unobserved selectivity, a condition not satisfied in many retrospective healthcare studies, especially those based on administrative claims databases.

PMD5

IMPROVING REPORTS OF PRO DATA TO SUPPORT AN EFFECTIVENESS CLAIM

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OBJECTIVES: The same standards should apply for measuring patient reported outcomes (PRO) as for any clinical measure used for an effectiveness claim. Yet, discrepancies between the number of submissions and the number of PRO claims granted illustrate how difficult it is to demonstrate the "substantial evidence" required by authorities. Reporting PRO data separately from the clinical data makes reviewing PRO claims difficult. However, International Conference Harmonization (ICH) guidelines provide no standard location for PRO measurement information. Better integration of PRO data in clinical reports and standardized documentation of PRO measures would improve the reviewing process and enhance the likelihood of securing claims. We will present the value of implementing a standardized approach to documenting PRO measures in regulatory submission reports. **METHODS:** Our recommendations are based on ICH guidelines and the ERIQA and PRO Harmonization group recommendations. While current ICH report guidelines provide no headings for documenting background information on PRO measures, appropriate headings can be added to report PRO methods and findings as part of the primary clinical trial report without modifying the ICH numbering system. However, the questionnaire development and validation relevant to the condition and treatment considered are better located in supporting appendices as are reviews of literature documenting the use and interpretation of data collected with it. **RESULTS:** These appendices should include evidence of the clinical significance of differences to help reviewers familiarize themselves with the instrument. **CONCLUSION:** Better integration of PRO in clinical study report guidelines and the development of a specific system for standardized documentation of PRO measures will enhance transparency and acceptance of PRO data, and thereby increase the acceptance by decision-makers of effectiveness claims based on PRO.

PMD6

ESTIMATING THE TRAJECTORY-ADJUSTED IMPACT OF ACUTE EVENTS ON PATIENT-REPORTED OUTCOMES

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OBJECTIVES: To establish clinical meaningfulness of effect sizes and validate measures of patient-reported outcomes (PROs), it is important to understand the effect of acute clinical events on PROs. When PROs are measured before and after an acute event, there are several options for measuring change. This example illustrates the benefit of adjusting estimates of change for patients' pre-event trajectories. **METHODS:** To determine the effect of pathologic fractures (PF) on PROs, we used data from a clinical trial of zoledronic acid versus placebo in patients with prostate cancer (N = 643). Only patients who experienced a PF were included in this analysis (n = 76). For illustrative purposes, the Functional Assessment of Cancer Therapy-General (FACT-G) total score was compared before and after each patient's first PF using two methods: 1) estimate simple mean change from pre-PF value to post-PF value and perform a paired t-test; and 2) use a linear mixed effects model to analyze all time points from baseline to the first time point after the PF, with a dummy variable indicating the pre-PF (0) and post-PF (1) status. The fixed-effect for the dummy variable is the trajectory-adjusted mean change (TAMC). (Note: analyses not reported here showed significant effects of PF on three of the four FACT subscales). **RESULTS:** The simple mean change was –4.03 (SD = 13.57), which was significant by a paired t-test (p = 0.04). The TAMC, however, was –2.00 (95% CI = –5.53, 1.52), and was not statistically significant (p = 0.26). **CONCLUSIONS:** In assessing the impact of acute events on PROs, simple pre-post comparisons may misestimate effect size and/or statistical significance. The mixed-effects model presented here more accurately assesses changes in PROs by adjusting for the pre-event trajectory due to prostate cancer with bone metastases, isolating the change in PROs attributable to the acute clinical event.

PMD7

THE CONGRUENCE OF SELF-REPORT WITH OTHER MEASURES OF MEDICATION ADHERENCE: A SUMMARY OF THE LITERATURE

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OBJECTIVES: The objective of this paper is to determine the congruence of self-report measures of medication adherence with other measures of adherence. **METHODS:** A literature search was conducted across 1978–2002. MEDLINE, PsychInfo, IPA and ISI databases were used to identify studies that met the following inclusion criteria: 1) study included at least one self-report measure and one non-self-report measure of adherence; 2) data were reported that would allow a comparison of the measures (e.g., individual scores or a correlation/concordance statistic); and 3) the report was in English. The studies were categorized by type of self-report adherence measure (questionnaire, diary, interview) and by type of non-self-report method (administrative claims, pill count/canister weight, biological assay, electronic mea-