Real options as sustainable business evaluation method in the biotech and med-tech industry. A qualitative and empirical approach.

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Real options as sustainable business evaluation method in the biotech and med-tech industry. A qualitative and empirical approach[1].

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ABSTRACT

Business sustainability can be defined as strictly related to the combination of environmental, societal, ethical and economical concerns in process, goods/products and services development by making the best use of innovation and research and development as drivers to overtake the competition. This is often defined as the capacity in managing the "triple bottom line" (Elkington, 1994): a process by which companies are involved in financial, social and environmental problems and opportunities, with implications in terms of profits, people and planet, since industrial, social, and ecological systems are closely linked (Fiksel, 2006). Business connected to what we can call social concerns creates economic value and contribute to healthy ecosystems and strong communities, feeding the "systemic living vision" (Golinelli, 2009) they work in. Moreover, this social and environmental involvement not only represents a strategic lever to beat the competition, but is a strategic driver to improve the value and the image of a certain territory and, by consequence, to decrease the foreign investors' perceived risk in investing capitals. We finally talk about the sum of policies and practices that can buster companies' competitive power meanwhile they improve community economic and social conditions (Porter, Kramer, 2011).

The aim of this study is to examine which evaluation methods can be utilized to guarantee the sustainability of innovative start ups in the biotech and med-tech industry.
In particular our empiric analysis examines the projects' evaluation instruments utilized by the Bioindustry Park, the managing company of the innovative cluster called bioPmed that is dedicated to bio and medical technologies (Italy). This biotechnological and med-tech cluster expresses the will to concentrate the know-how of the territory in a restricted area with a high concentration of structures and facilities for the development of firms. The projects of the innovative companies and start ups are principally based on products development both in biotech (pharma and diagnostic) and in innovative medical technologies. Long development processes, regulatory requirements, potential patent issues, strong competitive environment, are main elements of such markets. Evaluation plays an important role for these companies, both to raise funds, that can be a key factor in order to develop alliances and partnerships. However, for the same market elements, the evaluation process is difficult and risky. Too many variables have to be considered in a long timeframe.

The expected result is the analysis of possibility to the adapt the real options model as a method for the evaluation to guarantee the sustainability of innovative companies and start ups in the biotech and med-tech industry.

Recourse to the real options' method stimulates investment to build sequences of long multi-stage (i.e. continue or abandon the project, reduce or increase the investment). So this method can be particularly useful to identify risks with greater awareness and to select the biotech and med-tech projects that more than others can guarantee the businesses' sustainability.

Keywords: sustainability; social innovation; real options; evaluation methods; biotech and med-tech industry.

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1. INTRODUCTION

During the 1980s and '90s serious environmental problems, such as the reduction in the ozone layer and climate changes, caused a greater focus on the concept of '*sustainable growth*'. Nevertheless, the literature at that time still concentrated mainly on humanity's condition, recognizing man's dependence on nature.

The definitions of sustainability found in the literature are numerous and controversial, and these can be divided into three main areas (Mebratu, 1998):

a. *institutional version*: these represent definitions by international bodies;

b. *ideological version*, based on ideologies such as liberation theology, radical feminism and eco-socialism;

c. *academic version,* which can be attributed to conceptualizations by economists, ecologists and sociologists.

The most relevant and quoted definition is the one from the report entitled, "*Our Common Future*", published by the WCED (*institutional version*):

> *«Sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs»* (the "Brundtland Commission", 1987).

The modern concepts of sustainability began to take shape during the 1990s. Recent years have seen a proliferation in the business and management literature, with an explosion even of the international literature, in which sustainability is the main theme and is used to describe problems related to technology, economic development and managerial approaches in various areas such as *'sustainable technology'*, *'sustainable economics'*, *'sustainable business'* and *'sustainable agriculture'*.

Thus, in order to progress toward ensuring a sustainable economy, various key areas have been explored, such as environmental effects and the consequences for nature from unconstrained economic growth, along with the prospects for economic activity that takes greater account of the social and environmental consequences of market behavior (Lovins et al., 2007).

Sustainability is usually defined as:

> *«... a broad interpretation of ecological economics where environmental and ecological variables and issues are basic but part of a multidimensional perspective. Social, cultural, health-related and monetary/financial aspects have to be integrated into the analysis»* (Söderbaum, 2008) .

With regard to the economics of production units, sustainability means adequately sustaining businesses, avoiding periods of instability and discontinuity, and allowing economic activity to survive over time. The basic idea is that sustainability interfaces with the economy through the social and ecological consequences of economic activities (Daly & Cobb, 1989).

