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Evaluation of R&D investment projects for a new pharmaceutical product

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***Abstract* —**

The decision to invest in an uncertain situation is by definition risky. It often leads the decision-maker to buy additional information to limit the risk of wrong conclusions. But is it still a good solution? The objective of this state of the art synthesis is to present the different models for evaluating development strategies in situations of uncertainty in order to confirm the interest of carrying out a preliminary study to obtain new information. The models with the alternatives are all based on Monte Carlo method.

***Keywords*— risk management, decision, uncertainty, Monte Carlo simulation, R&D project, investment strategy, choice.**

I. INTRODUCTION

"To speak truthfully," wrote Keynes in 1936 [1], "we must admit that to estimate ten or even five years in advance the performance of a railway, a copper mine,[...] a pharmaceutical brand,[...] the data available to us are reduced to very little, if anything". Many hazards (climatic, political, social, etc.) frequently upset future estimates and are unknowns that underline the fundamental nature of uncertainty. However, every day, many decisions, including decisions investment, are taken by business leaders.

The launch of the development of a new product, such as a new drug, is an example of these many decisions. This investment, a long and risky process, is also subject to many uncertainties (technical, regulatory, market, etc.). Here, the company manager makes his decision while it has little knowledge of the future (development costs, costs of production, market size, drug performance, competition, etc.), it therefore takes many risks, the result of which could be the risk of failure of the investment.

The long development period, disruptions or changes in the project environment, the progressive acquisition of knowledge about the product, technical hazards are all factors that make it necessary to identify and describe several scenarios, particularly those of launch/pursue and shutdown. These factors are parameters that are difficult to estimate at the time of the decision. However, a choice must be made on the based on the only available data.

Be that as it may, a common point among all decision-makers is the desire to acquire additional information to ensure their decision. In the research and development community, this strategy of acquiring complementary information consists of conducting "preliminary studies", later referred to as pilot studies.

The evaluation of R&D projects has generated a lot of work. A study by Schwartz et *al.* [2] supplemented by Costello [3] and Danila [4] lists existing approaches and their use. We propose to classify the different approaches identified according to whether they allow:

- Maintain the multi-criteria dimension in the analysis (scoring method, check list, purely qualitative grid, strategic evaluation matrix BCG (Boston Consulting Group);

- To aggregate these criteria into a single criterion: economic (Net Present Value or NPV, return on investment

period for example) or without a specific work unit (multi-criteria methods such as AHP (Analytical Hierarchical Process);

- To preserve intuitive elements in the decision-making process (e.g. group work methods, nominal group technique, etc.).

II. INDUSTRIAL AND PROBLEMATIC CONTEXT: PHARMACEUTICAL R&D PROJECTS

In the pharmaceutical sector, new drug projects are uncertain and risky; only one in 20 projects will be successful and will see the commercialization of a new drug [1],[5]. The main causes of this high level of risk are: the complexity of the studies, the length of the development phase (10 years or more) likely to change the environment, the fragility of patent protection and the importance of economic issues if successful.

In addition, the major risks of a pharmaceutical R&D development project are related to the characteristics of the studies that make up the development [6]. These risks are classified into several categories: technical risks, competitive risks, economic risks, etc. They may be of internal origin to the project (for example related to the characteristics of the molecule such as the chemical instability of the molecule), or even (e. g. related to the competitive environment such as the detection of a competing molecule in development). The nature of the impacts and their importance can lead decision-makers to stop a project.

Indeed, in recent years, investors have shown certain mistrust towards companies designated as belonging to this new economy. The presentation of fixed results (e. g. business plan) makes potential investors even more confused [7]. The use of methods capable of taking into accounts the risks and uncertainties of these types of investments has now become a necessary step. The investor needs to see the potential of his investment but also to measure the risk he takes.

The problem is thus reduced to the development of an economic evaluation model for pharmaceutical R&D projects capable of integrating more realistic perspectives by considering that the project may follow different trajectories than initially planned and expected, to take into account the variability of the parameters during the project and ultimately to break the project down into sub-projects associated with different indications.

The development of the final product may therefore include parallel or sequential clinical trials in several indications, particularly for products designed to strengthen the immune system of patients.

III. THE SELECTION OF INVESTMENTS

Our objective in this synthesis is to present the model proposed in various research studies, intended to help in the choice between these different developments strategies. In the many studies, a strategy has always been considered an investment. The problem of choosing between several pharmaceutical developments strategies is thus oriented towards a selection problem between different investments in an uncertain situation. The selection of investments most often refers to the evaluation of their profitability. In the study [8] there was no mention of so-called multi-criteria methods, Zopounidis [9]. These methods do not generally make it possible to reconcile economic indicators and temporal phenomena.

R&D projects can be considered as investment (projects). Like each strategy we wish to analyse, they correspond to the category of "continuous input - continuous output" investments presented in Lutz's classification [10]. This means that expenses are spread over several years, as are revenues.

Much work has focused on investment evaluation and selection issues in general [11] or more specifically in situations of high uncertainty, such as R&D projects [12]; [13]; [14]; [4]; [3].

