SIMPLE APPROACHES FOR PORTFOLIO QUANTITATIVE DECISION-MAKING

Hugo Hadjur[1], Véronique Robert[2], Jean-François Collin[3], Gaëlle Saint-Hilary[1]

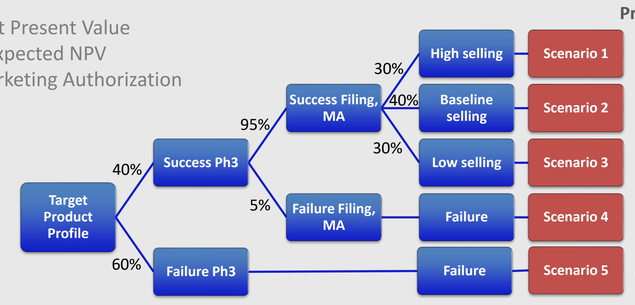
1 Quantitative decision-making and target product profile

Quantitative decision-making is an approach that involves the use of mathematical, statistical, and computational techniques to analyse data and inform decision processes. It guides strategic and operational choices at the stages of drug development (study, development or portfolio level).

This work focuses on the **portfolio level** and helps to determine the **strategy** (go/no-go and selection of development projects), the **financial resource allocation** and the **return-on-investment** evaluation.

Example of NPV calculation for one Target Product Profile of one drug

NPV: Net Present Value
eNPV: Expected NPV
MA: Marketing Authorization

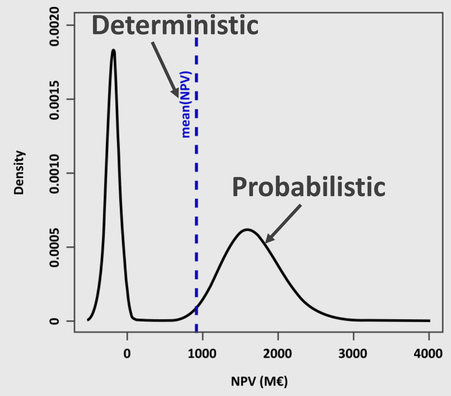


	Probability	NPV (M€)	Probability × NPV
Scenario 1	11.4%	30	3.42
Scenario 2	15.2%	25	3.8
Scenario 3	11.4%	20	2.28
Scenario 4	2%	-10	-0.2
Scenario 5	60%	-8	-4.8

eNPV = 4.5 M€
(= 3.42 + 3.8 + 2.28 – 0.2 – 4.8)

2 Objectives

From a deterministic to a probabilistic mindset in decision-making

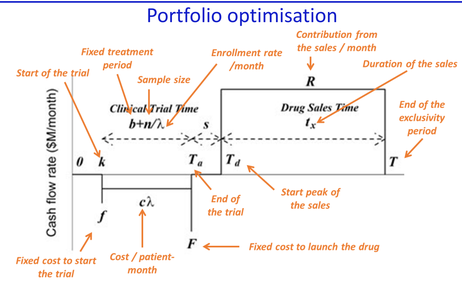


Example at the project level:
$Prob(NPV > 0\ M€) = 60\%$ "min value"
$Prob(NPV > 1000\ M€) = 58\%$ "target value 1"
$Prob(NPV > 2000\ M€) = 11\%$ "target value 2"

1. At the portfolio level, estimate the **probability to reach a target number of Marketing Authorizations** (MAs) over time
2. **Simulate the financial sustainability** of the portfolio and compare different portfolios
   → Calculate the probabilities to have:
   Portfolio Net Present Value (NPV) > pre-specified targets

Scale of complexity for portfolio decision-making

Portfolio optimisation



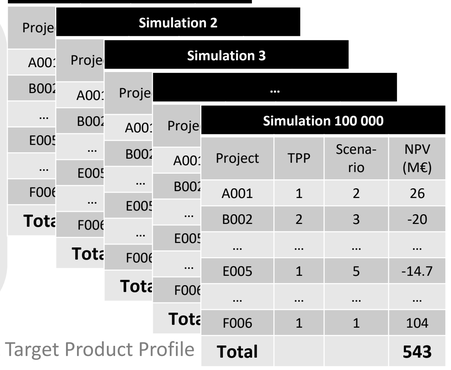
Patel et al. (2013), A mathematical model for maximizing the value of phase 3 drug development portfolios incorporating budget constraints and risk. (Statist. Med.)