As Costanza e Patten (1995) emphasized, taking the meaning of sustainability from biology, where the term originated:

> *«Biologically, sustainability means avoiding extinction and living to survive and reproduce. Economically, it means avoiding major disruptions and collapses, hedging against instabilities and discontinuities. Sustainability, at its base, always concerns temporality, and in particular, longevity».*

Along with this process to involve firms in promoting sustainable growth, and thanks in part to the publication of Elkington (1997), the Triple Bottom Line (TBL) has gained acceptance as a new instrument to measure company performance in line with three approaches: economic, environmental and social (Hubbard, 2009).

The positive aspect of the TBL is that it focuses the attention of companies not only on the economic value they achieve through their business activities, but also on the environmental and social value they produce or possibly destroy (Elkington, 2004).
In order to increase the dissemination of sustainable objectives, numerous international, national, state and local government protocols and policies, as well as the 'mission statements' of corporations and NGOs, include a commitment to sustainable development.
Based on the guidelines of the "Brundtland Commission" (1987), the United Nations has defined a series of Millennium Development Goals (MDGs) to be achieved by 2015. These goals aim at economic development and the elimination of poverty, and the objectives include human rights, health, education and environmental questions. In this context the: *"efficiencies of markets, combined with the resources and managerial expertise of large multinationals, are considered crucial success factors in achieving these goals"* (Seelos & Mair, 2005).
Recently Nidumolu, Prahalad, and Rangaswami (2009) underlined the necessity for companies to adopt sustainability as a real goal in order to achieve competitive advantage.
«In the future, only companies that make sustainability a goal will achieve competitive advantage. That means rethinking business models as well as products, technologies, and processes» (Nidumolu et al, 2009).
In this way, the authors proposed a five-stage process needed to emerge from the recession and make the firm sustainable:

- Stage 1: Viewing Compliance as an Opportunity
- Stage 2: Making Value Chains Sustainable
- Stage 3: Designing Sustainable Products and Services
- Stage 4: Developing New Business Models.

And Baumgartner and Ebner (2010) pointed out that management should pay more attention to several aspects that are indispensable for achieving business sustainability, such as:
- 'innovation and technology', in order to reduce environmental impacts from new products and from business activities;
- 'collaboration' with the various business partners (for example, suppliers, R&D institutions, universities);
- 'knowledge management', in order to implement the organizational knowledge base;
- 'processes' that must be planned and roles assigned in order to integrate sustainability into daily business life;
- 'purchasing', and thus relations with suppliers, in order to improve business sustainability;
- 'sustainability reporting', in order to evidence the results achieved.

Thus today *"there is wide consensus that the idea of sustainability figures as one of the leading models for societal development by indicating the direction in which societies ought to develop"* (Christen & Schmidt, 2012).

2. SUSTAINABILITY AND BIO-SCIENCE PARKS

The concept of sustainability is often associated with the term social innovation.
«Social innovation refers to new ideas that resolve existing social, cultural, economic and environmental challenges for the benefit of people and planet. A true social innovation is system-changing –it permanently alters the perceptions, behaviours and structures that previously gave rise to these challenges. Even more simply, a social innovation is an idea that works for the public good». (Centre for Social Innovation, 2008).

In this context, the institutions and the governance relations at the regional and local level have a fundamental role in promoting sustainable growth.
In particular we have to underline the role of science and technology parks in the generation of firm level social capital through university-firm relations.
In fact, Science Parks:

> *«may be viewed as a cluster of independent firms and support organizations that it is explicitly knowledge-based and attempts to exploit some competitive advantage in a specific field of technology. Another characteristic is that this kind of cluster normally is related to one or several universities, research institutes or other higher education institutions».* (Bellini et al, 2012).

In this way they can also promote the local cluster development and participate to the creation of shared value (Porter & Kramer, 2011).

