A NONMEM Data Strategy – Mitigating differing workflows, perspectives and processes

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Objectives: The pitfalls in building NONMEM datasets are many and are a source of much frustration for both the traditional clinical programmer and for the pharmacometrician. Both stakeholders have strikingly different perspectives, workflows and expectations of the data build process.

This work will focus on clarifying the different stakeholder perspectives and on organizing and defining a programming strategy that will readily mitigate the issues to improve the process, data quality and the delivery time.

Methods: An examination of the differing pharmacometrician and programmer perspectives, workflow collisions and process frustrations was conducted. Following the examination, some agreements on standards and processes were needed in order to further develop the programming strategy.

Results: The Pharmacometric data build does not readily translate from the traditional clinical programming approach. The NONMEM data records, record sequencing and variable standards are often not sufficiently understood or defined by the programmer and pharmacometrician.

At the same time, the pharmacometrician’s analysis progressions (poppk to pd or pkpd) and the availability of source data (Raw, SDTM, ADaM) along with data cleaning requirements often collide with the programmer’s best practices and data validation processes including the updating of documentation, maintaining date stamp integrity and adhering to reproducibility requirements.

Identifying these and similar issues along with obtaining agreement on data standards has led to a programming strategy consisting of nine principles and a programming framework that anticipates and mitigates the pharmacometric analysis progressions.

Conclusions: Understanding the different perspectives along with attaining a level of compromise allowed the pharmacometricians and programmers to produce quality data in a timely manner and to subsequently maximize the analysis potential and contributions of pharmacometrics in the drug development decision making process. The strategy helps the programmer to write programs to more easily anticipate and address directional changes in data content while continuing to code in a clear, transparent way while continuing to adhere to best programming practices. The pharmacometrician better understands how changes requests can collide with the data programming best practices and requirements.