Introduction

- Population pharmacokinetic (POPPK) analyses are an integral part of model-based drug development [1] and have become a standard component of regulatory submission in support of drug labeling [2,3].
- Model development is an iterative process through “learning” and “confirming” phases of clinical drug development involving years of time [4]. Assumptions and choices made by analysts during model building can appear subjective and are often influenced by the analyst’s experience, expertise, and tools used.
- Within a large pharmaceutical organization, the development and implementation of standard procedures for conducting and reporting POPPK analyses would facilitate consistently high quality output. The importance of improved efficiency through streamlined and standardized approaches should not be underestimated.
- An industry experience is shared which strives for improved consistency, efficiency and a more systematic approach to model building through the development of a guidance for POPPK analyses.
- Objective: To present the process by which the guidance was developed and some examples from the guidance document.

Methods

- Questions for key topics on base, full and final models, model selection and diagnostics were drafted and preliminarily discussed within the Pfizer Pharmacometrics group to elucidate recommendations.
- An internal wiki repository was then created to function as a hub for collating viewpoints across the Pfizer Global Clinical Pharmacology (PGCP) organization.
- An editorial board was formed to consolidate recommendations, capture pertinent examples, draft and revise the guidance. The draft guidance was circulated to PGCP and senior management for review and endorsement.

Figure 1 Process Workflow for Development of the POPPK Guidance.

Conclusions

- A POPPK guidance was developed to implement a systematic, streamlined, and standardized approach to optimize and harmonize the processes which contribute to the POPPK analysis.
- As population modeling is an area of continually evolving science and technology, the guidance needs to be updated and revised periodically.

References