

Technological pathway No. 1

New technologies for the pharmaceutical, diagnostics and biomedical fields- Innovative cellular and molecular therapies, molecular and imaging diagnostics

(Acronym: CellMolDiagIm - CMDI)

The present technological pathway is committed in the field of Life Sciences, concerning four main application areas, such as:

- **molecular diagnostics;**
- **diagnostic imaging;**
- development of **molecules- and stem cells-based therapeutics.**

Both the molecular and imaging diagnostics are associated with the optimization of therapies, although the latter has the advantage to find more applications both in diagnostic and therapeutic fields, depending on the potential related to the technologies involved. The recent improvements in both of them (diagnostics and therapeutics) move towards the **personalized medicine**, a new model of medicine.

The structure of the pharmaceutical and diagnostic markets involves the presence of SMEs developing innovative products at pre-clinical and early clinical phases (Phase I / II). The SMEs are focused on licensing or selling activities to larger companies, which proceed with the product development up to the entrance to market. The placement of SMEs at various areas of the therapeutic/diagnostic products development value chain, leads to the need of providing activities in outsourcing by the same small /medium sized biotech companies to large pharmaceutical companies. As consequence of that, the products pipeline of large pharmaceutical companies is increasingly populated by the products acquired under license from third parties. In this context, academia is an important player as well, especially in contract- and out-licensing activities, having both know-how and intellectual property produced within their research activities.

Other areas, not directly health care, promote technology processes and products that have a relapse on the same health and quality of their lives, with the use of innovative technologies arising from the convergence of technology platforms hard, soft and wet, with the aim to innovate in areas such as agri-food and environment related topics (eg, nutraceuticals, green Biotech).

The uniqueness at the regional level have a placement worldwide in the development of innovative foods, in particular companies bioPmed's members have a state of the art skills, especially in the area of mycorrhizal fungi and food probiotics, creating concrete perspectives for market development. Everything happens in a context, wherein the so-called wellness is strictly linked to a high quality of the food included in the diet, reason why the related market segment is becoming really interesting for the company operating in agri-food and green biotech sectors.

Direction of Development n. 1 (TP:CMDI)

Applications on High Medical Need Diseases (Acronimo HMNA 1)

The market sectors taken as a reference in the application field of diseases with high medical need are pharmaceuticals and diagnostics. Usually, these areas are characterized by the high number of start-ups, small and micro sized companies, industry or university spin-offs which are placed in the R & D value chain, basing its growth on venture capitalist financing. The main application areas identified are oncology, inflammation and regenerative medicine, which — as well-known — are rigorously regulated by dedicated regulatory agencies and the life cycle of a drug (in the order of 12-15 years) is affected by very relevant investment on research, including the relevant role of patent protection. The presence of start-ups and innovative SMEs that have expertise at the different phases of product development, enables the growth of SMEs "specialized" that, starting with research funding by venture capitalists, have the opportunity to be global players in a niche market.

As an indication, in 2007 the healthy industry in the U.S. has spent over 50 billion dollars in R & D and the forecast is for a further growth in 2010 and next years.

In a global vision, the Polo bioPmed wants to achieve two main macro objectives such as strengthening the competitive position of businesses in those sectors of reference, as well as the positioning of the resulting system at the international level with the presentation of projects for both the diagnostics and the development of new therapeutic products in the above application areas. Additionally, through the projects that companies have presented, the bioPmed's members have the goal both to growth their own capital and intellectual relationships — such as intangible assets — and to create a scientific network increasingly strong and qualified. Actually, fostering an osmotic flow in the know-how process between the University and privately held

companies will strengthen the application process of basic research results, improving communication between the world of university research and private enterprise, consolidating expertise in the field of mutual interests, and facilitating entry into the academic sector to private investment.

Direction of Development n.2 (TP:CMDI)

*Applications Not Directly Human Health Care (Acronym: **NdHCA 1**)*

The approach related to personalized medicine involves the simultaneous development of solutions having the aim at preventing or supporting in the diagnostic and therapeutic processes "traditionally intended". From an operational point of view, through a better control of the food quality, involving manufacturing technologies used, the agro-food companies could provide so-called "wellness solutions", concerning the entire environment that surrounds us, more healthy through prevention programs. As a start, this approach finds application in the innovative food field, which includes innovative SMEs having a very strong expertise on product development and strong networks with academia and large businesses, able to ferry these products to the market. The cited above companies are using technologies similar to those used for the development of solutions directly designed for human health, by using strong interacting tools at local level with local stakeholders (schools, hospitals, consumer groups, ...).

Globally, this market is strongly focused on prevention rather than on cure, considering wellness as the convergence of interests from different industry areas (food, nutraceutical, cosmetic, technical-instrumental, etc...), by strengthening the link between these areas and those closely related to human health, with an increase of expertise in innovative SMEs. Particularly, large companies operating worldwide work in the field of nutraceuticals with great opportunities – and most of all - in the fields of probiotics and functional foods (global market of nearly \$ 30 billion). To date, there are major opportunities in those areas wherein health benefits are known, such as e.g. in the production of Omega-3 for the reduction of cardiovascular diseases or plant sterols to reduce cholesterol level in the blood. It's important to emphasize that today even large pharmaceutical companies have divisions operating in the field of major food / nutraceutical and biotechnology, and they are following an approach in the development of food additives, including the validation of the effectiveness, by the implementation of clinical trials.

