The Italian Biotech Industry

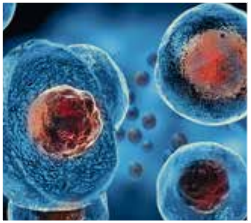
Facts & Figures

BioInItaly® Report 2018

FEDERCHIMICA ASSOBIOTEC
Italian Association for the Development of Biotechnology

ENEA
Agenzia nazionale per le nuove tecnologie, l'energia e lo sviluppo economico sostenibile

ITA
ITALIAN TRADE AGENCY



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Introduction

The new report on the Italian biotech industry, drafted thanks to the consolidated collaboration between Assobiotec (Italian Association for the Development of Biotechnology, part of Federchimica) and ENEA (National Agency for New Technologies, Energy and Sustainable Economic Development), offers an update on the current Italian biotech industry in 2017.

The analysis collects and processes updated information and estimates provided by firms in the sector at the end of 2017, as well as their 2016 financial statements, public data and data from the National Statistical System, presenting readers with a general picture of the sector which is one of a kind at an international level for its wealth and thoroughness.

The report focuses on the following main issues: the figures of Italian biotech, a chapter on research and development activities, a snapshot of the healthcare, agriculture and veterinary medicine, industry and environment sectors, a focus on bioeconomy and measures to support innovation. The data collected within the framework of the National Statistical Programme will be merged into the statistics on the biotechnology industry edited by the OECD – Organisation for Economic Cooperation and Development, whose methodology is adopted in this study.

On the basis of the estimated data, the biotech firms operating in Italy confirm their status as a highly innovative sector dedicated to research, with excellences in all the applicative biotechnology sectors. It suffices to think of the Italian leadership in precision medicine and advanced therapies, where three therapies out of the six currently authorised in Europe are the result of Italian research, development and production. It is therefore a dynamic, high-tech sector that is potentially ready to seize the challenges and opportunities of the biotech sector at an international level.

However, it is also an industrial sector that urgently needs a national strategy in favour of medium-long term innovation and research composed of measures that are stable over time, in addition to effective, certain and centralised governance: these measures would allow firms to overcome the limits of their often too-small dimension, in addition to guaranteeing important repercussions for the country in terms of economic and labour development in support of Italian growth and competitiveness.

Riccardo Palmisano
Assobiotec – Federchimica President

Federico Testa
ENEA President

1. Methodology

- This analysis was carried out thanks to the collaboration between Centro Studi Assobiotec and the Industry and Business Associations Unit – Contracts and Partnerships Management Directorate of ENEA.
- Information was collected from questionnaires filled in by the firms, their available financial statements, other public data and the companies' websites. Unless otherwise specified, the data on the number of companies refer to 2017, while other economic data refer to 2016 as the last available data.
  The data from the previous years were reprocessed on the basis of the population's expansion and the new information available. Particular effort was dedicated to the extension of the historical series to which the data refer, as well as to the expansion of the variables considered in the sector's analysis; the report also includes a series of data relating to patents and international trade.
- The definitions adopted and the data processing followed the guidelines developed in relation to the OECD*. These guidelines include the following categories of companies:
  – **biotech firms**: companies that use at least one biotechnological technique to produce goods or services and/or carry out research and development in the biotech field;
  – ***dedicated biotech R&D firms***: companies that invest at least 75% of their intra-muros research budget in biotechnology research.

- With reference to the sector of application for which each firm mainly carries out its biotech activities, the firms are classified follows:

  – **Healthcare firms**: companies operating in the human health sector using modern biotechnological methods for the research, development and production of products for the diagnosis, treatment and diseases prevention (drugs, new therapies, vaccines, diagnostic, molecular pharming);
  – **Agriculture and veterinary firms**: companies operating in the agriculture and livestock using modern biotechnological methods to improve animal and crop production, increase productivity and quality, improve the characteristics of adaptability to the environment and resistance to pathogens, or develop biological and environmentally-friendly products for the protection of plants and animals;
  – **Industry and environment firms**: companies using modern biotechnological methods in the industrial field for the retraining of many conventional production processes, the conversion of renewable biomass into bioproducts and energy, for applications in the food, nutraceutical and cosmeceutical fields, for the development of diagnostics and environmental remediation systems, or products for the restoration and conservation of artistic heritage;
  – **Genomics, Proteomics and Enabling Technologies firms (GPET)**: companies applying modern biotechnological methods in the field of the «omics» disciplines (genomics, proteomics, transcriptomics, etc.), as well as bioinformatics technologies, systems biology, biochips, biosensors and basic research.

*Friedrichs, S. and B. van Beuzekom (2018), "Revised proposal for the revision of the statistical definitions of biotechnology and nanotechnology", OECD Science, Technology and Industry Working Papers, 2018/01, OECD Publishing, Paris.

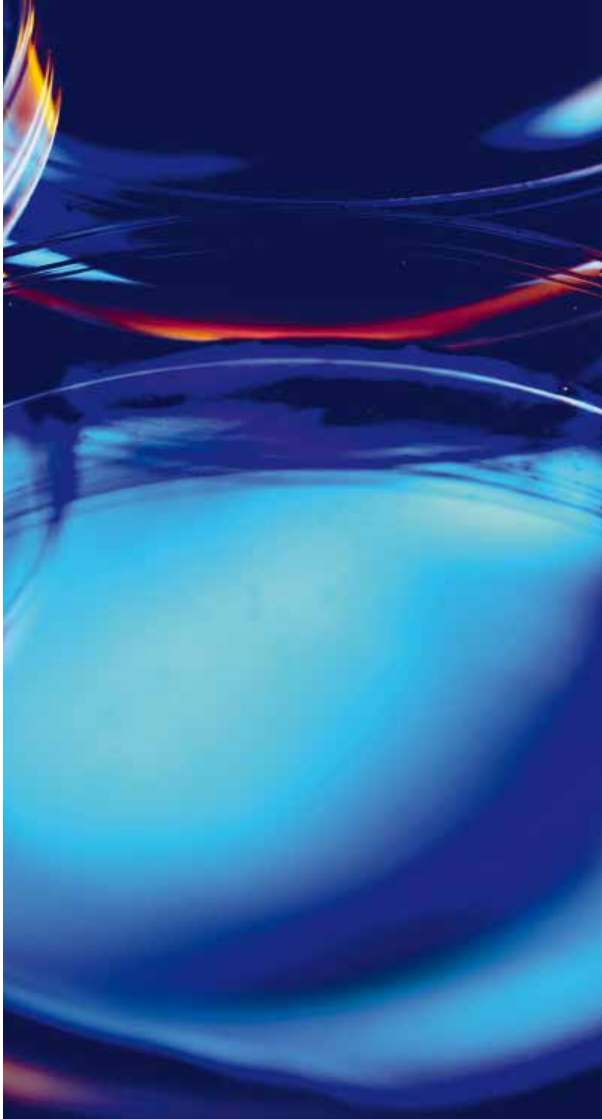
The sector is undergoing consolidation around the strongest and most competitive companies…

- The Italian biotech industry has been experiencing a phase of consolidation in recent years. On the one hand, the number of active companies in the sector is stabilising; on the other hand, all the main economic indicators are accelerating their growth rate. The snapshot given by this report therefore suggests that a structural change is taking place, with the sector's concentrating around the strongest and most competitive companies.

- At the end of 2017, 571 biotech firms were counted in Italy. More than half of these (57%, corresponding to 323 firms) are *dedicated biotech R&D firms* that devote at least 75% of their intra-muros R&D investments to biotech research activities.

- The vast majority of Italian biotech firms (76%) are of a micro or small size. Over the last few years there has been a shrinking trend in the percentage of micro firms on the total; this contraction is probably linked both to the sector's consolidation and the continuation of the negative economic situation.

- The total biotech turnover is over 11.5 billion euros, with an increase of 12% between 2014 and 2016. The number of employees is close to 13,000, registering an increase of 17% in Italian capital dedicated biotech R&D firms.



... with high research intensity

- The growth of the number of companies specialised in biotech R&D continues uninterrupted, reaching 57% of the total biotech companies in 2017, thereby confirming the strategic nature of R&D investments and technological innovation in the sector's competitive dynamics.

- The total R&D investments* of the firms surveyed amounted to 2.15 billion euros, with investments in biotech R&D exceeding 760 million, recording 22% growth between 2014 and 2016.

- The share of micro-small sized *dedicated biotech R&D firms* is about 89%: 13 percentage points higher than the total number of biotech companies. This is in line with the division of labour, which has been consolidated into the research value chain – especially in the health sector –: large companies seek increasingly specialised and state-of-the-art skills in smaller companies which are closer to the academic field and have higher research intensity.

* Intra-muros plus extra-muros

Healthcare sector

- The picture of Italian biotech firms confirms the primacy, which has already been found in previous surveys, of companies operating in the biotech sector applied to healthcare: there are currently 295, representing over half of Italian biotech firms (52%).

- There are 183 *dedicated biotech R&D firms*, which commit 75% or more of their total research costs in biotech activities, of which 161 are Italian capital companies.

- The healthcare sector generates a preponderant share of turnover, corresponding to over 8.5 billion (74% of the total) against higher investments (91%) and a higher number of employees (76%) working in biotech R&D.

- There are 314 projects in the Italian pipeline, of which about 80 are in the discovery phase, 145 have reached the preclinical development and 90 are in clinical development.

- Italian biotech invests in those diseases which still lack adequate therapeutic solutions, such as those in oncology, or diseases of increasing clinical and epidemiological importance such as neurological and degenerative diseases, due to the overall ageing of the population. Large investments are also directed towards infectious diseases and the development of vaccines.

- Rare diseases and advanced therapy medicinal products are among the sectors of Italian biotech excellence: on the one hand, Italy's academic research boasts the largest number of scientific publications on rare diseases, and on the other hand, out of the six advanced therapies medicinal products currently authorised for the EU market, three are the result of Italian R&D.

Agriculture and veterinary sector

- The panorama of firms operating in the agriculture and veterinary sector in Italy is quite diversified. 50 firms were registered (9% of the total), all characterised by considerable R&D activities.
- 80% of the total firms can be classified as small or micro businesses.
- The sector's turnover is close to 900 million euros.
- 2017 saw a significant opening of Italian public research, which is engaging in a vast and well-focused R&D plan, based on the most advanced biotechnology applied to plant breeding innovation. This plan represents a turning point which all the research can start from, especially in agricultural genetics and varietal improvement. It is placed in a context of innovation which integrates the progress of life sciences with the parallel perspective that precision farming can offer.
- The *dedicated biotech R&D firms* are all controlled by Italian capital and demonstrate an increase of more than 50% of investments in biotech R&D compared to the previous two years.

Bioeconomy and industry and environment sector

- 162 biotech firms operate in the industrial and environmental sector, accounting for 28% of all firms.

- The sector's turnover is close to 2 billion euros, registering 16% growth for the Italian capital dedicated biotech R&D firms compared to 2014 data.

- The application of these techniques can innovate mature sectors such as those of raw materials, energy production and intermediates while adhering to the principles of environmental, economic and social sustainability that are typical of bioeconomy. This is a complex concept that includes a multiplicity of sectors whose common basis is input of a renewable and biological origin, but which can follow different underlying development dynamics conditioned by the peculiarities of each specialisation.

- According to estimates by Intesa Sanpaolo-Assobiotec, bioeconomy in Italy had a production value of 260 billion euros in 2016, corresponding to 8.3% of the total national economy, experiencing moderate growth in respect to 2015.

GPET

- Genomics, Proteomics and Enabling Technologies, or GPET, is an emerging sector that often works in close synergy with healthcare biotechnology.
- There are 65 Italian firms working in this field, corresponding to 11% of the total biotech firms in Italy.
- These firms carry out basic research activities, with a particular prevalence in the use of «omics» technologies (genomics, proteomics, transcriptomics, etc.) and in the analysis of Big Data through bioinformatic approaches.

The key figures of the Italian biotech sector...

	Total firms	*Dedicated biotech R&D firms...*	*...of which, Italian capital dedicated biotech R&D firms*
Number of firms*	571	323	296
Biotech turnover**	11,535,929	4,583,022	1,124,316
Total R&D investment**	2,148,985	549,843	300,474
Total biotech R&D investment**	764,367	491,607	270,039
Biotech employees**	12,781	5,879	4,087
Biotech R&D employees**	3,790	2,875	1,868

Values in thousands of euros €/000

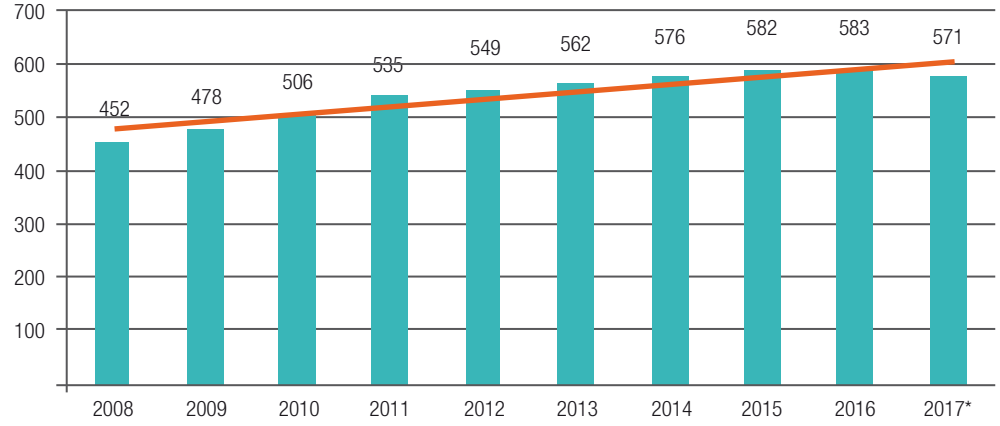
*Last available data, 2017
**Last available data, 2016

- At the end of 2017, there were 571 biotech firms in Italy.
- The total biotech turnover is over 11.5 billion euros, with an increase of 12% between 2014 and 2016.
- The number of employees is close to 13,000, registering an increase of 17% in Italian capital *dedicated biotech R&D firms*.
- The total R&D investment*** of the firms amounted to 2.15 billion euros, with investments in biotech R&D exceeding 760 million, recording 22% growth between 2014 and 2016.

