DEVELOPMENT AND PSYCHOMETRIC EVALUATION OF A CANINE DERMATITIS QUALITY OF LIFE QUESTIONNAIRE: RESULTS FROM THREE CLINICAL TRIALS Postorino-Reeves N1, Brohan K2, Tallock S2, Panter C2, Amodie D1, Gasper S1
1Zoetis, Florham Park, NJ, USA, 2Adelphi Values Ltd, Manchester, UK
OBJECTIVES: Atopic dermatitis is a common inflammatory skin disease in canines, charac-
terized by itching and scratching potentially leading to hair loss, excoriations and scabbing. Atopy can substantially impact both the owner and canine’s quality of life (QoL). The objective was to develop a short, 30 item questionnaire to assess QoL in canines with atopic dermatitis and their owners. METHODS: A 34-item draft questionnaire was developed through review of the literature and clinical input. This measure was included in three clinical trials of APOQUEL®. The trial consisted of an open-label contamination study in the United States (n = 44) and two random-
dominated, controlled, blinded clinical trial in Australia (n = 124; n = 226). Questionnaire data from each trial was individually subject to item response, dimensionality, and scale analysis. Statistical analysis was undertaken in QolMetric analysis software. Results: and of treatment efficacy. RESULTS: A total of 597 dog owners completed the question-
aire. Quality of completion was high (maximum 4.9% missing data). Across all stud-
ies, seven items consistently displayed ceiling effects (range: 23.5%–86.3%) and four displayed floor effects (range: 21.6%–70.4%). These results, together with the item discrimination index, confirmatory and exploratory factor analyses (CFA, EFA), item-total correlations and internal consistency, were used to guide item reduction. This resulted in a final model on which many guidelines for validity and response-
ness to change were examined. Overall, owners of dogs on APOQUEL demonstrated a positive mean change on six items across all three datasets, indicating improvement in these aspects of QoL. CONCLUSIONS: This study describes the development and psychometric evaluation of an innovative new instrument for measuring QoL in canines with atopic dermatitis and their owners. Findings from each study, along with consideration of the clinical relevance were used to support item reduction decisions. The final 

DATA QUALITY WITH MIXED-MODE ADMINISTRATION OF THE SHORT FORM-36 Briesing HM1, Paciorek A2, Carroll P2, Wilson LS1, Litwin MS3, Misakowski C1
1University of California San Francisco, San Francisco, CA, USA, 2University of California, San Francisco, CA, USA, 3University of California, Los Angeles, Los Angeles, CA, USA
OBJECTIVES: To examine the effects of survey mode of administration on data qual-
ity when using a mixed-mode (i.e., paper-mode vs. web-mode) approach. METHODS: A cross-sectional wave of 4,836 participants active in the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) registry, self-selected to complete the Medical Outcomes Short-Form 36 instrument. Data quality parameters com-
pared paper vs. complete at the item and computable scale score; difference in mean scales; and range of differences by criterion.
RESULTS: The majority of participants, 4,376 (90%), opted for paper-mode. Overall response rate was 77%; paper-mode 76% versus 88% web-mode (p < .01). Paper-mode respondents were older, 70.7 (SD 8.8) versus 68.8 (SD 8.5) (p < .001). Paper-mode participants had significantly more missing items (mean 6.7 vs. 10, p < .0001) and significantly lower proportion of computable scale scores for bodily pain, general health, vitality, social functioning, and mental health (p < .03). The social functioning scale had the largest difference for the proportion with missing data, 92.3% vs. 99.5% (p = .00). Mean scale scores were lower among paper-mode participants for all eight scales and the physical and mental component summary scores (p < .001). Significantly lower mean scale scores with small differences in effect size were noted for paper versus web-mode for the physical component summary, 47.5 vs. 50.2 (D = .30), physical functioning, 80.2 vs. 88.2 (D = .36), and vitality, 64.8 vs. 71.2 (D = .26). The regression model for the web-mode, four scales did not achieve a floor value (vitality 10–100), mental health (28–100); bodily pain 23–100, and general health (15–100). CONCLUSIONS: We observed significant differences in data quality with mixed-mode survey administration but effect size differences that suggest using mixed-mode administration did not introduce significant measurement differences.

ALGORITHMS TO ESTIMATE HEALTH UTILITIES FROM TOTAL JOINT ARTHROPLASTY DISEASE-SPECIFIC MEASURES Odum SM1, Troyer J-L1
1UNC-Charlotte, Charlotte, NC, USA
OBJECTIVES: Orthopedic researchers studying total joint arthroplasty (TJA) often use disease-specific measures (DSMs) of patient health as cost-effectiveness out-
comes. However, for cost-utility analysis, health utility scores are needed. The study objective was to develop regression algorithms to map five common disease spe-
cific TJA outcome measures to three preference-based utility scores. RESULTS: An electronic diary assessing patient experience of symptoms of endometriosis with a mixed methods approach, is presented herein. The involvement of the developers was also discussed with the developers. CONCLUSIONS: The cross-cultural adapta-
tion of the BRIEF in Balto-Slavic and Uralic languages required an international collaboration. The involvement of the developers during the whole process enabled the production of conceptually equivalent and culturally appropriate measures.

