A Browser-based NONMEM Data Specification Order Form
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Objectives: The objective was to develop a browser-based NONMEM data specification order form to improve the process for creating POP PK NONMEM data specifications. The order form needed to have end-user and administrator functionality and with the potential for PKPD and multi-study or project level expansion.

For end-users, the tool needed to be easy to understand, easy to use and to be immediately effective. It needed to provide clear, consistent instructions, and produce consistent layout. It needed to easily enforce standards (variable names, labels, instructions, code lists, and formulae) in a natural way and to control versions.

For the administrators, the tool needed to be sufficiently flexible to allow additions and updates of variable names and definitions; yet, sufficiently secure to prevent unauthorized changes. It needed to allow updates to on-the-fly instructions (pop-ups) and to manage and modify code lists, formulae, drop-down selections and variable groupings.

Methods: JAVA was used to program the browser-based order form with separate end-user and administrative capabilities. Oracle was used as the backend for storing, initializing and maintaining standards, formulae, code list, groupings, etc and for archiving and maintaining NONMEM specification versions.

Results: The tool is being used for all new studies as AstraZeneca. Legacy studies are considered on a case-by-case basis. Feedback from pharmacometricians has been positive. Suggestions for “nice-to-have” enhancements denote positive uptake.

Conclusions: The browser-based order form eases the burden in developing the NONMEM programming specifications. It produces fast and reliable data instructions with consistent variable definitions that can be efficiently applied across studies and drugs with minimal modification. Its natural enforcement of standards enables programmers to develop generic SAS code for data set generation and for diagnostic data summaries and diagnostic plots.