Quality, efficiency and industrialization initiatives during the evolution of a dedicated SAS programming group within a modeling & simulation department

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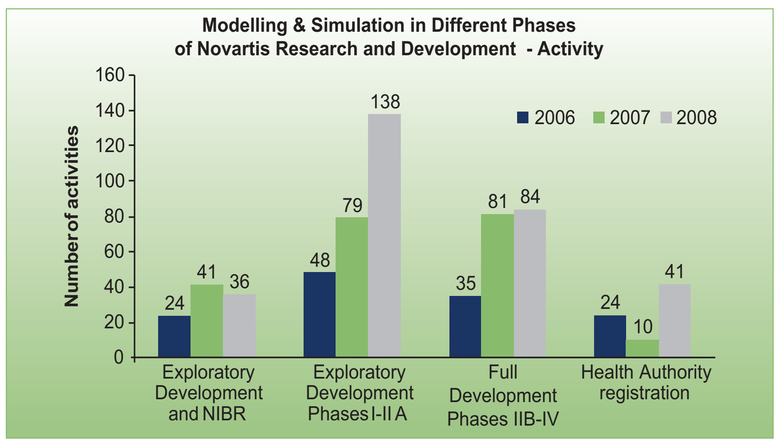
Background

- The role of modeling and simulation is currently expanding within pharmaceutical companies and becoming more recognized and valued by health authorities.[1, 2] The use of the methodology aims to provide excellence in quantitative support for informed decision-making from research through development to approval and beyond.
- To support the optimal development and use of drugs at Novartis, the Modeling and Simulation (M&S) department was created. M&S integrates the principles of biology, pharmacology, and statistics to address key decisions through the application of mathematical models. A dedicated group of programming scientists supports the modelers.
- The number and variety of requests addressed to the M&S department has risen each year (**Figure 1**).
- To address the growing demand, the M&S department had to adapt its structure and to increase its manpower. As a consequence, the programming group has grown and diversified.

Figure 1: *M&S activities are becoming entrenched within Novartis Research and Development since 2006*



- SAS programming remains the core competency however, the role has expanded. The roles of M&S programmers as compared to a traditional programmer have already been described in a former PAGE Congress.[3] We report herein about further experiences.

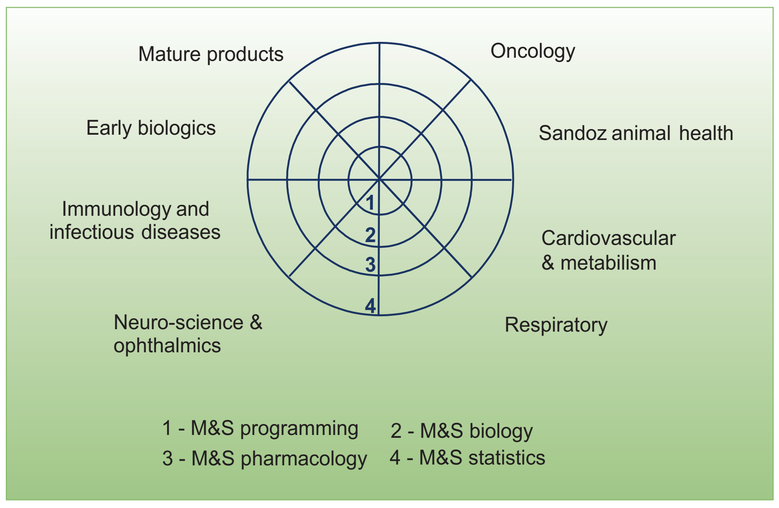
Objectives

- Highlight the opportunities and challenges that the continuing development of the programmer's role entails.
- Underline strategies for career development for associates working in such a group.

Methods

- The core role of the M&S programming group remains data preparation to support modeling while ensuring compliance with internal processes and regulatory guidelines.
- The following actions have been initiated for the programming group to extend its competencies:
  - The M&S department has defined "clusters" aligned with the main therapeutic franchises reflecting the customer base of the M&S department. Each cluster has a programmer assigned (**Figure 2**).