1Adelphi Values, Ballington, UK, 2Bayer Pharma AG, Berlin, Germany, 3Adelphi Values United States, Boston, MA, USA, 4Tiet Health Solutions, Research Triangle Park, NC, USA
OBJECTIVES: As a chronic condition characterized by pelvic pain, dysmenorrhea and dyspareunia, endometriosis is associated with significant individual and societal burden. Patient-reported outcomes (PROs) are being developed to meet this unmet need. The establishment of the content validity of the ESD and EIS through qualitative and quantitative studies, a mixed methods approach, is presented herein. METHODS: The development of the ESD and EIS was informed by qualitative and quantitative stages to establish content and construct validity. Focus group discussions (n=45) and cognitive debriefing (n=31) interviews. The quantitative stage utilized Rasch Model analyses to evaluate item performance based on baseline data obtained during a prospective, observational validation study (n=246). RESULTS: The ESD is an electronic diary assessing patient experience of symptoms of endometriosis with average patient characteristics and not with individual level data. CONCLUSIONS: Clinicians and researchers can input their disease specific data into these models to estimate health utilities to consider the cost-effectiveness of endometriosis-related interventions relative to interventions for very different diseases and conditions.

DEVELOPMENT OF THE BEHAVIOR RATING INDEX OF EXECUTIVE FUNCTION (BRIEF) IN FIVE LANGUAGES Amodie D1, Acquaro C2, Iqbal S2, Mapi, Lyon, France, 3Mapi Research Trust, Lyon, France, 4Dartmouth University, Norwich, VT, USA
OBJECTIVES: The Behavior Rating Inventory of Executive Function (BRIEF) is the most widely used questionnaire developed for parents and teachers of school-age children to assess executive function behaviors of children and adolescents in the school and home environments. It is composed of 86 items organized in eight clinical scales (Inhibit, Shift, Emotional Control, Initiate, Working Memory, Plan/ 
Organize, Organization of Materials, Monitor) and two validity scales (Inconsistency and Negativity). It is used to evaluate children/adolescents (5–18 years old) with a wide spectrum of developmental and acquired neurological conditions. The objec-
tive of this study was to develop the BRIEF in four Balto-Slavic languages (Bulgarian, Latvian, Lithuanian and Serbian) and one Uralic language (Estonian). METHODS: The following methodology was used: (1) Clarification of concepts with the develop-
ers, (2) forward translation and back translation, (3) validation of theforced translations, and (4) review by the developer. RESULTS: The transla-
tions procedure did not reveal any problems with the concepts assessed, which were cross-culturally relevant. The main difficulties consisted in finding conceptual equivalents of the original items with strong idiomatic content. For instance, the most problematic items were items 18, 55 and 71. Item 71 (‘‘around the house a lot (“couch potato”)’’) raised difficulties because of the expression ‘‘couch potato’’ which had to be removed in most of the translations. The intended meaning (the child loafs around the house, lying on the couch, doing nothing productive) was rendered in all target versions. Deletion of this expression in the original US version was also discussed with the developers. CONCLUSIONS: The cross-cultural adapta-
tion of the BRIEF into Balto-Slavic and Uralic languages required an international collaboration. The involvement of the developers during the whole process enabled the production of conceptually equivalent and culturally appropriate measures.
a recall period of the past 24 hours. The EIS is an electronic questionnaire assessing impaired daily functioning, measuring impairments over the past seven days. Conceptual saturation appears to have been achieved during concept elicitation, confirming full exploration of endometriosis symptoms and impacts. Pain emerged as the most frequent, severe and bothersome symptom, resulting in significant impairments in physical activity, social and household activities and sexual functioning. Cognitive interviewing of the ESD and EIS revealed both measures to be well understood and consistently interpreted by participants. Rasch analyses revealed no disordering of the response categories for the items, and the full range is covered with no gaps in measurement of the respective concepts. CONCLUSIONS: Developed using a mixed methods approach, the ESD and EIS have demonstrated strong content validity. Ongoing research will inform measurement properties of final instruments.

