



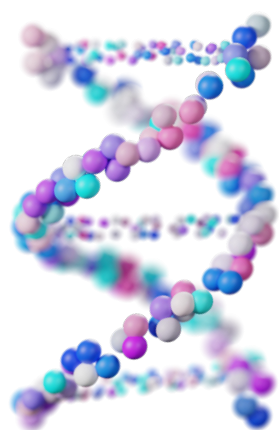
Ministero degli Affari Esteri  
e della Cooperazione Internazionale

# National Working Table for the Internationalization of Industries in the Biotechnology Sector



Courtesy translation, the original  
Report is in Italian

**Final report**  
**April 2025**





## PREMISE

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The National Working Table for the Internationalization of Industries in the Biotechnology Sector (NWTIB) was established by the **Ministry of Foreign Affairs and International Cooperation** (MAECI) in collaboration with the **Ministry of Enterprises and Made in Italy** (MIMIT), and the Italian Trade Agency (ICE), with the involvement of other ministries and national institutions such as the **Ministry of Universities and Research** (MUR) and the **National Research Council** (CNR). The group is composed of eminent persons, including entrepreneurs, scientists, and industry leaders, who participate on an individual and voluntary basis (*Annex I: list of members*).

The task of NWTIB is to formulate strategies and recommendations for the internationalization of emerging companies in the field of biotechnology (“Emerging Biotech Companies” or “EBCs”) with the aim of strengthening the entire national sector. This was done by conducting an in-depth examination of the progress and prospects of biotechnology on a global scale, collaborating with committees and agencies from other countries where available, and contributing to the formation of a competitive national and European strategy.

Specifically, the Working Group has examined the following items:

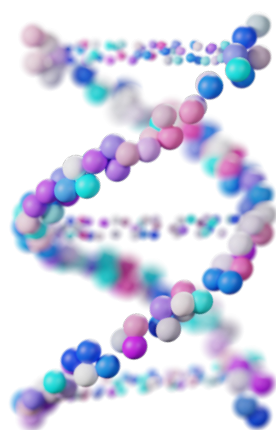
- Analysis and evaluation of the **main trends and opportunities in international scientific research**.
- Identification of **the diseases of national interest and strategic industrial and environmental biotechnology priorities** for developing a robust and internationally attractive biotech ecosystem.
- **Government investment policies** in close coordination with the Enea Tech and Biomedical Foundation and CDP Venture Capital SGR.
- Attraction of **international investments** and **resources** while protecting national assets.
- Promotion and internationalization of the entire Italian biotech ecosystem, including **research, technology transfer, training, talent attraction, enterprises, and capital**.
- The **strategic role of Research Infrastructures**, funded by the EU and the Ministry of University and Research, in supporting research and businesses through their technological resources, including data and analysis tools, as well as the provided biotech services.



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## 1. INTRODUCTION

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Biotechnology represents a set of techniques that use living organisms, cells, or their components to develop products, materials, and technologies with applications in various sectors, from medicine to agriculture, industry, and the environment. This definition broadens the traditional perspective of biotechnology, including integration with deep tech technologies such as artificial intelligence, quantum computing, nanomaterials, microelectronics, and advanced materials, opening new scenarios and extraordinary possibilities for human progress.

Artificial intelligence is emerging as a transformative force in biotechnology, revolutionizing research and therapeutic applications. Advanced algorithms accelerate the identification of promising drugs, modeling molecular interactions with unprecedented precision and reducing the time and cost of preclinical development. In personalized medicine, AI, for example, integrates genomic and transcriptomic data to identify predictive biomarkers, optimize therapies, and improve clinical outcomes. In the industrial sector, AI platforms design synthetic microorganisms and optimize metabolic pathways for biofuels and sustainable materials, shaping a future where innovation and sustainability progress hand in hand.

**The biotechnology sector, already significant, has been elevated to a strategic sector by leading nations following the SARS-CoV-2 pandemic. It is also a key sector for promoting the development of the circular and regenerative bio-economy,** which is essential for mitigating climate-altering emissions, pollution, and biodiversity loss. Advanced biotechnological capabilities allow a country to position itself at the technological frontier and grow in sectors crucial for sustainable socio-economic development and national security. **Italy can play a role in the global competition among leading countries in biotechnology** if scientific research and biotechnology enterprises are elevated to strategic priorities and supported by targeted government actions and policies.

