CASE STUDY

POINTING THE WAY TO THE FUTURE OF MANUFACTURING

SEVENTH FRAMEWORK PROGRAMME

Modelling & Simulation department

NOVARTIS

Novartis www.novartis.com

Novartis International AG is a Swiss multinational pharmaceutical company based in Basel, Switzerland, ranking number one in sales among the world-wide industry in 2013.

The Modelling & Simulation department at Novartis Pharma AG supports the optimal development of therapeutic drugs through the application of mathematical models. Principles of biology, pharmacology, and statistics are integrated in order to explain and to predict the quantitative consequences of decisions. Novartis M&S has very strong experience in model development, development of computational tools for simulation and analysis, and the application of models and their simulation across the complete drug discovery and development process.

Simulation and Forecasting Technology role
Optimal development, mathematical modelling, process development

Sector
Pharmaceuticals

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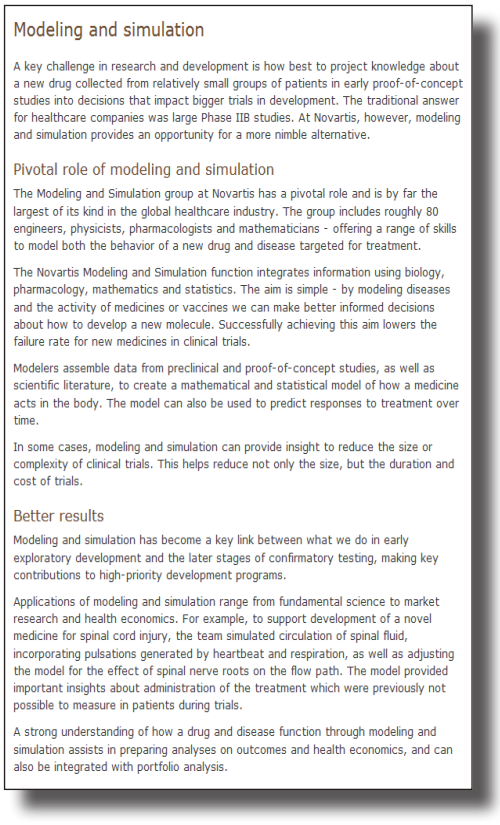

Modeling and simulation

A key challenge in research and development is how best to project knowledge about a new drug collected from relatively small groups of patients in early proof-of-concept studies into decisions that impact bigger trials in development. The traditional answer for healthcare companies was large Phase IIB studies. At Novartis, however, modeling and simulation provides an opportunity for a more nimble alternative.

Pivotal role of modeling and simulation

The Modeling and Simulation group at Novartis has a pivotal role and is by far the largest of its kind in the global healthcare industry. The group includes roughly 80 engineers, physicists, pharmacologists and mathematicians - offering a range of skills to model both the behavior of a new drug and disease targeted for treatment.

The Novartis Modeling and Simulation function integrates information using biology, pharmacology, mathematics and statistics. The aim is simple - by modeling diseases and the activity of medicines or vaccines we can make better informed decisions about how to develop a new molecule. Successfully achieving this aim lowers the failure rate for new medicines in clinical trials.

Modelers assemble data from preclinical and proof-of-concept studies, as well as scientific literature, to create a mathematical and statistical model of how a medicine acts in the body. The model can also be used to predict responses to treatment over time.

In some cases, modeling and simulation can provide insight to reduce the size or complexity of clinical trials. This helps reduce not only the size, but the duration and cost of trials.

Better results

Modeling and simulation has become a key link between what we do in early exploratory development and the later stages of confirmatory testing, making key contributions to high-priority development programs.

Applications of modeling and simulation range from fundamental science to market research and health economics. For example, to support development of a novel medicine for spinal cord injury, the team simulated circulation of spinal fluid, incorporating pulsations generated by heartbeat and respiration, as well as adjusting the model for the effect of spinal nerve roots on the flow path. The model provided important insights about administration of the treatment which were previously not possible to measure in patients during trials.

A strong understanding of how a drug and disease function through modeling and simulation assists in preparing analyses on outcomes and health economics, and can also be integrated with portfolio analysis.

PATHFINDER