Pharmacometrics Report Template

subtitle

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Table of contents

1 Executive Summary

- **Purpose of the analysis:**
  - [Description of the purpose]
- **Key Findings:**
  - [Key findings that affect drug use or labeling]
- **Summary:**
  - [Plain language summary of objectives, data, methodology, and conclusions]
- **Clinical Relevance:**
  - [Description of results in terms of their effect on clinically relevant drug exposures]
- **Visual Presentation:**

2 Introduction

- **Background:**
  - [Background information to place the population PK study in context]
- **Objectives:**
  - [Objectives for the population PK analysis]
- **Pharmacokinetic Characteristics:**
  - [PK characteristics of the drug]

3 Materials and Methods

- **Description of Trials:**
  - [Description of the trials and trial data, including dose, frequency, duration, subjects, samples, etc.]
- **Data Exclusion (if any):**
  - [Reasons for not including certain trials/data]
- **Hyperlinks to Original Reports:**
  - [Hyperlinks to original trial reports and bioanalytical evaluation reports]

- **Demographics and Covariate Information:**

  - [Detailed demographic and other covariate information]

- **Model Building and Evaluation:**

  - [Description of planned criteria, assumptions, procedures, handling of outliers and missing data, model-estimation method, equations, etc.]

- **Software Used:**

  - [Software and version used for analysis and simulation]

4 Results

- **Data Summary:**

  - [Summary of data and data exploration with graphical and tabular displays]

- **Model Description:**

  - [Description of final model, model building steps, validation, final parameter estimates, deviations if any, etc.]

- **Application of Model:**

  - [Application of model to objectives, including relevance of covariates on PK parameters and simulations of alternative dosing if applicable]

- **Tables and Figures:**

5 Discussion

- **Interpretation of Results:**

  - [Interpretation of modeling results including discussions on data adequacy, modeling approach, consistency or inconsistency between results, etc.]

- **Clinical Relevance:**

  - [Assessment of clinical relevance of results, physiological plausibility, and clinical significance of identified relationships]

- **Alternative Dosing Regimens:**

  - [Assessment of any alternative dosing regimens in the context of E-R analyses for safety and efficacy]

6 Conclusions

- **Summary of Findings:**

  - [Short summary of major findings from the analysis written in plain language]

7 Appendix

- **Supplemental Materials:**

  - [Supplemental tables, figures, methods and codes, listing of samples removed from analysis and reasons for removal, run record, diagram showing connection between input datasets, codes/control streams, and output datasets]