2.1 Bio-science Parks: which kind of sustainability?

The term of "life sciences research" is associated with an industry extremely dynamic. For instance, even in international crisis times Italian biotech companies show an amazing (?) ability to grow and optimize the investments in terms of value creation (Assobiotech, 2013).
The strength of biotech companies lies in extraordinary potential of the technologies that, once developed, can potentially be used in different industrial sectors; in order to increase efficiency and quality, in respect of environmental impact, is necessary consider the role of biotech clusters and of scientific parks.
Since that *"Biotechnology is the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services"* (OECD, 2003) and, in average in Europe and moreover in Italy, biotechnology companies are usually at an early stage or, in any case, are SMEs (is interesting that the 77% of biotech companies are micro - no more that 10 employees - or medium size – no more than 50 employees - enterprises)[2], during years bio-scientific parks arose in various territories. The aim has been to concentrate single efforts for creating synergies among realities which, if alone, would have been weaker and would have found bigger problems in developing their activities, starting from the research of funds in order to developing the research at the base of the business idea.
So, which is the role of a science park? If we consider the case of the Italian territory, is easy to underline that the development of the innovative activities has always been characterized by a limited presence of start up, if compared to what has been happening abroad. This fact, combined to the strong
European request of reducing the entrepreneurial risk and the major attention to what is called "life science", has started off biotechnological clusters (Büchi, Casalegno, Pellicelli 2010), characterized by the presence of a biopark, private firms, public laboratories, incubators and attracting a strong interest in biotech research of public institutions, in addition to the one of private firms. The biotechnological research is so composed: bioinfo 4%; environmental 9%; agrifood 14%; health 73% (Büchi, Casalegno, Pellicelli 2010).
Before to focus on parks and more in general clusters actions on the environment in which they are, is interesting to consider that three kinds of advantages are also identified by Porter (1998), when we talk about clusters: productivity advantages (reduction of transaction costs), innovation advantages (biotech clusters that mostly mainly arose near research centres of excellence in biotechnology-based disciplines), and new business advantages (the role of environment in the

[2] Assobiotec (2013).

creation of new biotech companies). Prevezer and Stout (1998) identify other advantages concerning the demand side: input-output multipliers (strong local demand), hostelling (spatial competition), search costs, and information externalities (transfer of tacit knowledge between people working within a cluster. On the supply side, major advantages are: technology spillovers, specialized labour and, infrastructures.
In this scenario it is possible to underline the interesting approach scientific parks have on the territory in which there are. Major functions are about complete kit of services which facilitate the start ups and spin off in the pre-start up phase (feasibility studies and selection of projects) in the start up phase (assistance in business planning, legal assistance, support in fund raising activities and/or partner research like venture capital or business angels) for the development (support in the start up phase, orientation and financial, legal, fiscal, technological and marketing assistance, in the 3-5 years of stay in the bio-incubator) and finally Way-Out (verify of results, orientation for the realization of a business plan of development, research of partner able to support the competitive development of the firm on the market) (Büchi, Casalegno, Pellicelli 2010).
Biotechnology is a set of enabling technologies that have applications in various industrial sectors, and could change and innovate already implemented process lowering impact on use of renewable resources. It is therefore easy to understand why the European Commission reserves the bio-economy as a winning strategy to accelerate the transition to a new economic model, based on smart, sustainable and inclusive growth.
Eventually, the constitution of territorial clusters – in which are fundable scientific parks and start ups incubators - is, therefore, an essential step, both for support the growth of the Italian biotech and to promote economic development and competitiveness at regional and national level.
This is even more true in a sector in which the efficiency and effectiveness of research has more to do with the intensity of the flow of knowledge with dimensional aspects. Clusters and parks also play a key role in harmonizing and enhancing the different regional, national and European level to support innovation. Moreover, the importance of clusters and bio scientific parks is demonstrated by the fact that, despite financial conditions and the average dimensions of innovative firms, Italy is at 29th place as innovations according to the Global Innovative Index (2013).

2.2 Territory value creation, clusters and social sustainability

Each territory promotes and subsidizes those skills that are part of the own tradition, for example the pursuit of high technology has always been a factor of excellence of Piedmont Region in Italy.
As well as the great development of the automotive, telecommunications and information technology over the years has resulted in a growing demand for skills with a high degree of technology, contributing to the emergence of modern history the Polytechnic University of Turin , the same need for technology - but this time in field of life sciences - has seen, in more recent times (since the late 90), the development of the School of Biotechnology of the University of Turin (MBC) , research center of excellence. To meet the needs of the pharmaceutical firms in terms of give the research in outsourcing (Büchi et al., 2010), and to make them willing to invest in the poles of excellence, the Piedmont region from the end of the Nineties he worked to the realization of works of incentives and promotion of university research , so that this will interface with more and more local businesses. Move the research on its territory, make sure that the start-up meet the big businesses and promote local search, it means being for the territory. Moreover is to consider that if large companies are opting to outsource basic research, this could take not only to create capital but also new jobs opportunity, ability to create new structures, well-being. They are therefore engines of the local economy.
Moreover, the fact that a scientific park and more in general a cluster, in general, is mainly

