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

PRM129
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 their 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. Additionally, discussions with sponsors and CROs regarding final reports, and the prevalence of the use of the information provided by COA providers across the industry were completed. RESULTS: Final reports 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 on 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 information 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 accompany every COA language version to document the translation and linguistic validation process completed.

PRM130
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 translatable and its subsequent translation and linguistic validation process completed.

PRM131
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-utility benefits conventionally based upon the general public’s preferences for different health states. Research from behavioural economics tells us that the elicitation of preferences to inform this analysis introduces a number of biases into the estimation of the utility generated by technologies. In response to this, various methods are considered to be 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. METHODS: 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 challenge of adopting alternative tariffs. RESULTS: 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 for different experiences of alternative tariffs. CONCLUSIONS: 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.

PRM132
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-CR, CRD, and PsycINFO using pre-defined 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 2,517 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 scores, to assess the image of health-related quality of life, sleep, fatigue, daily activities, resource use and work productivity can provide data for regulatory, reimbursement and patient decisions. Key concepts which can be used in clinical trials are as follows: QOL, patient reported outcomes, economic burden of disease, and stakeholder needs. CONCLUSIONS: It is critical to develop patient-focused measures which are sensitive to the course of RA and its sequelae and which can capture the impact of RA on patient’s daily life. Patient reported outcomes may be used to demonstrate the overall efficacy, tolerability, and value of a treatment to key stakeholders including regulatory and HTA bodies.

PRM133
REVIEWING TRANSLATABILITY PRIOR TO TRANSLATION AND LINGUISTIC VALIDATION OF PROS


OBJECTIVES: This study is based on a review of 19 PROs used in multinational clinical trials. It aims to assess the extent to which the process of reviewing translatability is currently conducted, and to identify potential areas for improvement. METHODS: The use of PROs in clinical trials in the last 5 years was reviewed. A total of 368 PROs were identified, of which 120 were used in multinational clinical trials. RESULTS: There is widespread use of PROs in clinical trials. However, there is a wide variation in the extent to which translatability is reviewed. CONCLUSIONS: It is recommended that a translatability assurance step is conducted before finalization and its subsequent translation and linguistic validation. A review of translatability and subsequent adaptation can reduce the chances of encountering difficulties related to concepts, response scales, or syntax once translation has started. This step helps identify potential issues and develop solutions that side-step potential problems in the later translation process. The aim of this study was to assess the nature of issues that translatability highlights. METHODS: Translation is assessed by native speakers representing several language groups (e.g. Europe, Africa, Asia, and Latin America). The linguists are asked to identify possible grammatical, lexical and cultural issues. Their recommendations are compiled and discussed with the developer of the measure, which is then adapted in accordance with these findings. The results of translatability checks were reviewed to find common issues that the process illuminates. RESULTS: Changes made to a PRO as a direct result of a translatability step can be varied but all work towards clarity of concepts and expression. Common changes are: 1) Complex sentences are segmented for clarity, 2) Ambiguity is removed, 3) Constructs common in English but not in other languages are changed, 4) Complex concepts are simplified, 5) Elaborations are added to clarify concepts; and 6) Unnecessary noun repetition is removed. CONCLUSIONS: The translatability assurance step can increase cross-cultural equivalence between original and translated documents, and also potential translation difficulties in clinical trials. Language validation begins. It is recommended as a step in all PRO development projects.

PRM134
REGRESSION METHODS FOR HEALTH-RELATED QUALITY OF LIFE DATA IN LONGITUDINAL SETTINGS: ARE MORE ADVANCED TECHNIQUES REALLY PERFORMING BETTER?

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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