Figure 2: *The central role of M&S programmers within the overall matrix organization of Novartis M&S, and M&S partners and customers*

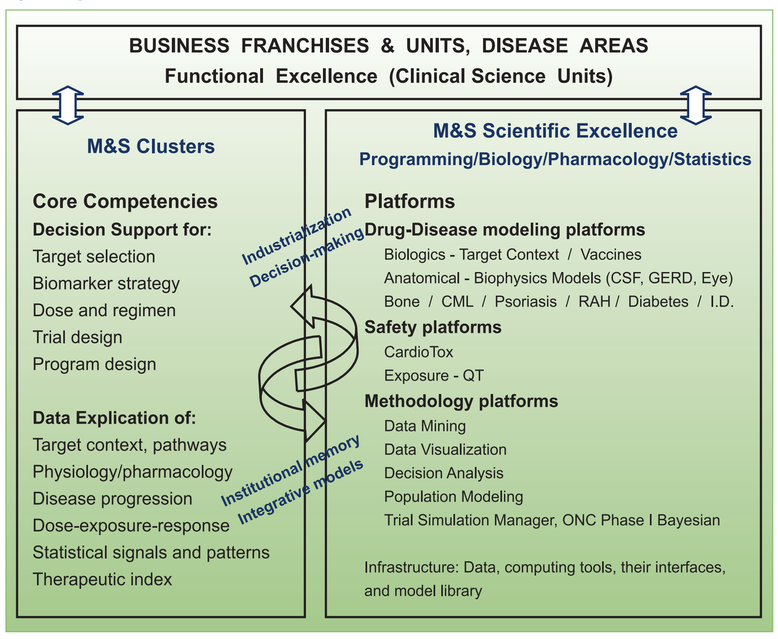


  - On the human resource side, a targeted hiring strategy has been applied in the programming group. The recruitment focused on Programmers with a combination of (1) Statistics, (2) Pharmacokinetics, (3) eCRF / data management, and (4) Drug development experience or (5) IT skills to M&S IT Infrastructure needs.
- The development of several industrialization tools have been initiated to
  - Automate routine requests,
  - Improve efficiency, and
  - Standardize working practices.

Results

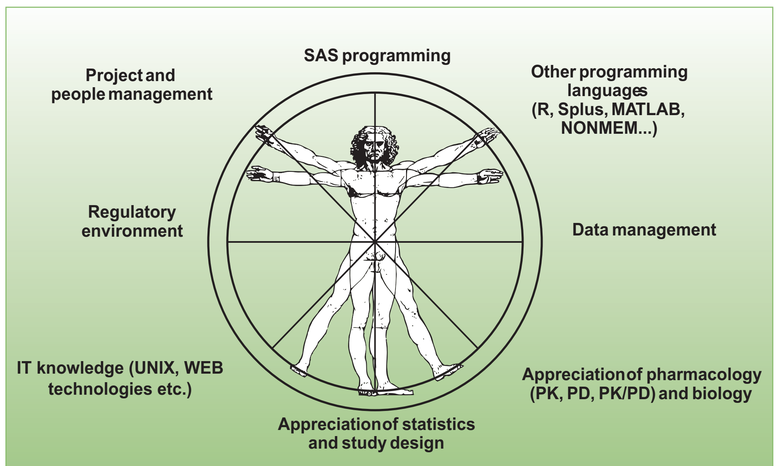
- Working in a cluster improves communication with M&S scientists and within the clinical team. Often, models and their input data are specific to the drug therapeutic area. The cluster framework thus allows programmers to get familiar and specialized with specific data requirements.
- The clusters enable information exchange between different projects in related indications to maximize cross-compound synergies. Also, this structure leads to a better anticipation and solving of recurrent issues ("platforms"), while remaining flexible (**Figure 3**).

