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FARMINDUSTRIA

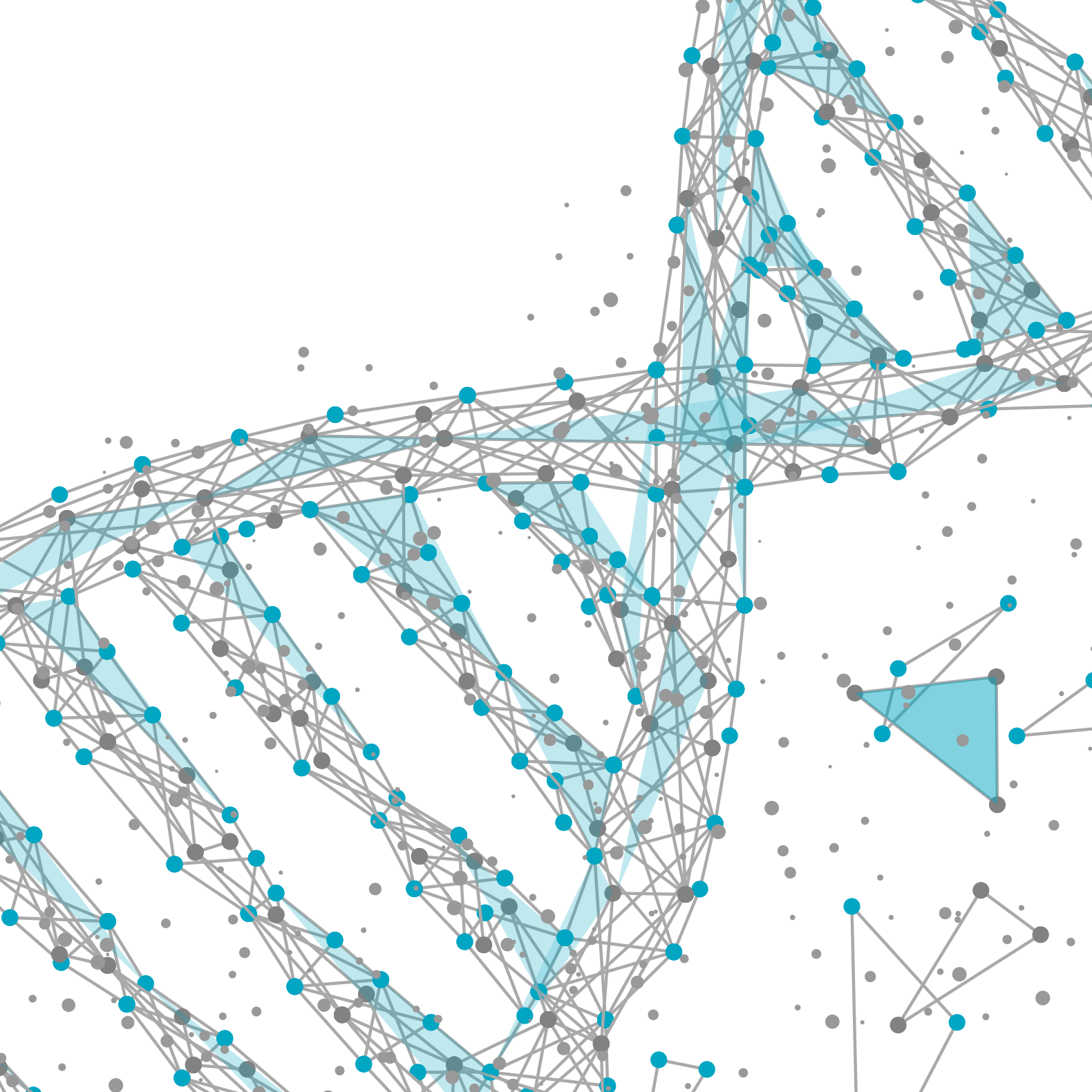
# The biopharma sector

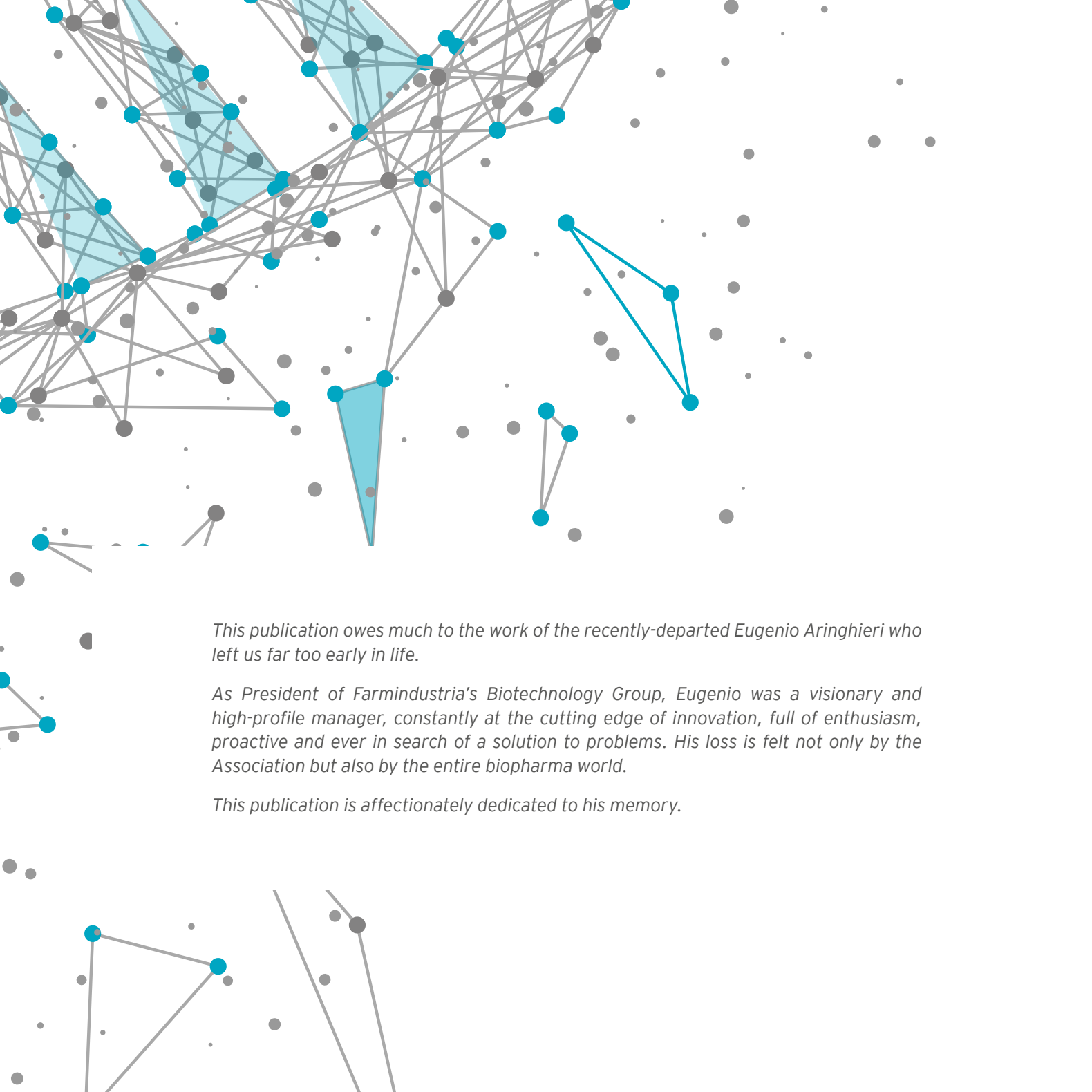
Innovation and  
growth for Italy



**EY**

Building a better  
working world

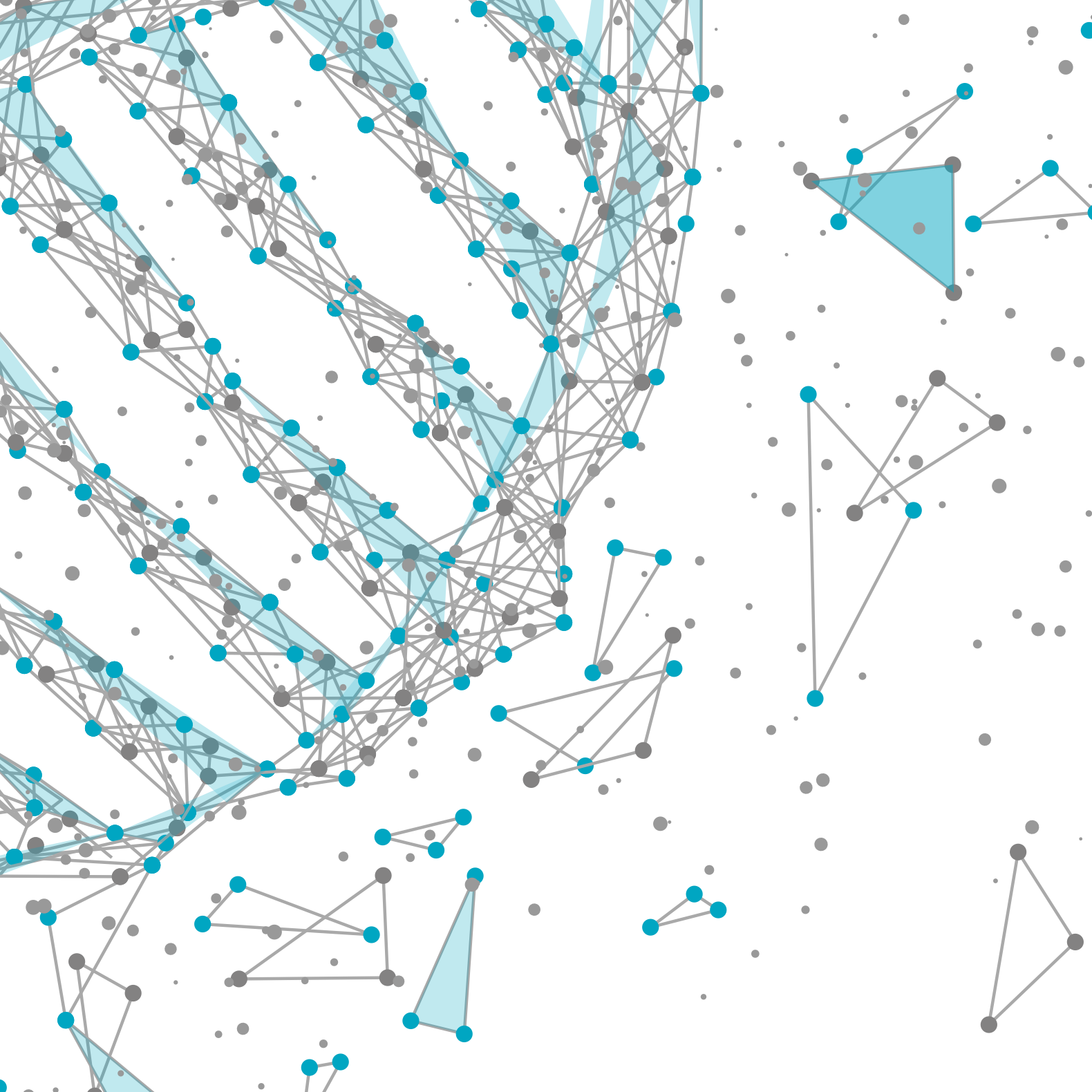




*This publication owes much to the work of the recently-departed Eugenio Aringhieri who left us far too early in life.*

*As President of Farindustria's Biotechnology Group, Eugenio was a visionary and high-profile manager, constantly at the cutting edge of innovation, full of enthusiasm, proactive and ever in search of a solution to problems. His loss is felt not only by the Association but also by the entire biopharma world.*

*This publication is affectionately dedicated to his memory.*





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# Towards a new role for biopharmaceuticals



**Massimo Scaccabarozzi**

*President of Farindustria*

We celebrated some important anniversaries in 2018: the first forty years of the National Health Service, a resource shared by the whole country, and the judgement handed down by the Constitutional Court in 1978 that, by allowing pharmaceutical patenting, created the conditions for the biopharma sector to grow and flourish in Italy.

For the past forty years, Farindustria's principal mission has been to cultivate this development. Furthermore, as a corollary to the major transformations taken place over this lapse of time, we are now witnessing even more radical changes engendered by an unprecedented acceleration in innovative processes.

Every phase in mankind's evolution has been marked by technological breakthroughs impacting at an ever faster pace. This exciting race for knowledge proceeds by leaps and bounds. Thus mankind needed 150 thousand years between the discovery and deployment of fire but only 66 years elapsed between the first human flight (40 metres) and the first flight to moon. In no more than 14 years the costs of sequencing the human genome have

