**POP PK Quality Control: Data Proofing and Model Verification**

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**Objectives:** Systematic and thorough data proofing and model verification methods strengthen credibility of POP PK results and allow reviewers to focus on analyses messages and conclusions.

Frequently, however, data collection and edit checks are not designed, nor sufficiently developed to clean data related to POP PK analyses. As a result incomplete or erroneous data are arbitrary excluded from analyses. These exclusions can have significant impact on results and interpretation.

In addition to data content credibility, tool-specific data formatting requirements can unnecessarily add iterations to the data build process. Slight deviations from the format requirements can prevent analysis from being executed resulting in multiple issue-resolution cycles.

Further, NONMEM control streams, outputs, and listings need to be reviewed against the analysis plan. The POP PK report needs to be verified against all data manipulations and modeling methods. Supporting plots, figures, tables and listings need to be verified against the data and analyses.

With this in mind, the objective was to develop data proofing and model verification solutions to deliver high-quality, analysis-ready data and to deliver verifiable modeling results.

**Methods:** A collection of re-useable data proofing programs (using SAS and R) has been created. The data proofing methods facilitate the identification and reconciliation of the data and formatting issues and minimize the iterative data review process.

Manual review steps were initiated to ensure that the modeling and analyses steps from source data to final report are transparent. Simulation models are checked against source descriptive models to ensure accurate translation of model specifications and parameter value transcription. Simulation scenarios are checked to ensure congruity with the modeling and simulation plan.

**Results:** Data issues and format issues are now more readily identified and corrected. Data review cycles are minimized. Unnecessary interactions are eliminated. Modeling verification activities ensure quality analysis results and conclusion.

**Conclusions:** By using verification methods, data preparation and modeling activities attain high-quality, fully transparent results allowing the reviewer to focus on the modeling messages and results.