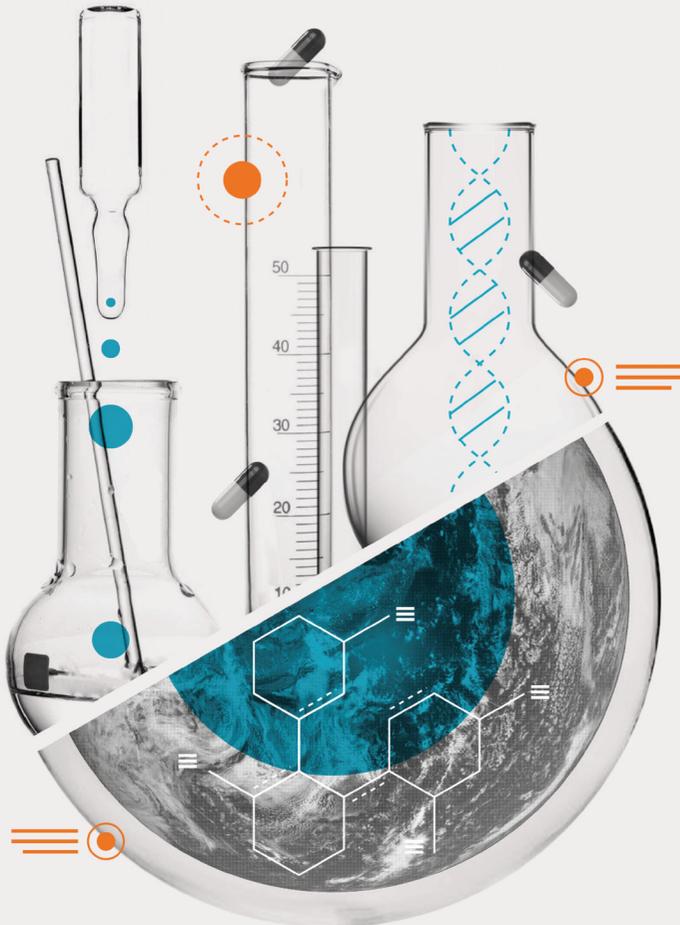




The role of the innovation ecosystem in Life Sciences for Italy's growth and competitiveness



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Executive Summary

01

Introduction

The Life Sciences Technology Forum was created in 2015 in collaboration with **Assobiotec**, the Italian association for the development of biotechnologies, **Alisei**, the Italian Life Sciences cluster, and a number of biotech companies that do business in Italy. The objective was to contribute to promoting the development of the innovation ecosystem in the Life Sciences sector in Italy and foster discussion among the highest levels of research, business, finance and government and institutions. Since 2018, the project has also been supported by **Sofinnova Partners**, a European Venture Capital company focused on Life Sciences, and **Telethon Foundation** which is specialized in researching cures for rare genetic diseases.

Specifically, the mission of the project is to transform Italy in **“the place to be for the biopharmaceuticals of tomorrow: a leading player in the research, development, production and access to innovative biotech products.”**

The report summarizes and categorizes the guidelines, considerations and findings of the fourth year of work of the Technology Forum Life Sciences Advisory Board, the intention being to build on what has been produced in previous years and—as has been reiterated on numerous occasions over the course of work—to **“progress from proposals to action”** through a tangible contribution during the implementation phase of a number of areas identified as priorities for the growth of the sector:

- **governance that is effective, reliable and centrally-guided**, and as such capable of capitalizing on research and innovation within a medium- to long-term perspective;
- **strategies to attract investment** that highlight the nation’s most-competitive areas, assist companies in their growth and provide support for anyone wishing to invest in research and production in Italy;
- **promote Technology Transfer** to create value through the transfer of knowledge from research to business.

A snapshot of the Life Sciences sector in Italy

02

Our increasingly-enhanced knowledge about living organisms and ecosystems, together with the availability of vanguard technological innovations, forms the basis of the progress in all Life Sciences sectors — pharmaceutical, biotechnology and biomedical sectors —and constitutes a major driver for economic and social development.