PRM104 MEASUREMENT PROPERTIES OF PAINDETECT BY SEVERITY OF NEUROPATHIC PAIN

Sudohky A1, Cappellen J1,2, Parliyan A3, Kudou V4
1Pfizer, New York, NY, USA, 2Pfizer Global Pharmaceuticals, New York, NY, USA, 3Pfizer, Inc., New York, NY, USA, 4Elasten Group, New London, CT

OBJECTIVES: To evaluate whether painDETECT, a screening questionnaire to identify neuropathic pain (NeP), can differentiate pain severity in patients with NeP. METHODS: Subjects (N=624, 55.4% male, 71.8% white, mean±SD age 55.5±13.7 years) with confirmed diagnoses of NeP were identified during routine office visits to U.S. community-based physicians. The Brief Pain Inventory was used to stratify subjects by mild (score 0-3; n=110), moderate (score 4-6; n=297), and severe (score 7-10; n=197) pain. In this regard, painDETECT assesses a pain symptom pattern, an open pain course pattern item, and one pain irradiation item) range from -1 to 3; the 7-item painDETECT scores (only pain symptoms) range from 0 to 35. The ability of painDETECT to discriminate pain severity was evaluated using analysis of variance or covariance models (with Tukey's adjustment for pairwise comparisons) to obtain unadjusted and adjusted (age, gender, race, ethnicity, time since NeP diagnosis, and country of residence) mean painDETECT scores. Cumulative distribution functions on painDETECT scores by pain severity were compared (Kolmogorov-Smirnov test). Cronbach's alpha assessed internal consistency reliability. RESULTS: Unadjusted mean scores were 14.5 for mild, 18.6 for moderate, and 22.7 for severe pain. The differences were statistically significant (P<0.0001). All pairwise comparisons of mean scores between pain severity groups were statistically significant (P<0.0001). Cumulative distribution functions showed distinct separation between pain severity groups (P<0.0001). Cronbach's alphas were 0.80 and 0.76, for the 7- and 9-item scales, respectively. CONCLUSIONS: This study is the first to psychometrically evaluate the content validity and reliability of painDETECT for distinguishing severity of NeP, further supporting its clinical relevance for identifying and characterizing NeP.

PRM105 ELICITATION OF HEALTH-RELATED QUALITY OF LIFE CONCEPTS ASSOCIATED WITH PERIPHERAL NEUROPATHY

Hawkins MA1, Holland KH1,2,3,4, Parliyan A3, Abraham S4, Abraham S5, Odeyemi IA1, Tsoumi M1, van Nooten FE1
1Cresteco-Ceutical, Luxembourg, Luxembourg, 2Astellas Pharma Europe GmbH, Leiderberg, The Netherlands, 3Cresteco-Ceutical, Paris, France, 4Astellas Pharma Europe Ltd, Chertsey, UK, 5Astellas Pharma Global Development

OBJECTIVES: There are several causes for peripheral neuropathy, including painful diabetic peripheral neuropathy (DPN) and post-herpetic neuralgia (PHN). DPN is a common complication of diabetes mellitus. PHN results from the reactivation of a dormant varicella zoster virus that follows resolution of acute herpes zoster infection and healing of zoster rash and consists and is characterised by chronic pain. Our aim was to identify and compare health-related quality of life (HRQL) dimensions in patients with DPN and PHN. METHODS: Thirty patients, 15 with DPN and 15 with PHN, participated in semi-structured individual interviews and were asked to cite important concepts related to the impact of DPN or PHN on HRQL. All patient responses were coded. Code frequency and bother ratings were used to identify salient patient experiences. RESULTS: Results indicated that patients of both populations experienced pain, sleep disorder, tiredness, limited mobility, social isolation and loneliness, a restricted life, loss of control, and fear for the future. Pain and particularly intermittent pain was reported as the most bothersome symptom. Patients discussed the implication of chronic persistent pain in terms of the limitations on their mobility that subsequently prevented them to engage in a large number of activities. Patients showed a similar impact of the pain on the social, work and role functioning of the patients with PHN or DPN. Although resolution of the pain is possible for the PHN patients, the fear of a worsening of the symptoms is more probable for DPN patients, both PHN and DPN patients experienced feelings of depression. Also, anxiety due to the pain and the unpredictable nature of the pain is consistently affecting patients with DPN or PHN. CONCLUSIONS: The concepts reported by DPN and PHN patients are similar and seem to have significant impact on patient’s quality of life.

