



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



Partners

Index

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	Introduction	5
01	The Life Sciences Community 2019	6
02	An update of the Life Sciences sector in Italy	7
03	An update on the situation of Technology Transfer in Italy	8
04	Patents in Europe and Italy	9
05	Life Sciences patents in Europe and Italy	11
06	The new frontiers of research and innovation in Life Sciences	12
07	The main technological and innovative trends in Life Sciences	13
08	The new technology players in the Life Sciences sector	15
09	Priorities for action for the ecosystem of research and innovation in Life Sciences in Italy	16



Executive Summary

Introduction

The European House – Ambrosetti’s Life Sciences Community is a **platform entirely dedicated to research and innovation in the Life Sciences in Italy**. Founded in 2015, its mission is to “*Make Italy the country we would like to see for the bio-pharmaceutical of the future: a major player in research, development, production and access to innovative and biotechnological products*”. The Community over the years has become central in driving the evolution of the Italian Life Sciences sector, thus becoming **the reference point for reflection on the actions needed to promote the growth and attractiveness of the Life Sciences’ ecosystem**.

The initiative aims to stimulate the debate, to promote a continuous evolution of the ecosystem of research and innovation in Life Sciences, starting a thorough reflection on the obstacles still present today, identifying new generators of growth and accelerating the positive transformation processes underway, to stimulate the development of new skills, business opportunities and employment.

To achieve these goals, the initiative is developed according to a multi-level working methodology, divided into blocks of activities that are synergistic with each other:

- the organization of **in-depth meetings** during the year, aimed at discussing the key issues for the growth of the sector with the main stakeholders of the national ecosystem of Life Sciences and experts in the sector, to learn about the national and international best practices and elaborate concrete reflections to bring the attention of national decision makers;
- the drafting of the **Position Paper** “The Role of the Ecosystem of Innovation in Life Sciences for the Growth and Competitiveness of Italy”, containing updated analyses of the trends of the national ecosystem of research and innovation in Life Sciences, together with thematic insights and priorities for action to enhance the potential of the sector;
- the design and implementation of the “**Technology Forum Life Sciences**”, a Forum of international visibility and scope to present and share the issues on which the

Community works and involve the political and business leadership, as well as the world of finance and research, in high-level reflections.

The Life Sciences Community 2019

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The Life Sciences Community program, now in its fifth edition, continued in 2019 with the aim of carrying on the work of the previous editions and achieving the following objectives:

- to encourage the implementation and concretization of the proposals presented in the previous editions.
- to strengthen direct interaction with national and regional institutions and policy makers, stimulating them to provide tangible and concrete responses for the growth of the sector.
- to expand the network, involving new entrepreneurs and young researchers.
- to continue with the work of positioning the Life Sciences sector, maintaining a high level of commitment from the players already involved and encouraging the involvement of new interlocutors.
- to increase, among decision makers, the awareness of the importance of considering investments in research and innovation in a systemic vision that gives visibility to market access.
- maintain the observatory on the main international benchmarks.
- to realize the fifth edition of the “Technology Forum Life Sciences” as a reference appointment for the discussion of the strategic agenda of the sector in Italy.
- to produce the new edition of the Position Paper “The Role of the Ecosystem of Innovation in Life Sciences for the Growth and Competitiveness of Italy”, as a document reporting the evolution of the sector and the priorities for action.

The Life Sciences Community 2019 activity path has four meetings throughout the year and a Forum halfway along the path. **(Figure 1)**



Figure 1 |

The activities of the Life Sciences Community 2019.

Source: The European House – Ambrosetti, 2019

The activity of Life Sciences Community 2019 is promoted by four leading partners in the national panorama of Life Sciences, strongly committed to the develop the Italian research and innovation ecosystem:

- **BiovelocITA**, the first Italian accelerator dedicated to companies that deal with biotechnology for human health.
- **Fondazione Telethon**, specialized in research for the treatment of rare genetic diseases.
- **Human Technopole**, the new Italian research institute on Life Sciences.
- **Sofinnova Partners**, an European Venture Capital company focused on Life Sciences.