The latest dynamics of development currently impacting on all areas of Life Sciences throughout the world, also offer major opportunities for Italy, both in terms of scientific progress that is potentially pursuable, as well as the prospect of becoming part of a value chain that is increasingly “global” and in which innovation and development of new products and treatments transcend the individual laboratory.

An analysis of the Life Sciences sector in Italy reveals an active and dynamic ecosystem capable of responding rapidly to the economic and technological challenges of the market, and in which growth and innovation go hand-in-hand:

- in 2016, the **biotech sector** invested over **€2.15 billion in Research & Development activities** to generate a turnover of €11.5 billion, the equivalent of a 15% increase over 2015, 74% of which generated by companies involved in human health biotechnologies (Red Biotech). Despite the continuous increase in turnover, the sector is currently consolidating and the number of companies has stabilized in recent years. At the end of 2017, the sector was comprised of **571 active companies**, 76% of which were micro or small-sized, a level that has remained substantially unchanged over the last four years¹;
- the Italian **pharmaceutical industry**, comprised of 290 companies, in 2017 finally became **no. 1 in Europe in terms of value produced** (€31.2 billion), overtaking Germany which, until the previous year, had produced the greatest value. The Italian pharmaceutical sector alone invests **€1.5 billion in R&D**, the equivalent of 7% of the

1 Source: Assobiotec, 2018

- total amount invested in R&D in Italy, and has showed a 22% growth in the last five years²;
- the **biomedical sector** is comprised of over 3,800 companies, most of which (95%) are SMEs and are highly interconnected. The medical devices sector has, in fact, the configuration of a “broad-based factory sector” that is very dynamic and in which the companies often form partnerships both inside and outside the supply chain in order to develop their business activity. During 2017, the medical devices market registered **overall demand of €11.4 billion**, of which almost 65% is accounted for by the national health service, and 35% by the private health sector. Exports totaled €4.9 billion, up 4.8% versus 2016³.

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The Life Sciences sector as a strategic driver for the nation’s development

The Italian Life Sciences sector has a **strong propensity to export** and internationalization, as well as a **major push towards innovation**.

Taking into account both its direct and indirect contribution, in 2016 the value of Life Sciences supply chain production in Italy was over €207 billion with an added value of €95.5 billion⁴.

Predominantly SMEs, the companies in the Life Sciences sector have shown themselves to be extremely flexible and competitive on international markets. Working above all on the basis of Open Innovation, they are able to operate in perfect synergy with all stakeholders in the supply chain.

In Italy, Life Sciences companies invest heavily in orphan drugs and advanced pathology treatments related to cancer or diseases of increasing clinical-epidemiological relevance, such as auto-immune and infective diseases, as well as research into vaccines, all of which puts their activity in the frontier of innovation.

2 Source: Farindustria, 2018

3 Source: Assobiomedica, 2018

4 Source: Assolombarda, 2018

Top-ranked for its industrial competitiveness, productivity, specialization and investment in R&D, the Life Sciences sector has proven to be extremely competitive, including from a scientific standpoint. In terms of scientific publications, Italy is in **1st place in Europe in the field of oncology** and **3rd in the medical field**.

The Life Sciences supply chain also has a considerable impact on employment. Along with the positive growth rates in sector employment already noted, is the total number of those employed in the Life Sciences supply chain—over 1.7 million.

It should be noted that for every job generated in the sectors/branches of activity related to technology, Life Sciences and scientific research, as a result of direct, indirect and induced effects, a further **2.1 jobs are generated** overall in the economy.

The role of public and private capital in providing support for the Life Sciences sector

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Research and innovation are the foundations for growth in the Life Sciences sector, but they require a significant academic, scientific, industrial and, therefore, financial effort. The development of new drugs is a demanding and highly-uncertain process of research and study that lasts from 10 to 15 years. On average, only one molecule out of 10,000 arrives at the end of the process, with costs that can reach up to \$2 billion.

Therefore, success in the Life Sciences sector is directly correlated to the **financial resources made available** for research and innovation and, above all, **to how these are allocated and managed**.

