PRM161
DEMONSTRATING METHODS FOR HANDLING MISSING PATIENT REPORTED OUTCOME (PRO) DATA IN CLINICAL TRIAL DATA ANALYSIS

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OBJECTIVES: Missing PRO data can introduce bias and interfere with the ability to evaluate treatment effects. Approaches to handling missing PRO data during data analysis should be pre-specified in the statistical analysis plan. This study sought to guide sponsors by critically demonstrating different approaches to handling missing PRO data where entire measurements are missing. METHODS: Four (4) approaches to handling missing PRO data were evaluated: full analysis dataset, complete case analysis, last observation carried forward (LOCF) and pattern mixture model. Analysis was conducted on data that comprised a dummy data set designed to represent a 12 week clinical trial data set including fictional treatments A and B, with PRO data based on the EORTC QLQ-C30. The resulting four imputed datasets were analysed using a variety of methods and differences were presented as mean differences with standard errors. RESULTS: Analysis performed under the assumption of missing at random (MAR) produced similar results to the complete case analysis. Analysis performed under the assumption of missing not at random (MNAR) produced different results. The pattern mixture model provided a degree of confidence around the complete case analysis that appeared related to the extent of missing data i.e. the more missing data, the greater the uncertainty. The LOCF approach was the least robust with the most unpredictable results. CONCLUSIONS: Results based on analysis of the dummy data demonstrated that the extent of missing data and the pattern of missing data affected the similarity of the comparisons. Some form of sensitivity analysis is highly recommended, especially ideally performed using the approach to analysis to the pattern of missing data identified in the data set. LOCF is not recommended as an appropriate approach to handling missing PRO data.

PRM162
QUALITATIVE EQUIVALENCE BETWEEN PAPER AND ELECTRONIC VERSIONS AND USABILITY OF 4 PRO QUESTIONNAIRES FOR WOMEN WITH UTERINE FIBROIDS

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OBJECTIVES: This study evaluated the qualitative equivalence between paper and electronic (eDiary) versions of 4 patient-reported outcome (PRO) instruments used in uterine fibroid studies: Menstrual Bleeding Scale, Uterine Fibroid Daily Symptom Scale, Non-bled Uterine Fibroid Symptom (NBUSFS) Questionnaire-Morning and NBUSFS-Evening. Usability of study medication questions was also assessed. Equivalence evaluation of these questionnaires in an eDiary was needed to document suitability of this mode of data collection for upcoming clinical trials. METHODS: A cross-sectional qualitative study was conducted among 21 US women and 18 women living outside the USA. Women diagnosed with uterine fibroids. The 4 symptom questionnaires and study medication questions were administered on HTC HD2 eDiary and paper versions. Participants were randomized to order of mode completion to control for order effects. Interviews were conducted in two rounds to allow for evaluation of issues between rounds. RESULTS: Mean age of the sample (N=10) was 38 years, (range 25-48), 90% were white, 70% were employed full-time, 50% had completed high school or some college, 50% had completed a college or graduate degree. All participants considered the formats similar. However, half the sample considered the layout different. The majority preferred the eDiary. Paper was easier to use. Medical usage related to the numeric rating scale, with participants suggesting increasing the size or other modifications to make answer selection easier. Discrepancies in response between formats were found, 3 participants reported format differences may have affected their answers, 2 participants considered the usability of the eDiary with a uterine fibroid population which preferred the eDiary and provided suggestions for improvement for future studies.

PRM163
WHEN IS IT EVENING, WHEN IS IT NIGHT? WHY IT IS CHALLENGING TO TRANSLATE TIMES OF THE DAY IN CLINICAL TRANSLATIONS

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OBJECTIVES: Questionnaires often use different times of day to indicate when a subject should complete tasks such as taking medicine, making diary entries, or visiting their doctor. Often this has to be done/reported on at the same time of day or weekly (e.g. “did you forget to take your evening dose?”) Terms for times of day do not necessarily have equivalents in other languages. We investigated translations of times of day as they relate to patient reported outcomes. METHODS: We explored times of the day and their meanings across 15 languages: Morning, day, morning/day, evening, night, middle of the night, and midnight, asking linguists if the phrase had exact equivalents in their language. We then investigated times of day as they relate to patient reported outcomes. OBJECTIVES: When translating times of the day, it is important to consider the local context of a patient's daily routine, as well as their cultural and personal preferences. It is also important to consider the potential for confusion or misunderstanding that may arise from using terms that are not culturally appropriate or that have different meanings in different cultures. For example, the term “evening” may be interpreted differently depending on the context. In some cultures, “evening” may refer to a specific time of day, while in others it may refer to a general time period or a state of being. Additionally, the term “night” may be used to refer to a specific time period, such as bedtime, or it may be used more generally to refer to the entire period of darkness. Therefore, it is important to consider the cultural and linguistic context of a patient's daily routine when translating times of day, and to use terms that are appropriate and meaningful in the patient's cultural and linguistic context.