2

An update of the Life Sciences sector in Italy

For the past five years, the Position Paper has been updated with the data available on the sector to provide an overview of the national ecosystem of research and innovation in the Life Sciences and of the general positioning with respect to the main European countries. This analysis takes into consideration the pharmaceutical sector, the biotechnology sector, and the medical devices sector.

The Life Sciences sector is one of the main high-tech sectors in which the Italian industry is specialized and has significant potential for the overall development of the country.

The industrial sector is made up of a **heterogeneous, innovation-oriented and highly specialized entrepreneurial fabric**, in which micro and small companies coexist with large industrial groups. Overall, there is **significant growth**, a **high level of research intensity**, a **high level of employment** and a **picture of consolidating companies**.

The analysis of the Life Sciences sector in Italy highlights an active and dynamic ecosystem, able to respond promptly to the economic and technological challenges of the market and where growth and innovation go hand in hand:

- the Italian **pharmaceutical** industry, consisting of 291 companies, reached an all-time high in 2018 in terms of production value, equal to 32.2 billion Euros, with a growth rate of 3.2% compared to the previous year. The Italian pharmaceutical sector alone invests **1.65 billion Euros in Research & Development**, +7.8% compared to 2017 and +35% in the last 5 years.
- in 2018, biotech invested more than **2.1 billion Euros in Research & Development activities**, generating a turnover of 11.5 billion Euros, +72% compared to 2012. Despite the constant increase in turnover generated, the sector is now in a consolidation phase and the number of companies has stabilized in recent years. At the end of 2018 there were 641 active companies.
- the **medical devices** sector is populated by more than 3,957 companies, mostly **small and medium-sized** (95%) and characterized by a high degree of interconnection. In 2018, the medical devices market saw a total demand of **11.4 billion Euros** and an export value of **5.1 billion Euros**, +4.7% on the previous year.

An update on the situation of Technology Transfer in Italy

3

Technology Transfer can be defined as the process that leads research innovations to be applied within industry.

To generate real impact, research results should not remain confined within the academic perimeter, but instead be disseminated to the public through the development of applications to be

in the market.

The **Technological Transfer Offices** have the task of promoting the contamination between the academic and industrial worlds, enhancing the creation of university-enterprise relations, managing issues related to Intellectual Property and encouraging the spread of entrepreneurial culture within the academic world.

It should be noted that the Italian Technology Transfer Offices have some disadvantages compared to their European competitors due to their undersizing, both in terms of personnel (4.2 vs 8.5 EU average) and financial resources allocated (€240,000 vs €825,500 EU average), and because of the lack of specialized skills.

Also thanks to the work done by the Life Sciences Community up to now to promote Technology Transfer in Italy and, above all, in the Life Sciences, some positive signals have recently been recorded at the policy level. The Ministry of Education, University and Research has announced the creation of a “**Consortium for the exploitation of the results of public research and Technology Transfer**”. In addition, the new **National Research Program 2021-2027**, which will be presented in the coming months, has placed Technology Transfer at the center of its planning.

4

Patents in Europe and Italy

“Patent activity is to be considered of fundamental importance in the modern economy, in which the value of companies is constituted for at least 90% by intangible assets, composed for the most part of Intellectual Property Rights”¹.

In 2018, **more than 174,000 patent applications** were filed with the European Patent Office, thus achieving a **new historical record**, +4.7% on the previous year.

The United States is the country with the highest number of patent applications, i.e. 43,612, equivalent to 25% of the total. Germany is the leading European country in number of applica-

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¹ Ministry of Economic Development, Italian Patents and Brands Office (UIBM)

tions filed, with over 26,000.

In the ranking of countries that have submitted the most patent applications to the European Patent Office, Italy ranks 10th, with about 4,400 applications, +0.9% compared to 2017.

