

Simulation Modeling to Predict Drug Pipeline Throughput

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Faculty Supervisors:

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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
 surce: 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 xyears, what should our pipeline look like?
- How can various pipeline levers affect pipeline productivity?

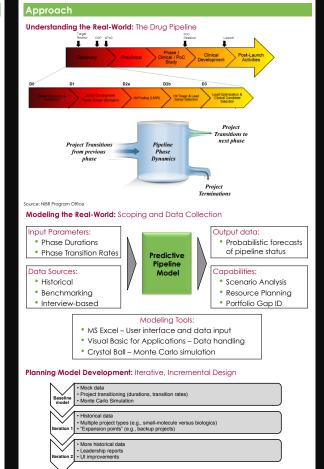
Internship Objectives

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



Results*	
Model Structure:	User input with
User Interface	probabilistic assumptions
Instructions for Use: Utilities: (optional) State: Installer for endel is diding here	200 50 59 59 50 FOC 0.04 2.0 2.15 200 50 59 59 50 Clinical 0.42 2.5 2.54
Driving strategic decision-making: (examples)	
Model output #1	Model output #2
"The model output shows a portfolio gap. The portfolio size will fall rapidly next year, but the high expected inflow of new projects will build it back up over the next 5 years."	"The model output suggests near-term growth in portfolio size, but the expected inflow of new projects cannot sustain the peak size achieved next year."
Near-term portfolio levers: • Current projects -> should we in-license? • Expansion points -> should we launch more backup programs?	Long-term portfolio levers: Incoming projects -> should we increase resources at specific R&D phases? Expansion points -> should we encourage specific types/balance of projects?
Model output #3	
"The model output shows that in 3 years, we will achieve at least 6 positive proof-of-concept studies with 59% certainty."	
*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 	

 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.

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