fallen from one hundred million to one thousand dollars, while in another fundamental area, namely information technology, we see the processing power of a microchip doubling every 18 months.

Today we are clearly living in one of these technological leaps. Moreover, the life sciences are an example of those fields where the boundaries between different disciplines and sectors are rapidly breaking down: genomics, big data, robotics, gene therapy, artificial intelligence, and nanotechnologies interact and cross-fertilise to produce extraordinary results. Personalised medicine and digital pharmaceuticals are now a fact of life and have completely changed our approach to many diseases, together with therapeutic improvements that only a short time ago would have been unimaginable. Pharmaceutical R&D is experiencing a period of great vivacity with 15,000 new potential medicinal products in the pipeline.

This is the context in which Italy has become the leading pharmaceutical manufacturer in the European Union thanks to a highly skilled workforce, the vitality of the companies operating in the territory and the quality of hi tech upstream sectors.

Moreover, the country's R&D expertise is second to none. Our pharmaceutical companies, whose investments in the last 5 years were higher than the European average, now operate at the centre of an ecosystem. In this environment, research is no longer confined to corporate boundaries but increasingly performed through partnerships with universities, SMEs, start-ups, no-profit bodies and clinical centres, where now almost 20% of the studies conducted in Europe are carried out. This outcome is due to the many excellences within the territory that have generated value for patients, as well as for the NHS and the scientific system as a whole.