composed by many little realities, all together, means that geographical proximity played a key role in network formation, company growth, and knowledge diffusion (Salvador, Mariotti, Conicella, 2012). Eventually, the existence of clusters and parks has frequently been identified in the literature as an important factor in regional development (Porter, 1990, 1998; Buchi, Casalegno, Pellicelli, 2010; Salvador, Mariotti, Conicella, 2012). Above all Porter (1990) writes about the importance for small and medium firms to be bounded in specific territories. In which way the territory contribute to the competitiveness of its territorial for profit realities? To understand it better, is useful to consider the Italian reality as item. According to results coming from Assobiotech (2013) analysis, science and technology parks are playing an increasingly important role in the development of biotechnology, especially in a very delicate phase represented by the technology transfer, that is when scientific research results can represent the base of some industrial applicability.
The value that could arise from efforts done in such environment is remarkable: in Italy more than half of pure red biotech companies (56%) operate within science parks or incubators and this is an interesting data if we consider that another huge percentage has the headquarter in Universities or in research centers (20%). Concerning the green biotech pure companies, the 43% operates within science parks or incubators, while the 14% in Universities or in research centers. Eventually, the 45% of white biotech pure companies has the own head quarter in science parks or incubators, while the 22% in Universities or research centers. This means that an environment in which small and medium companies find the chance to cooperate each others and to exploit parks services and facilities, can represent a competitive advantage for the value creation of a certain territory and, by consequence, for the society living there. This means new job opportunities, territory image development and awareness, eventually the chance for attracting capitals in order to fund biotech ideas and knowledge transfer.
Concerning the studied reality, Piedmont Region presents important data, considering the presence of bioPmed cluster in which Bioindustry Park science park play a key role. bioPmed work in an environment where investments in venture capitals national and international - including some seed capital initiatives (Piemontech and Eporgen) - as well as the presence of specialized incubators and science parks (2I3T, I3P, ENNE3, Incubator, Bioindustry) are elements of internal dynamics. Moreover, bioPmed has the goal to have a positive impact on the regional innovation system, in synergies with the implementation of specific strategic initiatives at regional level – such as Bioindustry Parkand "Health City initiative" - the international positioning, planning system based on a European scale and on cooperation agreements with neighboring land areas, such as the Rhone-Alpes district

2.3 Attracting capitals capability.

To invest in economies with high levels of research and innovation can be the turning point for the future, in terms of economic prosperity and well-being should however point out how, over the past decade, Europe has looked to the research as a "strategic player "in the scenario of innovation. In fact, the strategy "Europe 2020" sees innovation as the engine to promote smart growth, sustainable and inclusive growth, to the benefit of the entire economic and social system (Assobiotech, 2013).
Not surprisingly, the Seventh Framework Programme for Innovation, as well as the next Horizon 2020 program is aimed at creating an integrated and shared funding program.
As shown above, science park could play a key role in creating links with other territories and in attracting risk capital and in supporting the creation of trans-boundaries partneships and company alliances.. Since a high development degree is considered when talking about a biotech firm, is fundamental to understand the reason why we are talking about alliances: they can help these firms share resources and technological knowledge in order to create new products and technologies

(Gopalakrishnan S., Scillitoe J.L., Santoro M.D., 2008).
For instance is possible to consider as benchmark the reality of one of the most important European biotech cluster: Génopole (Ile del France). This is considered one of the most famous clusters because it is possible to find 71 biotech firms, 21 research labs, 21 shared platforms. Thanks to its biotech-dedicated preseed, G1J Ile-de-France - which was set up in collaboration with France's Caisse des Dépôts et Consignations state savings and investment bank - over the period 2000-2012, the fund invested €3.2M in Genopole portfolio start-ups and has leveraged investment totaling €170.65M in 30 companies (Génopole, 2013 Directory). Moreover, G1J IdF can invest up to €300,000 per company (in equity and/or as share warrants).
Concerning the Italian reality, as the latest Assobiotec research (2013) shows, this country is positioned at the third place in Europe by number of pure biotech companies, although these are on average slightly capitalized and suffer from limited access to Venture Capital investments, compared to their international competitors. In recent years, national and European policies have emphasized the importance of innovation, identifying the capital market risk rise one of the fundamental assumptions for the growth and stability of the system statement. However, the reality European VC remains immature, limited when compared with the U.S. As for Italy, then, the market Venture Capital and Business Angels are creating is insufficiently developed, not only in terms liquidity but also of specialization. Looking at the European leaders - United Kingdom, Germany, Switzerland - most of the capital raised by companies is provided by the VC , and the number of projects funded exceeds 20 for each country. By contrary, In Italy, is possible to underline that VC funds projects are just two in the process of early-stage, in the first half of 2012; this is a weak result if compared to 55 funded at European level. Yet, a recent study from the School of Management of Politecnico di Milano shows how an investment of € 300 million for the creation of innovative start-ups may have a relapse extremely positive on the Italian GDP, with a return in any case at least ten times the capital invested.
Concerning investments, Federchimica Assobiotech (2013) asserts that the ones in R & D amounted to EUR 1.8 billion, an increase of 8% over the previous year. The analysis of investment in R & D by type emerges as such investments are generated by pharmaceutical Italian (36%), and multinational corporations based in Italy (36%), from pure biotech (26%) and other biotech Italian (2%).
Since Italian biotechnology can represent one of the most valuable local sectors, it is useful to understand in which way such small and medium firms can attract the attention (and the funding) of venture capitalist or business angels. Indeed, the Italian biotech industry continues to be competitive at the European level: the Assobiotech 2013 report shall identify 394 companies and ranks Italy as the third European country in terms of number of biotech companies (248), ie in biotech companies that have their own core business, after Germany (397) and United Kingdom (282). The growth trend of the pure biotech companies (2.5%), is also in contrast to that recorded in the leading countries of Europe, instead they see a drop in these companies. They begin to become evident, however, the first signs of fatigue, with more than two dozen companies that appear to have gone out of business.
Who can attract capital? And who can make capital raise if the investment in Italy has always been perceived as too risky (Buchi, Casalegno, Pellicelli, 2010)?
The science parks are catalysts in attracting capitals. As Assobiotech (2013) states, the localization at a business incubator or in a science park is often the only opportunity for the birth and growth for a business in the biotech industry for a number of reasons among which surely the availability of financial instruments and the need to confront a global market. In this sense, PST, beyond the offer localization, are able to give concrete answers through the attraction of seed financing necessary to support the activities of the new businesses in their first years of life and allowing access, right from

