to alleviate pain. In contrast, other research (Mantovani, et al., 2005) suggests greater importance of perceived viral safety among both physicians and pharmacists relative to patients.

PSY42

EFFECTIVENESS OF ONCE-DAILY EXTENDED-RELEASE (ER) TRAMADOL IN ACHIEVING CLINICALLY MEANINGFUL IMPROVEMENT IN FUNCTIONING

Janagap C[1], Lee SP[2], Mody S[1], Ng DB[3], Schein JR[1]
[1]Ortho-McNeil Janssen Scientific Affairs, LLC, Raritan, NJ, USA, [2]Ortho-McNeil Janssen Scientific Affairs, LLC, Titusville, NJ, USA, [3]Ortho-McNeil Janssen Scientific Affairs, LLC, Chicago, IL, USA

OBJECTIVE: Assess the effects of tramadol ER once daily versus placebo in patients with moderate to moderately severe chronic pain due to osteoarthritis of the knee or hip. **METHODS:** Data for this post-hoc analysis were from a 12-week, randomized, double-blind, placebo-controlled, once-daily fixed dose-study of tramadol ER (100 mg–300 mg). Patients completed the WOMAC questionnaire at baseline and weeks 1, 2, 3, 6, 9 and 12. Items in each WOMAC subscale—pain (5-items), physical functioning (17-items) and stiffness (2-items) were combined and normalized from 0-to 100. The minimum clinically important difference (MCID) set at ten points improvement was determined from the literature. Mean subscale scores, percent mean change from baseline and the proportion of patients achieving a MCID at week 1 and 12 were assessed. **RESULTS:** A total of 809 patients were analyzed (604-tramadol ER; 205-placebo). Both cohorts had similar demographic and clinical characteristics at baseline. At week 1, mean change in WOMAC global and subscale scores from baseline for tramadol ER and placebo ranged from 12–16 and 7–10 points, respectively. Significantly higher proportion of tramadol ER treated patients achieved MCID versus placebo ($p < 0.05$) as early as week 1 except in the stiffness subscale. By week 12, mean change for each subscale and total WOMAC global score for tramadol ER treated patients were significantly greater versus placebo ($p < 0.01$), however, only higher doses (200–300 mg) of tramadol ER treated patients achieved MCID versus placebo ($p < 0.01$)On pain subscale, significantly higher proportion of patients treated with tramadol ER 100 mg achieved MCID versus placebo at week 1 and 12 ($p < 0.05$). **CONCLUSION:** This analysis showed that treatment with tramadol ER in patients with chronic pain extended to improvements in physical function and stiffness as demonstrated by achieving MCID in all WOMAC scores.

PSY43

DISCOVERING THE STRUCTURE OF THE POWER OF FOOD SCALE (PFS) IN OBESE PATIENTS

Cappelleri JC[1], Bushmakin AG[1], Gerber RA[2], Leidy NK[3], Sexton C[3], Karlsson J[4], Lowe MR[5]
[1]Pfizer Inc, Groton, CT, USA, [2]Pfizer Inc, New London, CT, USA, [3]United BioSource Corporation, Bethesda, MD, USA, [4]Sahlgrenska Academy at Göteborg University, Göteborg, Sweden, [5]Drexel University, Philadelphia, PA, USA

OBJECTIVE: To assess the psychometric properties of the Power of Food Scale (PFS) in diverse populations of obese and non-obese individuals. **METHODS:** Data were obtained from adults in a clinical trial for a weight management drug (n = 1739; mean body mass index [BMI] [SD] = 38.6 [6.7]) and a web-based survey (n = 1275; overweight and obese [BMI 27–76 kg/m2] and non-obese [BMI 18–27 kg/m2]). Exploratory and confirmatory factor analyses were employed to discover the structure of PFS using the clinical data. The model developed was then tested using data from the web-based survey. The relationship between PFS domains and BMI was also examined. Logistic regression was used in the web-based survey to evaluate the association between obese status and PFS scores. **RESULTS:** Psychometric assessment of data from the clinical study indicated that the scale was best represented by a 3-factor, 2nd-order model—three domains and a composite domain (average of the three domains)—which was confirmed within the web-based survey (Bentler's Comparative Fit Index: 0.92 and 0.91, respectively). Cronbach's alpha for both data sets were high, ranging from 0.81–0.94 (three domains and a composite domain score). The relationships between BMI and each domain were subtle and approximately linear. An increase of one point in a PFS domain score increased the odds of being obese by 1.6–2.4 times (depending on the domain; domain scores range from 1 to 5). **CONCLUSION:** The structure of PFS is represented by a 3 factor, 2nd-order model with three domains (Food Available, Food Present, and Food Tasted) and a composite of them. This structure has high internal consistency and reliability, relates to BMI, and distinguishes between obese and non-obese subjects. The data indicate that the PFS can be used to evaluate the effects of treatment on patient perception of the power of food in trials of obese patients.

PSY44

LINGUISTIC VALIDATION OF THE HAEMO-QOL AND HAEM-A-QOL FOR USE IN INTERNATIONAL STUDIES

Chevallet L[1], Weatherall JH[2], Von Mackensen S[3]
[1]Mapi Research Institute, Lyon, Rhone, France, [2]Novo Nordisk, Bagsværd, Denmark, [3]Institute of Medical Psychology, München, Germany

OBJECTIVE: Prior to use in an international study collecting data from haemophiliacs, the Haemo-QoL and Haem-A-QoL underwent linguistic validation in 17 languages. Whilst the original Haemo-QoL was developed in British English, the Haem-A-QoL had been developed in Italian. For the purposes of linguistic validation, an English version of the latter was used as a basis for the translations. Seven distinct versions exist: an adult form (Haem-A-QoL) and child self-report and parent proxy versions (Haemo-QoL) for 3 distinct age groups (4–7, 8–12, 13–16 years). A rigorous methodology was required to ensure conceptual equivalence and cultural relevance across different languages. **METHODS:** For languages where no translation existed, the process was conducted by a specialist in each target country using the following standardized methodology: 1) two forward translations by professional translators, native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by the specialist in the target country; 3) backward translation by a native English speaker; 4) comparison of source and backward version; 5) review by the developer for a selection of languages; creation of the different forms of the instrument; and 6) review by a clinician. Existing translations were integrated into the process as appropriate. **RESULTS:** Besides the challenge of ensuring conceptual equivalence with the original and cultural appropriateness, the translation process revealed two additional difficulties. When translating an expression, appropriate terms had to be found for each age group whilst maintaining consistency across all versions of the same language. **CONCLUSION:** The language versions of Haemo-QoL and Haem-A-QoL were established according to a rigorous translation methodology aiming to ensure conceptual equivalence across different language versions to facilitate international comparison and pooling of data. The linguistic validation process as a whole supports the advantage of integrating international feedback on concepts and wording before a questionnaire is finalized.