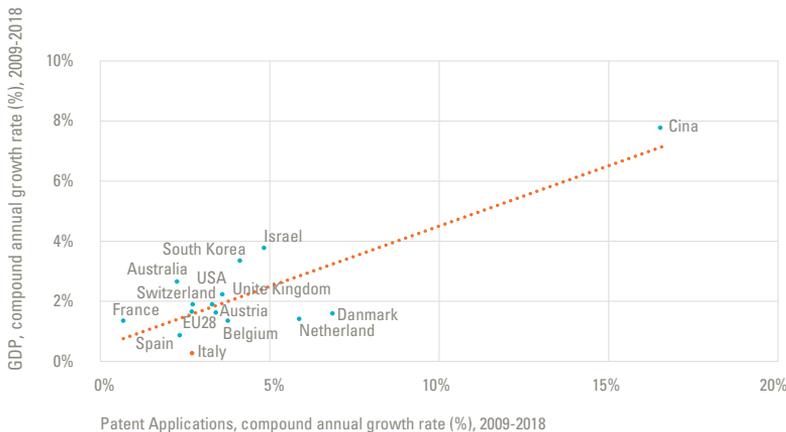
The critical situation for Italy emerges also considering the number of applications submitted per million inhabitants. **With only 71 applications per million people**, our country ranks 20th in the world ranking.

The number of **patents approved** in Europe has increased considerably in recent years: in just three years, since 2015, they have increased by 86.5%, reaching 127,625 in 2018.

USA remains the first country in terms of the number of patents approved, followed by Japan and Germany. In 11th place, **Italy is positioned behind all the main international players in this case too.**

Countries with a higher growth in the number of patent applications – an indication of productive scientific activity – are also those that have a higher growth in Gross Domestic Product. In fact, analyzing the average growth of Gross Domestic Product and the number of patents obtained from a sample of 14 countries worldwide and the European Community in the period 2009-2018, it has emerged that there is a positive correlation between the two variables. **(Figure 2)**

Figure 2 | Correlation between patent applications' Compound Growth Rate and GDP's Compounding Growth Rate, sample of 14 countries and EU28, 2009-2018. Source: elaboration by The European House - Ambrosetti on European Patent Office and World Bank Data, 2019



5

Life Sciences patents in Europe and Italy

The Life Sciences sector – which includes Medical Technology, Pharmaceuticals and Biotechnology – is the **most prolific** and represents 16% of the total number of patent applications filed in 2018.

This sector has been characterized by a continuous increase in patent applications in recent years, reaching 27,978 in 2018, **+35%** over 2009.

The **Medical Technology** sector is the 1st in terms of number of patent applications, in a stable position in the last 10 years. Pharmaceuticals and Biotechnology were respectively in 7th and 8th place in 2018, although they are in 1st and 2nd place for growth rate compared to last year (+14% Pharmaceutical and +12% Biotechnology).

Considering the patents filed in Life Sciences by country, it emerges that the top 3 positions have remained stable in the last 10 years, occupied by the United States, Germany and Japan. China has been new entry in recent years among the top 10 countries; in fact, the Asian country has seen a growth of +431% in the number of applications submitted compared to 2009.

In 2018, among the main European countries, most of the applications in the field of **Medical Technologies** came from Germany with 1,336 applications, or 9.6% of the total, followed by France with 545 applications, -10.2% compared to the previous year. Italy remains at the bottom of the ranking of the subset considered, with 246 patent applications submitted, -11.2% compared to 2017.

For the same year, patent dynamics in the field of **Biotechnology** are similar to the previous year: Germany is 1st, up 15.1% and Italy, with 96 applications submitted, is once again in last position – although this number is up 28.0% compared to the previous year.

Finally, in the **Pharmaceutical** sector, German applications stop at 584, equivalent to 7.8% of the total, but down by 4.3% compared to 2017. France and the United Kingdom follow, while Italy, with 160 applications, is once again in the last position.