Italy, therefore, can compete internationally in life sciences and biopharmaceuticals and it can attract an ever greater share of the financial resources invested every year in R&D throughout the world. However, our competitors are numerous and investments are made wherever the most efficient systems are to be found.

The biopharma industry is ready to invest even more in Italy, but our country, for its own part, must satisfy the criteria of efficiency requested. For this reason,

we are calling for a new governance that will allow companies to rise to the challenges posed by the rapidly transforming manufacturing environment in which they operate.

A system is at its most efficient when financing is sufficient, resources are used efficiently, the latest mechanisms for programming expenditure are in place, access to new pharmaceutical products is rapid and uniform throughout the territory but also, and above all, when the protection of intellectual property and patents is respected in order to guarantee the right to the most appropriate treatment for all citizens.

# Biopharma, an opportunity for the country

## The biopharma sector, an engine of innovation

With € **720 million invested in R&D in 2017**, biopharmaceuticals represent one of the sectors that is staking its future on innovation. By targeting biopharmaceuticals, we provide access to new therapies, improve the quality of patients' lives and reduce the social costs associated with pathologies.

## A significant worldwide role

With total sales of **10 billion** the biopharma companies in Italy represent about **5% of the sector** worldwide and **32% of the pharmaceutical industry** within the national territory.

## An excellence Made in Italy

Researchers with renowned expertise, technologically advanced centres of excellence, and an entrepreneurial community comprising **200 companies and 4,000 research employees**: the biopharma sector, an industry Made in Italy, is a source of pride for the country.

## The need for networking

Strategic planning, dedicated legislative measures and better public-private cooperation - specifically, cooperation between the institutions, universities, companies, physicians and patient associations - is essential for biopharma's growth.



## The Italian biopharma sector of 2017 in figures



**200 companies**

Large, medium-sized, small and micro companies operate in the biopharma sector, each with an ongoing commitment to innovation.



**4,000 R&D employees**

Professional personnel and researchers of recognised excellence, whose numbers have been growing at the rate of 1.8% per year since 2015.



**720 million euro invested in R&D**

Investments by biopharma companies in R&D are growing 2% for year and represent ongoing innovation benefitting not only patients but our country as a whole.



**10 billion euro in sales**

Biopharma confirms its importance for the health sector.



**5% share of the world biopharma market**

Italy boasts a significant worldwide sales performance.



**8.5% growth in biopharmaceuticals**

The growth of the biopharma sector is higher than that recorded for the world as a whole.

Data referring to companies that perform production activities in Italy in one or more of the following areas: R&D on biotech medicinal products and/or vaccines for human use, R&D on correlated services (drug delivery, or the development of technologies for transporting medicinal products to a specific site; drug discovery, or the provision of services correlated to the achievement of the final product or other correlated services), the production of biotech medicinal products and/or vaccines, the marketing of biotech medicinal products and/or vaccines, and the provision of correlated services (drug delivery, drug discovery).



# Innovation, the engine of growth

## Innovation always generates greater value for our country

In an era in which technology, speed and flexibility are the principle factors in determining a country's competitiveness, innovation and its dissemination should be understood as a means to generate value for an economic system. Innovation in Italy continues to grow, creating ever new development opportunities.



**4,300**

Italian patents in Europe 2017,  
+4.3% more than the preceding year.  
**Italy ranks 5<sup>th</sup> in Europe<sup>1</sup>.**



R&D spending as a percentage of  
GNP is forecast to grow from

**1.4% to 1.5%**

**in 2020**

which, however, remains **below the  
average European target of 3%<sup>2</sup>.**



**+18%**

more patent applications for  
pharmaceuticals Made in Italy  
in 2017, compared to the  
**European average of 8.1%<sup>1</sup>.**



**+16%**

growth in pharmaceutical exports  
from Italy in 2017<sup>3</sup>.

1. EPO (European patent office) statistics

2. Eurostat

3. Farindustria, Pharmaceutical Indicators 2018

4. EY Analysis

## Biopharmaceuticals: at the forefront of innovation in Italy

### 1.5€ billion

in R&D investments by the pharmaceutical industry, **+22% in 5 years**, and growing faster than the rest of Europe (+16%)<sup>3</sup>.

### 11%

of all corporate R&D investments are made by pharmaceutical companies; accounting for 6.5% of all Italian R&D<sup>3</sup>.

### 3 times the average

amount of investment in innovation for employee, with a 3.2% increase in R&D employees since 2016<sup>3</sup>.

**The biopharma sector:  
a strategic asset for  
the country**

### 32%

of all upstream production in the pharmaceutical industry in 2017 was generated by biopharma, which has been growing at a rate of about 8% per year since 2015<sup>4</sup>.

### 72%

of all investment in production and research by the pharmaceutical industry is in the biopharma sector<sup>3</sup>.

# Innovation and expertise: the opinion of a panel of companies<sup>1</sup> representative of the biopharma sector

## What does innovation in the pharmaceutical sector mean?



### Introducing new therapies

Making new therapies available that can change people's lives, especially in those therapeutic areas characterised by unsatisfied health needs such as oncological pathologies or rare diseases.



### Improving the life of millions of patients

Innovations in existing therapies to improve the quality of patients' lives and increase life expectancy.



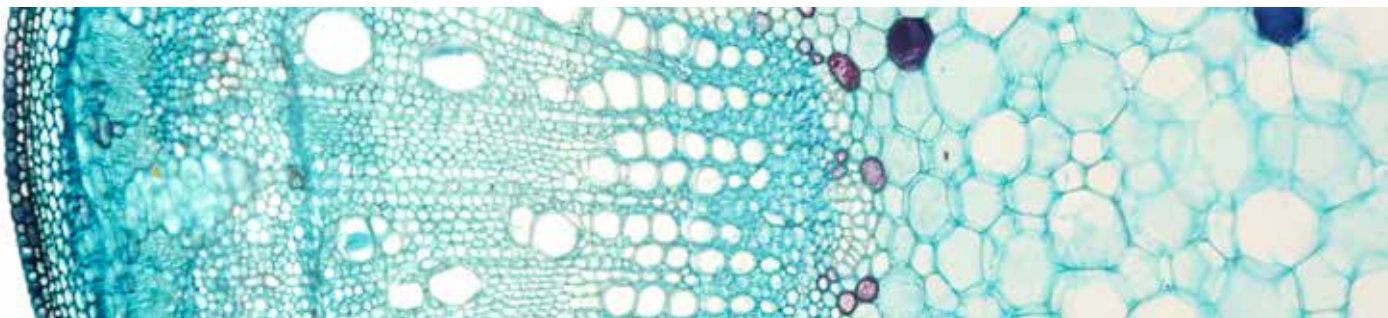
### Optimising processes with new technologies

Deploying new digital technologies, big data and robotics for basic research, pre-clinical and clinical trials, therapy production as well as for communicating with physicians and patients.



### Contributing towards the sustainable development of the National Health System

More effective innovative therapies can reduce hospitalisation times and costs and thus generate savings for the NHS and benefits for patients.



