Model-Based Evaluations to Select and Confirm Doses in the Clinical Development of Exenatide

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Abstract

By administering a range of doses in early-phase studies, one can achieve that same target.

Methods

Exenatide BID dosing for Phase 3 trials (CPT 2002;71:P29). The model-based dose selection process was designed to target exenatide

Results

Statistical Analyses

Table 3. Final parameter estimates and standard errors for the final PK/PD model

Conclusions

Figure 4. Population mean predicted % reduction in gAUC

Figure 3. Model predicted gAUC0-3h response, stratified by dosage regimen and antibody status, overlaid on an observed average

The results are shown in Figure 4.

References


Table 4. Relationship between fixed doses of exenatide and predicted percentage decreases in gAUC, stratified by model refinement

Table 1. Final parameter estimates and standard errors for the final PK/PD model

Table 2. Population mean values of CL/F and V/F based upon significant covariates identified in the final PK model

Table 5. Comparison of glucose responses (reduction in glucose AUC0-3h) greater than 50%, 75%, 85%, and 90% of their individual Baseline-predicted AUC0-3h

Table 6. Geometric mean (SE) ratio of postprandial gAUC0-3h (mg·min/mL)