PDB4

ESTIMATION OF STUDY POPULATION SIZE FOR EFFECTIVENESS OUTCOMES AT 6 AND 12 MONTHS VIA ELECTRONIC MEDICAL RECORDS

McAdam-Marx C, Brixner D, Oberg B
The University of Utah College of Pharmacy, Salt Lake City, UT, USA

The lag between product launch and prescribing impacts research timing. This will describe methods applied to a population treated with a new antidiabetic agent, exenatide, to project patient counts for 6 months and 12 months real-world outcomes analyses. Patients prescribed exenatide via the General Electric Electronic Medical Record (EMR) database by March 31, 2007 were identified. The proportions of patients remaining active 6 months and 12 months on March 31, 2007 and with baseline and follow-up hemoglobin A1C values were identified. Starts for 2Q07 were estimated based on 4Q06 to 1Q07 growth, and the number of patients who would have started exenatide at least 6 months or 12 months before December 31, 2007 was projected. Rates and portions with A1C values were applied to these counts to predict how many would be active at least 6 months and 12 months on December 31, 2007 and have outcomes data. Exenatide was prescribed for 8372 patients through March 31, 2007. A total of 5392 and 2240 started exenatide at least 6 months or 12 months prior to March 31, 2007. A total of 2853 (52.9%) had 6 months and 1152 (51.4%) had 12 months activity. Of these 1721 (60.3%) and 789 (68.5%) had baseline and follow-up A1C readings. The rate for 1Q07 was 20%; thus the estimated number prescribed exenatide by the end of 2Q07 was 10,043. Thus, 10,043 and 6946 would be prescribed exenatide at least 6 months and 12 months before December 31, 2007. Of these, 3207 and 2447 would be active and have baseline and follow-up A1C values. Estimates based on prescribing growth and patient retention was used to estimate patient counts for outcomes analysis. This facilitates research and planning for research on a new product. A validation of estimates will be conducted and reported when available.

PDB5

COMPARISON OF CLINICAL EFFECTIVENESS AND SAFETY OF GLULISINE VERSUS INSULIN LISPRO, ASPART AND REGULAR HUMAN INSULIN IN PATIENTS WITH TYPE 1 AND 2 DIABETES

Walczak J[1], Borowiack E[1], Kolodziej K[1], Lis J[2], Gierczynski J[2], Nogas G[1]
[1]Arcana Institute, Cracow, Poland, [2]Sanofi-Aventis sp. z o.o, Warszawa, Poland

OBJECTIVE: The aim of this analysis was to compare clinical effectiveness of insulin glulisine versus insulin lispro, aspart and regular human insulin in patients with type 1 and 2 diabetes. **METHODS:** The clinical effectiveness was analyzed according to guidelines of Cochrane Collaboration and HTA Agency in Poland (AOTM). The comparison of insulin glulisine with comparators was performed as direct comparisons. **RESULTS:** Patients with type 1 diabetes: There was no statistically significant difference between insulin glulisine and insulin lispro, aspart and regular human insulin in change in mean HbA1c from baseline. Also there was no statistically significant difference between groups in number of patients with hypoglycemia (overall, nocturnal and severe). The comparison of safety parameters for insulin glulisine versus insulin lispro, aspart and regular human insulin didn't show significant differences between analyzed groups. Patient with type 2 diabetes: Meta-analysis of two clinical trials showed no statistically significant difference between insulin glulisine and regular human insulin in change of mean HbA1c. However in one study there was statistically significant difference in favour of insulin glulisine compared to regular human insulin in change of HbA1c –0.11%(95% CI: –0.21; –0.008) after 26 week of follow up. There was relevant difference between the two groups in favour of insulin glulisine in reporting of nocturnal hypoglycemia OR: 0.73 (95% CI: 0.57; 0.94). Frequency of adverse events was comparable between groups. **CONCLUSION:** Insulin glulisine has efficacy comparable to insulin aspart, lispro and regular human insulin in patients with type 1 diabetes. Insulin glulisine, in comparison with regular human insulin is more effective in treatment of patients with type 2 diabetes. There are no differences in safety between analyzed comparators.

WITHDRAWN **PDB6**

PDB7

EVALUATION OF INSULIN CONTAINING ANTI-DIABETIC REGIMENS IN HIGH-RISK CARDIOVASCULAR PATIENTS WITH A PRE-TREATMENT A1C MEASUREMENT GREATER THAN 9%

Livengood K
University of Southern California, Los Angeles, CA, USA

OBJECTIVE: The purpose of this analysis was to determine if high-risk cardiovascular patients with concomitant diabetes and a pre-treatment A1c measurement greater than 9% experienced better outcomes with insulin containing anti-diabetic medication regimens than similar patients not taking insulin. **METHODS:** High-risk cardiovascular patients with concomitant diabetes and a pre-treatment A1c measurement of greater than 9% from a large western United States integrated health care system were evaluated for an A1c measurement at least three months prior to treatment initiation and a follow-up measurement at least three months following initiation. In the case of patients taking insulin, the three month follow-up period started with the initiation of insulin. Change in A1c resulting from medication treatment was evaluated using a two-step endogenous treatment regression model, with insulin as the endogenous treatment variable. Exogenous independent variables included hypertension diagnosis, hyperlipidemia diagnosis, age, gender, and distance from treatment goal (A1c less than 7%) at baseline. Standard errors for beta coefficients were computed using HCCM3. **RESULTS:** Of 11,181 diabetic patients, 707 (314 on insulin) patients met the inclusion criteria. Although both insulin and non-insulin containing treatment regimens reduced A1c from baseline to follow-up, patients on insulin were associated with a greater reduction in A1c than patients not on insulin. The difference in change was 2.6% and was statistically significant ($p = 0.0029$). **CONCLUSION:** Use of insulin in an anti-diabetic regimen in high-risk cardiovascular patients with concomitant diabetes and a pre-treatment A1c greater than 9% resulted in a significantly greater reduction in A1c compared to patients not taking insulin.

PDB8

DEFINING HYPOGLYCEMIA AND ASSESSING ITS AFFECT ON OUTCOMES IN THE HOSPITAL SETTING

Curkendall SM[1], Alexander CM[2], Haidar T[1], Natoli JL[3], Dubois RW[3], Nathanson BH[4]
[1]Cerner LifeSciences, Vienna, VA, USA, [2]Merck, White House Station, NJ, USA, [3]Cerner LifeSciences, Beverly Hills, CA, USA, [4]OptiStatim, Longmeadow, MA, USA

Quantify the impact of hypoglycemia on outcomes of hospitalized diabetic patients and determine how variations in the definition of hypoglycemia affect outcomes. This study used an EMR database of inpatient and ED encounters for adults with diabetes treated at 70 hospitals during 2000–2006. Patients presenting to