'beginning, at a national and international network of professionals.
In Italy, the main biotech parks are concentrated in the North: in Lombardy are the Insubrias Biopark Gerenzano and the Parco Tecnologico Padano in Lodi, the first active in bio-medical field, the second in the so-called green, dealing with dairy products and innovations for the genetic breeding of animal species. In Piedmont, in the area of Ivrea, is located the Bioindustry Park Silvano Fumero. In the Northeast, finally, there is the Area Science Park of Trieste and the Science and Technology Park of Venice.
Also significant is the presence of parks in other parts of Italy, including Tuscany, where it operates the Toscana Life Sciences, Campania, where Technapoli, the Park which houses the TIGEM - Telethon Institute of Genetics and Medicine, Sicily with the Science and Technology Park of Sicily and Sardinia, with Sardegna Ricerche.
Concerning Piedmont reality, by focusing on the territorial system of Piedmont, despite a rapid growth of the importance of biotechnology research, is possible to analyse lacks of the entire system concerning the systemic problem of venture capital in Italy not easy to solve. If this is true in general for other sectors of the Italian economy, it is even more true for the life sciences whose research is evidently perceived as a risky investment not only by the Italian lenders, but also and especially by foreign ones (Buchi et al., 2010).
The development of internationalization actions considered above may represent a response to the deficiency; is useful to consider works in progress in the center of the Bioindustry Park, in which research funds, as well as infrastructures and facilities funds, comes mainly from the private sector (70% of the total amount), rather than the public one (30%) (Buchi et al., 2010).
Since for Italian biotech firms is difficult to attract capital, the role of bio parks and scientific cluster is fundamental in order to develop the territory awareness and to build long term national and international relatioships. Eventually the final question is: how to find a good way to evaluate firms and their project, in a business model driven by a very long term run?

3. REAL OPTIONS AS EVALUATION METHOD TO GUARANTEE THE SUSTAINABILITY IN THE BIOTECH AND MED-TECH INDUSTRY

In the biotech and med-tech industry, the business evaluation process is complex. It is besides very difficult to estimate the market share and the competitive position of future businesses.
Too many variables have to be considered in a long timeframe.
The projects of the innovative companies and start-ups are principally based upon products development, both in biotech - pharm and diagnostics - and in innovative medical technologies. Long development processes, regulatory requirements, potential patent issues, strong competitive environment are main elements of such markets.
Evaluation plays an important role for these companies, both to raise funds, which can be a key factor in order to develop alliances, and partnerships.
However, for the same market elements, the evaluation process is sometimes difficult and risky.
In this overall context, it is necessary to analyse continuously:

- *risks and potentials* of each project;
- available *resources* for each project;
- *comparison* of the potential of different projects.

Therefore, in the biotech and med-tech particular fields it can be more useful to evaluate the single projects in order to guarantee sustainability of innovative start-ups in the biotech and med-tech industry and use the real option method, that is more dynamic than traditional approaches and capable of competitive strategies in an uncertain environment.

As a number researches have shown, environmental discontinuities can make a firm's investment - in specific technologies, markets, or business models - obsolete (Henderson & Clark, 1990; Eisenhardt & Martin, 2000; Zollo & Winter, 2002; Vassolo et al, 2004).
Besides, the initial investments for the projects are not rarely very expansive and the firm's management has to adapt and revise investment decisions in response to market developments.
In this way, according to Smit and Trigeorgis (2006):

> *«It is well accepted by now that the value of many strategic investments does not derive so much from direct cash inflows, as it does from the options to invest in future growth. Indeed, strategic plans often encompass projects which, if measured by cash flows alone, typically appear to have a negative net present value (NPV), when in fact they may have a positive total strategic value»* (Smit & Trigeorgis, 2006).