*** Intra-muros plus extra-muros

...reflect a sector undergoing a phase of consolidation

Number of biotech firms in Italy

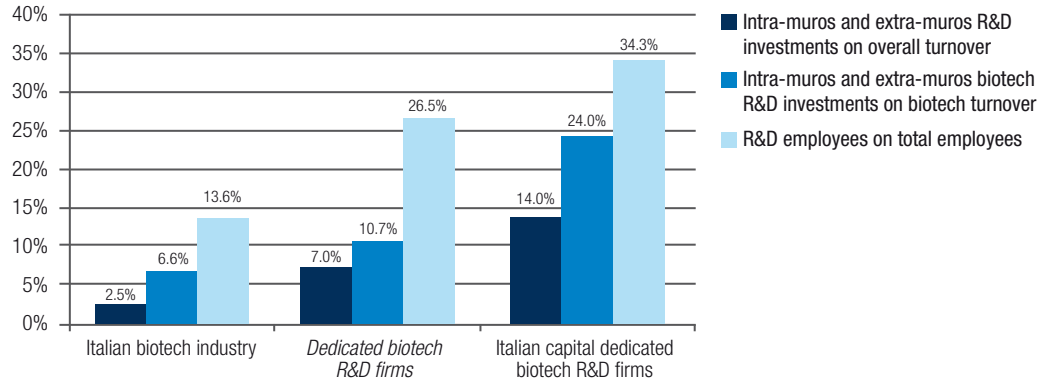


* Provisional data

- In the last 4 years, the number of Italian biotech companies has remained stable. Such demographic dynamics, to which the long standing negative situation of our economy is no stranger, is mainly due to the progressive increase of the number of companies which are no longer in business, parallel to a number of new born companies which are now active in the biotech field.
- The demographic trend recorded is a further confirmation of how prolonged negative economic phases often tend to jeopardise the most innovative, and therefore riskier, business initiatives instead of stimulating them; so, these initiatives require special attention in times of crisis.

... which believes in R&D

R&D Intensity

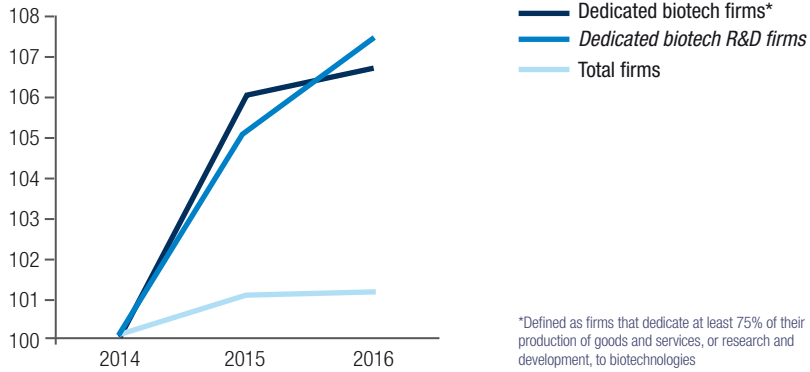


- More than half of the active firms (57%, corresponding to 323 firms) dedicate at least 75% of their intra-muros and extra-muros R&D investments to biotech research activities. Of these, 296 have Italian capital, a number that grew by 16% from 2014 to 2016.
- As far as the Italian capital dedicated biotech R&D firms are concerned, the average incidence of total R&D investments on turnover is 24%**, exceeding the 40% for more than 63% of these firms. The activity of the large part of these companies is exclusively R&D, not including productive processes, if not occasionally.
- The intensity of intra-muros and extra-muros investments and the number of employees dedicated to research and innovation are greater in the Italian capital dedicated biotech R&D firms. Since the latter are mainly micro or small firms, they are more focused on research operations than production and sales.

**Intra-muros and extra-muros biotech R&D investments/Biotech turnover

... and is increasingly specialised

Growth dynamics of biotech firms
(index number 2014=100)



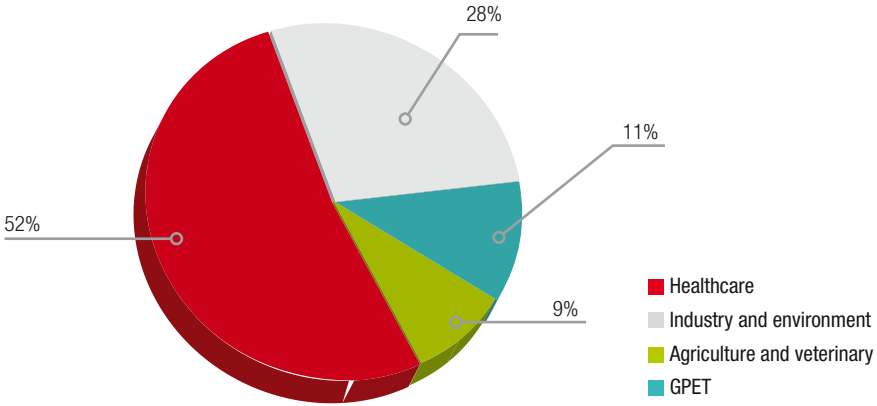
*Defined as firms that dedicate at least 75% of their production of goods and services, or research and development, to biotechnologies

The intensity of research and innovation in the sector is confirmed at a high level and investments in biotech R&D are experiencing sustained growth. This is reflected in an increase in the share of companies specialising in biotechnology, and even more so in those specialising in biotech R&D.

More and more companies among those surveyed tend to concentrate their business on biotech products and/or services, trying to seize the strong growth opportunities that these markets envisage compared to the more traditional ones. Competitiveness is predominantly technological in these markets, therefore investment in research and development and the innovation capacity of individual companies are fundamental assets.

Firms active in all sectors of application…

Analysis by field of application



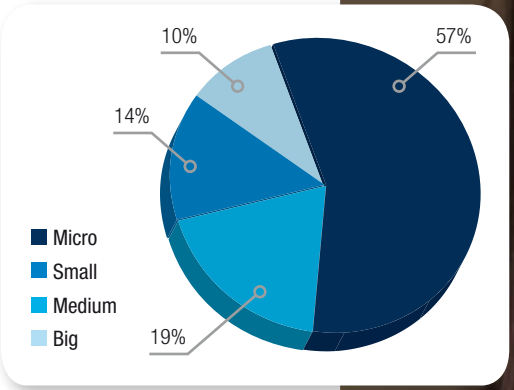
The picture of Italian biotech companies confirms the primacy of firms operating in the biotech sector applied to healthcare, which represent over half of Italian biotech firms (52%). These firms are followed by those focused on industry and environment, which represent 28% of the total. A portion of the total is also reserved for firms active in Genomics, Proteomics and Enabling Technologies – GPET (11%) and the agriculture and veterinary biotech sector (9%).

... moving towards a more sustainable future, guided by a strong spirit of innovation

- Developing diagnostic systems and innovative therapies which lead to a series of important repercussions in many therapeutic, diagnostic, nanobiotechnology and cosmetic fields. More than half of the Italian biotech companies (295) are active in the healthcare sector, presenting innovative solutions in the medical and pharmaceutical fields.
- Improving agricultural production, generating bioactive substances whose presence is limited in nature (biopharming), increasing production without enlarging the cultivation surface area, reducing water consumption and the effects of pests and plant diseases, protecting animal health. There are 50 companies active in the agriculture and veterinary biotech sector.
- Offering tools to optimise the transformation of biomass into eco-sustainable bioproducts and third-generation biofuels, or to improve the yield and environmental sustainability of traditional production processes. There are 161 biotechnology firms active in industrial and environmental sectors.
- Carrying out basic research activities, being a powerful accelerator for all the other applicative fields of biotechnology. From genes to proteins up to bioinformatics technologies and biochips, there are 65 firms working in the field of Genomics, Proteomics and Enabling Technologies - GPET, with a particular prevalence in the use of «omics» technologies and in the analysis of Big Data through bioinformatic approaches.

Biotech firms: analysis by size

- 76% of Italian biotech firms are micro or small-sized organizations.
- In the four years considered in the analysis, there is a shrinking trend in the percentage of micro-firms on the total.
- This contraction is probably linked both to the consolidation of the sector and to the continuation of the negative economic situation.



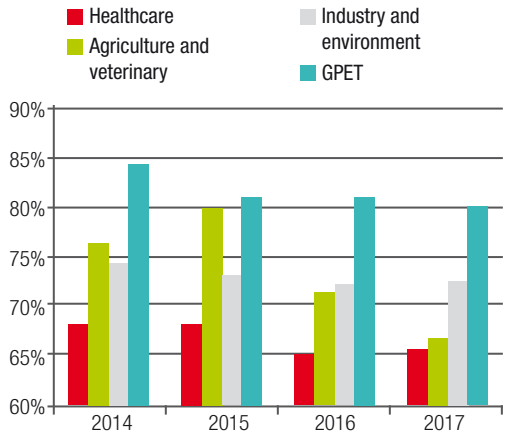
Micro: 1-9 employees
Small: 10-49 employees
Medium: 50-249 employees
Big: 250+ employees

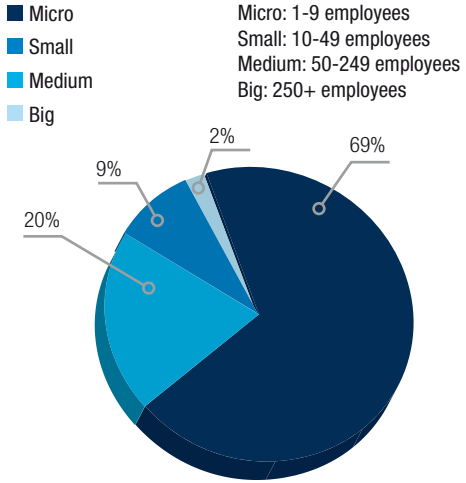
	2014	2015	2016	2017
Micro	60%	59%	58%	57%
Small	17%	18%	18%	19%
Medium	13%	13%	14%	14%
Big	10%	10%	10%	10%

Dedicated biotech R&D firms: analysis by size

- Of the total number of *dedicated biotech R&D firms*, the percentage of those which are micro or small-sized is nearly 90%.
- The reduction in the percentage of micro-sized firms is particularly marked in the agriculture and veterinary sector and GPET sector, for which there has been a contraction in the number of firms of this size respectively of 15% and approximately 14%.

Distribution of micro-firms by sector



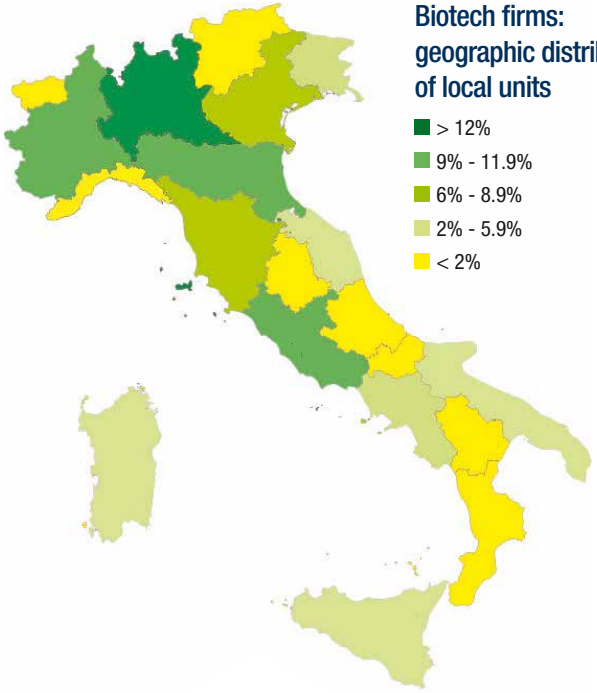


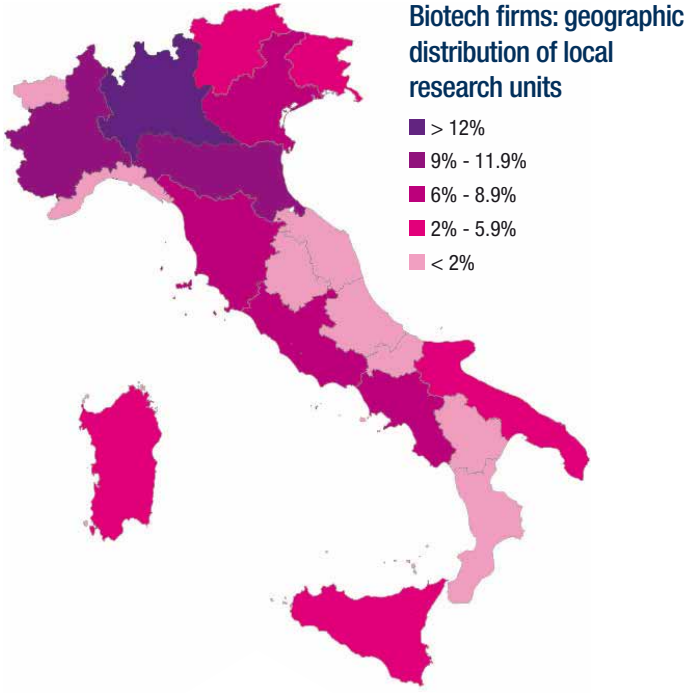
Analysis by geographic distribution

Region	Firms						Contribution to intra-muros biotech R&D investments	Contribution to biotech turnover
	Registered offices 2016		Local units 2016		Local research units 2016			
	Numero	%	Numero	%	Numero	%		
Lombardy	162	28%	235	28%	182	27%	23%	32%
Latium	58	10%	82	10%	59	9%	17%	21%
Emilia-Romagna	57	10%	88	11%	65	10%	6%	10%
Piedmont	52	9%	75	9%	61	9%	11%	4%
Veneto	47	8%	64	8%	47	7%	3%	3%
Tuscany	42	7%	67	8%	56	8%	22%	16%
Campania	34	6%	44	5%	42	6%	5%	2%
Friuli-Venezia Giulia	30	5%	33	4%	35	5%	7%	0%
Sicily	17	3%	24	3%	21	3%	1%	0%
Apulia	15	3%	23	3%	21	3%	1%	4%
Trentino-Alto Adige	14	2%	16	2%	14	2%	1%	1%
Sardinia	14	2%	18	2%	17	3%	0%	5%
Marche	12	2%	18	2%	13	2%	0%	1%
Liguria	8	1%	12	1%	10	1%	0%	0%
Umbria	5	1%	7	1%	7	1%	0%	0%
Abruzzo	5	1%	8	1%	5	1%	1%	0%
Molise	5	1%	6	1%	5	1%	0%	0%
Other Regions	6	1%	10	1%	7	1%	1%	0%
Total	583	100%	830	100%	667	100%	100%	100%

