tool will be upheld (Coons, et. al., 2009). Major changes to the measure would warrant additional testing. The LSP should work with the instrument developer, sponsor and ePRO vendor to modify source instructions as necessary to accommodate the intuitive nature of electronic administration. For example, explicit skip pattern instructions may disappear in the electronic version. In paper administration, a respondent may be instructed "If YES, proceed to question 8," whereas ePRO eliminates the need for this direction. "Check a box" may become "touch a box." After ePRO adaptation has occurred, the ePRO vendor should furnish the LSP with a path or "road map" through the screens, showing their logical progression and contingencies based on responses to previous items. All localized screens must be checked against this source, to ensure ePRO accuracy.

Because ePRO creation may involve separating questions and response sets, all translations must be proof-read within the context of the questionnaire in its entirety, as well as per screen. Each screen should be checked for corrupted characters, and to ensure that the ePRO mirrors the paper version. Multiple quality assurance steps should be applied before and after cognitive debriefing, ensuring equivalency with the English source and a logical path through the questionnaire. If existing device instructional materials are available, they should be provided to the LSP in order to maintain consistency with terminology.

Achieving a successful ePRO end-product requires a flexible, innovative LSP, a dynamic relationship between both vendors, and careful planning during project inception. These pieces are essential in yielding a high-quality, error-free ePRO translation.

## REFERENCES

Coons SJ, Gwaltney CJ, Hays RD, et al. Recommendations On Evidence Needed To Support Measurement Equivalence Between Electronic And Paper-Based Patient Reported Outcome (PRO) Measures: ISPOR ePRO Good Research Practices Task Force Report. *Value in Health* 2009;12(4):419-429.