Industry benchmark and subjective assessment

Usually provide limited (and sometimes unreliable) information

3 Our method

- **Monte-Carlo simulations: permit to assess the variability of the number of MAs and portfolio NPV**
- **Descriptive statistics: mean, median, variance, confidence intervals**
- **Prob(number of MAs > target)**
- **Prob(portfolio NPV > target)**



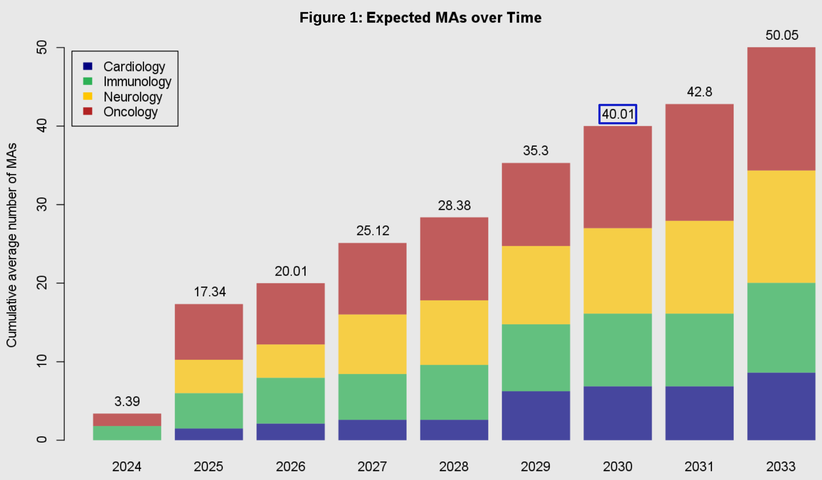
TPP: Target Product Profile

- Necessitate a substantial amounts of resources, input data and assumptions
- Challenging communication with governance boards
- Need knowledge from experts from many different teams (statistics, finance, strategy, regulatory affairs…)

4 Simulation and results: fictive portfolio of 76 projects in 4 therapeutic areas (oncology, neurology, immunology, cardiology)

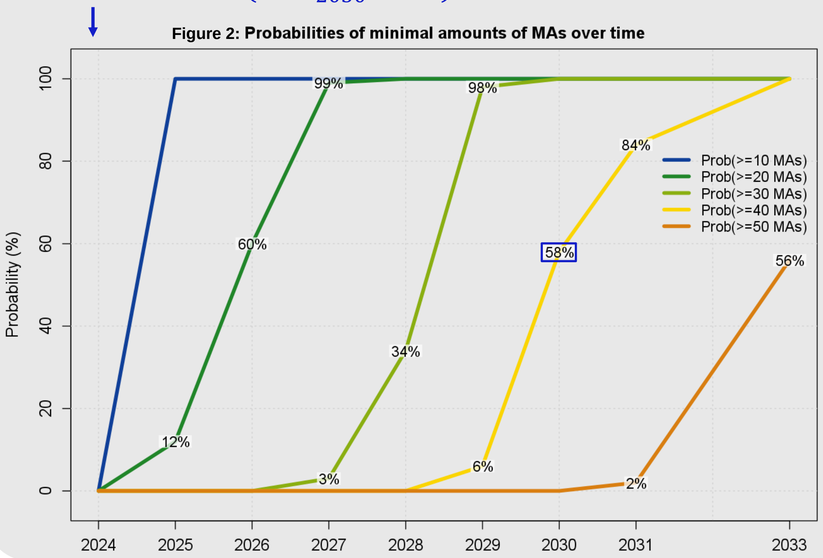
Marketing Authorizations

Figure 1: Expected MAs over Time



Deterministic: $Mean(MAs_{2030}) = 40.01$
Probabilistic: $Prob(MAs_{2030} > 40) = 58\%$

Figure 2: Probabilities of minimal amounts of MAs over time



NPV

- Simulations allow to **identify quantiles at a certain time**. In the example of Figure 3, the median NPV in 2033 is 497.3M€, there is a 75% probability to generate more than 435.3M€ and a 25% probability to generate more than 555.2M€
- **Uncertainties are taken into account in the simulations**: around the probability of MA, the timing of MA, the costs and the revenues. Results between different scenarios (different types of curves on Figures 4 and 5) can be compared.