Biotech firms: geographic distribution of registered offices

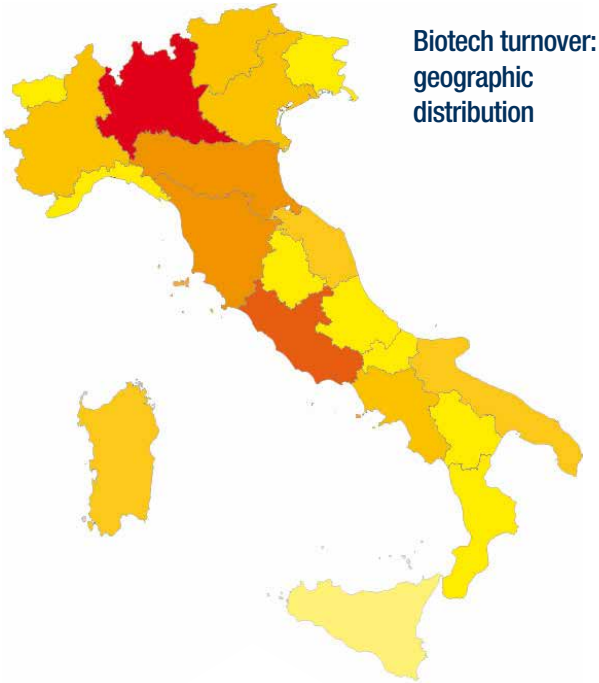
- > 12%
- 9% - 11.9%
- 6% - 8.9%
- 2% - 5.9%
- < 2%



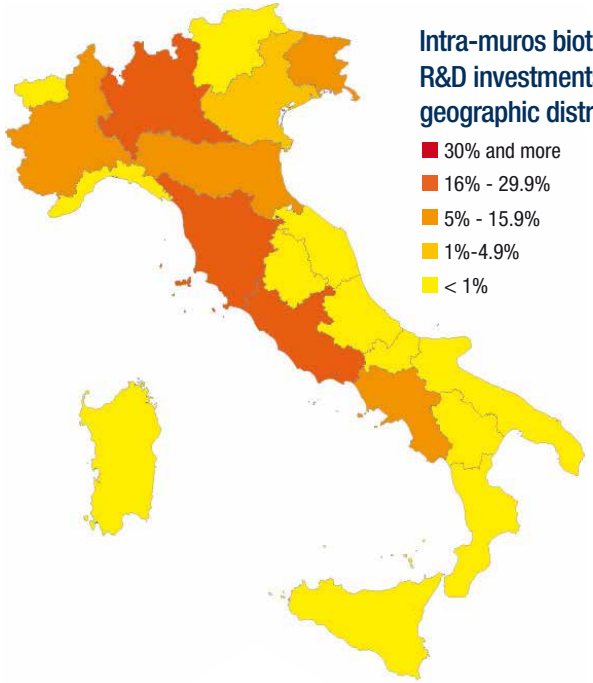


- With 28% of firms and local units in its territory, 23% of investments and 32% of turnover, Lombardy is confirmed as the first region for presence, commitment and results in biotech. It has therefore maintained the leadership role for national biotech.
- Lombardy is followed by Latium and Emilia-Romagna for number of firms, in particular for registered offices and production sites, and Emilia-Romagna and Piedmont for the number of offices where research activities are carried out.

Biotech turnover: geographic distribution



Intra-muros biotech R&D investments: geographic distribution

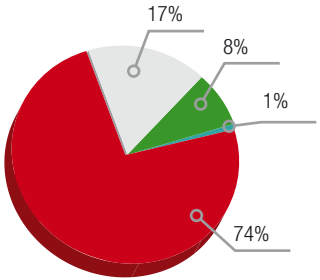


- Looking at investments in R&D, Tuscany ranks second for biotech investments, preceded by Lombardy and followed by Lazio. About two thirds of investments in biotech research are concentrated in the three regions of Lombardy, Tuscany and Latium, true leading areas for Italian research.
- Considering the turnover, Latium is in second place preceded by Lombardy, and followed by Tuscany.
- The contribution to turnover is greater than the contribution to national investments in six regions: Emilia-Romagna, Latium, Lombardy, Marche, Apulia and Sardinia.
- The three regions with the highest average investment in relation to the number of production sites are Basilicata, Friuli Venezia Giulia and Tuscany.

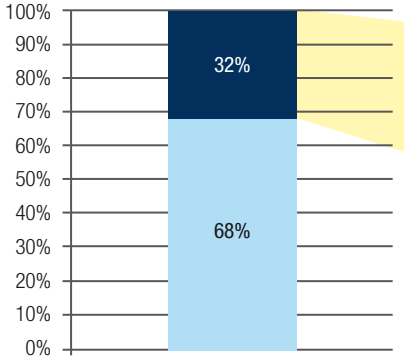
Biotech turnover analysis

- Considering the total number of firms, those active in the healthcare sector generate almost three quarters of the total biotech turnover.
- 68% of the biotech turnover is generated by foreign-owned firms, which represent only 13% of the firms surveyed.
- While foreign-based firms make most of their turnover in the human health sector, the Italian capital firms make most of their turnover in the sector dedicated to industry and environment.

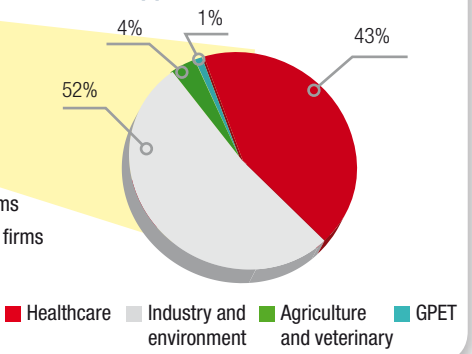
Total companies: breakdown of turnover by field of application



Total companies: breakdown of turnover between Italian capital and foreign invested firms



Italian capital dedicated biotech R&D firms: breakdown of the turnover by field of application



Export turnover

- There are 214 exporting biotech firms, on the base of ISTAT data on foreign trade, equal to 37% of the total in 2016.
- At the end of 2016, biotech firm exports amounted to 11.3 billion euros, while the biotech product exports by biotech firms amounted to 834 million euros, equal to 7.4% of these firms' total exports.
- Biotech product exports are driving the foreign competitiveness of firms in the sector: in fact, they are up by almost 11% compared to 2014, in an open contrast to the entire export volume of biotech firms, which also includes non-biotech products, where a significant decrease was recorded (–15%).
- The figure for biotech products (+11%) confirms its absolutely positive trend, also when compared to the growth of total national exports (+ 4%).

	2014	2015	2016
Total Italian firm exports	378,553,915	390,833,847	394,443,779
Biotech firm exports	13,277,230	11,408,756	11,285,058
Biotech firm exports vs. total Italy exports	3.5%	2.9%	2.9%
Biotech product exports by biotech firms	752,531	808,278	833,454
Biotech product exports vs. total biotech firm exports	5.7%	7.1%	7.4%

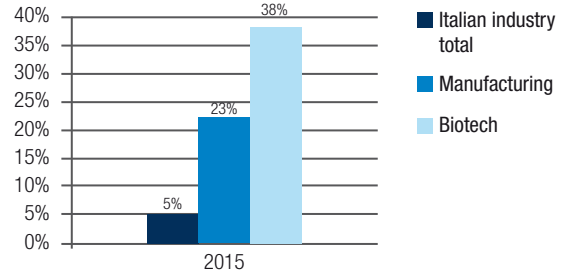
Values in thousands of euros €/000

Source: elaboration on ISTAT data, 2014-2016
Note: The export data are collected on the basis of the combined nomenclature, a classification that follows a product criterion, not a technological one. Consequently, the analysis of export flows is subject to potential bias due to the fact that both biotech and non-biotech products can be included within a given commodity code. Furthermore, the data only refers to product exchanges and does not consider service flows. [See OECD, A Framework for Biotechnology Statistics, 2005].

Export: comparison with Italian industry

- As already highlighted, biotech firms are characterised for their high projection on foreign markets (38% of exporting firms in 2015). The percentage of exporting firms has tended to increase over the last few years, and is on average more than one and a half times that of the manufacturing sector (with 23% of exporting firms in 2015) and more than seven times that relating to Italian industry as a whole, which substantially stops at just under 5%.
- Among the most active biotech sectors in terms of exports, the agriculture and veterinary sector must be highlighted, where more than one in two firms is an exporter.
- At the same time, there is also an increase in the export vocation in the field of biotech productions. All the firms in the sector compete with this trend, but in this case as well, the firms in the agriculture and veterinary sector show much more accentuated average growth.

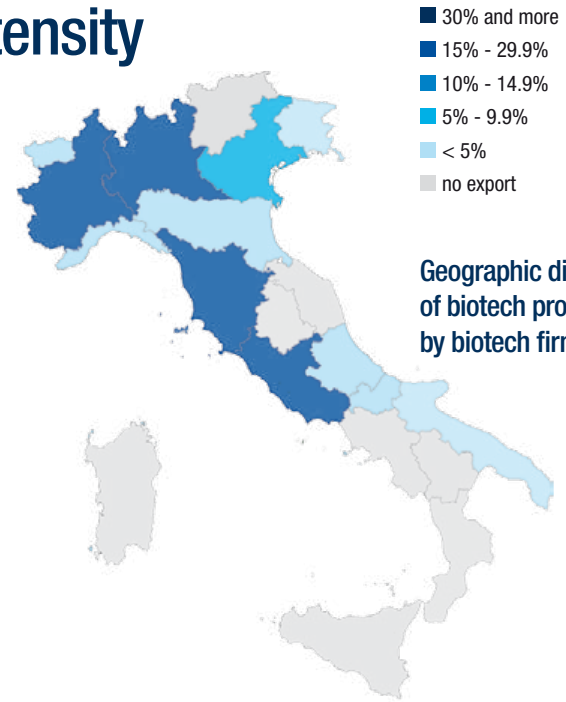
Percentage of exporting firms by industry sector



2016	Number of exporting biotech firms vs. total biotech firms	Number of biotech firms exporting biotech products vs. total biotech firms
Healthcare	38%	11%
Agriculture and veterinary	53%	13%
Industry and environment	36%	10%
GPET	19%	4%

Export: analysis by regional intensity

Geographic distribution of total exports by biotech firms



Geographic distribution of biotech product exports by biotech firms

- The distribution of biotech exports is strongly polarised around four regions in Italy (Lombardy, Piedmont, Tuscany and Latium), which represent more than 90% of the total, even if with variable contributions over time.
- Of note are the significant increase in the percentage relating to Piedmont, which started at 7.6% in 2014 to reach 18% in 2016 and, in parallel, the decrease in the percentage relating to Tuscany, which from almost 40% in 2014 fell to below 25% in 2016, contributing to counterbalance the weight of the overall export of biotech products among the major regions.

Research is the growth engine of any economic system

- According to a report from the European Commission*
  - those EU Countries that have invested in innovation, knowledge and growth of business skills, could better overcome the crisis;
  - adequate investments in research and technological innovation are behind the higher levels of productivity of the leading European economies.

- This is why Italy too needs to support research, and biotechnology research in particular.

- Not by chance, the European Union has included biotechnologies among the Key Enabling Technologies, based on their potential impact and retrain on a broad number of industrial sectors.

*Source: The drivers of Total Factor Productivity in catching-up economies - DG ECFIN 2014

R&D investment

	Total firms	*Dedicated biotech R&D firms...*	*... of which, Italian capital dedicated biotech R&D firms*
Total intra-muros R&D investment	1,579,916	427,248	221,720
Intra-muros biotech R&D investment	506,892	421,165	216,394
Total extra-muros R&D investment	569,069	122,595	78,755
Extra-muros biotech R&D investment	257,475	70,442	53,644
Total R&D investment	2,148,985	549,843	300,474
Total biotech R&D investment	764,367	491,607	270,039

Values in thousands of euros €/000 - Investments 2016

- Considering total companies, the share of biotech R&D investment amount to 35% of total R&D investments; this figure rises to 90% when only considering the Italian capital dedicated biotech R&D firms.
- The amount of biotech R&D expenditure is around 764 million euros, up 22% compared to 2014.
- 34% of the total biotech investments are for financing research activities carried out in outsourcing (extra-muros biotech investments), while 67% of the research activities are carried out within the companies (intra-muros biotech investments).
- The *dedicated biotech R&D firms* invest just over 491 million euros, using 64% of all the resources invested in biotech by the entire sector.

