OBJECTIVES: To define the term ‘usually’ in order to ascertain potential pitfalls in its translation. When translating the target language, a particular issue in translation of the ADSC (Activities of Daily Living Inventory) in which the term appears 28 times in the form of either ‘usual’ or ‘usually.’ Discussion with the client confirmed the desired and contextual meaning of the term for this instrument. RESULTS: After in-depth discussion between ICON Language Services and the client, it was agreed that a more specific definition of the term ‘usually’ should be clarified and applied to the translations so as to avoid risk in incorrect data collection and potentially causing offence to the target population. Concern was raised that the term could be mistaken for ‘normally’, which could lead to specifying what is ‘normal’ vs. ‘abnormal’, i.e. making a judgement about the behaviour. We ensured that the term ‘usually’ was not translated as ‘normally’, did not imply ‘normal’ vs. ‘abnormal’ behaviour and rendered the concept of frequency present in the source term ‘usual’. CONCLUSIONS: Ensuring that the term ‘usually’ should carry a wholly descriptive value, meaning that the phenomenon in question occurs with high frequency or by habit/custom. This should not be confused with the concept ‘normally’, which can carry a prescriptive connotation irrespective of the client’s culture or rule/order. To avoid any ambiguous or incorrect translation of the word ‘usually’, it is strongly advised that this be clearly defined from the start and checked throughout the linguistic validation process. Discussion between the client and linguistic staff reveals the importance of close collaboration in resolving terminology issues and improving data integrity through the conceptual equivalence of translations.

PM195 MIGRATION OF THE FATIGUE SYMPTOMS AND IMPACTS QUESTIONNAIRE—RELEASING MULTIPLE SCOLIOSES (FSIQ-RMS™) FROM PAPER TO AN ELECTRONIC DEVICE (eDiary). Eremence S1, Shaffer S2, Schuler R2
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OBJECTIVES: The FSIQ-RMS™ is the first patient-reported outcome (PRO) measure of fatigue measured in RMS disease developed in the 2009 FDA PRO guidance.1 A qualitative study was conducted to provide evidence of adequacy after adapting the FSIQ-RMS™ from paper to an electronic handheld device (eDiary). METHODS: Migration of the FSIQ-RMS™ from paper to an electronic handheld device was assessed. Instructions and landscape formatting with one item per screen. The FSIQ-RMS™ was administered to adult RMS patients at 2 US sites in a cross-sectional study. After training on the eDiary, each participant completed paper and electronic versions of the FSIQ-RMS™ in randomized order, then a device-usability questionnaire followed by one-on-one semi-structured cognitive interviews to assess comprehension of the FSIQ-RMS™. RESULTS: Compared to those interviews which were unmonitored, the first languages to undergo LV. A total sample 524 participants were monitored, the first languages to undergo LV. 30% of those interviews were monitored, the first languages to undergo LV. The first languages to undergo LV. Monitoring the client noted any sub-threshold issues that were outside of typical LV data capture rubric. Upon noting such issues in more than one country, the test authors would convene a meeting to consider if the FRO linguistic validation protocol or PRF instrument required revised questionnaire. RESULTS: Results confirmed the conceptual equivalence of the FSIQ-RMS™ eDiary to the paper version and its appropriateness for use with RMS patients. Further validation of the FSIQ-RMS™ will be conducted in a Phase III RMS trial. Value Health 2015;18(3):A26.

PM196 MONITORED COGNITIVE DEBRIEFING INTERVIEWS: A CASE STUDY. Taltab M1, Cole J2, Brands M1, McKeown S1, Gawlicki M1
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OBJECTIVES: This study sought to determine the benefits to sponsor, developer, and translation provider of monitored cognitive debriefing interviews with patient questionnaires. Monitored cognitive debriefing (CD) was theorized to be particularly suitable for newly-developed questionnaires with minimal or no previous linguistic validation (LV), and for adapted questionnaires (i.e., a disease-specific instrument adapted to a new disease). METHODS: Thirty (30) CD interviews were carried out on a newly-developed patient instrument in six languages. Of those, sixteen (16) interviews were monitored by the sponsor. All languages were selected by the sponsor and a percentage of those interviews were monitored, the first languages to undergo LV. The translation provider recruited patients, provided interpreters, secured facilities with two-way mirrors and audio-visual recording capabilities, and performed the interviews. The monitor noted any sub-threshold issues that were outside of typical LV data capture rubric. Upon noting such issues in more than one country, the test authors would convene a meeting to consider if the FRO linguistic validation protocol or PRF instrument required revised questionnaire. RESULTS: Results confirmed the conceptual equivalence of the FSIQ-RMS™ eDiary to the paper version and its appropriateness for use with RMS patients. Further validation of the FSIQ-RMS™ will be conducted in a Phase III RMS trial. Value Health 2015;18(3):A26.

PM197 MEASUREMENT INVENTORY OF THE WHOQOL-OLD MODULE ACROSS DIFFERENT DEMOGRAPHIC GROUPS IN TAIWAN’S ELDERLY PEOPLE. Hsieh P, Yao G
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OBJECTIVES: The purpose of this study is to examine the measurement inventory of the WHOQOL-OLD Module across different demographic groups in Taiwan’s elderly people. By testing the differential item functioning (DIF), the presence of DIF indicates measurement variance. In other words, item score of measurement scale is dependent on some irrelevant characteristics. If this condition is observed the interpretation of items would be confounded. METHODS: A total sample 524 participants aged between 65-96 years were recruited in this study across three sites in Taiwan. The WHOQOL-OLD questionnaire was used. The WHOQOL-OLD Module across different demographic groups. It was concluded that age, gender, and education have significant influence on the latent factors and demographic variables. Data was analyzed by using the Mplus7.0 and SAS9.4 software. RESULTS: Multiple-indicator multiple-candidate latent cause model showed significant differences were observed on sensory abilities, death and dying and social participation facets. No significant differences were observed on different education. However, the significant differences can be eliminated when adjusting for DIF on item1 and item18, respectively, on sensory abilities and on social participation. CONCLUSIONS: The results implies that age and education should be controlled when comparing sensory abilities, death and dying and social participation facets.