We need to remember that the real options are difficult to use for the evaluation of high-tech start-ups, while they can be very useful when applied to singe projects.

The term *'real options'* indicates the *'nodes'* in which the management can decide whether to continue to invest, abandon or change the amount of the investment.
As a financial option gives the right, but does not involve the obligation to buy or sell financial assets, real options give the management the right, but not the obligation to proceed in the sequence of the phases of an investment.
If an investment has more stages of progress, following the end of each stage the management has new information; may decide to continue or abandon; can assess whether the project is likely to add value or not.
Smit and Trigeorgis (2006) explain the superiority of real options compared to other methods of evaluation of investment projects:

> *«The traditional approach to project evaluation and investments uses discounted present value (DPV) or discounted cash flow (DCF) methods. These methods explicitly assume the project will meet the expected cash flow with no intervention by management in the process. All the uncertainty is handled in the (risk-adjusted) discount rate. It is static. ... However, management discretion has value, which is not incorporated into the DPV. The real options methodology goes beyond this naïve view of valuation and more closely matches the manner in which firms operate»* (Smit & Trigeorgis, 2006)

Also Lueherman (1998), by comparing the methodology of real options valuation with the Net Present Value (NPV), writes: *"In financial terms a business strategy is much more like a series of options than it is like a series of static cash flows"*.
Morin and Jarrell (2000) argue that resorting to the theory of real options to build sequences stimulates investment along several stages (continue/abandon, reduce /increase the investment). This can help to identify risks with greater awareness. Anyway we need to outline the possible risks in using real options with an evaluation method.
The implementation of the whole process could encounter four major risks:

1. risk of developing a product that meets the expectations of the market;
2. the risk that a question arises with the volumes and rates of growth than projected;
3. the risk that the strategies of competitors conflict to launch the new product;
4. the risk of the advent of a new technology that makes it more convenient not what you plan to adopt.

The management can estimate the initial investment, but it is not able to predict the extent of subsequent adjustments that may be forced to do. It can, however, identify a set of critical strategic decisions that may be forced to take.
Thus, for example, if during the phase of development of the prototype and launch preparation market conditions suggested not to proceeding, may:

- fully cancel the program;
- suspend the execution of the program pending events;
- sell the idea, or the progress of the prototype, or the project of construction of the plant to another company that intends to take the risk;
- continue in the program by reducing the production capacity.

If during the development phase, the conditions turn out to be better than expected, would be other options to choose.

The risk in proceeding in stages is thus less than what is assumed in the analysis NPV, and this risk is embedded in the cost of capital by estimating the same.

Is very difficult to apply a real option based methodology in biotech sector, at list is very difficult to prove that this is the most effective reasoning in evaluating long run project value creation. This happens because the high innovation degree present in every biotech and medtech project. On the other hand is useful to remember evaluation methods tell investors or potential investors "whether it is worthwhile to risk the bet and how much you should bet, but it does not tell you whether you are going to win". (Villinger, Bogdan, 2005). Knowing this, when is necessary valuation applicable?

According to various authors (Denison, C.A.; Farrell, A.M.; Jackson, K., 2012) "The most popular, widespread methods of evaluating long-term investment decisions are internal rate of return and net present value analysis". In addition, the classical managerial approach rather concerns the concept of *discounted cash flow*, even if various authors sentence that this could be not the most suitable way to evaluate high tech projects (Villiger, Bogdan, 2005).

The attempt of the present paper is to show, starting from the analysis of the literature, that it is possible to use real options in order to estimate, considering the presence of the prototype – which is the result of an already financed long standing research, after the approval of a business plan – which can be the most suitable path in order to reach profit. While in DCF calculations the estimated future trends are a given numerically, in real options valuation the sales estimate fluctuates. The degree of this uncertainty is called volatility (Villiger, Bogdan, 2005).

The construction of a model, of a simple (even if limited) model can help evaluators to understand which path is advisable to finance.

4. REAL OPTIONS AND DECISION TREES FOR RESEARCH PROJECTS IN LIFE SCIENCES

Objective

The objective is to define a tool/methodology that permits the identification and valuation of hypothetical development paths related to a research project and consequently to determine the most promising scenario. Such methodology has to be easy to implement, it has to consider the main (not all) scenarios and has to be considered a tool to identify suitable development path for a project results. The methodology is not conceived as a company evaluation methodology but instead a decision support methodology.