1. Companies involved: AbbVie, Amgen, Chiesi Farmaceutici, Dompé Farmaceutici, Menarini Group, Merck Serono, MSD Italia, Novartis Farma, Pfizer Italia, Roche, Sanofi

## What skills are needed to excel in the biopharma sector?



### Multi-disciplinary training

In the biopharma sector, technical skills go hand-in-hand with an understanding of corporate processes. Biopharma companies offer training schemes for newly graduated employees so they can acquire experience in several different areas such as research, production, market access, communication and regulatory affairs.



### Work and study courses

Theoretical training and practical applications are necessary to prepare young people entering employment for the first time. Training courses must be encouraged that, for example, include internships in companies, scholarships and joint degrees.



### International experience

The joint pursuit of research, business and innovation is now a global concept. Italy competes with foreign countries to attract resources and develop talents while our researchers cooperate on international research projects. Language skills and exchange programmes between international research centres are now essential features of the industry.



### University - company partnerships

Research is not an end in itself but a means to develop new therapies. R&D projects conducted jointly between the academic and business worlds are ever more widespread. Managerial and soft skills, within multi-disciplinary teams, are necessary in order to dialogue profitably with industry and investors.



### New technologies

Innovative biotechnologies, big data and robotics have radically changed the reference context. A knowledge of new technologies, their operation and possible applications, is essential for success in biopharmaceuticals.



### Flexibility and willingness to learn

“Learning to learn”: universities must teach students to keep themselves updated and conversant with a continually changing world that requires new skills and ever more flexible professional figures.

With 4,000 R&D employees, growing at an average rate of 2% for year, biopharma is one of the sectors that offers the best job opportunities in Italy.



# Cooperating to innovate

## The role played by universities, companies and institutions

The innovation process calls for close cooperation between the universities, as promoters of research, and companies as facilitators of the development and uptake of new biotech therapies. The institutions also play a key role in creating an ecosystem favourable to innovation through measures aimed at reducing red tape, encouraging investments and promoting cooperation.



### Universities

#### Teaching new skills for a changing world

- Providing students with skills appropriate for future employment
- Investing in research
- Encouraging researchers and safeguarding intellectual property
- Acquiring the skills needed to develop technological transfer processes.



### Companies

#### Innovating to compete as well as to improve patients' lives

- Investing in basic and clinical research in association with universities, research centres and hospitals
- Making new therapies available
- Supporting programmes for efficient training
- Offering opportunities for the professional development of researchers in Italy.



### The institutions

#### Encouraging an innovation orientated ecosystem

- Developing a system of clear rules that remain fixed over time to stimulate investments in innovation
- Streamlining bureaucratic processes for public-private cooperation
- Broadening access to innovative therapies
- Safeguarding and valorising intellectual property.

## Outstanding examples of public-private partnerships



### **Dompé and ophthalmic research**

*A successful Italian public-private partnership*

From the cooperation between Dompé and the Universities of Chieti and L'Aquila, the Centre of Excellence in Ophthalmology and the Abruzzo Region, the first ever biotech therapy was developed to treat neurotrophic keratitis, a rare disease of the cornea that can lead to blindness. Altogether, 1,000 sq. m of laboratory space and over 70 researchers have been earmarked to preclinical and clinical trials for the development and manufacture of new therapies. The culture of innovation is promoted by teaching provided by Dompé personnel in its partners' facilities. 10 scholarships are also awarded every year to pre-and post-graduate students.



### **The Merck Serono establishment in Bari**

*The South of Italy as an engine of pharmaceutical innovation of international renown*

Over time Merck Serono has developed what is now a cutting-edge production facility for biotech medicinal products. Today it is the leading exporter in the city and province of Bari (31% of all exports from the area) and contributes 4% to Italian pharmaceutical exports overall. This is an automated «fill & finish» facility that guarantees the entire productive process commencing from the preparation of a biotech medicinal product to its despatch to around 150 countries throughout the world. It represents a successful case of public-private cooperation. Currently, the site has about 300 employees, and over the past 5 years, received € 85 million in investments, of which about 20% co-financed by the Puglia Region.



### **Istituto Mediterraneo per i Trapianti**

*Biotech and high-level specialisation, Sicily's recipe for excellence*

ISMETT (Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione) [the Mediterranean Institute for Advanced Specialisation in Transplants and Therapy] is a centre of excellence for transplants. The institute, the outcome of a partnership between the Sicilian Region and the University of Pittsburgh Medical Center, is an example of innovative and efficient healthcare management. In June 2017 the Ri.MED Foundation became one of ISMETT's partners, in order to promote biotech projects and research. Within its 12,000 sq. m, the institute possesses 4 operating theatres, clinical, microbiology and anatomical pathology laboratories, a radiological department and multi-specialist outpatient clinics.



### **San Raffaele Biomedical Science Park**

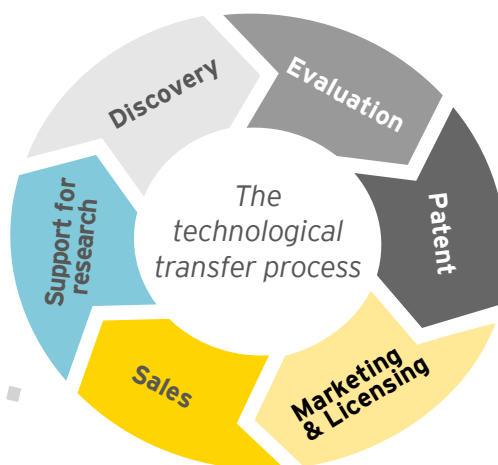
*The cluster as a means to promote technological development and transfer*

The San Raffaele Biomedical Science Park is one of the largest biomedical scientific parks in Europe. Financed autonomously, it sets out to perform integrated research and development, training and cooperation programmes with companies. It assists researchers and companies with its research and development activities, laboratory management, access to technological donations and consultancy on intellectual property and technological transfer. It also includes a Biotech Research Department (DIBIT) that comprises 12,000 sq. m of laboratory space, entirely dedicated to basic research.

# Technological transfer to sustain innovation in biopharmaceuticals and its reference models

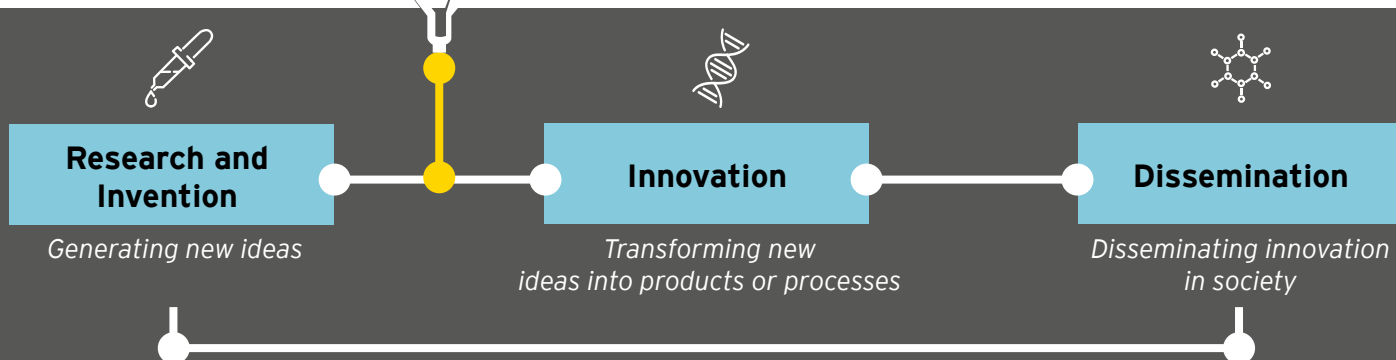
**Technological transfer is the process whereby biopharma research results are transformed into new therapies or medicinal products**