In this sector, as in the broader field of life sciences, international cooperation should be enhanced through dialogue and joint action with key international partners, promoting the protection of public goods, global public health, and addressing global challenges such as climate change, all of which are central to the G7 agenda under Italy's Presidency and, more generally, diplomatic action.

Such is also the intent of studies conducted by the European Commission, March 2024<sup>1</sup> report:

*“Biotechnology and biomanufacturing are key for the competitiveness and modernization of our economy due to their high growth potential and increased labor productivity. They also strongly enhance the EU's open strategic autonomy and*

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<sup>1</sup> [https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT\\_24\\_1610](https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_24_1610)

*resilience by reducing the industry's dependency on fossil-based inputs and other sources of raw materials and increasing circularity. They help advance the European Health Union and achieve the European Green Deal objectives. Biotechnology has also been identified as a critical technology from the economic security perspective, given its cross-cutting nature. It is also one of the technologies prioritized in the Strategic Technologies for Europe Platform (STEP) regulation.” (Annex II- A and B)*

The biotech sector is also thoroughly addressed in the Draghi Report on European competitiveness and, indirectly, in financial terms in the Letta Report, which were later consolidated into “A Competitiveness Compass for the EU<sup>2</sup>.” This document firmly establishes that only a future for Europe driven by innovation will allow our continent to maintain (and improve) its current standard of living and various social achievements:

“Investing in the new growth engines. Life sciences are driving innovation in biotechnology and hold great potential for competitiveness across sectors, from pharma to agriculture to energy to food and feed. The EU Bioeconomy Strategy will position the EU in the rapidly expanding bioeconomy market with significant growth potential in bio-based materials, biomanufacturing, biochemicals, and agri-biotech sectors, reduce our reliance on fossil fuels, and improve the economic perspectives of our rural areas. A new European Biotech Act will provide a forward-looking framework conducive to innovation in areas like health technology assessment and clinical trials and more generally to leverage the potential that biotechnologies can bring to our economy.”

In this context, attention must also be given to the forthcoming “European Biotech Act<sup>3</sup>” in the preparation of which Italy must play an authoritative and assertive role to ensure the inclusion of principles and directives aligned with national interests. These interests, in turn, cannot be separated from a robust EU biotech ecosystem, driven by the presence of actors operating at least on a pan-European scale.

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2 [https://commission.europa.eu/document/download/10017eb1-4722-4333-add2-e0ed18105a34\\_en](https://commission.europa.eu/document/download/10017eb1-4722-4333-add2-e0ed18105a34_en)  
3 [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_24\\_1570](https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1570)

## 2. SUMMARY

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In summary, the strategic lines and actions suggested by NWTIB are:

- Identification of the **diseases of national interest and strategic industrial and environmental biotechnology priorities**.
- Identification of **emerging biotechnologies** that can address identified diseases and priorities.
- Census of Research Infrastructures with biotech equipment and services.
- Selection of national companies developing emerging biotechnologies capable of addressing selected diseases and priorities and the consequent establishment of a **Special List of Emerging Biotech Companies (SLEBC)**.

Actions in favor of industries listed in the SLEBC:

- Organization of an **international marketing campaign** with the support of MAECI, the network of Embassies and Consulates, the ICE Agency, and the Government's Innovation Centers abroad.
- Support for **research and development activities, talent and investment attraction**, collaboration with the country's research centers, and involvement of government investment agencies.

## 3. TERMINOLOGY AND KEY MESSAGES

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**The Biotech sector**, as understood in this NWTIB Report, refers to the research and development of new therapeutic products, industrial biotechnologies, biotechnological production, and the supply chain of the sector.

**Internationalization**: the development of a favorable ecosystem for Emerging Biotech Companies (EBCs), capable of addressing and solving the Diseases of National Interest and Strategic Industrial Biotechnologies priorities, while maintaining strategic assets in Italy, through:

1. **Talent recruitment**: qualified professionals and researchers and encouraging "bio-entrepreneurs" to establish their activities within the Italian ecosystem.
2. **Attraction of investments**: growth of the national venture capital sector by attracting private funding sources, including co-investments with government funds.
3. **Enhancing the attractiveness of Italian research and experimentation centers**: the ecosystem thrives through collaborations with multinational companies in the pharmaceutical, chemical, and biotechnological sectors, engaged in preclinical, clinical, and industrial research, forming alliances that

strengthen the international scope and impact of the sector.