Figure 3: Distribution of NPV in 2033 (probabilistic always on time)

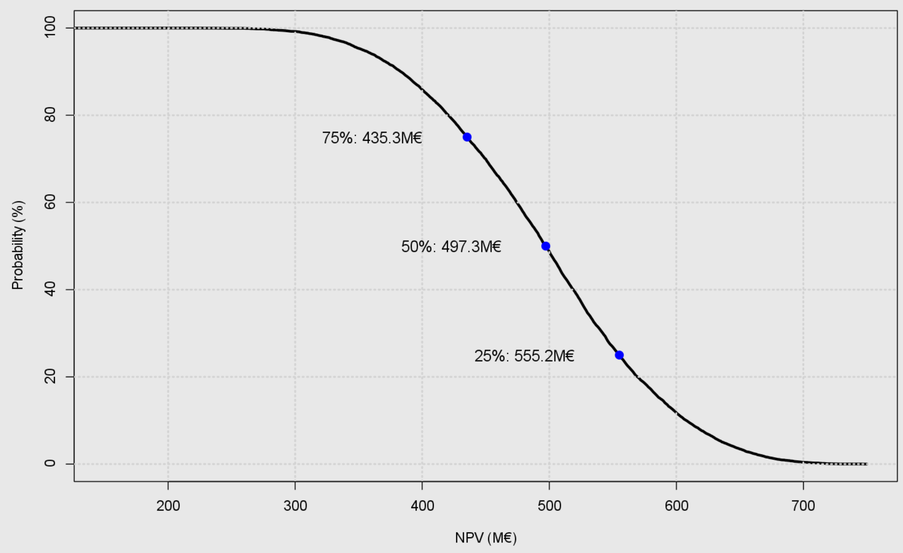


Figure 4: Probabilities of minimal amounts of NPV over time

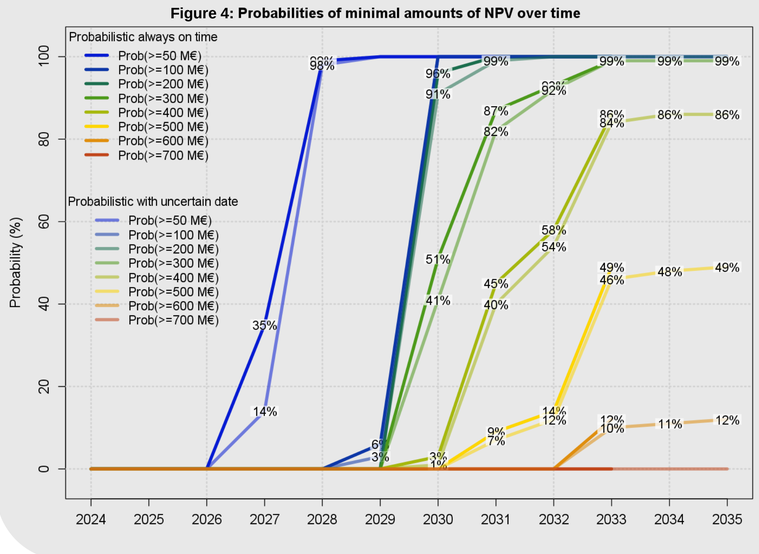
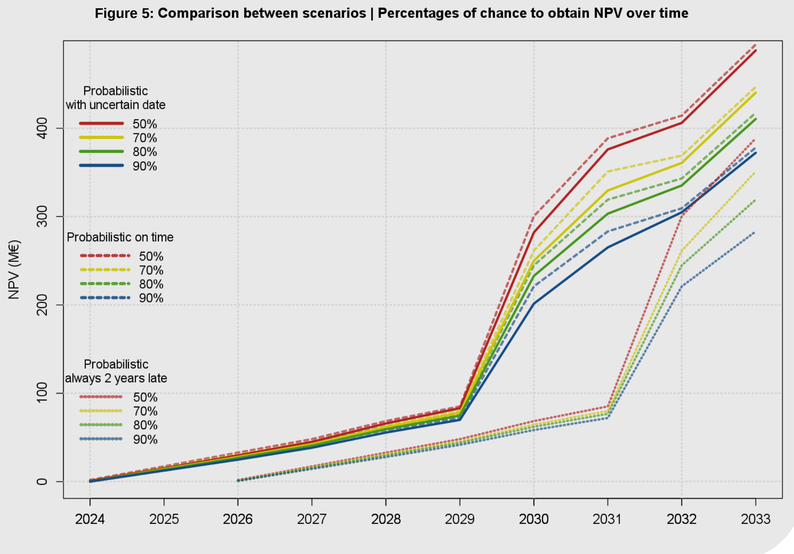


Figure 5: Comparison between scenarios | Percentages of chance to obtain NPV over time



1 Department of Statistical Methodology, Saryga, Tournus, France
2 Daiichi-Sankyo Oncology, France
3 Ceva, France