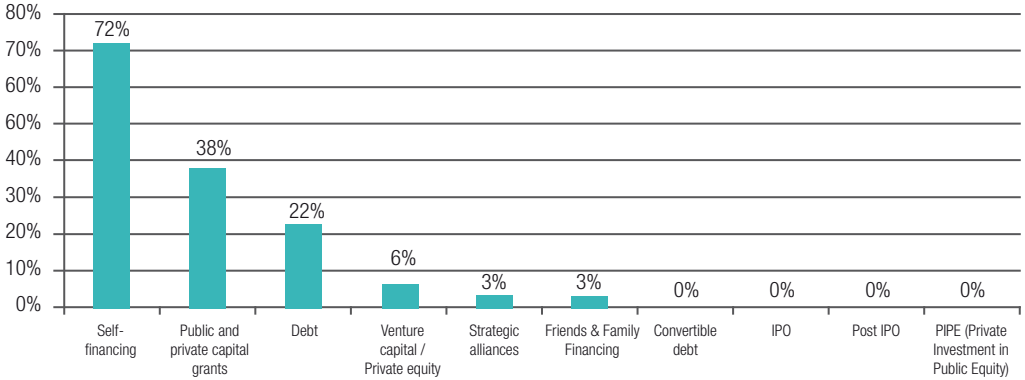
R&D investment by field of application

	Healthcare		Industry and environment		Agriculture and veterinary		GPET	
	Total firms	*Dedicated biotech R&D firms*	Total firms	*Dedicated biotech R&D firms*	Total firms	*Dedicated biotech R&D firms*	Total firms	*Dedicated biotech R&D firms*
Total intra-muros R&D investment	1,321,717	390,875	182,016	24,793	49,834	5,533	26,350	6,047
Intra-muros biotech R&D investment	445,073	386,613	40,391	23,041	11,705	5,519	9,722	5,993
Total extra-muros R&D investment	486,178	109,294	66,593	12,232	15,453	661	845	409
Extra-muros biotech R&D investment	253,010	68,817	2,035	900	2,053	547	376	178
Total R&D Investment	1,807,895	500,169	248,609	37,025	65,286	6,194	27,195	6,456
Total biotech R&D investment	698,083	455,430	42,427	23,941	13,759	6,066	10,098	6,171

Values in thousands of euros €/000 - Investments 2016

Sources of financing

Analysis of the financing sources by kind



Total firms: analysis of the financing sources used in 2016 (data obtained from the answers provided to the questionnaire)

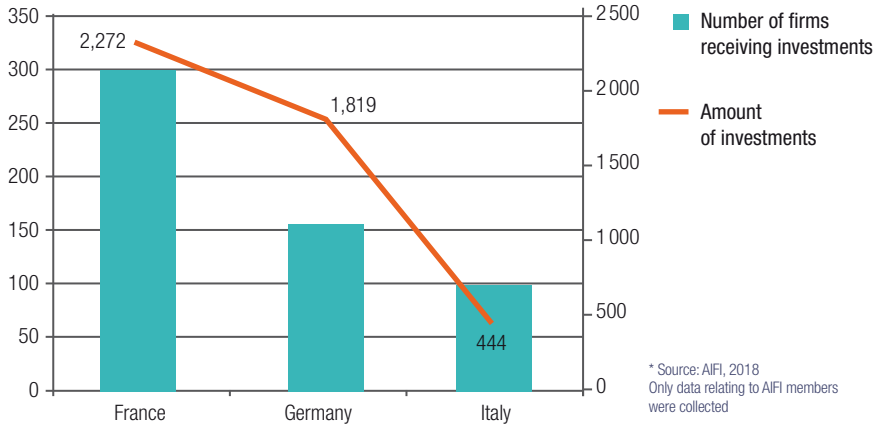
- Self-financing is always the predominant form of financing for biotech firms: in 2016, almost three quarters of them (72%) self-financed. Almost 40% of the firms analysed had access to public or private grants, and 22% resorted to debt capital.
- The Italian equity market is weak: only 6% of the firms surveyed were able to access venture capital funds.
- Government funding is still an essential source of funding available for companies, especially in the early stages of development.
- The firms do not resort to more sophisticated financing instruments. The small amount of revenue from strategic alliance agreements indicates the lack of maturity of the Technology Transfer and the valorization systems of Italian research.
- Italian biotech firms have not yet taken advantage of the opportunities offered by the recent introduction of the individual savings plans known as PIR (Piani individuali di Risparmio), which are financing instruments that can be useful for introducing liquidity into the firms, stimulating the development of the stock market: less than 5% of the firms are interested in a possible stock exchange listing.

Venture Capital investments

- Although biotech is the second largest sector in Italy for the number of investments in high-tech firms*, the number of transactions and the total amount of investments are still too far from those of the main European economies.

- 71% of the biotech transactions detected in Italy involved start-ups, while the remaining 29% represents firms in expansion. The average investment amount is significantly lower than in other sectors.

Total biotech and medical investments



* Source: AIFI, 2018
Only data relating to AIFI members were collected

Values in millions of euros € / 000,000

Biotech patent analysis

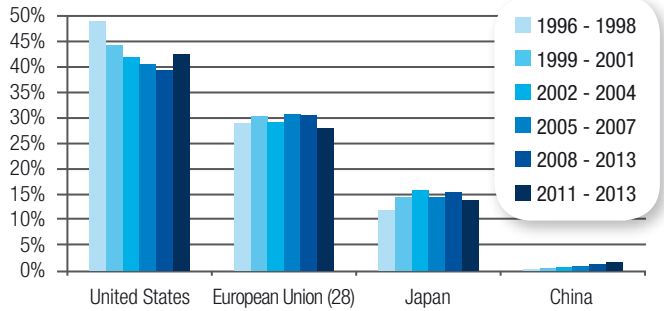
- Italy plays an important role in the international framework thanks to the quality of its science and scientists focusing on Life Sciences: the bibliometric indices prove that Italy is the first country in the world in terms of number of citations and number of publications per researcher*. Italy also boasts a strong specialisation in the field of rare diseases and orphan drugs and is the first in the world for the number of scientific publications on the subject**.

- It is useful to combine these data which testify the excellent research carried out in Italy with an analysis of Italian biotech patents, which can provide further information on the innovative activity in this sector.

- The international panorama shows how most of the global biotech patent shares are concentrated in few macro-geographical areas. After a prolonged growing trend in the worldwide share of patents, Europe has seen a slight decrease over the latter period. A step backwards that has benefited more the United States than the new emerging countries. This points out how the competition for the technological leadership in the biotech sector still involves the United States and Europe as its main players, hence its relevance for the competitiveness of advanced countries.

* Source: The European House-Ambrosetti, 2017
**Source: Scopus

Triadic biotech patent families by inventor's country of residence and first priority date - worldwide percentage shares

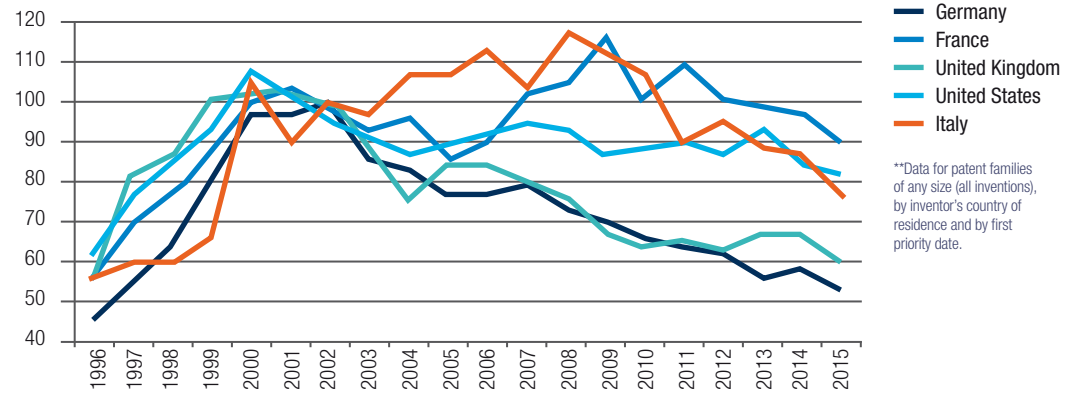


Source: elaboration of OECD Patent Statistics data, April 2018.

Note: To compile patent statistics aimed at reflecting the inventiveness of the local laboratories and labour force of a given country it is recommended to use the inventor's country of residence.
Furthermore, «*the priority date is the first date of filing of a patent application, anywhere in the world, to protect an invention and therefore can be considered as the closest to the invention date*».
Lastly, in an international comparison, «*patent indicators constructed on the basis of information from a single patent office show certain weaknesses. The "home advantage" bias is one, since, proportionate to their inventive activity, domestic applicants tend to file more patents in their home country or region than non-resident applicants. Patent families are a way of working out patent indicators that are comparable across countries. A patent family comprises all patents or applications protecting the same invention. A particular type of family is the triadic patent family. According to the OECD definition, a triadic patent family is a set of patent applications filed at the EPO and at the JPO and granted by the USPTO, sharing one or more priority applications. The restriction to the USPTO grants instead of applications is due to the non-publication of applications by the USPTO until 2001, which rendered statistics based entirely on applications impossible. Patents included in the family are typically of higher value, as patentees only take on the additional costs and delays of extending protection to other countries if they deem it worthwhile*». [Cf. the OECD Patent Statistics Manual, 2009].

- In the period considered, the worldwide annual number of new applications for biotech patents sharply decreases after 2002. This decline is largely due to the consequences of the completion of the Human Genome Project in 2003*, which raised the level of scientific knowledge and triggered a public debate on genetic engineering, leading to a lessening of inventions considered patentable. On the one hand, national and international regulations have been steered in a more restrictive direction; on the other hand, some Patent Offices have considered many human gene product inventions no longer patentable due to a lack of the novelty requirement.

New biotech patent applications** - index number (2002=100)



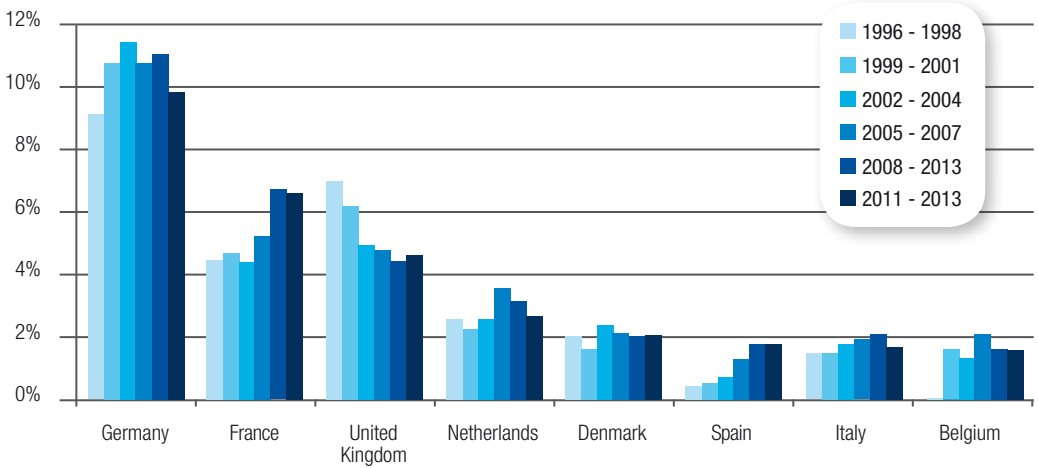
**Data for patent families of any size (all inventions), by inventor's country of residence and by first priority date.

Source: elaboration of orbit.com data - extraction April 2018

- Within this sectoral trajectory, whilst taking account of the different total number of applications, Italy shows a less negative trend than some of the main players of the biotech sector.

*OECD Biotechnology Statistics, 2009; Mueller H et al. Pharm Pat Anal. 4(5):349-50, 2015

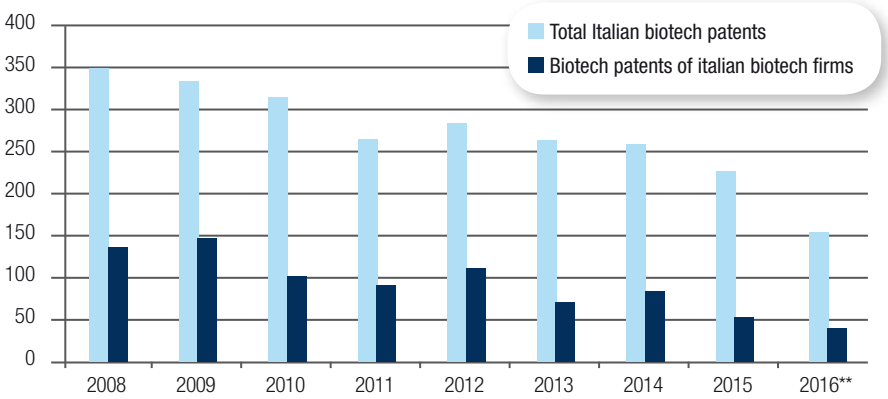
Biotech patent applications filed at the EPO (European Patent Office), by inventor's country of residence and first priority date - worldwide percentage shares



Source: elaboration of OECD Patent Statistics data, April 2018.

Focusing on European countries, it is possible to highlight a steady growth in the worldwide percentage share of Italy's biotech patent applications filed at the EPO (European Patent Office) up to 2010. This share rises from 1.4% in the three-year period 1996-1998 to 1.7% in the last three-year period for which the data is available, after peaking over 2% in the three-year period 2008-2010.

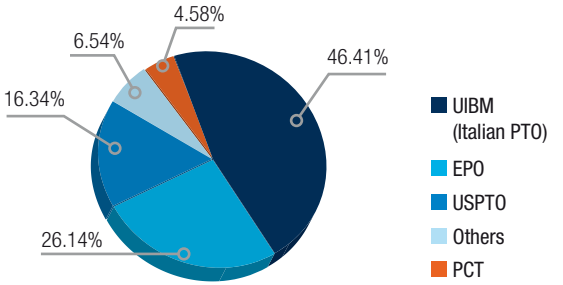
Number of applications for Italian biotech patents*



- Focusing the analysis on the most recent years, there is an absolute decline in the number of new Italian biotech patents broadly in line with international sectoral trends.
- On average, the share of Italian biotech patents generated by firms remains constant at around 30%, while the remaining 70% is generated by other players including primarily the public and university research system.

- Among the main patent authorities where Italian biotech patent applications are filed, the UIBM (Italian Patent and Trademark Office) and the EPO (European Patent Office) are the most used competent offices, with a growth in the share of initial filing applications from 36% to 46% for the UIBM, and from 20% to 26% for the EPO between 2008 and 2016.
- The first filing strategy has certainly been affected by the signing of an agreement between the UIBM and the EPO which calls for the EPO's drafting of a prior art search accompanied by a written opinion for all patent applications for industrial inventions filed in Italy from 1st July 2008 which do not claim any priority. Obtaining such an authoritative technical opinion on the patentability of an invention facilitates, at a lower cost, the decisions on the international extension of patent protection.