Technological transfer acts as bridge between the academic world, whose objective is to guarantee the dissemination of research, and industry whose aim is to transform the results of scientific research into new therapies for patients. There are currently 225<sup>1</sup> officers in the technological transfer offices of Italian universities, with an average of 4.2 FTE<sup>2</sup> for each office, which is still a limited number compared to the European average of 8.5 FTE<sup>2</sup> per office. The dissemination and efficiency of technology transfer processes should be seen as priorities if innovation in the biopharma sector is to be sustained. Universities and research bodies must endow themselves with appropriate skills to evaluate the potentiality of new discoveries, as also to safeguard intellectual property and develop agreements with companies.



1. NETVAL 2018 report  
2. Full Time Equivalent

*Technological transfer: the bridge between research and innovation*







## **Technology Transfer Company**

### *The Israeli innovation model*

Israel has adopted the Technology Transfer Company (TTC) model as an alternative to the traditional American model of the Technology Transfer Office (TTO), which consists in setting up a dedicated office for technological transfer inside a university. Instead, TTCs are independent (founded by one or more universities and possibly with private partners) and have the mission of sustaining R&D by making projects financially autonomous, assisting industry to access inventions and financing, and safeguarding not only the independence and the public utility of the research but also intellectual property rights. Unlike the TTO, TTCs enjoy greater independence and autonomy of movement as they are, in actual fact, spin-offs created by the universities.

A TTC sets itself the task of:

- evaluating an innovative project and its potential
- reaching agreements with industry to finance research projects
- protecting the intellectual property of a university and its researchers through patents
- supporting the dissemination of an invention through commercial agreements and licensing.

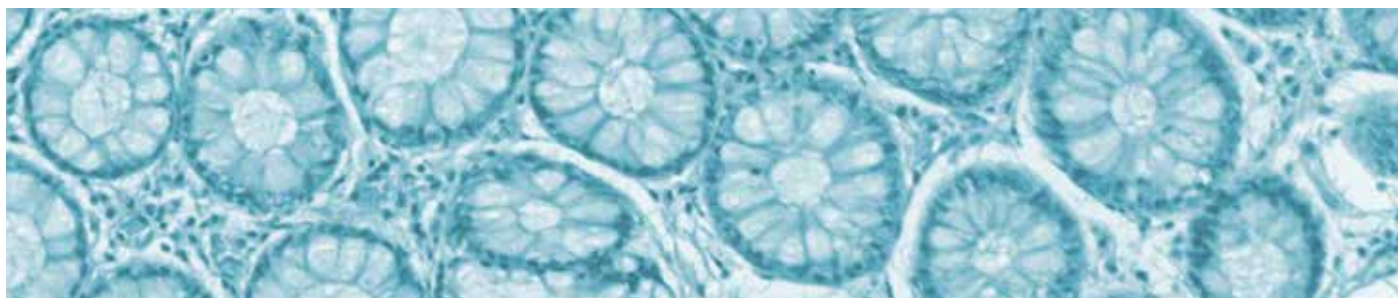
It would appear that the TTC is a successful model for innovation: the Weizmann Institute of Science's TTC, YEDA, at Rehovot, Israel, comprising 12 partners, has, between 2013 and 2015, helped WIS's scientists register over 260 patents, obtain financing for 90 R&D projects and present over 4,500 developed research projects to companies<sup>1</sup>.

The activities of the TTCs in Israel have benefited the entire country.

- Israel is a leading country in terms of innovation with R&D expenditure accounting for almost 4.4% of GNP; twice the OECD average<sup>2</sup>
- Israel attracts more start-ups and investments than any other country in the world.

1. YEDA statistics

2. OECD: The Organisation for Economic Cooperation and Development



## Reinforcing partnerships between the academic world and the biopharma industry



**Maria Cristina Messa**

*Rector of the Bicocca University of Milan and President and CEO of the University for Innovation (U4I)*

### **The biopharma sector is undergoing continual innovation. How can universities contribute towards such innovation?**

First of all, biotech courses must be brought up-to-date so that students can keep abreast of this changing world and be suitably qualified for a job when they graduate. Thus, the curricula of newly graduated students must include a thorough knowledge of the new technologies, digital tools and, more in general, the processes for developing and marketing biotech medicinal products. With this objective in mind the Bicocca University of Milan is participating in a round table with regional and national institutions.

Moreover, as cooperation with companies is of ever greater importance for the universities, PhD courses play a key role. More and more scholarships are financed by companies and 70% of students who complete a PhD course find employment in companies in this sector. The Bicocca University of Milan has, in cooperation with biopharma companies, introduced PhD courses specific to the industry in order to train professional figures to develop autonomous research skills and prepare themselves for work in this sector.

### **What incentives exist to encourage cooperation between universities and biopharma companies?**

The principal limits to cooperation between universities and companies are cultural and bureaucratic.

It is necessary, in the first place, to disseminate a culture of cooperation as a means for developing joint research programmes aimed at stimulating innovative therapies. Bureaucratic procedures must be streamlined and harmonised, and guidelines defined that clearly regulate relations between universities and industry.

In conclusion, the universities must acquire the technical, legal and managerial skills necessary to manage technological transfer processes.

“ New didactic programmes and greater cooperation with companies are the key to the success of tomorrow's universities.”



## U4I - *University4Innovation*

### *Outstanding cooperation between universities*

U4I, the first Italian project for the valorisation of inter-university research, is the product of cooperation between the Bicocca University and the Universities of Milan, Bergamo and Pavia.

U4I sets out to attract important international investors, valorise its unique portfolio of patents, stimulate the growth of spin-offs and create and disseminate a culture of innovation.

U4I's objective is to:

- ▶ identify and evaluate the most promising research projects
- ▶ finance R&D costs, especially through public-private collaboration
- ▶ facilitate the protection of the three universities' intellectual property
- ▶ cooperate with the industry to exploit innovation
- ▶ promote joint innovation between the three universities in order to develop new discoveries.

U4I represents the first example of technological transfer in Italy aimed at increasing patenting capacity and entrepreneurship among researchers.

U4I's success in figures: 41 departments involved, over 2,000 researchers, more than 100 patent families.



There can be no progress without innovation: we must transform ideas into projects and projects into progress.



# How can we attract resources for innovation?

## The key elements for sustaining innovation

The biopharma sector in Italy has the chance to play a leading role in the international arena. However, human resources must continue to be developed, intellectual property safeguarded, bureaucratic simplification guaranteed and long-term stability of government measures ensured.