PRM106 VALIDATION OF FACT-LYM AND FACT-FATIGUE AS SCALES MEASURING HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH MYELOPROLIFERATIVE SYNDROMES IN COLOMBIA

Romero M1, Marrugo R2, Simboguera E3, Parliyan A4
1Mapi, Lyon, France, 2Merck, Whitehouse Station, NJ, USA

OBJECTIVES: Validate the use of Fact-Lym and Fact-Fatigue as instruments measuring of health related quality of life (HRQoL) of patients with myeloproliferative syndromes for Colombia. METHODS: Under mean prevalence data of myeloproliferative syndromes in Colombia ranging from 0.3 to 1.5 per 100,000 people, was estimated a simple random sample of 46 patients distributed throughout the country to develop a validation sample. Applying an index of 0.85 for the Fact-Lym scale, (0.70 for Fatigue scale. As a comparison scale items, was applied a vision analogous scale (VAS), which assessed the homogeneity of the questions by averaging all correlations between all items to see effectively will be consistent. Translations of the instruments were not needed as these were already available in Spanish. Using a validation sample of a total of 5% it was not able to answer. Through each having dimensions of the scales, Cronbach’s alpha coefficient was estimated using the results of the VAS, obtaining a 84.19 alpha coefficient for the scale of well-being, 87.00 for family and social environment, 64.3 for general state, personal functioning 78.17, other concerns 92.80 and to the level of fatigue 92.53. Results suggest high levels of reliability above 75% (except the dimension of emotional state) of the scales and the results obtained through this CONCLUSIONS: There is a strong coherence between the results of the study and the scale of fatigue regarding the estimate of Cronbach’s alpha coefficient, thereby it’s considered reliable for use in patients with myeloproliferative syndromes in Colombia.

PRM107 THE ALLAIS PARADOX IN THE SELF-PERCEPTION OF QUALITY OF LIFE

Montero A1,2, Parliyan A3,4
1Instituto de Evaluación Tecnológica en Salud - IETS, Bogotá D.C., Colombia, 2TransPerfect, New York, NY, USA, 3TransPerfect, Boston, MA, USA

OBJECTIVES: Preference-based Quality-of-Life Indexes (QlI) represent the utility value related with health status. QlI consist of 1) a descriptive system of health states and 2) an algorithm to calculate values for each health states described in the system. When QlI are combined with life years, it is possible to obtain quality-adjusted life years (QALYs). For QALYs to be useful in the prioritization of resources and decision-making in health, QlI must reflect a cardinal order in the preferences of patients. Psychological evidence provides an axiomatic framework to reach a cardinal order in preferences was the von Neumann-Morgenstern Expected Utility Theory (EUT). According to the von-M’s EUT patients prefer alternatives that provide the maximum utility expected value (which, in the context of health, would be a higher QlI). To ensure the maximization of expected utility value, independence is a necessary condition. However, in 1953 Maurice Allais demonstrated the violation of the independence condition using an experimental design. The purpose of this study was to redesign the Allais’ experiment using 13 health states described with the EQ-5D system, in order to verify whether the paradox of Allais is also present in the QlI, which are calculated as V-N: m utilities. METHODS: First, the QlI were calculated using the standard gamble approach. Second, we carried out the experience in 20 individuals in Colombia. RESULTS: Results showed that maximization of the expected utility value is not fulfilled because the violation of independence condition. CONCLUSIONS: These results cast doubts on the accuracy of QALYs a measure of patient preferences and their validity to support the process of decision-making in health, as suggested by other researchers.

PRM110 THE IMPORTANCE OF DEVELOPING COUNTRY-SPECIFIC VERSIONS OF SPANISH-LANGUAGE CLINICAL OUTCOME ASSESSMENTS (COAS) DURING LINGUISTIC VALIDATION

Sweeney K1, Poppelnicks A2
1TransPerfect, New York, NY, USA, 2TransPerfect, Boston, MA, USA

OBJECTIVES: The development of country-specific versions of Spanish-language COAs is an important process. In order to ensure that the language used is widely understood by the target audience while maintaining conceptual equivalence to the original instrument. This poster will offer examples of how a Spanish version may vary significantly from its English and Spanish-speaking populations, while also providing details related to target populations, regional dialects, and instrument types. METHODS: A review of previous linguistic validation projects that included multiple Spanish-speaking countries was conducted. A comparison of the difference of results obtained, semantic, cultural, and stylistic decisions, and details relating to the demographics of the respondent population were analyzed. RESULTS: The review of various COA instruments determined that the Spanish versions often required country-specific adaptation for wide-reaching comprehension, as well as the use of appropriate local medical terminology. Instruments developed for use with adolescents or elderly populations frequently required country-specific adaptation to ensure that the items were fully understood. Other factors included references to education levels, measurements, and idiomatic or colloquial verbiage. CONCLUSIONS: When making decisions regarding language versions, the target population should be taken into consideration. COA instruments are increasingly being developed for adolescents and elderly populations. These audiences may not have the language experience that is conducive to the same understanding of idiomatic or region-specific language that other populations might have more likely to comprehend. In addition, medical terminology and specific location, and the description of its consequences. The objective of this abstract is to present the challenges of the translation of one story into 24 languages. METHODS: The translation was performed with translators and a speech therapist, living in the target countries. Criteria for adaptation to the context of the target