

Simulation Modeling to Predict Drug Pipeline Throughput

Jeff Heyman, LGO 2010

Company Background

Novartis AG is a global leader in pharmaceuticals, vaccines, generics, and consumer health products. Its mission is to discover, develop and successfully market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life.

- Headquartered in Basel, Switzerland
- 100,000 associates in 140 countries

Novartis Institutes for Biomedical Research (NIBR) is the global research organization of Novartis. Its research approach prioritizes **patient need** and **disease understanding**, and emphasizes **proof-of-concept trials** – small-scale studies used to get an early read on the safety and efficacy of drug candidates.

- Headquartered in Cambridge, MA
- 2008 R&D investment = \$7.2B, or 17.4% of sales

Source: Novartis Company Website: www.novartis.com

Project Background

Pharmaceutical R&D involves considerable uncertainty, including:

- High attrition** – a large number of projects must be undertaken to yield a relatively small number of compounds that enter clinical development; the likelihood of commercial success for any single discovery project is extremely low.
- High project-to-project variability** in time and resources required to reach subsequent phases of development
- Long concept-to-commercialization time (~8-12 years)**

Senior leaders must make decisions today about pipeline size and balance, the impact of which will not be observable for many years.

NIBR's Portfolio Management Group (PMG) aims to create tools that aid senior management in understanding pipeline status and progress. The PMG cites **forward projection** as a desired capability not currently achieved in a systematic, aggregated fashion. Key questions include:

- Given the current pipeline, **how many successful proof-of-concept (POC) studies can we expect in x-years?** To achieve a desired number of POCs in x-years, **what should our pipeline look like?**
- How can various **pipeline levers** affect pipeline productivity?

Internship Objectives

Primary goal: To create a forward-looking pipeline model that

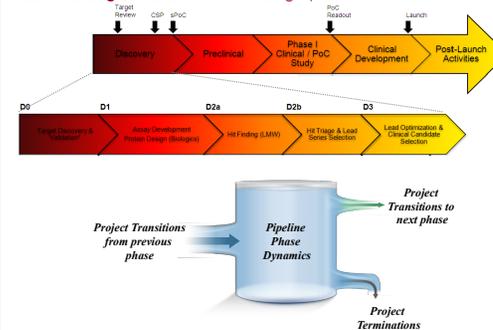
- Accounts for system complexity and uncertainty
- Incorporates historical performance data
- Is easy to use to support real-time managerial decisions

Expected benefits: Bridging strategy and execution by facilitating

- Scenario Analysis
- Resource Planning
- Portfolio Gap Identification and Resolution

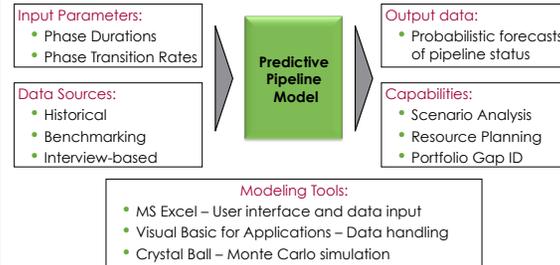
Approach

Understanding the Real-World: The Drug Pipeline

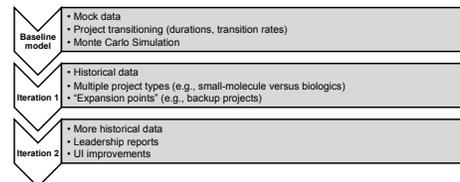


Source: NIBR Program Office

Modeling the Real-World: Scoping and Data Collection

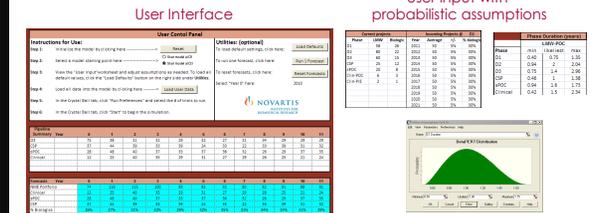


Planning Model Development: Iterative, Incremental Design

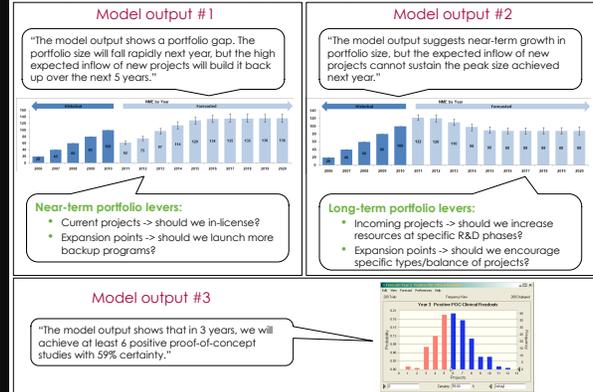


Results*

Model Structure:



Driving strategic decision-making: (examples)



*Note: Shown data is for demonstration purposes and not representative of Novartis' actual research portfolio.

Conclusions

Model Assessment:

- Accuracy:** Validation against historical data shows good predictability for aggregate forecasts, but weaker predictability for finer metrics; questionable historical data represents greatest source of error
- Usability:** Iterative design and frequent user feedback led to extremely user-friendly design; Fast simulation time (e.g., 1-3 minutes) allows real-time scenario analysis
- Leadership buy-in:** Strong response from research management; will present new capability to broader NIBR leadership in February 2010; trained an internal technical expert and champion to allow future model growth.