Technology pathway n.2

Innovative technologies and services for biomedical field, biotechnologies and for not directly human health care applications

(Acronym: TECNINN)

Innovative technologies for the biomedical sector and the impact of these technologies in not-strictly health care sectors represent a real opportunity for biomedical products development. In particular, we emphasize the three macro-trends leading biomedical, such as:

- research on surgical micro-invasivity (reduced costs, increased quality of life of the patient, ..)
- the search for biocompatible materials, and innovative new "tissue" (reduction in risk of rejection, promoting cell adhesion / tissue regeneration, reducing costs, ..)
- computer science, applied to medical and biological sciences (database management, modeling, ..) –

The macro-trends cited above arise from the interaction between several technologies (even redefined converging technologies) with the aim to create complex technological solutions (hard), and the related technologies can be summarized in the following: technologies related to materials, ICT data management and modeling (soft), and micromechanics electronics, nanotechnology, etc.. and wet-type technologies.

These technologies, following the above mentioned trend towards micro-invasivity and biocompatibility as well as their integration with disease management systems based on ICT, may be declined on different application areas, such as cardiovascular, orthopedic and prosthetic dental tissue engineering and the more general regenerative medicine with more "hybrid" applications, such as DES (drug-eluting stents), the drug delivery and formulation, surgical techniques, and information based medicine. One of the main features of the bioPmed's members – companies operating in the biomedical field as well - is the presence of strong skills and know-how in the evaluation of the biocompatibility of a material, or in the determination and definition of parameters that indicate the harmfulness of a substance / material for an organism, wherein e.g. an orthopedic or dental prosthesis (e.g. used materials: titanium, hydroxyapatite).

As a support to many solutions/processes in the biomedical field, there is informatics, applied to pharmaceutical or biotech areas, and considered as a powerful accelerator in the development of products and information databases management. In particular, informatics "easily" interacts with biology, but relies on contributions

from other disciplines, such as statistics and mathematics. An estimation of the bioinformatics market is worth more than 5% of the global biotechnology market and the growth rate is around 20% per year. With reference to bioPmed, strong bioinformatics skills are present and they are really essential to achieve an important goal as the creation of technological platforms where different expertises, fed from areas not specifically biotechnological, can connect themselves to express their potential in making medical devices and instrumentation for biomedical applications. The widespread presence of micro-enterprises operating in the field at national and European level, as well as at regional level, confirms that tissue engineering and research and application of innovative materials in this area is a promising, dynamic and relatively new field.

Direction of development n.1 (TP:TecnInn)

Applications on High Medical Need Diseases (Acronym: HMNA 2)

In the biomedical field, the integration between different disciplines and technologies affects the quality of life of patients in positive terms, providing e.g. innovative therapeutic or diagnostic solutions to follow their care. The development of biomedical technologies related to new materials, nanotechnologies, ICT, electronics and mechanics of extreme precision - very popular in various technological domains in territorial contexts - allows us to find niches of interest and new paths development for production applications, particularly in areas wherein high medical need barriers to entry are defined by competitors holding wealth of knowledge locally available. In particular, regenerative medicine may provide a promising therapeutic alternative to transplantation, and this strategy - providing tissues and / or organs immunologically compatible with the recipient — immunosuppressive therapy can prevent and overcome the chronic shortage of donor organs and tissues.

Even the textile industry finds its placement in the biomedical market, with the development of both textiles for external use and implantable materials (sutures, staples, vascular) for internal use. The results of converging technologies fusion are products resulting from the combination of drugs and innovative drug delivery systems, where the name comes from the combination product "intended use" indicated on the device. The projects presented in the current year show a strong connection between university research and privately held companies skills, leading to the identification of innovative materials with high biocompatibility and non-cytotoxic effects to be used in various applications (such as orthopedic and dental prosthetic). So, with particular reference to enterprises members of bioPmed with activities focused in the biomedical field, they are micro-enterprises with high technological content, able to transfer and improve the know-how from academia to the industrial production.

Direction of development n.2 (TP:TecnInn)

Applications not directly Human Health Care (Acronym: NdHCA 2)

As known, one of the strengths of biotechnology is their ability to integrate with different technologies and disciplines such as chemistry, materials science, physics, etc., placing itself as the key to the development (enabling technologies) for other industrial sectors. The need to gather skills that micro and small enterprises do not have in some cases internally, involves academic institutions and external consultants as a vital source of knowledge able to obtain short-term goals. This type of training and advice can be more useful for SMEs than for larger companies which are able to find it internally. For example, always in this early stage, the need to define the most appropriate formulation of a drug allows companies specialized in the formulation and drug delivery to fit with its own know-how in the value chain of a therapeutic.

Analogously to converging technologies, bioinformatics was born from integration of computer science, molecular biology, IT and statistics in order to collect data from different experiments conducted in different areas, but converging to a single information. The bioinformatics tools helps large companies also in the drug discovery step through virtual screening process, with the ability to collect and organize data for analysis and visualization of molecular structures, by getting these skills by third parties.

At the regional level, computer skills are applied to the diagnostic industry, in particular cancer related, whose project activities include the development of software and hardware, or provide solutions to others as targets of computerization with the prevention, diagnosis and optimal treatment of oncological diseases. In general, the confluence of disciplines such as microelectronics, innovative research on new materials applied to biology, bio-mechanics, optics, sensors, robotics, ICT, mechatronics and nanotechnology is just one example of potential applications in life sciences in general and in biomedicine in particular.