

Joint Event

21<sup>st</sup> International Conference and Exhibition on

**Materials Science and Chemistry**

**33<sup>rd</sup> Annual European Pharma Congress**

5<sup>th</sup> World Summit on

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## **Identifying the sweet spots in milestone decision making–Monte Carlo simulation of net present value for pipeline projects in pharma**

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Uncertainty is by definition an unpreventable aspect of all projects. In the pharmaceutical industry development projects for a New Chemical/Biological Entity (NCE/NBE) are generally associated with low probabilities of success compared to other industries. Assessing the sweet spots of favourable risk-return-relationship in milestone decision making of pipeline projects–also under a portfolio point of view–is tricky but nicely achievable.

At start of development, a project's rate of success is only 4% to 7%, the time span of a project from start of development to the potential launch of a product being 10 years or even more. Thus, effective management of commercial risk and uncertainty becomes tremendously important.

The Pharmaceutical Benchmark Forum in the United States collected industry-wide historical data on the drug development process. The result of this research shows that the total project development costs for a NCE which reaches the market are in the range of \$1 billion. The actual costs of a successful project are usually significantly lower, but every successful project needs to cover the costs of multiple other projects which did not in the end reach the market.

In addition to the low success rates of pure development, further uncertainties affect the continuation of a project and its final accomplishment. Examples are commercial risks like the potential competitive landscape a product faces at launch, the uncertainty whether a certain Target Product Profile (TPP) can be achieved, pricing, market access risks and others (the TPP defines the potential product characteristics and benefits, like the drug's efficacy, safety and formulation at launch). All these factors are dynamic over time, thus complicating the forecasting of these projects. As the development progresses over the years the potential TPP evolves gradually, resulting in success or failure–and therefore financial gain or loss.

The path to get FDA's and EMA's approval to market a new drug is uncertain and the project must overcome several hurdles. So best informed milestone decisions must be taken. The–at least historical–success rates and time spans for each development step are known and can be used as a proxy for the implied future success rates in a Monte Carlo Simulation Model.

**To summarize:** The mixture of high and early upfront investments and a high uncertainty about a project's development and commercial success puts pressure on forecasting and even more on controlling, which aims to show a balanced picture of the project's opportunities and risks. Here the reliability and transparency of strategic forecasts become key success factors to support senior management in their decision-making process. Often

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risk and uncertainty are (closely) intertwined, leading to misinterpretation of forecasts and erroneous decisions.

Patient-based strategic forecasts, with certain base, best and worst-case scenarios are an important source of information within the process of development. Even though, these types of forecasts all plan for success of the project, which is human nature. But unfortunately, this is the case associated with the lowest likelihood compared to the unfortunate more likely failure of a pharmaceutical pipeline project.

To make this risk of failure transparent, Monte Carlo Simulation is a useful and powerful method to simulate each project's Net Present Value (NPV) distribution at each time, a milestone decision must be taken. When combining these NPV simulation results with the patient-based scenario forecasts, Senior Management can compare different projects more equally and should be able to manage a company's overall portfolio development risk more accurately and take more informed decision. Monte Carlo Models do not need to be over complex and as such are nicely explainable to Management, which generates trust in the results. Without trust in the validity of the method a forecast is worthless. That's a big plus compared to other even more sophisticated forecasting methods.

There is a high degree of competition between the different pipeline projects of a company to get budget for the next phase of development. So the NPV simulation of each project should be standard information included at each milestone decision to be taken. It's not only the commercial attractiveness of a new product, measured in peak sales, which plays a role. It's like in other businesses: Identify the sweet spot of a favourable risk and return relationship to run a company's pipeline development successful and maximize a company's mid to long term wealth.

## **Biography**

Christian Schäfer is a Full-Professor at the Department of Business Administration at Baden-Württemberg Cooperative State University Mannheim (DHBW) Germany. He teaches quantitative Methods, simulation in strategic forecasting and market research in healthcare. His research interests are in the fields of quantification of uncertainty, *Patient-Behaviour-Modelling* and Partial Least Squares Structural Equation Modeling (PLS-SEM). He also runs special forecast-simulation and market research projects for the Pharmaceutical Industry. Prior to taking this role in 2015, he covered different Management and Director Positions in Marketing, Competitive Intelligence, Strategic Forecasting and PM-Strategy within two International Pharmaceutical Company for 8 years. He earned a Diploma (Master) in Economics, a Master of Business Administration (MBA) degree from University of Gavle, Sweden and received his PhD (Dr.) from the Department of Business Administration and Economics at Johannes Gutenberg-University Mainz, Germany, where he worked 4 years as a research assistant. He published more than 25 articles and 4 Books.

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