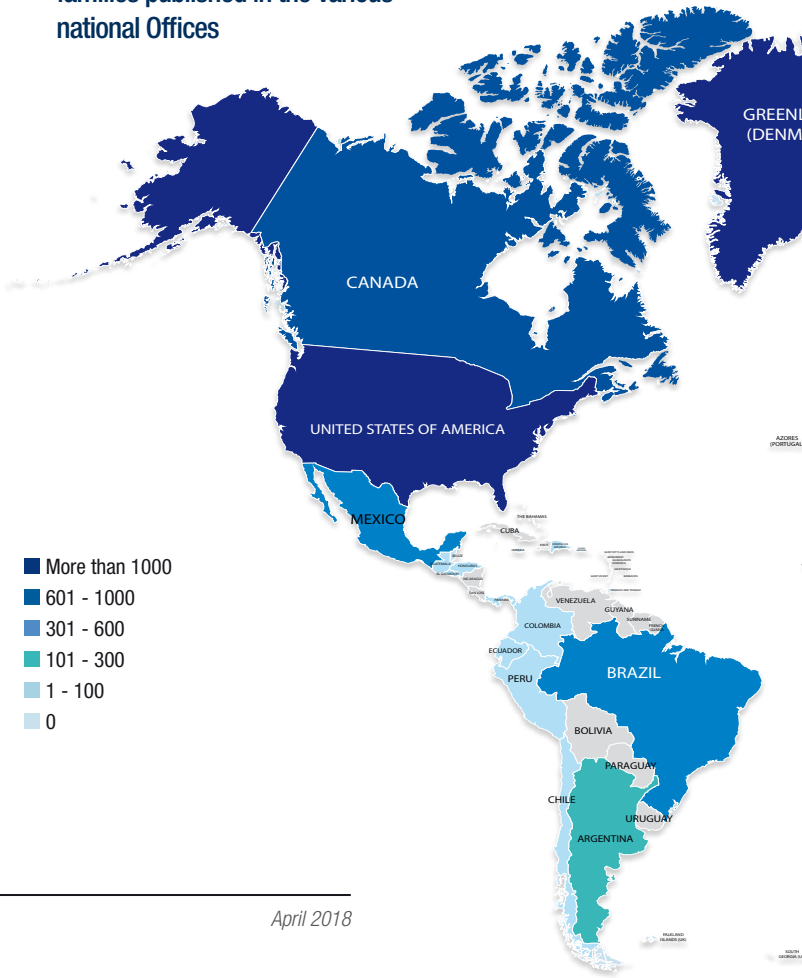
Patent authorities where the initial filing applications were submitted for Italian biotech patents in 2016**



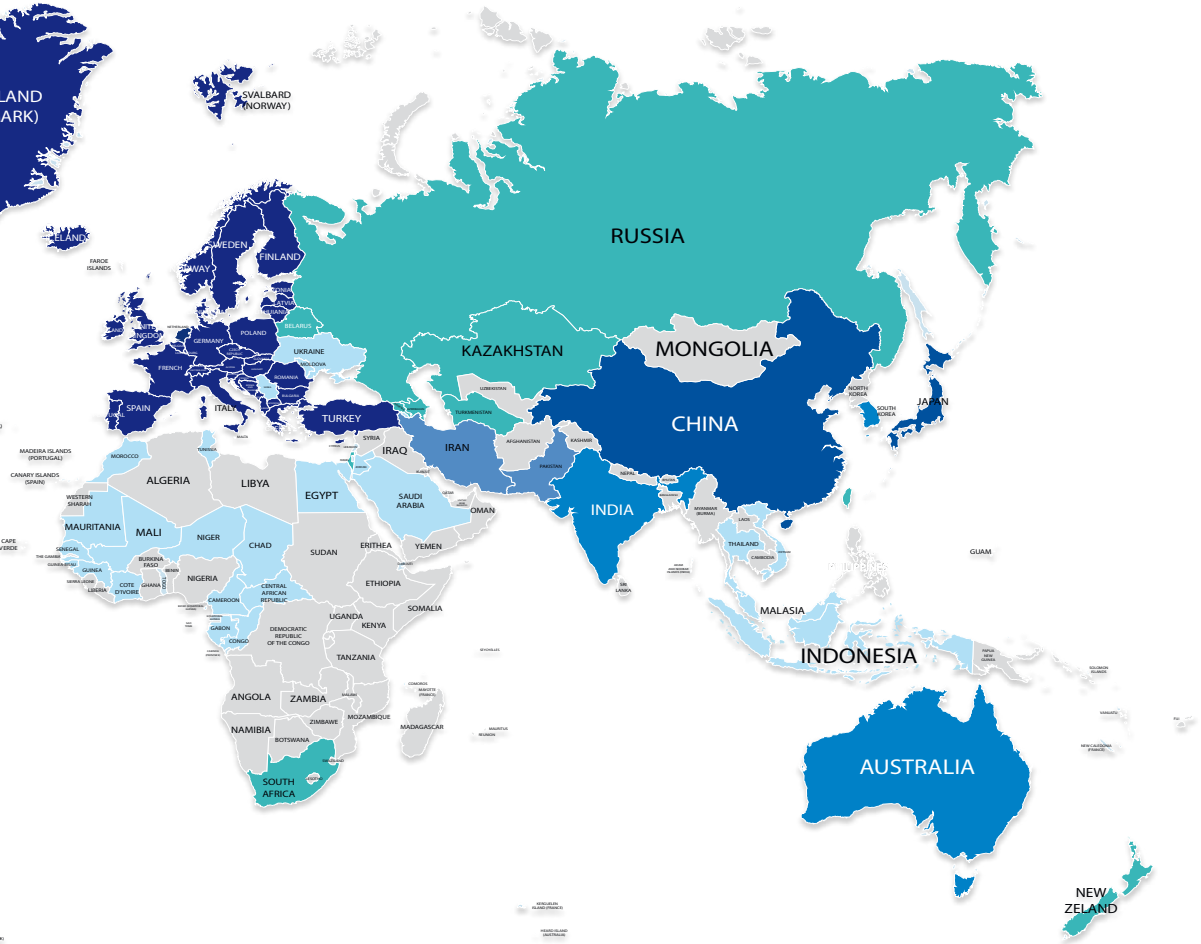
* Data for patent families of any size (all inventions), by inventor's country of residence and by first priority date.
** Provisional data
Source: elaboration of orbit.com data - extraction April 2018

Number of documents of Italian biotech patent families published in the various national Offices

This graph, representing the number of documents published in the various national Offices, provides information on the main international markets for the Italian actors of the biotech sector, as the national filings are a good indicator of the markets that need to be protected. Over two thirds of all the extensions are concentrated in nine patent authorities and one third of the total are published at the EPO (European Patent Office), the USPTO (United States Patent and Trademarks Office) and the CIPO (Canadian Intellectual Property Office), confirming the strategic role for the biotech sector of the European and North American markets.



Source: elaboration of orbit.com data - extraction April 2018


SVALBARD (NORWAY)
RUSSIA
SWEDEN
FINLAND
NORWAY
ESTONIA
LATVIA
BELARUS
POLAND
GERMANY
UKRAINE
MOLDOVA
ROMANIA
FRENCH
SPAIN
ITALY
TURKEY
KAZAKHSTAN
MONGOLIA
CHINA
NORTH KOREA
SOUTH KOREA
JAPAN
SYRIA
IRAQ
IRAN
AFGHANISTAN
PAKISTAN
INDIA
MADEIRA ISLANDS (PORTUGAL)
CANARY ISLANDS (SPAIN)
MOROCCO
ALGERIA
LIBYA
EGYPT
SAUDI ARABIA
OMAN
WESTERN SHAHARA
MAURITANIA
MALI
NIGER
CHAD
SUDAN
ERITHEA
YEMEN
SENEGAL
GUINEA
BURKINA FASO
NIGERIA
COTE D'IVOIRE
GHANA
CENTRAL AFRICAN REPUBLIC
ETHIOPIA
CAMEROON
GABON
CONGO
DEMOCRATIC REPUBLIC OF THE CONGO
UGANDA
KENYA
SOMALIA
TANZANIA
ANGOLA
ZAMBIA
ZIMBABWE
MOZAMBIQUE
MADAGASCAR
NAMIBIA
BOTSWANA
SOUTH AFRICA
MYANMAR (BURMA)
LAOS
THAILAND
CAMBODIA
GUAM
MALASIA
INDONESIA
AUSTRALIA
NEW ZELAND

A snapshot of firms involved in the healthcare sector

	Total firms	*Dedicated biotech R&D firms...*	*...of which, Italian capital dedicated biotech R&D firms*
Number of firms*	295	183	161
Biotech turnover**	8,583,049	4,362,434	940,447
Total R&D investment**	1,807,895	500,169	261,506
Total Biotech R&D investment**	698,083	455,429	243,012
Biotech employees**	8,513	4,853	3,122
Biotech R&D employees**	2,877	2,369	1,397

Values in thousands of euros €/000

- Investments in biotech R&D have increased by 22% and biotech turnover has increased by 10% compared to 2014.
- The incidence of research investments on turnover, or on operating costs, for the Italian capital dedicated biotech R&D firms is on average 26%.

*Last available data, 2017 **Last available data, 2016

Advances in science drive the transformation of the healthcare world

- Genomics, Big Data, «chemical surgery» to mend genetic material, nanobiotechnologies, theranostics, machine learning, 3D modelling, smart pills: today biotech firms have new tools for responding to the population's growing health demand. In this context, today the therapeutic process benefits from more and more timely diagnoses, therapies designed for individual patients thanks to precision medicine and therapeutic response monitoring. Added to this is the remarkable progress in terms of prevention, thanks for example to the possibility of diagnose diseases on a genotypic basis and the identification of a genetic predisposition to a disease in presence of certain susceptibility genes.

- At the end of 2017, 295 firms were working on all stages of the therapeutic process in the healthcare sector, representing the majority of national biotech firms (52%). There are 183 *dedicated biotech R&D firms* which commit 75% or more of their total research costs to biotech activities, of which 161 with Italian capital.

- The healthcare sector generates a preponderant share of turnover (74%) against higher investments (91%) and a higher number of biotech R&D employees (76%).

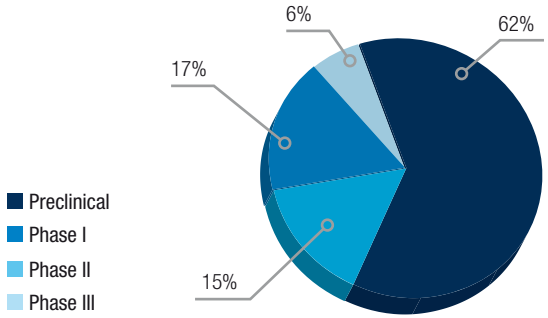
- The increase in R&D investments recorded in Italy is in line with what is occurring at a global level, where a recovery in investments has been recorded in the pharmaceutical sector.

Therapeutics: focus on the Italian pipeline

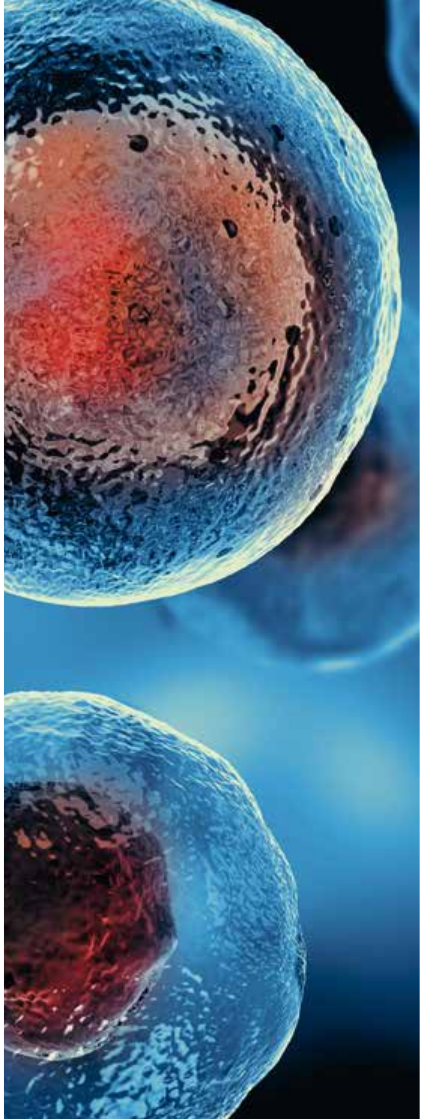
- The data collected from 84 firms with Italian capital*, through firm websites and responses to questionnaires, about products being developed showed a total of 314 projects, including about 80 in the discovery phase.
- Of the remaining 235, 145 are projects in preclinical development and 90 in clinical development (15% in Phase I, 17% in Phase II and 6% in Phase III).
- Added to these projects are 7 more projects and products that are the result of Italian R&D carried forward by firms that have become foreign-owned over time (due to acquisitions or moving the firm's registered office).
- Compared to the previous analysis, 28 products have left the Italian pipeline because the 11 firms they originated from are no longer present in Italy, having ceased their business or having been the subject of acquisitions.

	Number of projects
Discovery	79
Preclinical	145
Phase I	35
Phase II	40
Phase III	15
Total	**314**

Product analysis by development phase



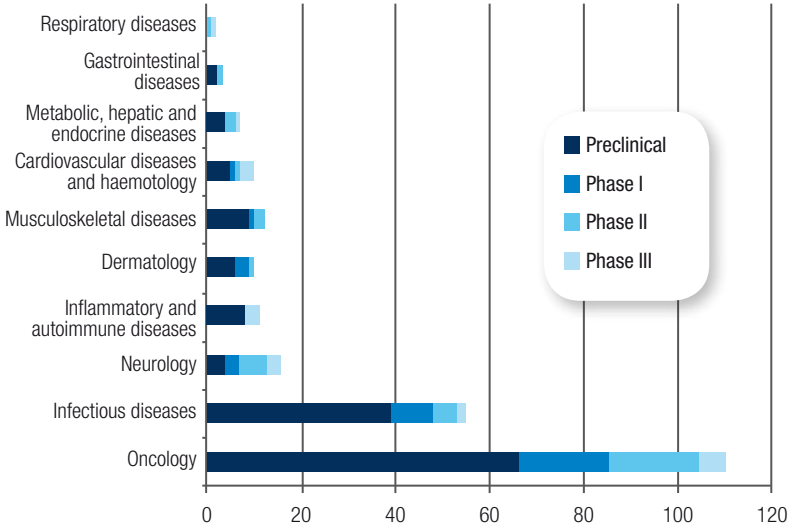
* Only firms with Italian capital were considered. The number of products should therefore be considered partial compared to the total biotech products entirely developed in Italy.



