ing cognitive interviews during the linguistic validation process of COAs. Further research is required to develop industry guidelines to ensure that the interviewers are able to achieve their purpose: garnering accurate and meaningful feedback from respondents in order to increase comprehension and cross-cultural equivalence of multiple language versions.

PRM158
DEFINING STANDARDS OF CLINICIAN QUALIFICATIONS FOR THE LINGUISTIC VALIDATION OF CLINICAL OUTCOME ASSESSMENTS (COAs)

Sweeney S, Nkowane Y
TransPerfect, New York, NY, USA

OBJECTIVES: As the linguistic validation of COA instruments often involves a review of medical terminology, it is important to confirm that the in-country clinician reviewer has sufficient qualifications to ensure quality as well as to elicit the highest level of conceptual equivalence in a linguistic validation project. This poster will consider minimum clinician qualification standards and recommend guidelines for the qualifications of medical reviewers. METHODS: An examination was conducted of past linguistic validation projects involving an in-country review step with a medical professional. A review was conducted of COAs (Clinician-Reported, Caregiver-Reported, as well as Patient-Reported questionnaires and diaries) within various therapeutic areas. This review also included an analysis of the specific background of each in-country clinician reviewer. RESULTS: In the examination of linguistic validation projects that included a medical review step, it was determined that the experience level of clinician reviewers varied between projects. In an effort to standardize this step, a minimum experience requirement based on study needs and project type is proposed. CONCLUSIONS: After a thorough review of past linguistic validation projects, it is concluded that a clinician reviewer should, at a minimum, encompass the following qualifications: 1) 2+ years experience diagnosing and/or treating the patient population; 2) M.D. or relevant professional license in the target country; 3) Native language and/or advanced medical terminology training in the target language/country. Implementing minimum qualifications standards will help to ensure that an in-country medical reviewer will conduct a high-quality review for linguistically validated COAs.

PRM159
EVALUATION OF THE PSORIASIS AREA AND SEVERITY INDEX (PASI) AS PATIENT RELIEF OUTCOME IN THE BENEFIT ASSESSMENT OF PSORIASIS THERAPIES

Gutknecht M, Augustin M, Rustenbach S.J, Schäfer I
University Medical Center Hamburg-Eppendorf, Hamburg, Germany

OBJECTIVES: Psoriasis vulgaris is one of the most frequent chronic diseases in dermatology and can cause a high disease burden and reduction of quality of life. The severity of psoriasis is determined by the clinical parameter PASI (Psoriasis Area and Severity Index). It is the most often cited measurement to determine the efficacy of therapeutic agents. The effect of patient relevant treatment benefit on the evaluation of potential recurring translation issues between same language groups. Within the German, French and Spanish languages, technical terminology was translated alike but there were differences in the way technical terms and disease-specific terms were translated. CONCLUSIONS: With the insight of the linguistic validation process, important differences were identified and resolved between technical terms and general wordings across same language groups. Cognitive debriefing is highly recommended and this will ensure appropriate comprehension across cultures and facilitate International comparison and pooling of data.