In summary, the Life Sciences sector is the main area of interest in patent production. In particular, Medical Technologies have been the most prominent category for the past 10 years and are the group with the highest number of applications filed and patents obtained, confirming the importance of these technologies.

At country level, Germany is the country with the highest number of applications and patents obtained, but at the same time with the lowest growth rate. Italy, on the other hand, is the country with the highest average productivity in Life Sciences, despite the fact that the number of applications and patents obtained is much lower than in other countries – with the exception of Spain. Once again, this result indicates the need for Italian research and innovation players to work to increase patent activity, given the high level of Italian research.

The new frontiers of research and innovation in Life Sciences

6

The innovation brought about by the results of research in Life Sciences has a potential revolutionary effect on all aspects of the daily life of human beings and is a determining factor in the definition of scientific progress.

The Research & Development activities of Life Sciences companies not only result in therapies that have positive effects on the health of citizens and the improvement of patients' living conditions, but also constitute a strategic investment for the national economy.

This is a sector in continuous growth, whose potential is demonstrated by the trend of **investments in Research & Development** in Biotech and Pharma all over the world, which from 2012 to date have increased steadily (+34% from 2012 to 2019) and for which a significant growth trend is expected in the coming

years, reaching **213 billion Dollars in 2024**.

The number of FDA-approved² drugs in 2018 reached a **record 59 new approved drugs**, 27% of which were for cancer therapies.

Similarly, investments in Venture Capital in Life Sciences in 2018 reached a record **60 billion Dollars**, +93% over 2016.

Research in Life Sciences is facing a paradigm shift, increasingly linked to a logic of **personalized medicine** and the development of **next-gen therapies** with the possibility of proposing better prevention activities, better diagnoses, more targeted therapies and reduced side effects.

Companies in the sector are being asked to invest more and more in **automation and digitalization**, capable not only of making research more productive, but also of having an impact on production, on the relationship with patients and, above all, on the use of available data. The intersection with **ICT technologies** and the availability of **Big Data** analysis tools, are allowing to collect, track and process huge amounts of data in all phases of development, making this path more efficient and effective.

7

The main technological and innovative trends in Life Sciences

The dynamics described above inevitably have an impact on the market and on business creation.

To date there are **38 “unicorns”³ globally in the Life Sciences**, which in aggregate have a value of almost 100 billion Dollars. From the analysis of the business models of the 38 “unicorns”, it emerged that the three main areas in which these companies operate are:

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2 The Food and Drug Administration is the U.S. government agency that regulates food and pharmaceuticals.

3 Unicorns are newly established companies with a market valuation of more than 1 billion Dollars.

- **Big Data & Artificial Intelligence.** Data collection and Data usage in the Life Sciences is one of the areas with the highest growth potential. Similarly, the Life Sciences sector represents one of the fields with the best prospects for the application of Artificial Intelligence.

The health sector has become an important testing ground for Artificial Intelligence technologies, so much so that the related investments have reached a record level of **1.3 billion Dollars in 2017**, more than 10 times the figure of 2013.

These new technologies have the potential to predict the effects of certain types of molecules on the human body and identify possible side effects of a drug, significantly reducing the time needed to develop a new cure. Artificial Intelligence technologies are also transforming smartphones and devices for everyday use into real home diagnostic tools, able to detect the progress of people's health and alert doctors in case of abnormalities.

Access to data is one of the enabling key factors for the use of Artificial Intelligence technologies, whose operation is effective only when the data is available on a large scale.

- **Technologies related to Genomics.** DNA sequencing is already revolutionizing the way we do research and conceive health care and bio-pharmaceutical development. The objective is to reach increasingly personalized and precise levels of intervention – so-called “tailor-made” – for the care and treatment of the patient and with an approach that privileges prevention.

The entry into the clinical scenario of Genomics has radically changed the history of some serious diseases, including cancers, potentially changing completely the clinical evolution.

Strong evidence of the potential of Genomics is linked to the **cost of genomic sequencing**, which fell from 95 million Dollars in 2001 for each genome, to 1,300 Dollars in February 2019.