Therapeutic areas of strategic interest

- Italian biotech invests in those diseases which still lack adequate therapeutic solutions, such as those in oncology or autoimmune diseases, or those of increasing clinical and epidemiological importance such as neurological and degenerative diseases, also in relation to the general ageing of the population.
- Large investments are also directed towards work on infectious diseases and the development of vaccines.
- It should be noted that, compared to the previous survey of 2016, the area relating to dermatology has risen three positions, from eighth to fifth, tripling the products in clinical development, and the area relating to inflammation and autoimmune diseases has gained a position, reaching fourth place for order of development.

Product analysis by therapeutic area and phase of development



In recent years Italian research has provided therapies that have been able to restore sight, treatments capable of guaranteeing a new life perspective for "bubble children" (affected by ADA-SCID) and treatments that have made it possible to intervene when transplants are rejected. The first therapy tested on a "butterfly child" suffering from epidermolysis bullosa is Italian.

The growing share of biopharmaceuticals

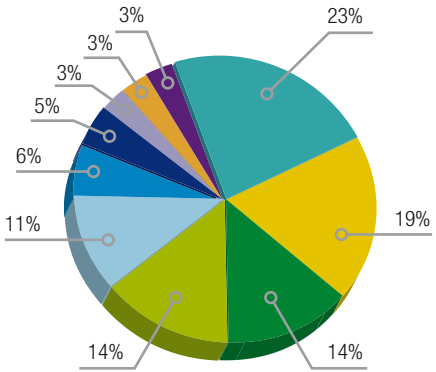
- For the first time, well over half (56%) of new therapeutic products are concerned with the development of active principles classified as biopharmaceuticals: monoclonal antibodies, recombinant proteins, vaccines and products Advanced Therapy Medicinal Products (ATMPs). The projects' analysis also includes research on new active principles of chemical synthesis – such as small molecules and peptides – developed thanks to biotech methods.

- The number of vaccines has risen from 5% to 11%: it has more than doubled compared to the previous survey of 2016. In addition to these, 2 DNA vaccines that actually fall into the category of gene therapies (a cancer vaccine for B-cell lymphoma and a prophylactic one for Lupus Erythematosus).

- The oncological application of monoclonal antibodies and recombinant proteins is predominant: of all the monoclonal antibodies being studied (60 products), 47 (78%) have an application in oncology; out of the 45 recombinant proteins being studied, an impressive 31 (69%) are used for the treatment of tumours. It should be noted that the number of recombinant proteins has risen from 9% in the previous survey to 14%.

Product analysis by type

- Small molecules
- Monoclonal antibodies
- Recombinant proteins
- Peptides
- Vaccines
- Gene therapy
- Natural Products
- Cell therapy
- Regenerative medicine
- Other



Orphan drugs and Advanced Therapy Medicinal Products

- The rare disease and ATMPs sector are among the areas of excellence of Italian research: on the one hand, Italy's academic research boasts the largest number of scientific publications on rare disease, and on the other hand, out of the six ATMPs currently authorised for the EU market, three are the result of Italian R&D.
- 14 Italian biotech firms have obtained the Orphan Drug Designation (ODD) for 21 products. An impressive 10 of these are dedicated to the treatment of rare oncological diseases, 4 to rare neurological diseases and 4 others to rare dermatological diseases.
- In the area of ATMPs, there are a total 36 projects, of which 22 in the preclinical phase and 8 in clinical trials. To these are added 3 other products in Phase III, which have been developing as transplant products according to the Italian transplant legislation, concerning tissues for regenerative medicine starting from the donation of amniotic cells, dermis and other human tissues. One third of these products are applied within oncology, followed by the musculoskeletal (19%) and dermatological (17%) areas.
- The most used technologies in gene therapy include the use of oligonucleotides* (30%) and platforms for the preparation of viral vectors for the correction of genetic defects at the origin of the pathologies in question (13%).

Orphan Drug Designation	Number of projects
EMA	8
FDA	2
EMA + FDA	11
Total	**21**

*All oligonucleotides with a DNA or RNA base are included in the count, while PNA-based oligonucleotides (peptidonucleic acid) are excluded, even if they are used for similar purposes, as they are considered within the category of peptides based on their chemical-physical characteristics.

	Cell therapy	Gene therapy	Regenerative medicine	Total
Discovery	1	5	0	6
Preclinical	5	9	8	22
Phase I	0	4	0	4
Phase II	4	0	0	4
Total	**10**	**18**	**8**	**36**

Diagnostics

- With the advent of molecular diagnostics, including the set of molecular biology techniques for the analysis of nucleic acids, proteins and metabolites, new identification, quantification and predictive methods have been developed that identify and analyse the disease and its causes in an accurate, rapid and timely manner.

- Molecular diagnostics makes it possible to maintain the highest-quality care levels thanks to tools that not only allow the correlation of a diagnosis with therapeutic schemes reflecting the patient's characteristics, but also to monitor its effectiveness in a constant manner. An advantage for the patient, therefore, but also for the entire economic system, thanks to the optimisation of the use of resources and the rationalisation of public health costs.

- There are 189 Italian firms active in this sector with at least one research project, i.e. 64% of those in the entire healthcare biotech sector. Of these, the vast majority is micro-sized (64%), located in Lombardy and focused on projects relating to cancer.

- The need to monitor the progression of diseases by means of a method with good sensitivity, high reproducibility and low invasiveness has led to the recent development of so-called "liquid biopsy" that make it possible to study circulating tumour DNA (ctDNA) through a simple blood sample. Liquid biopsy is the frontier of in-vitro diagnostic research: they can be used to analyse a spectrum of mutations associated with cancer – biomarkers –, which are useful for diagnosis and the development of personalised therapies, but also for the segmentation of the population eligible for a given treatment or for monitoring relapses. The information acquired thanks to ctDNA analysis made it possible to create the first cancer drug in the United States to treat tumours identified by biomarkers and not by their localisation. Moreover, the drug's approval is associated with the approval of its relative companion diagnostic for this indication. Precisely because of their importance not only from a medical point of view, but also for the optimisation of public health spending, regulatory bodies are streamlining the authorisation procedures for oncological profiling tests, for example for the early detection of the type of drug to use according to the specific mutation present in the patient.

A snapshot of the firms in the agriculture and veterinary sector

	Total firms	*Dedicated biotech R&D firms...*	*...of which, Italian capital dedicated biotech R&D firms*
Number of firms*	50	24	24
Biotech turnover**	892,552	33,316	33,316
Total R&D investment**	65,286	6,194	6,194
Total Biotech R&D investment**	13,759	6,066	6,066
Biotech employees**	1,134	141	141
Biotech R&D employees**	180	99	99

Values in thousands of euros €/000

- The sector's turnover is close to 900 million euros.
- 36% of the total firms are not only involved in agriculture, but also in veterinary medicine and the improvement of animal production, while the remaining 64% are focused on agriculture and the development of products to improve yields.
- All the *dedicated biotech R&D firms* have Italian capital. This explains the recorded increase of more than 50% (exactly 53%) of the investments in biotech R&D compared to the previous survey.
- The incidence of research investments on turnover, or on operating costs, for the Italian capital *dedicated biotech R&D firms* is on average 18%.

*Last available data, 2017 **Last available data, 2016

Agri-food chain, the challenge of innovation based on sustainability

- The panorama of firms operating in the agriculture and veterinary sector in Italy is quite diversified; it is difficult to identify a decidedly prevalent activity in the 50 firms surveyed, which are all however characterised by considerable research and development. 80% of them can be classified as small or micro-firms.

- The types of activities these firms focus on can be summarised as follows:
  – Molecular diagnostics and characterisation
  – Research and development using molecular biology techniques, mainly as a service activity
  – Production of biological plant protection products, biostimulants and biofertilisers
  – Experimentation of plant varieties and biomaterials in the field
  – Genetic improvement (breeding) of plant varieties
  – Advanced veterinary therapies

- These firms' shared mission lies in the use of more or less advanced molecular biology techniques for the progress and innovation of sustainable agriculture, with particular attention to the needs of Italian agriculture, although some firms are actually the Italian branches of large international groups.

- 2017 saw a significant new perspective for the Italian public research, which is engaging in a vast and well-focused research and development plan based on the most advanced biotechnologies applied to plant breeding innovation. This plan represents a turning point which all the research can start from, especially in agricultural genetics and varietal improvement. It is placed in a context of innovation which integrates the progress of life sciences with the parallel perspective that precision farming can offer.

- Support for research on genetic editing can also offer an important contribution to preserve the typical plant varieties of the Italian agricultural environment and to study their genomes in detail. Italian research already excels in this context: the results obtained thus far are a valid premise for exploiting the most of what the frontiers of new genetics promise.

- The cooperation between the scientific and political-decisional level that has recently emerged in Italy can be the right tool for facing the challenges of the future with effective interventions and solutions for agriculture which are simultaneously sustainable and productive. This opening not only leads Italian agriculture to expect increased operational capacity as regards the most advanced research, but also a concrete economic impact on the entire agri-food sector.

A snapshot of firms involved in the industrial and environmental sector

	Total firms	*Dedicated biotech R&D firms...*	*...of which Italian capital dedicated biotech R&D firms*
Number of firms*	161	76	73
Biotech turnover**	1,988,943	151,009	115,538
Total R&D investment**	248,609	37,025	26,419
Total Biotech R&D investment**	42,427	23,941	14,890
Biotech employees**	2,640	605	556
Biotech R&D employees**	489	254	222

Values in thousands of euros €/000

- The sector's turnover is close to 2 billion euros, registering 16% growth for the Italian capital dedicated biotech R&D firms.
- Investments in biotech R&D are about a fifth of total R&D investments, with an increase of 44% compared to the previous two-year period.
- The incidence of research investments on turnover, or on operating costs, for the Italian capital dedicated biotech R&D firms is on average 13%.
- Among the Italian capital firms, about 52% of the biotech turnover is totalized by the sector dedicated to industry and environment, highlighting it as one of the Italian biotech industry's competitive strengths.

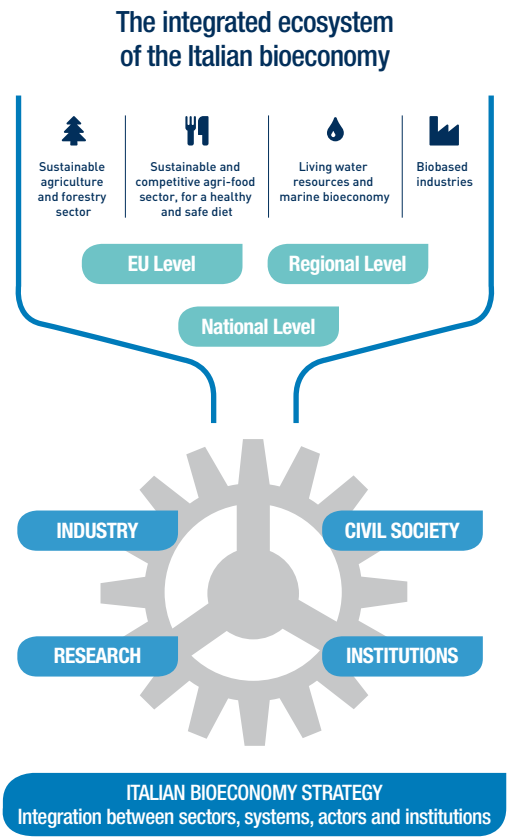
* Last available data, 2017 ** Last available data, 2016

Industrial biotechnologies, growth engine for sustainable development

- Industrial biotechnology use cells – yeasts, moulds, bacteria, plants – and enzymes to give life to bio-based products such as bioplastics, biological building materials, organic pharmaceuticals, cosmetic products and biofuels, to name only a few. The conscious and consolidated use of the wealth nature offers by an industry capable of transforming natural products and processes into solutions for the market is not a novelty. It suffices to mention that the first enzyme specially designed for the detergent industry was placed on the market as early as 1988.

- Thanks to industrial biotech, today it is possible to have products with high added value and greater efficiency in terms of cost and environmental sustainability; they are often easily biodegradable solutions which require less consumption of water and fossil fuels and create less waste during their production cycle. The fields of application of industrial biotech are numerous: from biotransformations through enzymatic catalysis for the redevelopment of traditional industrial processes, to the preparation of chemical compounds by fermentation; from the production of bioplastics to bioremediation and environmental diagnostics, from bioenergy production to the restoration and conservation of artistic heritage, up to the design of new fabrics for the clothing industry.

- The application of these techniques can make it possible to innovate mature sectors such as those of raw materials, energy production and intermediates while adhering to the principles of environmental, economic and social sustainability that are typical of bioeconomy.



Source: National bioeconomy strategy.
BIT - Bioeconomy in Italy. A unique opportunity for reconnecting the environment, economy and society, 2017.

Production of goods and energy from renewable natural resources

- The bioeconomy, of which industrial biotechnologies are the real engine, is an economy that uses biological resources from both the land and the sea as input for energy, industrial, food and feed production. The definition of bioeconomy includes the sectors of agriculture, food, fishing, forestry, the wood and paper industry and that of bio-based industries.

- For example, the biowaste from the agri-food industry contains a high potential in itself, to the point that the European Union has set itself the goal of deriving the production of 2% of renewable energy from this source.

- The topic of reusing waste and by-products is central to the industrial sectors that traditionally use biological resources as their main source of supply (forest, starch, sugar, biofuels/bioenergy, biotechnology sectors) and in others for which biomass is among the raw materials used (chemical, plastics and consumer goods).