PRM160
THE INFLUENCE OF CHOICE TASK LAYOUT ON THE OUTCOMES OF A DISCRETE CHOICE EXPERIMENT


OBJECTIVES: To test to what extent the presentation of choice tasks contrasting display in words or graphics, influences the attribute estimates, relative importance and participation probability and the conclusions drawn from a Discrete Choice Experiment (DCE). METHODS: A DCE questionnaire was sent to the parents of 2,500 newborn babies. The questionnaire contained two versions of the same 9 choice tasks, one in which the levels were presented in words, and one with graphic attribute levels. The DCE consisted of five attributes: vaccine administration; frequency of severe side effects; protection during and after vaccination; out-of-pocket costs. Choice consistency was estimated, panel-mixed logit models were conducted to estimate the relative importance of the attributes and internal sample validation was calculated. RESULTS: In total 13% answered all of the choice tasks, 27% answered 1-5 choice tasks, and 51% answered inconsistently in more than two choice tasks. Respondents who were presented with word choice tasks at first were significantly more consistent compared to respondents that were presented with graphic choice tasks at first. Although out-of-pocket costs was the most important and frequency of severe side effect was the least important attribute in both datasets, the relative importance of the other attributes differed. All results differed by educational level. Estimated and observed choices showed higher correlation in the word dataset. CONCLUSIONS: The presentation of the choice tasks by either using words or graphics influences study outcomes. The use of graphics to present attribute levels in choice tasks seems less preferred by respondents and showed a reduced validity. Besides extensive pilot testing, discussions about the presentation of the choice tasks should be included in the focus group stage of the designing process. Extensive research on respondents’ comprehension of choice tasks should be conducted to enable the formation of task presentation guidelines.

PRM161
SIMILARITIES AND DIFFERENCES ACROSS SAME LANGUAGE QUESTIONNAIRES FOR DIFFERENT COUNTRIES: LINGUISTIC VALIDATION OF THE ASTHMA SYMPTOM DIARY (ASD) AND KIDNEY DISEASE AND QUALITY OF LIFE (KD-QOL) IN 30 LANGUAGES

Steenwijk S, Schacht L
ICON PLC, Oxford, UK

OBJECTIVES: Prior to use in an international study, the Asthma Symptom Diary (ASD) and Kidney Disease and Quality of Life (KD-QOL) 30 were translated into 30 languages. This involved linguistic validation work on common languages targeted for different countries via the forward/ backward translations or adaptation steps and cognitive debriefing step. This study aims to investigate similarities and differences in the translation of key terms and wordings and determine potential patterns across groups of languages. METHODS: This investigation was carried out in the following ways: 1) Identification of key terms and wordings, 2) Collation and comparison of the translations across the language versions, 3) Analysis of similarities and differences; and 4) Review of discussions and issues from the translation process. RESULTS: The linguistic validation process was shown to be able to identify and resolve translation issues. Key findings included the identification of potential recurring translation issues between same language groups. Within the German, French and Spanish languages, technical terminology was translated alike but there were differences in the way technical terms and disease-specific terms were translated. emotions and symptoms were translated due to such factors as idiomatic formulations and cultural differences. Across the English languages, the text was simplified or elaborated as part of the adaptation process. Across the Russian and Chinese languages there were differences in the way technical and disease-specific terms were translated. CONCLUSIONS: With the insight of the linguistic validation process, important differences were identified and resolved between technical terms and general wordings across same language groups. Cognitive debriefing is highly recommended and this will ensure appropriate comprehension across cultures and facilitate International comparison and pooling of data.

PRM162
DETERMINING THE MAGNITUDE OF A DETECTABLE AND A RELEVANT TREATMENT BENEFIT IN AESTHETIC MEDICINE USING A PHOTOGUIDE AND THE INTERNET

Keil A, Bushkin AG, Shields A, Jensen J, Cappeller J

OBJECTIVES: Photographs are used as measures of treatment effect. To interpret the results, an understanding of what change is “enough” is required. The purpose of this study was to test to what extent differences in the way technical and disease-specific terms were translated. METHODS: With the insight of the linguistic validation process, important differences were identified and resolved between technical terms and general wordings across same language groups. Cognitive debriefing is highly recommended and this will ensure appropriate comprehension across cultures and facilitate International comparison and pooling of data.

PRM163
PARENT RATINGS OF ABILITY TO CONSENT FOR CLINICAL TRIALS IN FRAGILE X SYNDROME

Raspa M, Verfaellie MC, Duyckaerts C

OBJECTIVES: Advances in understanding the neural underpinnings of intellectual disabilities (ID) such as fragile X syndrome (FXS) have led to clinical trials testing medications addressing disease-specific targets. Individuals with ID ought to have a voice in research. However, few clinical trials for ID have been conducted. The purpose of this research is to evaluate the use of a survey to conduct with 422 families who have a child with FXS. Parents rated items assessing their child’s abil-