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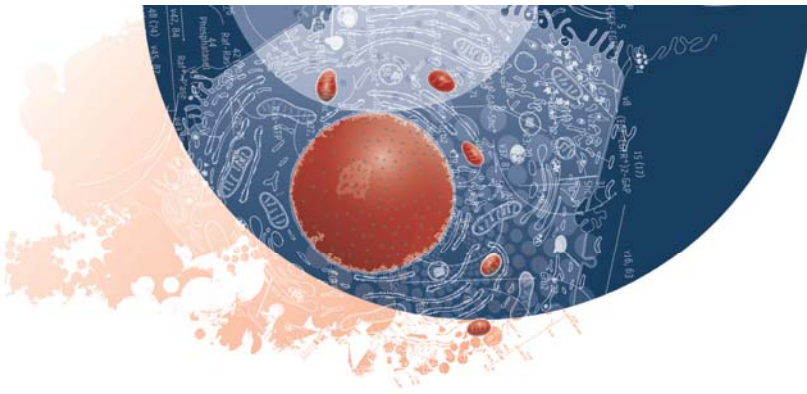

APPLYING COMPUTATIONAL SYSTEMS BIOLOGY TO PHARMACEUTICAL R&D

Jörg Lippert

Bayer Technology Services GmbH, Leverkusen, Germany

Along the whole life cycle of pharmaceutical R&D projects as well as in project portfolio management, two classes of scientific questions are of utmost importance. The first question is whether a drug candidate or a therapeutic concept is still promising. It addresses the development success probability of a project and the answer decides about continuation or discontinuation of a project or a development program. In case of continuation, the second question is how to design the next project steps. Getting the answer to both questions is challenging due to several specifics of pharmaceutical development programs. Successful projects run for more than ten years with hundreds of scientists contributing to the program. The results of the countless experiments performed until a given project step are already hard to grasp for individual decision makers. Interpreting the available information and predicting the consequences is literally impossible for any human mind. By contrast, the ethical, medical and economic pressure to do so is extremely high whatsoever. Once in clinical development, every decision directly impacts on the medical condition of patients and volunteers. Individual late stage clinical trials may cost more than a billion Euros and success or failure in such huge trials decide about the future of pharmaceutical companies with tens of thousands of employees.

Mechanistic modeling & simulation, computational systems biology contribute to improved understanding and better informed decisions from early stage discovery projects through clinical development projects to product life-cycle management. The integrative nature of systems biological models allows to represent the diversity of knowledge, assumptions, information and data established and generated during R&D projects and available from public sources. The explicit and implicit check of consistency of this information landscape, the identification of potential conflicts is a first major contribution of modeling & simulation and helps to maintain or challenge confidence in a project's success. The translation of available information into predictions for future project steps is the second contribution. Efficient prediction ensures the optimal design of experiments and maximizes the scientific, medical and economic success probability of the project.

To illustrate the role of computational systems biology, project examples will be presented and the impact on pharmaceutical R&D projects will be discussed.