Italy towards a leading role in the Euro-Mediterranean scenario

- Italy boasts some of the world's leading industrial players operating in the context of the bioeconomy, but also first-level research with real academic excellence as well as a highly innovative biotech start-up and SME system.
- The first biorefineries in the world for the production of biobased chemicals are Italian, which have allowed the industrial revamping of abandoned production facilities and the creation of new jobs.
- The Italian bioeconomy model is based on the development of local areas, in a logic of territorial regeneration. There is a system of national technological clusters supporting this model with three active entities: SPRING – Italian Cluster of Green Chemistry; CL.AN. – National Technology Agrifood Cluster, and BIG – Blue Italian Growth Cluster (marine and maritime sector). These three entities act as resource catalysts to coordinate and strengthen the link between the research world and the business world.
- Italy is decisively aiming at a leading role in the Euro-Mediterranean bioeconomy scenario with a very challenging objective, as indicated in the National bioeconomy strategy: passing from 251 billion euros in turnover and 1.7 million employees – as estimated in an analysis by the Intesa Sanpaolo Research Department in reference to 2014 – to 300 billion euros and over 2 million employed by 2030.
- According to estimates by Intesa Sanpaolo-Assobiotec, bioeconomy in Italy produced a value equal to 260 billion euros of production in 2016, corresponding to 8.3% of the total national economy experiencing moderate growth.

The National bioeconomy strategy presented in April 2017

- In April 2017 the National bioeconomy strategy was presented thanks to the teamwork involving many subjects[1]: it is part of the implementation process of the National Smart Specialisation Strategy (National S3) to ensure the reconciliation of economic growth with environmental sustainability.
- The strategy emphasises the importance of research and innovation to increase productivity, product quality and sustainability in every sector that makes up the bioeconomy.
- The interconnection of the various sectors is necessary in order to encourage the development of this meta-sector, in particular between those in the agri-food chain and the chemical and energetic valorisation of lignocellulosic and residual biomasses. In Italy there are three million hectares of land which are no longer cultivated: vast agricultural areas that can be regenerated today to produce indigenous and/or industrial biomass to feed Italy's biorefineries; there are 15 million tons/year of by-products and waste from the food industry, a rich availability of woody biomass guaranteed by over 13 million hectares of forest, which is generally used very little; non-food biomass (algal and posidonia but also microorganisms) generated by the country's seas that can be enhanced from a chemical and energy perspective.
- As explained by the Bioeconomy Investment Summit held in Helsinki in December 2017, a major boost in civil society awareness, education and training is envisaged: it is not merely a question of integrating biological knowledge into traditional industry, as the transition also takes place at the social level.

"The strategy aims to offer a shared vision of economic, social and environmental opportunities and challenges related to the implementation of an Italian bioeconomy rooted in the territory. It is also an important opportunity for Italy to strengthen its role in promoting sustainable growth in Europe and the Mediterranean basin".[2]

1. Ministry of Economic Development, Ministry of Agriculture, Food and Forestry Policies, Ministry of Education, University and Research, Ministry of the Environment and Protection of Land and Sea, Conference of Regions and Autonomous Provinces, Agency for Territorial Cohesion, National Technological Clusters SPRING and CL.AN.
2. BIT - Bioeconomy in Italy. A unique opportunity for reconnecting the environment, economy and society, 2017.

Bioeconomy in Italy

Production value in 2016, net of the water cycle

Italy	Millions of euros
Agriculture, forestry and fishing	56,003
Food, beverages, tobacco industry	132,801
Textiles from natural fibres and tanning	17,153
Timber industry	13,156
Paper industry	23,098
Biobased chemicals	3,037
Biobased pharmaceutical products	5,107
Biofuels	350
Bioenergy	2,237
Management and recovery of biodegradable waste	7,366
Bioeconomy Total	**260,308**
Bioeconomy weight on the total economy	8.3 %

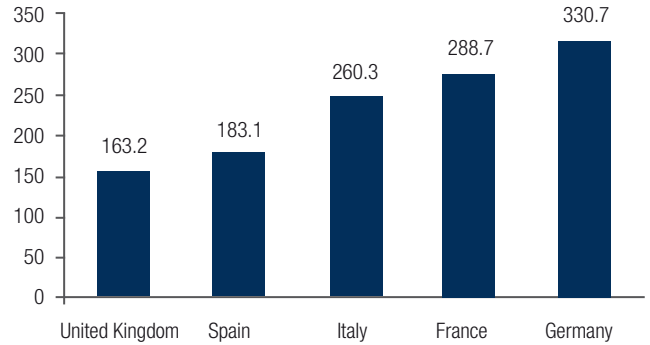
Values expressed in millions of euros €/000,000

Source: Intesa Sanpaolo elaboration of various sources

Bioeconomy is a complex concept that includes a multiplicity of sectors whose common basis is the renewable and biological origin of their inputs, but which can follow different underlying development dynamics conditioned by the peculiarities of each specialisation.
In terms of production, the Bioeconomy in Italy is worth 260 billion euros, corresponding to 8.3% of the national total experiencing moderate growth.

Bioeconomy in Europe in 2016

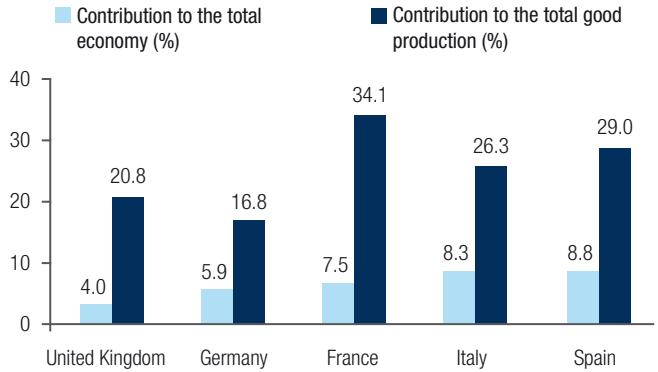
The European Bioeconomy in 2016, net of the water cycle



Values in billions of euros €/000,000,000

Source: Intesa Sanpaolo elaboration on Eurostat data

Weight of the bioeconomy on the economy, 2016 (% values)



Note: The data relating to the % weight on the total production of goods is calculated using the bioeconomy value net of the waste component.

Source: Intesa Sanpaolo elaboration of Eurostat Data

Germany stands out in absolute terms for production value, even if the weight that the bioeconomy has on the total German economy is less than that observed in other countries (5.9%). In relative terms, the weight that the bioeconomy has on the Spanish economy stands out most, equal to 8.8% (29% only on the production of goods) despite an absolute value of 183.1 billion euros. With its production value of 260 billion euros , Italy is in third place after Germany and France; instead by bioeconomy weight on the total economy of 8.3%, it is second after Spain.

Composition of bioeconomy in Europe

Value of the production in 2016 by sector

	United Kingdom**	Spain	Italy	France	Germany
Agriculture, forestry and fishing*	23.8%	28.2%	21.5%	28.8%	15.5%
Food, beverages, tobacco industry	54.4%	56.4%	51.0%	55.2%	55.5%
Textiles from natural fibres and tanning	0.7%	1.2%	6.6%	0.6%	0.7%
Timber industry	6.1%	3.2%	5.1%	3.8%	7.3%
Paper industry	8.2%	6.4%	8.9%	5.7%	11.1%
Biobased chemicals	1.3%	1.4%	1.2%	1.2%	2.0%
Biobased pharmaceutical products	1.1%	1.4%	2.0%	2.5%	2.7%
Biofuels	0.0%	0.2%	0.1%	0.0%	0.4%
Bioenergy	1.2%	0.2%	0.9%	0.3%	1.3%
Management and recovery of biodegradable waste	3.3%	1.4%	2.8%	1.9%	3.5%
Bioeconomy	100.0%	100.0%	100.0%	100.0%	100.0%
Total Bioeconomy (millions of euros)	163,193	183,107	260,308	288,685	330,673
Bioeconomy weight on the total	4.0%	8.8%	8.3%	7.5%	5.9%
Water cycle (millions of euros)	19,139	8,250	10,026	13,961	21,728
Total Bioeconomy and Water Cycle	182,332	191,357	270,334	302,646	352,401
Bioeconomy and water cycle weight on total economy	4.5%	9.2%	8.6%	7.8%	6.3%

Values in million of euros €/000,000 - Source: Intesa Sanpaolo elaboration on Eurostat data

* Source: National Accounts **year 2015

The results of public support for R&D activities

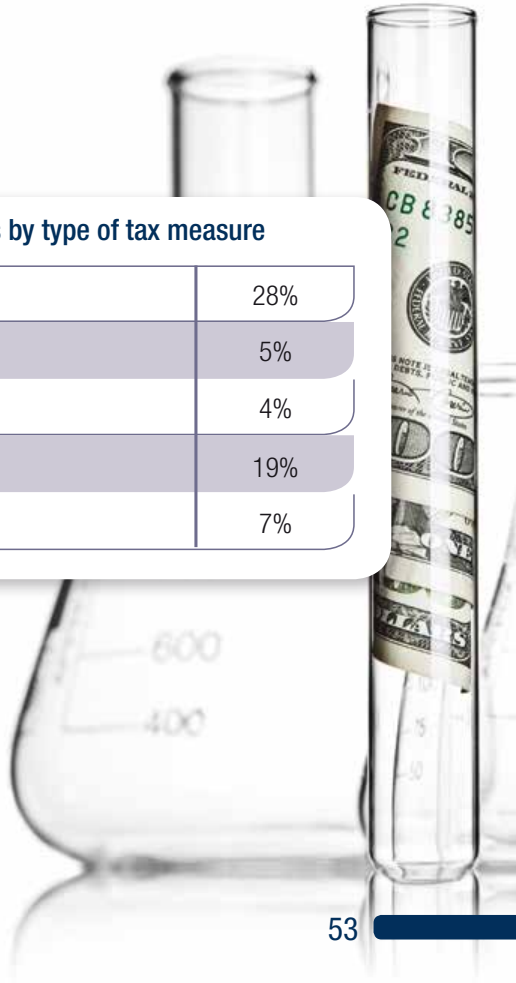
- In 2016, around 50% of firms benefited from at least one form of public support for their R&D activities, 51% of which came from local administrations.

Share of beneficiary firms by type of contribution

Regional and local government administration	21%
Central government administration	17%
European Union and other supranational administration	24%
Other	2%

Share of beneficiary firms by type of tax measure

R&D tax credit	28%
IP Box	5%
IRES deductions	4%
Super-amortisation	19%
Other	7%



- With regard to tax benefits, the R&D tax credit measure remains the most important tax benefit for companies. To date, more than a quarter of the firms in the biotech sector have already taken advantage of the measure, and this number is growing over time. The need to stabilise this measure in the near future by making it permanent is therefore quite clear.

- The recourse to super-amortisation and other measures has doubled, which mainly include the reductions related to hiring highly qualified personnel.

A look at what has been done in recent years

Numerous steps have been taken forward in recent years: policymakers are generally paying increasing attention to the sector; the ambition to put Research and Innovation at the centre of a strategic vision is spreading out.

Various aids have been fundamental in this path: the recognition of the status of innovative start-ups and innovative SMEs, the adoption of a preferential taxation regime on income from intellectual property (Patent Box), initiatives for the financing of new firms in Life Sciences, tax credit mechanism on R&D costs and investments and the introduction of the individual savings plans, known as PIR (Piani Individuali di Risparmio). These important measures then led to the adoption of the National Plan «Impresa 4.0» in 2017, with which all the effective measures were upgraded and addressed in a 4.0 logic and new measures were envisaged in order to fully respond to the emerging needs.

Within this scenario, the following measures must also not be forgotten: the National Research Plan, the Smart Specialisation Strategy, the presentation of the National Bioeconomy Strategy in April 2017 and the resources allocated to a three-year plan to relaunch genetic improvement in agriculture.

An indication of this virtuous path is Italy's ranking in second place for the rate of adoption of entrepreneurship incentive measures, according to the European Digital Forum Crowdsourcing Network, 2016.

10. Italian Biotech Companies

- 3 C.I. srl
- 4F Biotech srl
- 4Lab Diagnostics srl
- A&A Fratelli Parodi spa
- A. Costantino & C. spa
- AAT Advanced Analytical Technologies srl
- AB Analitica srl
- Abbvie srl
- Abich srl
- Abiel srl
- Aboca spa
- Accelera srl
- Acqua & Sole srl
- Acque del Chiampo spa
- ACS Dobfar spa
- Active Cells srl
- Actygea srl
- Aczon srl
- Adienne srl
- Advanced Accelerator Applications Italy srl
- Advanced Molecular and Biological Computation AMBC srl
- Advent srl
- AEP Polymers srl
- Aethia srl
- Agri New Tech srl
- Agrifutur srl
- Agritest srl
- Agroalimentare Sud spa
- Agrobiotech soc. coop.
- Agroils Technologies spa
- Agrolabo spa
- Alexion Pharma Italy srl
- Alfasigma spa
- Alga&Zyme Factory srl
- Algain Energy srl
- AlgaRes srl
- Allergan spa
- Allergopharma spa
- Alltox srl
- Alphagenics Biotech srl
- Also Biotech srl
- Altergon Italia srl
- Ambiotec sas
- Ambrosialab srl
- Amgen srl
- Amiko srl
- Anallergo srl
- Ananas Nanotech srl
- Angelini ACRAF spa
- Anika Therapeutics srl
- Apotech Peptidi & Cosmesi srl
- Apta Regenerative Technologies ART srl
- Aptenia srl
- Aptuit srl
- Apulia Biotech scrl
- Archimede R&D srl
- Ardis srl
- Areta International srl
- Arterra Bioscience srl
- Asoltech srl
- Astrazeneca spa
- Autifony srl
- Avantea srl
- Axxam spa
- BASF Italia srl
- Baxalta Italy srl
- Baxter spa
- Bayer Cropscience srl
- Bayer spa
- BBA Biotech srl
- Be Biotech srl
- Bio Fab Research srl
- Bio Soil Expert srl
- Bio Tools srl
- Bioaesis srl
- Bioagro srl
- Biobanca Biogem srl
- Biocell Center spa
- Biochemtex spa
- Bict srl
- Biodermol Ambiente srl
- Biodiagene srl
- Biodiversa srl
- Bioecopest srl
- BIOerg srl
- Biofarmitalia spa
- Biofer spa
- Biofordrug srl
- Biogas Italia BTS srl
- Biogen Italia srl
- Biogenera spa
- Bio-Ker srl
- Biological Tools for Mediterranean Agricolture BTM srl
- Bioman srl
- Biomedical Research srl
- Biomedical Tissues srl
- Biomerieux Italia spa
- Biomolecular Research Genomics srl
- Bionat Italia srl
- Bio-on srl
- Biopharma srl
- Bioplantec srl
- Biopolife srl
- BioPox srl
- Biorep srl
- Bioridis srl
- Biorigen srl
- Bioscience Genomics srl
- Biosearch Ambiente srl
- Biosearch srl
- Biosensing Technologies srl
- Biosensor srl
- Bioside srl
- Biosphere srl
- Biosynth srl
- Biotec Fermenti srl
- Biotec Sys BTS srl
- Biotecgen srl
- Bioteck srl
- Biotecnologie BT srl
- Biotecnologie Innovative per Ricerca e Diagnostica - BIRD srl
- Biotecnomed scarl
- BioTekNet scpa
- Biouniversa srl
- Biovalene srl
- Bio-Ve-Oil Olimpo srl
- Blast Research srl
- Boehringer Ingelheim Italia spa
- Bracco Imaging spa
- Braindtech srl
- BRD Lab srls
- Bristol-Myers Squibb srl
- BSA Ambiente srl
- BSL Cosmetics srl
- BSP Pharmaceuticals srl
- Byflow srl
- C. Sandroni & C. srl
- C4T scarl
- C5-6 Italy srl
- Cage Chemicals srl
- Campus Regi Biologia CAREBIOS srl
- Capua Bioservices spa
- Caresilk srls
- CCS Aosta srl
- Ceinge Biotecnologie Avanzate scrl
- Celgene srl
- CellDynamics srl
- Cellply srl
- Centro Ricerche Applicate ARC srl
- Centro Sperimentale del Latte srl
- Cereal Docks spa
- Charybdis Vaccines srl
- Chemi spa
- Chemical Center srl
- Chemicare srl
- Chiesi Farmaceutici spa
- Chrono Benessere srl
- Clonit srl
- Clover Therapeutics srl
- Colorobbia Italia spa