4. **Development of collaborations:** the ecosystem thrives on collaborations with multinational pharmaceutical and biotech companies engaged in pre-clinical, clinical, and industrial research, forming alliances that enhance the sector's international reach and impact.

**Technology Transfer, Education, and Training:** The positioning of IBEs (Innovative Biotech Enterprises) and bio-entrepreneurs at the center of the ecosystem drives the process of technology transfer. It is therefore essential to support the education and skill development of future “bio-entrepreneurs,” with a particular focus on patent-related skills, which are crucial for attracting foreign professional investors and for “incubating” biotech research talent within the entrepreneurial system, thereby preventing the so-called “brain drain.”

**Venture Capital:** The impact of venture capital is not the same in countries with technological leadership compared to so-called follower countries. In the latter, including Italy, venture capital risks becoming an intermediary for the transfer of technologies to leading countries. To prevent this phenomenon, the intervention strategies of government investment agencies must be revised. Currently, these agencies focus exclusively on guaranteeing investments in Italy without regulating the divestments of supported funds and companies. Additionally, national venture capital tools must be strengthened by increasing dedicated public funds, particularly enhancing so-called “growth” funds—those intended for investments of €15–20 million or more per company.

**Stock Market:** Venture capital flourishes when there is an attractive and developed stock market capable of ensuring liquidity for investments and keeping founders at the helm of their companies. Listing on the stock exchange (IPO) can mitigate or prevent the phenomenon of “company flight,” which involves the loss of know-how, technology, and talent. The national stock market, although integrated into the Euronext network, is likely not adequate to support investments in high-tech strategic companies and to retain assets in Italy. The preferred path should be the creation of a single pan-European stock market, known as the Capital Market Union, overcoming the fragmentation of numerous small or medium exchanges and establishing a single European technology exchange modeled after the NASDAQ in the United States. However, this proposal should balance national and community interests.

In Italy, since 2009, there has been an SME Growth Market (EGM - Euronext Growth Milan) that has financed a significant number of innovative startups and SMEs, serving as a valuable tool for accessing risk capital and enabling companies to capitalize on their exits in a competitive environment that accelerates internationalization and growth through M&A.

In recent years, alongside the Capital Law, which introduced regulatory simplifications to make the national stock market more competitive, a joint initiative by the Ministry of Economy and Finance and the Cassa Depositi e Prestiti has been launched. This innovative tool is dedicated to long-term investments and aims to:

1. Create a dynamic financial ecosystem that promotes the sustainable growth of Italian companies, attracting both national and international capital.
2. Strengthen the role of startups and SMEs in the country's economic landscape by facilitating capital access and improving the liquidity of the national stock market.

By enhancing the liquidity of listed companies that suffer from a lack of institutional investors and available capital, the initiative enables balanced and sustained economic growth over time.

## 4. STATE OF THE ART

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The actions of the Working Group align with the EU's vision for the biotech sector and acknowledge and address the challenges highlighted by the Commission's report:

*"The main bottlenecks include fragmented research, administrative and regulatory burdens, limited specialized support for technology transfer, lack of access to risk-tolerant venture capital and data, and, finally, to markets."* (EU Biotech Report<sup>4</sup>, Annex II).

The Working Group aims to outline an actionable plan, with a strategic approach, to implement and encourage the faster internationalization of the Italian biotech ecosystem.

Any consideration of Italy's international positioning in the biotech field cannot be separated from political and geostrategic considerations. Italy must have a strong presence at the key forums where biotech issues (health and bioeconomy) are addressed, such as the G7, the G20, the United Nations and its various organizations, NATO (which has published an *"International Strategy on Biotechnology and Human Enhancement Technologies"*<sup>5</sup>, where industrial capabilities will play a prominent role), and especially the EU. The EU holds great potential in R&D but often falls short in technology transfer and access to capital, not matching the quality of its scientific research, frequently due to regulations that are not always enabling.

The European Commission has initiated a process aimed at reducing the competitive gap compared to other countries; it is imperative for Italy to participate as a key player in this process, ensuring that future European sector-specific legislation reflects the fundamental interests of the national system.

In addition to its relationship with the EU, it is equally essential to maintain bilateral relations with major countries (e.g., *Bold Goals for US Biotechnology and Biomanufacturing*<sup>6</sup>, Annex III) for cooperation in the biotech field, starting with the strategic partnership with the United States. The U.S. is the world's leading market in the sector, which in recent years has seen a revival across the entire industry, supported by ambitious government initiatives.

