lematic. There is no single ICD-9 code to identify FN; therefore an algorithm must be created to identify FN patients. Previously published algorithms are generally comprised of 3 main codes: (1) neutropenia (primary designation (ICD-9 code 288.0)) (2) fever (ICD-9 780.6) (3) infection. However, the primary designation of neutropenia is only used if there is no clear source of infection. Additionally, infection in the neutropenic cancer patient can often be difficult to confirm due to the lack of neutrophils and typical clinical symptoms and signs; the febrile response may also be blunted. Therefore, the FN algorithm may use neutropenia alone, likely identifying patients with neutropenia alone in addition to those with FN. In a study utilizing claims data, FN was defined as primary or secondary diagnosis of neutropenia or infection during the first chemotherapy course; 41% of cancer patient newly initiating chemotherapy were classified as having FN. When the FN definition was narrowed to primary or secondary diagnosis with neutropenia and either 1) fever or 2) infection 4.5% were classified as having FN; when the definition was broadened to diagnosis with neutropenia or fever or infection or a procedure code for infection treatment 64.7% were classified as having FN. There is a strong need to validate the coding associated with submitting medical claims for the treatment of FN in cancer patients receiving chemotherapy in real-world practice in order to utilize claims data to investigate FN.

PCN158

A METHOD TO INCREASE SAMPLE SIZE BY REMOVING THE CONTINUOUS ENROLLMENT REQUIREMENT

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OBJECTIVES: We introduce a method whereby the continuous enrollment requirement can be removed to increase the sample size and correct for incomplete information with an advanced statistical technique. METHODS: The inverse probability weighted least squares model is used to estimate the outcomes from a sample that does not require continuous enrollment in the inclusion criteria. This method involves two steps: probabilities are estimated using a non-parametric approach, and standard errors of the outcomes regression are adjusted for the first step estimation. RESULTS: To demonstrate the technique, we used U.S. claims data. Patients with incidents of cases of lung cancer were used. A total of 236 patients were identified without the continuous enrollment requirement of one year after diagnosis. With the continuous enrolment requirement, our sample size would be 87. Incomplete cases were more likely to have surgery and higher rates of comorbidities. R-squared increased 25% with the inverse probability weighted technique. Standard errors decreased with 35% and therefore improved the precision of our estimators. CONCLUSIONS: The continuous enrollment requirement does not have to be applied for pharmacoeconomical studies. Results might be biased if there are substantial differences between complete and incomplete observations. Even though there are no differences, removing this requirement increases the sample size and provides efficient estimators, especially in rare events.

PCN159

HFS 14: A SPECIFIC QUALITY OF LIFE SCALE FOR PATIENTS WITH HAND-FOOT SYNDROME

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BACKGROUND: Hand-foot syndrome or Hand-Foot skin reaction is a common adverse effect of certain chemotherapy agents, such as capecitabine or pegylated doxorubicin, where it is estimated to occur in 50% of cases. **OBJECTIVES:** The aim of this study is to develop and validate a hand-foot syndrome-specific quality of life scale in order to be able to measure the impact of the condition on patients and secondly to be able to assess the value of certain specific treatments in this indication **METHODS:** The questionnaire was developed after conducting a series of structured interviews with patients with forms of hand-foot syndrome of varying severity, which yielded a detailed and rigorous collection of verbatim transcripts. The Pilot-Testing are realised. **RESULTS:** Thirty-one items were identified, and 14 items were selected as being relevant and non-overlapping after initial evaluation. The first question in the HFS14 addresses which member is affected (hand, foot or both). The second question addresses the pain with three possible responses (very, moderately or not painful). The 14 items can be organised in 2 modules: the first module more specifically assesses the handicap generated by involvement of the "feet" and the second assesses the handicap generated by involvement of the "hands". **CONCLUSIONS:** The hand-foot syndrome-specific HFS14 scale is easy to use and meets the requirements of a quality of life scale. This scale now needs to be tested in longitudinal studies (for example in clinical trials) to confirm its ability to measure a change in status.