### Human resources

#### Targeting instruction in biopharmaceuticals in order to attract and develop talents

In a highly innovative and continually changing sector, cross-disciplinary skills are essential. Universities must update their didactic courses, and companies must cooperate with them to provide on-site training and create the skills needed for tomorrow's jobs. Mapping out an educational path for biotechnologies represents an opportunity for young people's future.

### Research and intellectual property

#### Stimulating technological transfer processes to maintain competitiveness

Disseminating technological transfer processes will enable Italy to maintain a competitive international role in biopharmaceuticals. However, there are three areas where action needs to be taken:

- streamlining bureaucratic procedures for efficient cooperation between universities and industry
- endowing universities with technological transfer skills, also through the creation of special-purpose structures (e.g. U4I the Bicocca University)
- providing incentives for scientific production and valorising the intellectual property of researchers.



## Financial resources

### **Attract investments in R&D in order to continue to grow**

Italy competes with other countries in the world to attract the financial resources held by companies and investors. This activity presupposes three requisites:

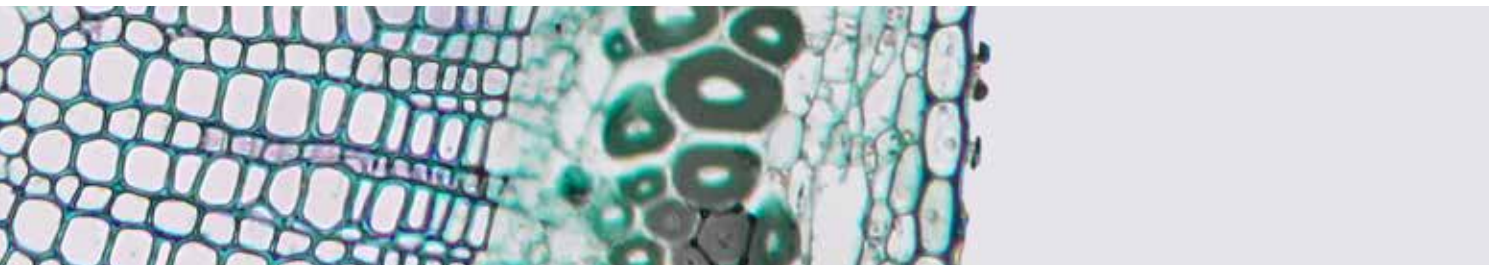
- a culture that can capitalise on the support provided by investors specialised in R&D processes
- the presence of specialised investors in the biopharma sector
- a plan for fixed and long-term measures to boost investments.

## Governance and the regulatory framework

### **Guarantee uniform access to innovative therapies for the well-being of all patients**

Enlarging and speeding up access to new therapies is a priority as it will improve patients' lives and provide hope for the treatment of still incurable pathologies. A dialogue is needed between institutions and companies for:

- an administration that is fully aware of the country's needs
- the streamlining of bureaucratic procedures
- reimbursement policies that take account not only of a therapy's cost but also of the benefits expected and the social and hospitalisation costs avoided.



## How to make the Italian biopharma sector attractive to specialised investors?



**Federica Draghi (FD)**  
*Business Development Director*



**Claudio Giuliano (CG)**  
*Innogest's Founder*

### **What factors attract investments in the biopharma sector?**

**(FD)** Success in this sector entails the following components: a high level of innovation for single projects but also for the research ecosystem as a whole; the human factor, understood as the skills and experience of the actors involved in developing a project; and access to specialised capital able to sustain the various stages of the long path toward the production of a medicinal product such as public grants, business angels, venture capital, strategic investors and a receptive public market.

**(CG)** The presence of specialised investors and, therefore, of persons able to understand and relate to scientific, clinical, regulatory, and pharmacoeconomic matters is fundamental if we are to attract investments. Given that today venture capital investments in Italy only amount to about € 200 million compared to € 2 billion in France, there is still ample room for growth. 4 venture-capital funds are now operating in Italy, and each year they invest in about 3 - 4 innovative companies.

### **What biopharma segments are the most attractive for investors?**

**(FD)** Currently rare diseases attract considerable attention as also do highly complex therapeutic areas representing still largely unsatisfied medical needs such as oncology and neurology.

**(CG)** A specialisation in key therapeutic areas is important. In Italy, we find major excellences in the field of cardiology, metabolic pathologies, immunoncology and neurology.

### **What legislative measures are sustaining biopharma investments in Italy and abroad?**

**(FD)** In recent years the institutions, (e.g. the Ministry of Economic Development) have become more willing to discuss our needs and adopted measures in favour of investments in innovation, although these are scheduled to be phased out by the end of 2020. The hope remains that our dialogue with the institutions can continue. We are now finally competitive at the European level but we need stability if we are to remain so.

**(CG)** France is an excellent example of a country that over the last 20 years has shown itself able to create a culture in favour of innovation and investments in research thanks to a policy centred upon venture capital. In Italy, it is necessary to introduce measures aimed at increasing both the number and the scope of venture capital operators by deploying not only public capital - in the form of mutual funds - but also tax measures to facilitate investments in such funds by major institutional investors, such as banks, insurance companies and pension funds. Italy must find the will and the courage to sustain a large-scale system of innovation rather than continuing with small-scale, albeit appreciable, incremental measures.



# Tax measures to sustain innovation in Italy and abroad

Italy has introduced various instruments in favour of innovation. However, the continuity of such interventions must be guaranteed in the long term if investments in our country are to be encouraged.

	Tax credit	Patent box	Super and hyper depreciation	Other
<b>Italy</b>	Up to 50% of incremental R&D costs Up to 25% for asset acquisitions related to innovative development in the South of Italy	Up to 50% of income from copyright, patents or trademarks is excluded from the assessment of tax liability	140% of the acquisition cost of new assets 250% for the purchase of fixed assets related to Industry 4.0	Reverse brain-drain: 4 year exemption on 90% of the taxable income of professors and researchers; 5-year tax exemption of 50% of taxable income of foreign workers seconded to Italy Deductions for investments start-ups and innovative SMEs (30%)
<b>France</b>	Up to 30% of incremental R&D costs for a maximum of € 100 million 5% on excess spending	15% preferential tax rate on national and European patents (the invention must be patentable in France)	Accelerated depreciation	Favourable tax regime for capital gains from investments in innovative start-ups (from 50% to 85% according to the duration of the investments)
<b>Spain</b>	Up to 25% of incremental R&D costs Up to 42% of the amount exceeding average R&D spending recorded in the 2 preceding years	60% abatement of the taxable income of companies holding patents	Accelerated depreciation	40% reduction in social security/pension contributions for R&D personnel
<b>Germany</b>	No measures provided	No measures provided	No measures provided	Direct 75% subsidy of R&D investment costs
<b>UK</b>	Up to 12% for incremental R&D costs	10% preferential tax rate for income derived from patents	No measures provided	Tax relief for SMEs increased to 230% of qualifying R&D costs