10. Italian Biotech Companies

- Congenia srl
- Consorzio Interdisciplinare di Studi Biomolecolari ed Applicazioni Industriali scrl
- Consorzio Interuniversitario di Ricerca in Chimica dei Metalli nei Sistemi Biologici
- Consorzio Italiano Biogas e Gassificazione
- Consorzio per il Centro di Biomedicina Molecolare scrl
- Controllo Genetico Piante/Cibi COGEP srl
- Cooperativa di Ricerca e Studi per la Pesca l'Acquacoltura e l'Ambiente CYPRAEA
- Cooperativa Produttori Bieticoli COPROB sca
- Corion Biotech srl
- CPC Biotech srl
- Crabion srl
- CRC Biotek srl
- Croda Italiana spa
- Crucell Italy srl
- CryoLab srl
- Cutech srl
- Cyanagen srl
- Daimar srl
- Dalton Biotecnologie srl
- Danone spa
- Demethra Biotech srl
- Detoxizymes srl
- Dia-Chem srl
- Diadem srl
- Diagnostic Bioprobes Dia.Pro srl
- Diamante srl
- DiaSorin spa
- Diatech Pharmacogenetics srl
- Diatech srl
- Diatheva srl
- Dicofarm spa
- Diesse Diagnostica Senese spa
- Dival Toscana srl
- DNA Analytica srl
- Dompe' Farmaceutici spa
- Dott. Dino Paladin - CRS
- Dow Agrosciences Italia srl
- Dow Italia spa
- Ebios Futura srl
- Ecobioservices and Researches srl
- Eco-Sistemi srl
- Ecotechsystems srl
- Edgelab srl
- Eggplant srl
- Elettra - Sincrotrone Trieste scpa
- Eli Lilly Italia spa
- Elitechgroup spa
- Eltek spa
- Enbiotech srl
- Engenome srl
- ENI spa
- Enrico Giotti spa
- Enthera srl
- Ephood srl
- Ephoran Multi Imaging Solutions srl
- Epi C srl
- Epigen Therapeutics srl
- Epinova Biotech srl
- Epitech Group spa
- Eridania Italia spa
- Erydel spa
- Espikem srl
- Etna Biotech srl
- Eudendron srl
- Eugenomics srl
- Euroclone spa
- Eurocoating spa
- Eurofins Genoma Group srl
- Eurospital spa
- Eurovix spa
- Euticals spa
- Ever srl
- Evolution Technology Laboratories srl
- Evvivax srl
- Exenia Group srl
- Exosomics Siena spa
- Experteam srl
- Explora srl
- Exprivia spa
- Fabbrica Italiana Sintetici FIS spa
- Farma ID srl
- Fastest srl
- Fastissues srl
- Fatro spa
- Fem2 - Ambiente srl
- Ferrania Technologies spa
- Ferring spa
- Fertirev srl
- Fic Htmd srl
- Fides Pharma srl
- Fidia Farmaceutici spa
- Fin-Ceramica Faenza spa
- Flora Conservation Società Semplice Agricola
- Flowmetric Europe srl
- Fly Life srl
- Fotosintetica & Microbiologica srl
- Franvax srl
- Fresenius Medical Care Italia spa
- G&Life spa
- Galascreen srl
- Galatea Bio Tech srl
- Galileo Research srl
- Geltis srl
- Genechron srl
- Genedia srl
- Genefast srl
- Genenta Science srl
- Generon srl
- Genesis Bioscience srl
- Genespin srl
- Geneticlab srl
- Genomix4Life srl
- Genomnia srl
- Genovax srl
- Genprobio srl
- Gentium spa
- Gentoxchem srl
- Gentras snc
- Gexnano srl
- GFBiochemicals Italy spa
- Gilead Sciences srl
- Giotto Biotech srl
- Glaxosmithkline spa
- Glaxosmithkline Vaccines srl
- Glures srl
- Gnosis Bioresearch srl
- Gnosis spa
- Graphene Nanotechnologies Hub srl
- Green Service srl
- Greenbone Ortho srl
- Greentech srl
- Gruppo Ricerche Avanzate Per l'Enologia GRAPE srl
- GSK Vaccines Institute for Global Health srl
- Hera spa
- HMGBiotech srl
- Holostem srl
- Hospira Italia srl
- HPF Nutraceutics srl
- Hygeia Lab srl
- IGA Technology Services srl
- Immagina Biotechnology srl
- ImmunePharma srl
- Immures srl
- In3Diagnostic srl
- In4Tech srl
- Inbios srl
- Incyte Biosciences Italy srl
- Indena spa
- Industria Meridionale Alcolici srl
- Industriale Chimica srl
- Inkidia srl
- Innoven srl
- Integrated Systems Engineering srl

- Intercept Italia srl
- IOM Ricerca srl
- Ion Source & Biotechnologies ISB - srl
- Ipsen spa
- IRBM Science Park spa
- Isagro spa
- Istituto Biochimico Italiano Giovanni Lorenzini spa
- Istituto di Ricerche Biomediche Antoine Marxer RBM spa
- Istituto Ricerche Applicate IRA srl
- iSweetch srl
- Italfarmaco spa
- Italia Biogenomic Technology BGT srl
- Italian Bio Products IBP spa
- Izo srl
- Janssen Cilag spa
- Kayser Italia srl
- Kedrion spa
- Kemira Italy spa
- Kemotech srl
- Kialab srl
- Kither Biotech srl
- Kos Genetic srl
- Kron Morelli srl
- Kronosdna srl
- Ktedogen srl
- Labor srl
- Laboratori Biomicron srl
- Laboratori Turval Italia srl
- Laboratorio Analisi Veterinarie LAV srl
- Laboratorio Di Micro E Submicro Tecnologie Abilitanti Dell'Emilia Romagna - Mist E-R scrl
- Lamberti spa
- Lati Industria Termoplastici spa
- Lay Line Genomics spa
- Lazzeri Società Agricola a r.l.
- LB Lyopharm - Laboratorio Biontologia srl
- Lead Discovery Siena srl
- LEBSC srl
- Lesaffre Italia spa
- Lgv1 srl
- Lifegene sas
- LifeLineLab srl
- Liosintex srl
- Lipinutragen srl
- Lofarma spa
- Lundbeck Pharmaceuticals Italy spa
- Magis Lab srl
- Mater Biotech spa
- Materias srl
- Matrica spa
- Mavi Sud srl
- Mediapharma srl
- Medical Research Institute MRITLab srl
- Mediteknology srl
- Mediterranea Biotecnologie srl
- Menarini Biotech srl
- Menarini Ricerche spa
- Menarini Silicon Biosystem spa
- Merck Serono spa
- Merial Italia spa
- Meristema srl societa' agricola
- Metagenics Italia srl
- Micro Biological Survey MBS srl
- Micro4you srl
- Microbiol snc
- Microbion srl
- Microbiotec srl
- Microgem srl
- Microgenomics srl
- Micromilk srl
- Micron Research Service srl
- Microspore spa
- Microtech srl
- Mindseeds Laboratories srl
- ML Biotech Italia srl
- Mogu srl
- Molecular Biotechnology srl
- Molipharma srl
- Molirom srl
- Molmed - Molecular Medicine spa
- Molteni Therapeutics srl
- Monsanto Agricoltura Italia spa
- Monteresearch srl
- MSD Italia srl
- MSD Vaccines spa
- Mybatec srl
- Naicons srl
- Nanofaber srl
- Nanomed3d srl
- Nanoshare srl
- Nanosilical Devices srl
- Nanovector srl
- Natimab Therapeutics srl
- Natural Technologies Italia srl
- Navhetec srl
- Naxospharma srl
- NCR Biochemical spa
- Nealys srl
- Need Pharma srl
- Neotron spa
- Nerviano Medical Sciences srl
- Neuheart srl
- Neuro Visual Science Technology srl
- Neuro-Zone srl
- Newron Pharmaceuticals spa
- Newronika srl
- Next Genomics srl
- Nextage srl
- Nextgen srl
- NGB Genetics srl
- Nib Biotech srl
- Nice srl
- Nicox Research Institute srl
- No Self srl
- Nobil Bio Ricerche srl
- Norgine Italia srl
- Nouscom srl
- Novaetech srl
- Novagenit srl
- Novaicos srls
- Novamont spa
- Novartis Farma spa
- Novo Nordisk spa
- Noxamet srl
- Nurex srl
- Nutraceutica srl
- Nutrigene srl
- NuvoVec srl
- Olon spa
- Oncoxx Biotech srl
- Ophera srl
- Orphan Europe Italy srl
- Oxi.Gen Lab srl
- Pentares Biopharma srl
- Personal Genomics srl
- Petropark srl
- Pfizer Italia srl
- Pharma Life srl
- Pharmadiagen srl
- Philogen spa
- Phytoremedial srl
- PinCell srl
- Pioneer Hi-Bred Italia Servizi Agronomici srl
- Plasfer srls
- Plasmore srl
- Pomona Ricerca srl
- Prigen srl
- Primm srl
- Prindex srl
- Probiotic CGB srl
- Probiotical spa
- Proge Farm srl
- Promis Biotech srl
- Proteotech srl
- Proxenia srl
- ProXentia srl
- Ptc Therapeutics Italy srl
- Raresplice srl

10. Italian Biotech Companies

- Recordati Industria Chimica e Farmaceutica spa
- Reithera srl
- Remembrane srl
- Repros srl
- Research & Innovation srl
- Research Toxicology Centre spa
- Resindion srl
- Ricerche Sperimentali Montale srl
- Rigenerand srl
- Roche spa
- Roelmi HPC srl
- Roquette Italia spa
- Rottapharm Biotech spa
- Sacace Biotecnologies srl
- Sacchetto spa
- Sacco srl
- SAFAN Bioinformatics sas
- Safood srl
- Salentec srl
- Sandoz Industrial Products spa
- Sanofi spa
- Sclavo Diagnostics International srl
- Sea Marconi Technologies sas
- Sedicidodici srl
- Seno Seed srls
- Sentinel CH spa
- Serge Genomics srl
- SetLance srl
- Shire Italia spa
- Shoreline Societa' Cooperativa
- Sienna Biopharmaceuticals srl
- Sigea srl
- Silk Biomaterials srl
- S-in Soluzioni Informatiche Srl
- Sirius-Biotech srl
- Smile Biotech srl
- Società Industria Farmaceutica Italiana SIFI spa
- Società Italiana Sementi spa
- Società Metropolitana Acque Torino spa
- Società Prodotti Antibiotici spa
- Società Produttori Sementi spa
- Sooft Italia spa
- Spaceland Italia srl
- Spike Renewables srl
- Stallergenes Italia srl
- Stemgen spa
- STMicroelectronics srl
- Synbiotec srl
- Syngenta Italia spa
- Syntech srl
- Takeda Italia spa
- Takis srl
- Technogenetics srl
- Tecna srl
- Tecnobios Procreazione srl
- Tectronik srl
- Telea Biotech srl
- Tensive srl
- Teracell srl
- Tes Pharma srl
- Tethis spa
- Thankstem srl
- Tib Molbiol srl
- Tissue and Organ Replacements TOR srl
- Tissuegraft srl
- Tissuelab spa
- Toma Advanced Biomedical Assays spa
- Transactiva srl
- Trustech srl
- Tydock Pharma srl
- UB-Care srl
- UCB Pharma spa
- Ufpeptides srl
- Ulisse Biomed srl
- UNECO Srl
- Unilab sas
- Unistrains srl
- University of Pittsburgh Medical Center Italy srl
- Ustem srl
- Valagro spa
- Vaxxit srl
- Vaxynethic srl
- Veneziana Energia Risorse Idriche Territorio Ambiente Servizi - VERITAS spa
- Vera Salus Ricerca srl
- Versalis spa
- Vetogene srl
- Vetspin srl
- Vevy Europe spa
- Villani spa
- Virostatics srl
- Vismederi Research srl
- Vismederi srl
- Vitroscreen srl
- VivaBioCell spa
- Wellmicro srl
- Wetware Concepts srl
- Xeda Italia srl
- Xeptagen spa
- Yenetics srl
- Ylichron srl
- Zoetis Manufacturing Italia srl

Companies tracked by internet analysis

Assobiotec - Federchimica
Rita Fucci
Elisabetta Molteni
Leonardo Vingiani

ENEA
Gaetano Coletta
Oscar Amerighi
Daniela Palma
Marco Casagni

Graphic design and creation: Studio ABC Zone (MI)
Photo: Shutterstock
Printed by: La Compagnia della Stampa Srl