PCN160

PATIENT-REPORTED OUTCOMES SUPPORTING ONCOLOGY PRODUCT LABELING CLAIMS: TRENDS AND CHALLENGES

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The FDA has advocated the PRO Draft Guidance released in 2006 as the main vehicle for evaluating PRO and HRQOL claims in oncology product approvals. Additionally, FDA-affiliated researchers have identified factors inhibiting acceptance of HRQOL-based claims for oncology product labels, including: trial design, missing data, multiplicity, and inconsistent findings of HRQOL data. The views of the FDA on PRO and HRQOL claims are extensive per its own guidance, which puts forth detailed, restrictive requirements on use. These matters clarify why the FDA has not yet allowed the utilization of PRO or HRQOL data as primary evidence to support an oncology product approval. In contrast, the EMEA since its establishment in 1995 has conducted authorizations without an explicitly defined approach for evaluating HRQOL and other PRO data. Further, a reflective paper released in 2005 offered only broad recommendations on HRQOL labeling claims. As a result, the importance of HRQOL or other PRO data in the review process is based more broadly on its relevance to a given drug and overall assessment of the study in the eyes of the reviewers. The varying approaches between the FDA and the EMEA partly stem from divergent underlying organizational characteristics. The FDA enforces laws regarding medical product quality. Alternatively, the EMEA serves as a coordinating body, leaving enforcement responsibility to member states. Consequently, the EMEA provides more generic advice, whereas the FDA insists on rigorous criteria for conceptual and study design issues surrounding PRO claims. Otherwise, the EMEA is more likely to accept use of well-established PRO and HRQOL measures, whereas the FDA is inclined to request new PRO measures that explicitly satisfy the agency's most recent evaluative standards. Finally, the FDA places greater focus on symptom-based endpoints reflecting the direct consequences of treatment, whereas the EMEA is more willing to accept global HRQOL claims.

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

ASSOCIATION BETWEEN GLYCOSYLATED HEMOGLOBIN AND CARDIOVASCULAR OUTCOMES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A NESTED CASE-CONTROL STUDY

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OBJECTIVES: To describe the association between the three-year average glycosylated hemoglobin (A1C) and cardiovascular outcomes in adults with type 2 diabetes mellitus (T2DM). **METHODS:** In this nested case-control study, 245,346 adults (≥18 years) with T2DM were identified among members of Kaiser Permanente Southern California. Type 2 diabetic patients had at least two ICD-9 diagnosis codes for T2DM (250.x0, 250.x2) and either A1C > 7.5% or prescriptions for hypoglycemic agents from 2002–2007. Using hospital records and death certificates, cases were defined as patients with a nonfatal MI, nonfatal stroke, or death due to cardiovascular (CV) causes (MI, stroke, heart failure, arrhythmia, sudden cardiac death) in the period 2005–2007. Four controls from the T2DM pool were matched to each case based on age, sex and index date (date of the case defining event). A conditional logistic regression model was used to estimate the odds-ratio (OR) of cardiovascular events comparing patients with an average A1C ≤ 6 % and those with average A1C > 8% to patients with average A1C between 6–8%, considered 'near A1C target'. A1C categories were assigned to each patient based on average A1C over the three years prior to the index date. **RESULTS:** A total of 44,628 controls were matched to 11,157 cases. After adjusting for CV related medications, comorbidities, and other confounders, patients with an average A1C ≤6% were 50% more likely to experience a CV event than the 'near A1C target' T2DM patients (OR = 1.50, 95% CI 1.33–1.69, $p < 0.0001$). Patients with an average A1C > 8% experienced a 14% increase in odds of a CV event (OR = 1.14, 95% CI 1.03–1.26, $p = 0.01$). **CONCLUSIONS:** Compared to those with mean A1C levels between 6–8%, patients with T2DM who achieved mean A1C levels of ≤6% or failed to decrease their A1C below 8% over a 3-year period are at increased risk for cardiovascular events.

PDB2

THE IMPACT OF ORAL ANTIDIABETICS ON WEIGHT IN THE ELDERLY WITH TYPE 2 DIABETES MELLITUS IN THE AMBULATORY SETTING

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OBJECTIVES: To assess the impact of oral antidiabetics agents on weight change in Type 2 Diabetes Mellitus (T2DM) patients age 65 years and older. **METHODS:** An electronic medical record, General Electric Centricity research database, containing the ambulatory health records of US patients was used to conduct a historical cohort study of the T2DM elderly patients identified by ICD-9 codes, OAD prescription or both. Six months of continuous OAD monotherapy activity was required, and study period included 395 days pre/210 days post from the index date. Two BMI/weight readings were mandated, at baseline, and follow up. Data were analyzed using ANOVA with Tukey test to correct for multiple comparisons. **RESULTS:** A total of 2720 patients with a primary diagnosis of T2DM were included in the study. The overall mean age was 72.7 years. Statistical significant differences between users of different OADs at baseline were found for diastolic blood pressure ($p = 0.0009$), and age ($p < 0.001$) The most prescribed OAD medications were metformin (58.9%), glipizide (14.52%) and glimepiride (7.76%).The overall mean change in A1C level was –0.92 ($p < 0.001$) units and statistically significant differences were found when compared Metformin/Glipizide (mean difference 0.51320, 95% CI 0.06411–0.96230). The overall mean baseline BMI among all of the OAD groups was 29.08 kg/m^2. Significant differences in BMI units change were found for meglitinide users, (-1.27), metformin users (-1.06), and the sulfonylureas (-0.14). An average of 3.97 lb weight loss for all of the OAD groups was found. Major weight loss was found in the Metformin group (-6.41lb), and the Sulfonylureas group reported the least weight loss (-0.89lb). **CONCLUSIONS:** An association was found between the OAD use and