Source: EY analysis

## Non-European countries targeting biopharmaceuticals



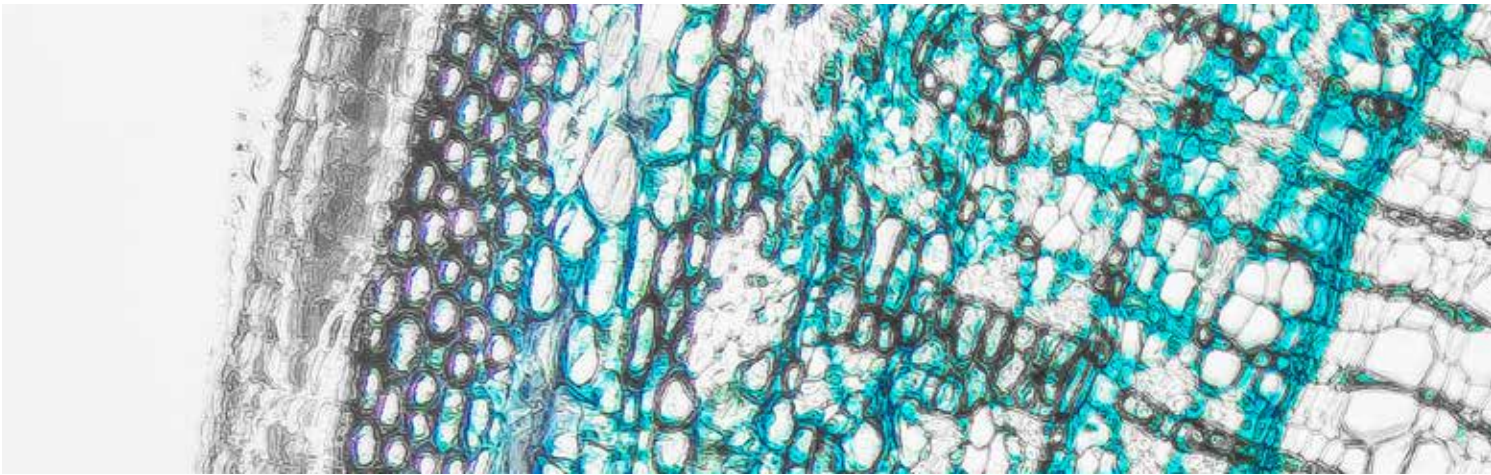
### The biotech industry in China<sup>1</sup>

Biotech lies at the heart of China's growth strategy and, hence, is one of the objectives included in the country's 2016-2020 strategic plan. By 2020 income from biotech is forecast to account for more than 4% of GNP.

Also by 2020 and with investments for \$ 1.45 billion, China plans to build between 10 and 20 biomedical parks, which will be in addition to the already 100 scientific parks existing in the country.

#### China today: innovation and biotech

- Over the last 5 years China has ranked second in the world for publications and patent applications
- Over \$ 100 billion in public investments to finance an ambitious strategic plan forecast for the life-sciences sector
- With its «*Thousand Talents*» programme, over 7,000 scientists returned to China, of whom 1,400 in the biopharma sector
- \$ 45 billion in Chinese venture capital and private equity has been raised for biopharma investments in only 30 months
- The universities cooperate with inventors to develop start-ups and spin-offs (technological transfer).



1. Source: EY analysis



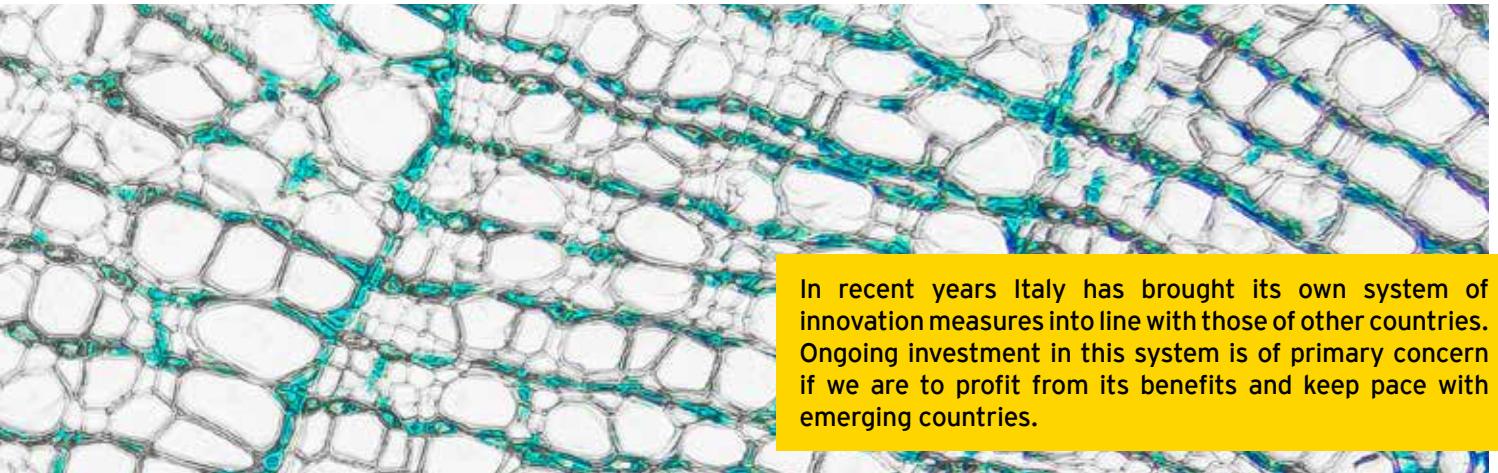


## The priority voucher mechanism as an incentive for innovative start-ups in the USA

The priority voucher mechanism was introduced by the Food and Drug Administration (FDA) in 2007.

Companies that develop a product designed to treat orphan or rare paediatric pathologies (the criteria are laid down by the FDA), receive a voucher giving them a privileged right to submit a dossier to the FDA.

A company awarded a voucher can either sell it (e.g. to other pharmaceutical companies) to finance research or use it to submit its invention or the results of other studies to the FDA, thus avoiding long delays and reducing evaluation time from 10 to 6 months.