The Investment Choice Criteria are a set of financial decision support tools that provide managers with the means to evaluate and compare different competing investment projects. There are two types of criteria: time criteria such as payback period, and economic criteria such as net present value, profitability index and ultimately internal rate of return.

IV. PROPOSED MODEL

Several models have been proposed in the various studies, such as study [15] and [6], which respectively present an evaluation model that, based on positive and negative cash flows and their uncertainty, makes it possible to reproduce a criterion of expected profitability with its distribution. The

second model [6] is based on a formalism of the decision tree type. The decision tree allows you to compare three development strategies: The first is to carry out the project according to a "R&D tunnel", i.e. without buying any information complementary, the second is to carry out the project by successively carrying out a pilot study and a pivotal study (split R&D) or the last to stop the project immediately and do nothing.

The model, applied to a new development project drug is coupled to a Monte Carlo motor.

By utilizing Monte Carlo simulation method, the dissemination of every conceivable result of an event is created by dissecting a model a few times, each time utilizing arbitrary information esteems chose from the likelihood dispersions considered ordinary of the parts that include the model.

A. Monte Carlo Method, concept and historic evolution :

Monte Carlo reproduction technique appearance is put around the year 1944. This strategy has seen numerous translations, got different definitions, thusly we can express that this technique has come a long and procedure of advancement and improvement. At first, an imperative issue of the technique [16] was to create vast arrangement of irregular numbers. In the main stage, there were utilized pseudo-arbitrary numbers, and after that, with the improvement of PC innovation, this obstruction has been expelled.

These days, the generally low computational exertion contrasted with the trouble of the issues that could be comprehended, makes this technique great to tackle an assortment of issues, with less exertion.

Monte Carlo technique produces fake estimations of a probabilistic variable by utilizing an irregular consistently circulated number generator in the [0, 1] interim and furthermore by utilizing the total dispersion work related with these stochastic variable.

Recreation of financial choices can be connected to all evaluations of issues that incorporate working principles, approaches and methodology, for example, those concerning the choice adjustment, choice control and value strategy.

The activity of reenactment procedure isn't, truth be told, a procedure of choice improvement. Taking care of issues utilizing reenactment procedures includes the utilization of intuitive calculations and the presence of very much decided strides so as to accomplish the goal. The information are normally irregular factors created by an arbitrary number generator.

The method algorithm is shown in its succession interactive five steps:

Step 1: Creating a parametric model, y = f(x1, x2, .., xq) ;

Step 2: Generation of random input set of data, xi1, xi2, ..,xiq;

Step 3: Effective calculations and memorizing results as yi;

Step 4: Repeating steps 2 and 3 for i = 1 to n (n ≥5000);

Step 5: Analyzing the results using histograms, confidence intervals, other statistic indicators resulting from the simulation, etc.

The crucial distinction among deterministic and stochastic models is shown in *Figure 1*. This figure speaks to the two models, deterministic and stochastic.

Parametric deterministic model builds up a lot of info factors, answered to a lot of yield factors. In the stochastic model of engendering of vulnerability, the information factors are randomized (being portrayed by an irregular dissemination) and the outcome will be arbitrary also, generally following the Normal Distribution. This is the essential rule of Monte Carlo recreation.

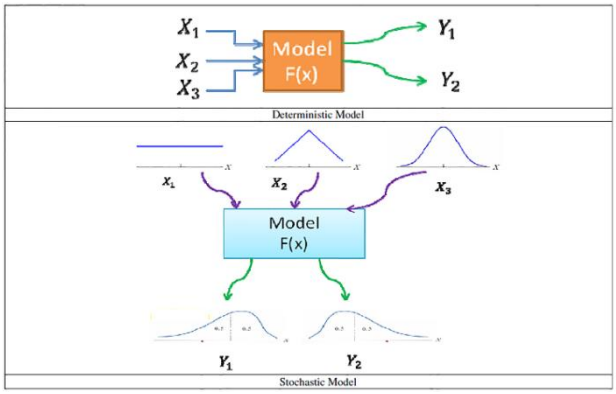

Figure 1: Deterministic and stochastic models.[17]

As pointed out, learning of risks is vital as it encourages us to discover how it influences interest in monetary and money related terms.

Monte Carlo technique is moderately simple to perform and gives vital data with respect to the dangers of venture ventures.

After recognizable proof, investigation and assessment of subjective and quantitative monetary and budgetary risk of speculation ventures, there might be distinctive techniques and methodologies for overseeing and reacting to risks.

V. CONCLUSION

In this synthesis, we have proposed different models for evaluating development strategies for highly uncertain projects such as R&D projects.

The application presented is a pharmaceutical development. This model, based on Monte Carlo simulation, takes into account the specificities of projects in this sector to ensure a more accurate evaluation of the value of these products and to allow the choice of an optimal development strategy.

It should be noted that most of the models identified in the literature or with evaluation practitioners are adapted to relatively certain situations, i.e. for projects whose outcome is easily predictable (high chances of success) and where the uncertainty about the data being manipulated is low.

In our thesis project, unlike conventional models, we would discuss an approach that is perfectly applicable to early projects (upstream phases, preliminary project) as well as highly uncertain projects such as those in the pharmaceutical sectors.

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