A dedicated SAS® Programming Group working in a pharmaceutical Modeling & Simulation organization - Current role, experience and prospects

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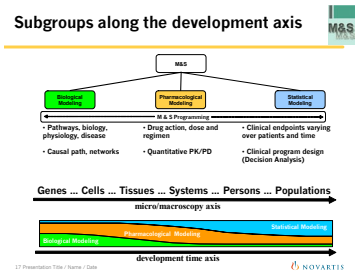
Purpose

The poster's purpose is to share our experiences and present the innovative group of qualified and skilled programmers dedicated to support pre-clinical and clinical modeling and simulation. We wish to encourage and enhance feedback and collaboration from colleagues in other Pharma companies.

Abstract

Modeling and Simulation at Novartis consists of 4 subgroups: Biology, Pharmacology, Statistics and the SAS® Programming group. Programmers work in close collaboration with the 3 other modeling subgroups.



Most modelers have the skills to format data, but do not have formal training in database programming so they are unable to efficiently extract and merge data into a suitable format for their use. The extraction and merging of data from disparate data sources to create a modeling database requires a knowledgeable database programmer. Programmers extract the data, harmonize and pool them into a format suitable for the relevant modeling software. This activity is done in compliance with health authority and in-house pharmaceutical standard operating practices, in a validated audit trail environment. A dedicated programming group that is integrated with the modeling group increases the efficiency of the modeler while ensuring reproducibility and quality.

Objectives

The objective is to raise awareness of the benefits and advantages of having SAS® programmers working in Modeling and Simulation (M&S). We would like to share our experience and future plans, to solicit feedback and to encourage collaboration with other similar groups.

History

In 2001, the Modeling and Simulation group at Novartis had only one part-time programmer who supported the entire group of 17 modelers. The added value was recognized such that the M&S Programming subgroup has seen a sustained growth and is today constituted of 6 associates with mixed background and expertise.

Current activities

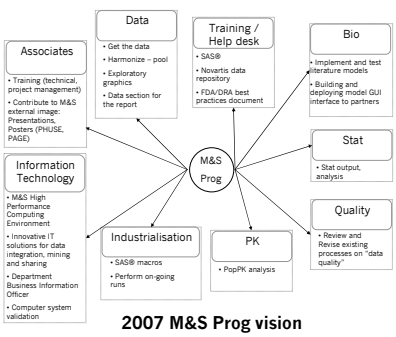
A) Data delivery: The M&S Programming core activity is one of data delivery (1) and data summary. They are tasked with finding and extracting data from different databases (Pre-clinical, Clinical, Watson Lims, Legacy database, Biomarker database, Clinical database). This is harmonized, combined, pooled and delivered to the modeler in the appropriate format (NONMEM®, Matlab®, S-Plus®, SAS®, Berkley Madonna®, ….).

B) Quality: The data processing activity is done in a validated audit trailed environment. If the modeling activity is of high criticality (e.g. a pivotal regulatory-type analysis), a second programmer might be requested to independently re-do the work and compare it to guarantee high quality input data.

C) Statistical analysis, PopPK analysis: The role of the programming scientists within M&S is currently expanding. For some projects, M&S/Prog conducts exploratory statistical analysis, produces graphics using SAS®, Matlab®, S-Plus® or R (2), prepares computer code for some literature models or conducts initial modeling work in collaboration with an experienced modeler. That aim is actually supported by regular attendance to team meetings, ad-hoc discussions and trainings.

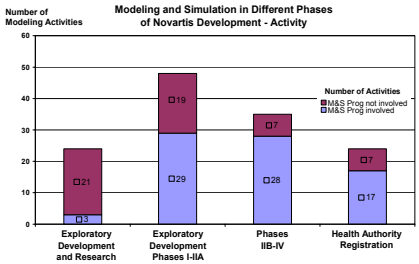
D) Training: Programmers share their expertise in order to bring the modelers to the next step of the data manipulation task by providing internal SAS® courses based on modelers needs. They also train the modelers to properly use Novartis data repository system to be more efficient.

E) IT support and improvement: As modeling and simulation becomes a key component in drug development (3) (4), it is vital that hardware and software match our needs. Some global IT projects are currently on-going; M&S Prog is a business representative for the M&S group into all IT projects. The group tracks all software validation and facilitates some key software installation.



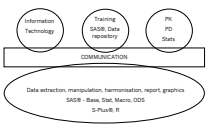
2007 M&S Prog vision

Involvement of Programmers in M&S Projects in 2006



In 2006, M&S Prog was involved in nearly 60% of the projects, with a ratio of 1 programmer for 6 modelers. There was a higher focus on late phase projects due to the complexity on data generation and the need for regulatory rigor.

Programmers skills



A good programmer, within M&S, must have strong technical SAS® programming skills and experience in data handling. S/he must be open to changes, innovative and creative. S/he must be able to convert (sometimes vague and changing) modeling requests into a dataset specification. Communication between the modeler and the programmer must be good, the programmer must understand the modeler's needs, the modeler must understand possible data issues and discuss with the programmer actions to be taken.
Data extraction and manipulation are the key components. All programmers have at least a Master-level statistics background, which allows them to conduct basic statistical analysis. Others have in addition an IT or scientific background, which allows them to do computational and modeling platform development work.

What are the main differences between a dedicated M&S Prog group vs. a Statistics department programming group ?

Dedicated M&S Prog group	Statistics department programming group
•Pool data across studies and programs	•Work at the study level – within a program
•Cope with ad-hoc dataset specifications, update the input dataset based on modeling results	•Follow the pre-defined specification

A strong similarity is that both groups are transparent about what they are doing and follow good clinical practices.

Prospects

Due to the diversity of talent in the group, we are considering to expand the role of the programmers to do more statistical analysis and commence PopPK analysis. The plan is to develop talented programmers into modelers, thereby providing a career ladder.

Conclusion

The authors believe that a dedicated programming group can significantly improve the efficiency of a modeling and simulation organization within a pharmaceutical company.

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