The public sector is involved on a number of levels in support of research and innovation and in a fragmentary way. It is the government which, in most cases, guarantees financing of the most risk-laden phases of research that are the life-blood of the entire Italian innovation system. Private investors generally consider long-term and uncertain projects to be highly risky because

there is no guarantee of economic return on this investment, as often happens in Life Sciences.

The ideal model of financial support is that in which a **positive public/private cycle** is created: the public sector identifies those areas of greatest competitiveness for the country and, focusing on these, guides and supports private investments.

An inspiring example of this process is France, which is a driving force within the European market, also thanks to its strategy of support for innovation and research implemented in recent years that promotes national competitiveness through **ongoing interaction between the public and private sectors**.

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Mapping of public resources available for research and innovation in Life Sciences in Italy

Starting from the gap in awareness of the resources actually available to those wishing to undertake Life Sciences research and innovation in Italy, The European House – Ambrosetti working group, in accord with the Advisory Board, has undertaken an analysis of **public funding available for Life Sciences research and innovation in Italy**.

The mapping process took into consideration the main European and Italian funds involved in research and innovation and able to have an impact on the Life Sciences sector in order to outline a concise framework of the opportunities available, analyze how they work and the main results achieved by the individual programs. This made it possible to identify the main strength and weaknesses on which to formulate concrete and effective proposals for improvement.

The analysis carried out—which was not exhaustive—provides an **extremely fragmented picture** of research and innovation initiatives and programs with a potential impact on Life Sciences. This is a direct consequence of the governance of the Italian research system.

It is clear that no **unified and integrated strategic approach** to managing public funding for research and innovation is immediately perceptible, and this leads to **inefficient allocation of the resources** to the detriment of all economic sectors, including that of Life Sciences.

A clear **difficulty for small- and medium-sized companies** to access the resources available can also be seen, as well as a significant **problem regarding the quality of the projects presented** by Italy, which is unable to withstand competition from the main European countries, as well as a clear **gap in entrepreneurial skills**.

Also emerging clearly is the strategic value a National Research Agency could have. Such an agency would define national strategies involving research and set financing processes on the basis of detailed study of trends in each economic sector, the productivity results obtained and expectations in terms of international competition.

It is essential that the financing model for Italian research ought to be based not only on public/private involvement, but also take into consideration **the capabilities and areas of excellence, assessment of the performance** of scientific research and its **real potential**, to guarantee an adequate and correct distribution of resources to ensure that scientific research be able to respond to real, existing needs, while at the same time fully expressing its creative potential.

In order to gain competitiveness within a European and global context, the Life Sciences sector requires **overall action to harmonize and integrate research and innovation programs** which, because they are run under the auspices of different bodies, are currently highly fragmented.

Factors that influence investment attraction

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The theme of attracting investments has been a central focus of the work of the Technology Forum Life Sciences since 2015 and it remains an area of extreme importance for the competitiveness of the Life Sciences sector and, more generally, Italy as a whole.

It is a very broad theme that has always been approached primarily from the standpoint of the measures and actions (mainly tax-related) capable of optimizing and rendering more effective investment into research and innovation.

In this report, an attempt has been made to provide a broad-ranging view on investment attraction with special focus on the Life Sciences sector, while also offering an updated picture of issues already examined in past years and completing it with new elements of evaluation. The purpose behind this is to offer government and institutions a model that contains the main factors that impact on the attractiveness of the Italian innovation ecosystem within the global context and which, as such, could be strategic areas of intervention to increment Italy's competitiveness.

Specifically, the efficacy of an ecosystem in catalyzing investment can be traced to the interconnection of three main enabling factors:

1. **Stability and credibility of the ecosystem:** investment is more apt to go where there are ecosystems ready to accept it. Political instability, excessive bureaucratic red tape, the absence of a medium/long-term strategic vision and the lack of clear governance of the research are just some of the factors that have a negative influence on the general attractiveness of the ecosystem and for which, therefore, action is urgently required;
2. **Incentives that promote innovation:** In recent years, the Italian government has created a number of means designed to promote new investment, especially in research and innovation. If it is true that, today, positive effects have been produced by many of the means implemented to foster the attraction of investment, it must also be noted that the results obtained cannot be considered sufficient;
3. **Capitalization on areas of national excellence:** the excellent quality of Italian research—which is recognized on an international level—must be supported by conscious and integrated communication of the expertise found throughout the country. Improving the policies for managing the nation's resources and investing in the promotion of its strengths points in the Life Sciences sector would increase visibility and increase the likelihood of attracting the investor's interest.