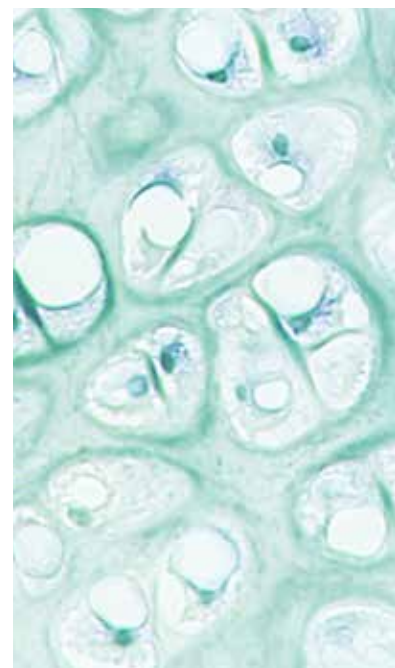


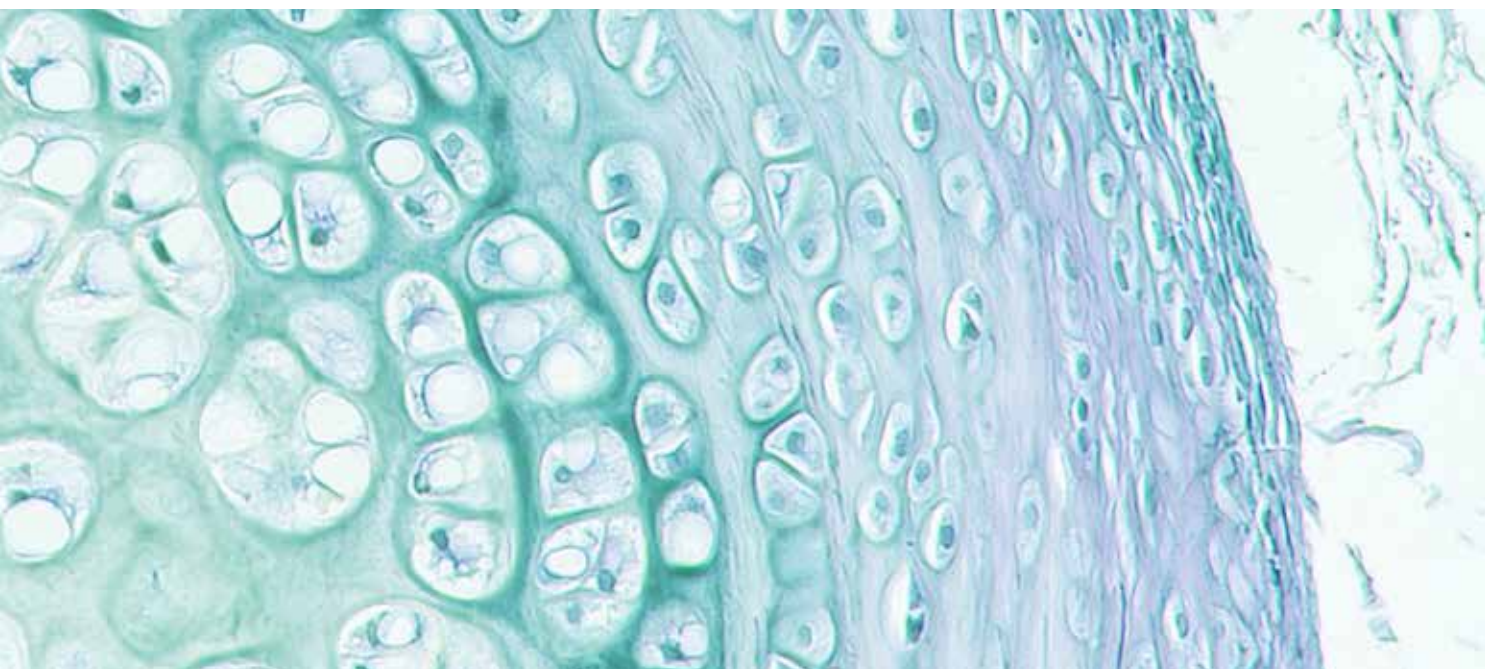
In recent years Italy has brought its own system of innovation measures into line with those of other countries. Ongoing investment in this system is of primary concern if we are to profit from its benefits and keep pace with emerging countries.

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Innovation is the ability to see change as an opportunity: focusing upon the biopharma sector constitutes the key to success for the entire country.

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# Companies in the biopharma sector

AAA - Advanced Accelerator  
Application S.r.l.

AbbVie S.r.l.

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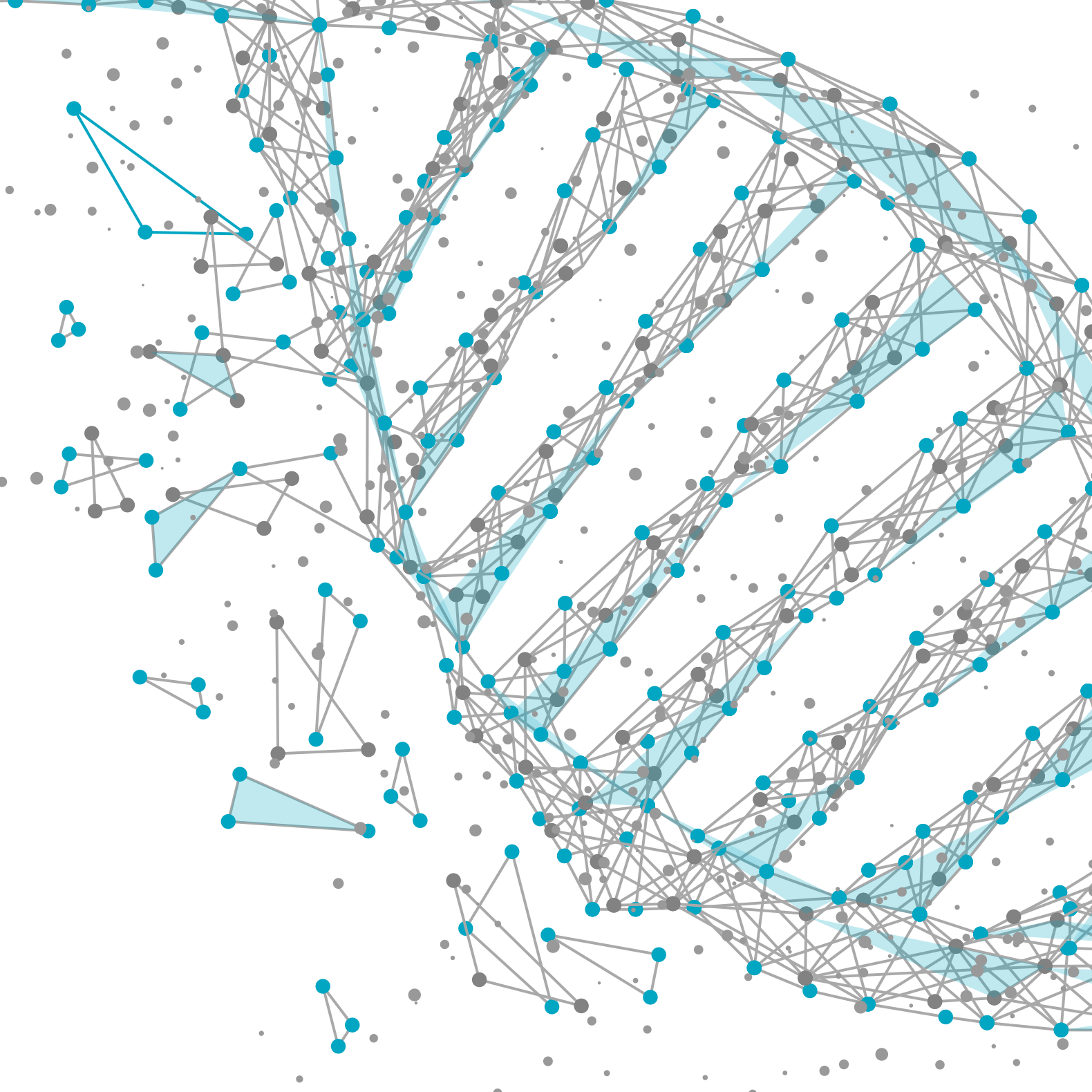
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