The new path of treatments that is generated is part of what is now defined by the term of **personalized precision medicine**, i.e. that part of medicine that applies

technologies and processes for the diagnosis, prevention and treatment of diseases in view of the variability of genomics, the environment and lifestyle of each individual. The oncological field, in particular, is one of the main fields on which precision medicine is focusing today, especially in relation to the correlations between genome and neoplasms.

- **Online Platforms & Telemedicine.** One of the technological areas with the greatest impact is that of Online Platforms and Telemedicine, or Virtual Assistance.

In fact, services that allow patients not to go physically to the doctor, but to make visits simply by connecting from their devices are becoming more and more frequent.

The use of these online tools is an **important opportunity to improve the health system**, both for doctors, who can organize and plan their working day more efficiently, and for patients, who reduce travelling and waiting times at health care facilities and can save money by comparing the prices of medical products.

Telemedicine services can be classified into 3 application areas: Specialist Telemedicine, Telehealth and Telecare. There are also types of platforms that offer services related to health, other than direct healthcare. These are, for example, platforms for booking medical examinations or comparing drug prices.

8

The new technology players in the Life Sciences sector

The role of technologies is becoming increasingly important for the development of the Life Sciences sector. As a result, the entry of new players, particularly Big Tech companies, into this market is intensifying, causing radical changes in competitive dynamics.

To understand how this is happening, strategies by three of the world's leading technology players in the Life Sciences sector (Apple, Google and Amazon) were analyzed. It is possible to iden-

tify some general macro-trends:

- **use of data generated by users of core business services** (e.g. iPhone for Apple or google.com for Google) and elaborated using the latest technologies (e.g. Artificial Intelligence, Machine Learning and Big Data) to define services and products in the field of Life Sciences;
- **use of hardware devices** (e.g. iPhone, Amazon Eco and Pixel Phone by Google) to assist and monitor user health;
- **close collaboration with the scientific, academic and hospital world** for the research, development and testing of new services and products;
- **interoperability of data on different devices and sharing between different actors** in the sector to allow the full deployment of the potential that arises from the collection, use and analysis of information.

Priorities for action for the ecosystem of research and innovation in Life Sciences in Italy

9

One of the objectives of the Life Sciences Community is to elaborate reflections and proposals for action for the growth of the Italian ecosystem of the Life Sciences, to be shared with the business community and national policy makers.

The intent is to **analyze every year new aspects and lines of action** that can bring new life to the sector, as well as to **maintain high attention** on proposals developed in the previous years and not yet fully implemented.

Therefore, given the analyses presented in this Position Paper and the reflections already shared in previous years, the following 6 priorities are recommended for the ecosystem of research and innovation of Life Sciences:

1. **Define a medium-long term vision and strategic plan that gives priority to research, innovation and the Life Sciences, and establish a National Research Agency.**

It is essential that a country equips itself with national

research and innovation programs, containing lines of development to direct the growth of the national ecosystem, and that these are supported by a strategic, unitary vision, integrated in the medium-long term.

Although Italy is not distinguished by an elaborate and clear vision, it has its own reference document, the National Research Program, and there are positive signs for developments in the coming years on this front. The new National Research Program 2021-2027 will be elaborated by the Ministry of Education, University and Research, involving more than one thousand Italian researchers and professors, with the aim of elaborating a long-term strategy.

The creation of the new Ministry for Technological Innovation and Digitization is also a positive sign, demonstrating the growing importance that innovation issues are assuming in the definition of national policies.

2. Increase national investment in Research & Development

Investment in Research and Development in Italy is still far from the European target of 3% of Gross Domestic Product.

To date, the level of Italian investment has only reached 1.35% of Gross Domestic Product, equal to 23.3 billion Euros. Compared to its main European competitors – Germany, France, the United Kingdom and Spain – Italy is almost in last position, ahead only of Spain, whose weight of investment stands at 1.20% of GDP. Germany holds the top position with investments exceeding 3% of GDP.