Methodology

The methodology components and steps are the following ones:

1- Decision trees (applications and related final markets)

The first step consists in designing a decision tree that represents all main possible development strategies for a technology starting from results obtained at an early stage of the research project.

The objective is to develop the decision tree until to reach final markets. This concept is based on the fact that a technology can find applications in different markets.
The second step is to attribute a score (intermediate score) for any development paths chosen at each intersection (node) based on the evaluation of different parameters.

2- Parameters and score

Parameters used to determine the intermediate scores can be classified in 5 main categories:

- Team: evaluation of the capacity of the team to bring the technology to the market.
- Intellectual property: evaluation the project in terms of legal property according to the status of the claims and the geographical coverage.
- Time: evaluation of the remaining time to reach the market based on the typology of the technology, the development stage and the age of the patent portfolio.
- Risk: evaluation of technological and regulatory risks based respectively on failure rate and requirements needed for health authority approval.
- Market: evaluation of market environment related to the project based on market size/appeal, competition and freedom-to-operate.

For each parameter, that has to be assessed in a subjective way, a score from 1 to 5 is attributed (except for some criteria that better require a ranking from 0 to 5, for example criteria related to intellectual property).

The intermediate score corresponds to the association of the scores obtained for each parameter.

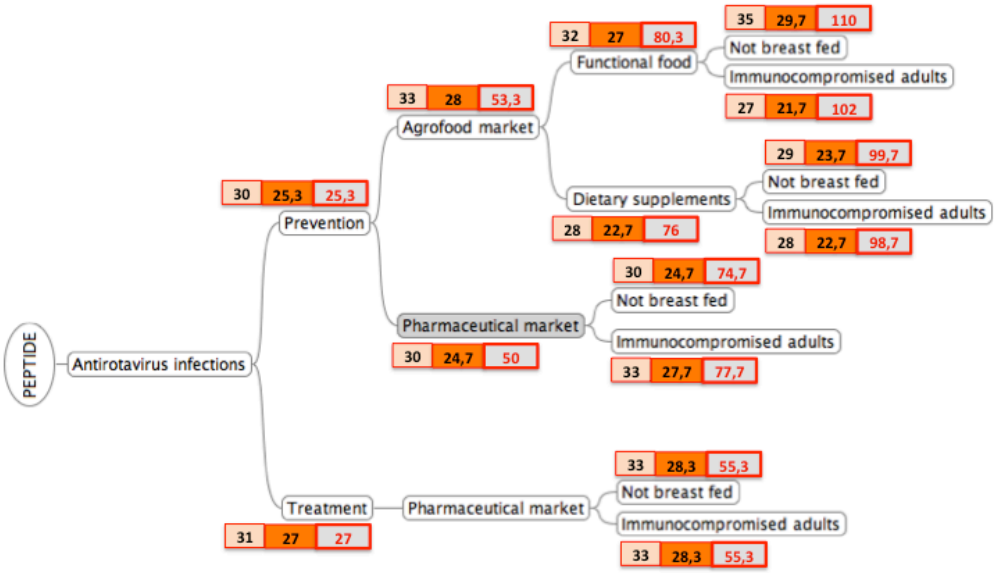
3- Identification of the most promising scenario.

For each single hypothetical path, a final value (or final score) that corresponds to the association of intermediate scores obtained at each intersection is determined. The research project's best paths are defined as those that have obtained the highest final scores.