Figure 3: *Platform structure to maximize collaboration synergies*



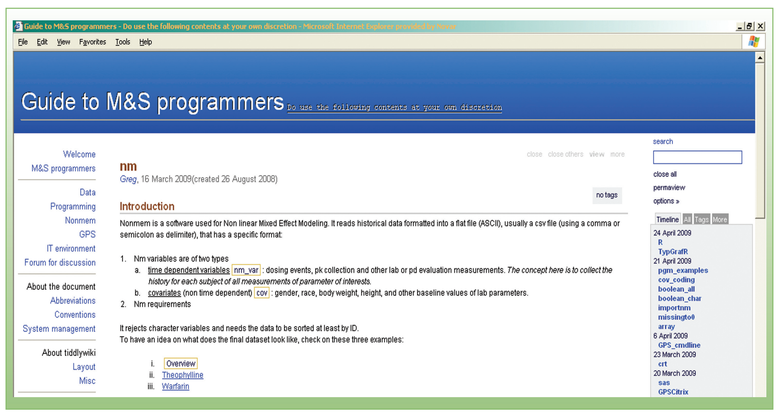
- With respect to individual career progression each step of building, growing and retaining associates requires specific attention.
  - Well defined core business perspective matched to the hiring strategy,
  - Adequate training to a new discipline, and
  - Further development of skills – both hard and soft using individualized development plans.
- Each M&S programmer has a unique value, defined by his / her set of skills, or combination of specialties as represented on **figure 4**.

Figure 4: *M&S programmers skills set*



- A typical profile for a programmer requires
  - Proficiency in ≥ 1 programming languages,
  - Databases skills,
  - An appreciation of the clinical science,
  - An eye for potential data quality issues,
  - An in-depth understanding of the regulatory requirements, and
  - A conceptual knowledge of how the data will ultimately be modeled.
- By facilitating communication through regular and informal meetings, on-line tools, the programming group is building a collective memory of best practices.
- To help new comers of the M&S programming group on-line tools are constantly being developed. *e.g.* a guide to new M&S programmers. It contains programming tips, data preparation hints, as well as other useful information for programmers (**Figure 5**).

Figure 5: *M&S programmers on-line guide*



- Another system for designing and agreeing data specifications is currently being developed. It should allow the modelers to request data according to types of analysis and format.
- Clear business guidance, programming standards, and standard tools to transform data are all used to streamline the daily work of the programmer. This ongoing process of continuous improvement is to speed up routine tasks, ease on-boarding onto new projects and transferring activities from programmer to programmer.
- To allow modelers to use published literature in their modeling efforts, a database is being developed,[4] (described elsewhere in this PAGE meeting). The objective is to allow a rapid search among published literature in order to extract relevant information from a *modeling* perspective to benchmark Novartis compounds against the current standard of care.
- The number of mathematical models developed at Novartis and elsewhere – pharmaceutical industry, academic groups, and regulatory authorities - leads to an increasing trend to "reinvent the wheel". The M&S group is developing a Drug and Disease Model Library to promote internally model re-use and to share externally the models which proved "useful". M&S / Programming is part of this ongoing effort.

Conclusions

- The structure in clusters of the M&S group allows a close and efficient collaboration between modelers and programmers.
- The great variety of competencies of the M&S programming group is essential to cover the expending responsibilities of this sub-group.
- The creation of tools which automate routine tasks leads to better efficiency.
- The critical role for a dedicated programming group that is integrated within an M&S department has been proven over the past years through numerous key deliveries and support. It has been estimated that such a group saves up to 70% of the modeler's time in data preparation, should he/she have to do that.
- As the M&S group at Novartis grows and together with the development of IT tools to improve efficiency it is likely that programmer's role will continue to develop.
- The diverse and expending responsibilities undertaken by programmers facilitate the development of new skills. Ultimately, this helps retain and motivate staff.
- In order to attract, develop and retain associates individual development plans are agreed between the individual and his/her manager. This is a means of distinguishing the group from the traditional role played by SAS programmers in the industry.
- A key factor in driving model-based drug development[5] in a pharma M&S department is to maximally use such a group to support efficiency and industrialization efforts. Together these actions should improve the productivity of the M&S group at Novartis to support the rising demand from internal and external customers.

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