In order to match, at least, what France is investing today, Italy would have to increase its R&D budget by 26.7 billion euros, which would still be only half of the amount invested by Germany.

3. Create a Master for Technology Transfer in Life Sciences

As described in this Position Paper, Italian research proves to be excellent in the production of high-level content, extremely competitive on the international scene, but finds it difficult to translate these works into market innovations.

Following the input of the Life Sciences Community and with the aim of stimulating the transfer of knowledge from research to business, in August 2019 the Ministry of Education, University and Research established the “Consortium for the exploitation of the results of public research and technology transfer”. This subject will support the patent activity of researchers and help them in the prototyping phase, acting as a meeting point between the university and research systems, investment funds and companies to promote the spread of innovation at the national level, in order to stimulate productivity, growth and employment. To carry out these activities, the Consortium has been provided with an initial public allocation of 4 million Euros, which, according to the promoters, could reach 20 million through private contributions.

Although this is a positive sign for the Italian research and innovation ecosystem, these sums represent only a small amount of the resources that would be needed, and they should be accompanied by a clear and effective planning as well.

In order to improve Italy’s Technology Transfer situation, it is important to promote concrete initiatives capable of bridging those gaps that still have a strong impact today.

The creation of a Master for Technology Transfer in Life Sciences would therefore go in this direction, with the aim of training professionals in the exploitation of the research results in Life Sciences.

4. Promoting programs for the development of future technological skills in the Life Sciences

New players, in particular Big Tech companies and startups, are becoming prominent actors in the field of healthcare. In fact, advanced technology is linked to many developments in the field, with the creation of new solutions, therapies and instruments of control and measurement.

It is therefore essential to update the skills of Life Science professionals in line with these new trends. Life Sciences knowledge must be combined with technology knowledge.

5. Creating an Open Innovation Platform for the Life Sciences

Online platforms are becoming more and more a reference and facilitation point for the development of new skills and collaborations. Also, in the field of the Life Sciences online platforms can be used to increase the potential of research and help those who do research to get in touch with the business world and vice versa.

Developing a national Open Innovation platform for Life Sciences would allow to easily create a solid network of actors operating within the same ecosystem, with the objectives of:

- provide a virtual point of reference for research and businesspeople.
- bring together the world of research and the world of business.
- promote networking and knowledge share between different professional figures.
- enhance the know-how and skills of Italian research in the Life Sciences.
- help Italian companies, especially SMEs, to interface with new sources of knowledge.

6. Encouraging the establishment of advanced manufacturing in the Life Sciences

Manufacturing is a fundamental component of the economies in developed countries: it guarantees, with its companies, high employment and innovation rates, it stimulates the development of new skills and professionalism, it activates supply chains in other economic sectors and it overcomes the constraints of the local market and falling internal consumption. It is also the sector that can ensure the best, most stable, most technologically advanced employment prospects.

The Life Sciences sector in Italy boasts consolidated know-how in manufacturing, enriched by a dynamic ecosystem of Research & Development and the presence of excellent researchers.

In order to encourage the development of the full potential of advanced manufacturing in the Life Sciences sectors, it is essential to define mechanisms for rooting production on an industrial scale in the territories where the underlying research has been carried out and to create incentives fostering the implementation of industrial plans 4.0 that exploit the latest technologies in production to optimize processes and increase their efficiency and that of the entire industrial system.

The shift towards 4.0 industry models is profoundly transforming both the internal processes and the production processes of companies in the sector. Manufacturing is changing from batch to continuous production – with increased efficiency, flexibility and quality control. The quality by design approach, sensors and devices for integrated monitoring, connectivity, real-time data analysis and Artificial Intelligence systems are more often integrated into manufacturing processes, enhancing quality control, real-time risk management and integrating the potential of automated self-learning and self-improvement mechanisms⁴.

4 Source: The European House – Ambrosetti, Pharma Manufacturing 2030, Manifesto for Italy's leadership in the innovation-driven manufacturing industry, September 2019

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