CONCLUSIONS: The translation evidence tracking tool is a unique device enabling researchers to submit a consistent and comprehensive translation dossier for FDA review.

PM129
FINAL REPORTS FOR TRANSLATION AND LINGUISTIC VALIDATION OF CLINICAL OUTCOME ASSESSMENTS
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OBJECTIVES: As the use of existing translated clinical outcome assessments (COAs) across studies is common and continues to increase, appropriate documentation of the translation and linguistic validation processes utilized to create target language versions is essential. METHODS: A review of the contents of final reports and certifications for previously completed COA translations was conducted. Additional discussions with sponsors and COOs regarding final reports, and the prevalence of language versions is essential. RESULTS: Results for linguistic validation are not provided consistently across the industry. While some companies provide a final report for every project, upon further discussion with sponsors within the industry it was revealed that some companies do not automatically generate reports or provide them to sponsors upon completion of the linguistic validation process. Based upon regulatory expectations for review of translated COAs, it is recommended to utilize a final report which summarizes the overall linguistic validation project. This report should document the process used in detail, the reasoning for linguistic decisions at each stage, evidence of cognitive interviewing, cognitive interviewing population, demographic information of the respondents, a summary of the findings, the final formatted version of the questionnaire, and the relevant certification. CONCLUSIONS: Final reports for COA language versions provide valuable insights to regulatory authorities to make critical decisions regarding the use of existing translations. Linguistic validation reports should be structured as a complete package addressing each item regulatory authorities require for review of translations, so the sponsor may easily include this in their submission packages. Final reports should provide every COA language version to document the translation and linguistic validation process completed.

PM130
TRANSLATABILITY OF RESPONSE SETS USED IN PATIENT REPORTED OUTCOMES AND BEST PRACTICES FOR DEVELOPMENT
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OBJECTIVES: To determine the best response sets for use in Patient Reported Outcomes (PRO) instruments intended for translation and subsequent data collection in multinational clinical trials, and to make recommendations for response options to avoid. As sound response sets are essential for data collection, a high degree of translatability is vital. METHODS: Twelve response sets from previously translated PRO instruments were analyzed. Additionally, linguists provided their feedback on translatability of the response sets. Observed response sets included measures of patient treatment satisfaction, improvement, discomfort level, frequency of symptoms or adverse affects and agreement level with statements about treatment or condition. RESULTS: A response set constructed of “Strongly agree, agree, uncertain, disagree, strongly disagree” was conceptually equivalent to the five choices in German, 94% of observed back-translations. In comparison, response options including the phrase “... of the time” were conceptually equivalent in 42% of back-translations. The concept of “fair” was conceptually equivalent in 64% of back-translations and was found to have problems in some languages. Common changes are: 1) using ”worse” or ”2nd best” as the negative option; 2) Using ”2nd best” as the negative option; 3) Using ”2nd best” as the negative option; 4) Using ”2nd best” as the negative option; 5) Elaborations are added to clarify concepts; and 6) Unnecessary noun phrases are removed. CONCLUSIONS: Response sets in PROs should achieve equivalence across languages, with no overlap between options. The aforementioned agreement set is easily localized, and is thus recommended. Use of verb phrase terminology and concepts which are non-existent in other languages should also be avoided. A translatability assessment of response sets is recommended during instrument development. Where appropriate the use of numerical rating scales or visual analogue scales is recommended. Such response sets avoid concept overlap, and numerical results avoid translatability issues.

PM131
HOW MIGHT EXPERIENCE-BASED UTILITY MEASURES INFLUENCE REIMBURSEMENT DECISIONS?
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OBJECTIVES: The measurement of the ‘quality’ part of the QALY used to assess health-related utility gains based on experience-based estimates of health related utility gains. This paper compares the ICERs for a range of interventions estimated based on both preference-based and experience-based valuation techniques. METHODS: Tariffs were used to estimate the theoretical possibility of replacing the preference-based approaches with experience-based estimates of health related utility gains. This paper compares the ICERs for a range of interventions estimated based on both preference-based and experience-based valuation techniques. RESULTS: Tariffs associated with changes in health states were extracted from published data. Tariffs based on four methods were identified: TTO, standard gamble, life satisfaction, and day affect. These data were combined with estimates of the cost and effect of a range of interventions to model the impact on ICERs of these alternative tariffs, how this varied with intervention type and tariff method, and the challenges of adopting alternative tariffs. CONCLUSIONS: Experience-based tariffs generate lower ICERs for interventions that generated improvements in the social and mental dimensions of health outcomes, and higher ICERs for those that target the pain dimensions of health outcomes. This trend is not, however, replicable in different experience-based tariffs. RESULTS: Experience-based utility represents an alternative to the preference-based utility measures conventionally employed within health economics. If optimal use is to be made of health care budgets, further work is required to understand why different utility measures produce different ICERs, and further debate is required to inform the appropriate basis for reimbursement decisions.

PM132
USING CLINICAL OUTCOME ASSESSMENTS AND ECONOMIC DATA TO FACILITATE PATIENT ACCESS IN RHEUMATOID ARTHRITIS
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OBJECTIVES: Rheumatoid Arthritis (RA) is a chronic autoimmune disease, affecting over 2.9 million adults in Europe. A challenge for new RA therapies is demonstrating added value not only in efficacy and tolerability but also in terms of overall benefit for patients, carers, health care systems and society. The aims of this study were to document current unmet needs in RA in terms of patient-reported and economic burden and how such concepts may be assessed to capture the value of RA treatments. METHODS: Articles were identified via searches in MEDLINE, EMBASE, EMBASE-CRD databases and PCS/CINTO using predefined search terms and limits. PRO measures were identified via the literature and the Patient-Reported Outcome and Quality of Life Database (PROQOLID) and were assessed in context of FDA guidelines. RESULTS: The literature search revealed 2571 abstracts of which 123 articles were reviewed in full. RA symptoms significantly impact patient’s physical functioning, daily activities, and ability to work. Financial stability of patients and caregivers is affected and direct and indirect costs are incurred by health care systems. A conceptual model summarising patient-reported economic burden of RA was developed to identify key measurement concepts which can demonstrate efficacy, tolerability, and wider impact of RA treatments. Relevant endpoint measures were identified; beyond traditional symptom reporting the assessment of health-related quality of life, sleep, fatigue, daily activities, resource use and work productivity can provide data for regulatory, reimbursement and patient decision making. CONCLUSIONS: The potential for inclusion of clinical trials there exists opportunity to demonstrate the overall efficacy, tolerability, and value of a treatment to key stakeholders including regulatory and HTA bodies.

PM133
REVIEWING TRANSLATABILITY PRIOR TO TRANSLATION AND LINGUISTIC VALIDATION OF PROS
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OBJECTIVES: The statistical analysis of health utilities and health-related quality of life (HRQL) scores poses various challenges due to the distributional properties such data commonly exhibit. These include skewness and heteroscedasticity