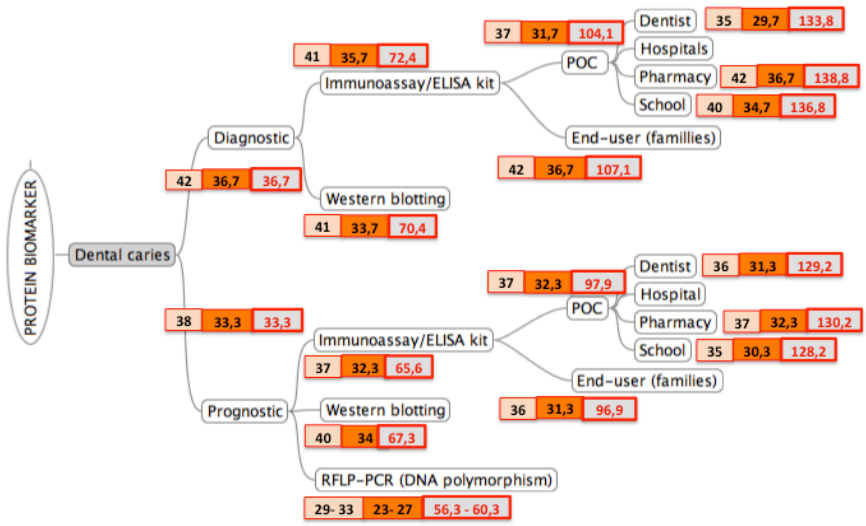
Experiment

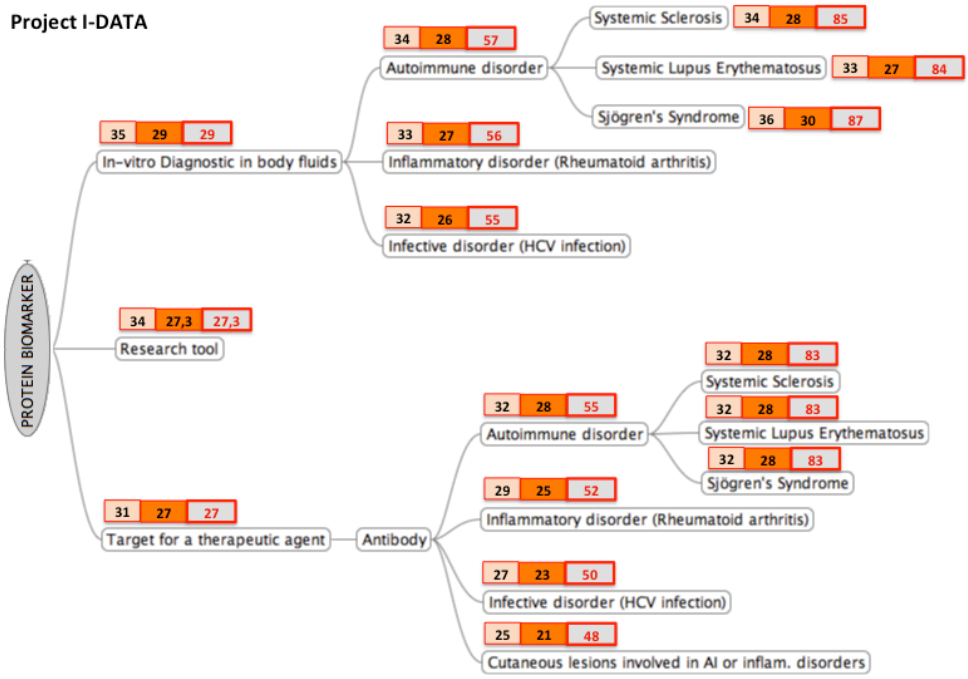
The methodology previously described was tested on three research projects:
1: A peptide to treat or prevent a viral infection (Iaro);
2: A protein used as a biomarker for the prognosis/diagnosis of dental carie (TrCD);
3: A protein used as a biomarker for diagnosis of auto-immune diseases and development of a therapeutic approach (I-Data).

Project IARO



Project SMILE





CONCLUSIONS

In conclusion the real options' method can be used for the projects evaluation and to guarantee the sustainability of innovative companies and start ups in the biotech and med-tech industry.
Recourse to the real options' method stimulates investment to build sequences of long multi-stage (i.e. continue or abandon the project, reduce or increase the investment).
This method can be particularly useful to identify risks with greater awareness and to select the biotech and med-tech projects that more than others can guarantee the businesses' sustainability.
Real options valuation can fill DCF lacks concerning the cost of increased complexity (Villiger, Bogdan, 2005), since that considers risks and opportunities (in a qualitative and in a quantitative way) of every strategic choice. However, once the industry has overcome the beginner's problems of this valuation method, biotech companies (as the ones considered in present cases) and scientific parks management need to take real decisions in terms of project and portfolio management (Villiger, Bogdan, 2005), license contracts and empirical evaluation of the market potential with real and proved arguments rather than a vague experience.

LIMITS AND FURTHER IMPLICATIONS

The model presented above is useful to understand how to reach competitive advantage, but is unquestioned that presents its dark sides.
- To be comparable, the different scenario should have the same level of analysis
- The attribution of the scores is not always objective. A subjective element could be one of the critical elements of the methodology.
- It requires an accurate and previous analysis of the project and its environment that has to be based on IP analysis f possible, scientific results analysis and freedom to operate analysis

The approach in not including evaluation of potential business strategies and way out solutions than in any case could be added.
Actually, it is possible to say that this is just a research early stage, but such a model can be implemented in order to better understand in which way a high tech prototype can create value. Indeed in high technology markets is difficult, after years of research and development in order to reach the goal of building a first prototype, to clearly understand which kind of scenario could be the most suitable for the development of a new product based on the first output. The use of a decision tree, based on a quantitative evaluation, can help managers to understand which path to follow and, at the same time, takes to objective results useful to present to investors. Moreover, an implemented method could be firmly adopted by scientific park in order to use just one methodology able to compare different projects.

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