Incentives that promote research and innovation

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Within a context in which Italy struggles to gain competitiveness on an international scale, public policies that favor innovation and research take on a decisive role because of their widespread capacity to work hand-in-hand with the renewal efforts implemented by companies.

Many means have been implemented by government and institutions to promote new investment, especially in research and innovation, for example the R&D tax credit, hyper- and super-depreciation, the Patent Box, the so-called “New Sabatini Law”, the guarantee fund, innovation agreements, development contracts, the Smart & Start initiative, incentives for investment in innovative SMEs, individual savings plans and the Industry 4.0 Competence Centers.

As can be seen from the data presented in the report, much work remains to be done along the road undertaken to **perfect, strengthen and extend** what already exists so that it becomes truly capable of rewarding those who want to invest in the future. **Instruments to measure and assess** the efficacy of the actions taken must also be defined. This could also facilitate the definition of mechanisms for adjusting and/or updating the norms already in-place, while also guaranteeing a better use of public resources.

As already proposed last year, the introduction of **innovative financing tools** (such as the Research Investment Bond) could help to catalyze investor attention in strategic areas of growth, such as research, that produce significant positive impacts on society.

Life Sciences competence hubs in Italy

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The difficulty of the Italian ecosystem in attaining a competitive position is also due to a lack of confidence in the potential of the country which is often perceived by international markets as a great reservoir of companies of excellence but which struggle to

communicate and coordinate with each other to create a united front in the face of external players.

Implementing an ongoing activity of mapping, analysis, contact and monitoring of projects undertaken by Italian centers of excellence would be a resource available to political decision-makers in developing regulatory initiatives and targeted investment. In addition to this, lawmakers could also act as a point of coordination among the centers throughout the country in order to maximize synergy and minimize duplication of costs and time.

The analysis presented in this report highlights Italy’s main areas of excellence in the Life Sciences in order to offer government and institutions a point-of-departure in developing a new model for the management of research and innovation, including in Life Sciences.

While clearly not complete, the survey carried out by The European House – Ambrosetti working group identified **8 poles of excellence**: Biotech Valley (Lombardy), Transplants Excellence (Piedmont), Biomedical District (Emilia-Romagna), Pharma Valley (Tuscany), Global Vaccine Hub (Tuscany), Biosciences District (Latium), Precision Medicine Hub (Apulia), Tech Transfer Hub of Southern Italy (Campania)

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Strategic priorities for research and innovation in Life Sciences in Italy

Italy’s future depends on its capacity for innovation. Great ideas and scientific capabilities must be transformed into products and services that will allow the economy to grow and create jobs. It is essential that investment in vanguard research, guided by excellence, be guaranteed. It is often from here that the innovations and technological achievements that give rise to new opportunities and market expansion are born.

Given the analysis presented in the report and the context in which companies active in the Italian Life Sciences sector operate, the Advisory Board of the Technology Forum Life Sciences 2018 believes it is fundamental that government and institutions urgently take on these four priority areas:

1. Tackle the problem of governance in research and innovation by **creating a National Research Agency** that would draw up a **medium/long-term strategic plan**.
2. Institute a **One Stop Shop**, connected with the National Research Agency, to attract investment and act as a unique point-of-reference for anyone interested in investing in research and production in Italy.
3. Capitalize on Technology Transfer by launching a **Tech Transfer Competence Center**.
4. Provide for a **publicly-owned investment bank** that could efficiently channel available resources, including in compliance with the strategic guidelines of the National Research Agency, and thus stimulate a public-private sector partnership.

As underscored a number of times the Technology Forum Life Sciences 2018, **the time to act is now**, but to take advantage of the opportunities being offered this sector, Italy must develop a model of interaction among research, business and government to put the sector in the best conditions possible to compete on an international level and attract major investment and qualified human capital.

We have the opportunity to prepare ourselves to play a new game-all that is required is to translate words into action.