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4 [https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT\\_24\\_1610](https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_24_1610)

5 [https://www.nato.int/cps/fr/natohq/news\\_222980.htm?selectedLocale=en](https://www.nato.int/cps/fr/natohq/news_222980.htm?selectedLocale=en)

6 <https://www.whitehouse.gov/wp-content/uploads/2023/03/Bold-Goals-for-U.S.-Biotechnology-and-Biomanufacturing-Harnessing-Research-and-Development-To-Further-Societal-Goals-FINAL.pdf>



## 5. EXECUTIVE PLAN IN FIVE STEPS

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1. Identify high-impact diseases, **the Diseases of National Interest**, and through the identification of key industrial challenges in Italy, the **Strategic Industrial and Environmental Biotechnology priorities**.
2. Select the **Emerging Biotechnologies** best suited to address the Diseases of National Interest and tackle Bio-industrial and Environmental priorities.
3. Identify the **Emerging Biotechnological Companies (EBCs)** involved in the R&D of emerging biotechnologies applied to the Diseases of National Interest and the development of Strategic Industrial Biotechnologies: **Special List of Emerging Biotech Companies (SLEBC)**.
4. Support EBCs in internationalization through a dedicated marketing program, the “**Montalcini Global Biotech Tour;**” support their R&D investments, and provide them with direct and privileged access to the Italian research ecosystem (network of IRCCS, Italian Institute of Technology, Human Technopole, Biotechnopolo Foundation of Siena, National Anti-Pandemic Center CNAP, etc.).
5. Support IBEs with a network of national research infrastructures to promote the upscaling of scientific maturity and biotechnological development in line with international standards.

### 5.1. DISEASES OF NATIONAL INTEREST AND INDUSTRIAL AND ENVIRONMENTAL BIOTECH PRIORITIES

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#### Disease of National Interest

The identification of the Diseases of National Interest is based on criteria of impact in terms of mortality and incidence on quality of life. Strategic industrial and environmental biotech priorities expand this impact, involving areas ranging from nutrition to the environment.

1. **Cardiovascular diseases:** these account for 35% of all deaths in Italy, including ischemic heart disease and stroke, and remain one of the leading causes of death in Italy.
2. **Cancers:** these account for about 29% of deaths in Italy. The most common include breast cancer in women and prostate cancer in men, followed by lung and colorectal cancers.
3. **Respiratory diseases:** conditions like chronic obstructive pulmonary disease

(COPD, with estimates indicating that about 6-10% of Italian adults suffer from it) and asthma significantly impact public health, exacerbated by environmental factors such as pollution and smoking.

4. **Chronic-degenerative diseases:** conditions like diabetes and rheumatoid arthritis have a significant impact on an individual's quality of life and require long-term management. Diabetes (affecting about 6% of the adult population) is increasing, partly due to lifestyle factors and rising obesity rates.
5. **Infectious diseases:** despite the decline in infectious diseases due to medical advances and vaccinations, they remain a major concern. Recently, the SARS-CoV-2 pandemic has highlighted the vulnerability of modern societies to emerging infectious diseases. In Italy, these include Dengue, Chikungunya, Malaria, and avian influenza.
6. **Antibiotic resistance (Bacterial Antimicrobial Resistance-AMR):** changes in bacteria render the drugs used to treat infections less effective, and such resistance is emerging as one of the major health threats of the 21st century. A report commissioned by the British Government states that AMR could cause 10 million deaths annually by 2050 ([https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02724-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext)). In Italy, there were 70,000 AMR-related deaths in 2023 (National Observatory on Antimicrobial Resistance - Onsar)<sup>7</sup>.
7. **Neurological/neurodegenerative diseases:** there are 50,000 new cases of stroke each year, with approximately 800,000 individuals who have survived a stroke but live with disabilities; 300,000 patients with Parkinson's disease; 120,000 people currently affected by Multiple Sclerosis; 5 million individuals suffering from migraines, particularly women, and 800,000 affected by chronic migraines, experiencing persistent pain for more than 15 days per month. Up to 1 million people are affected by cognitive decline (SIN data, 2024).

## Industrial and Environmental Biotech Priorities

1. **Reduction of greenhouse gas emissions responsible for climate change** (through gas fixation via forestry, soil, oceans, seas, microbial fermentation of greenhouse gases, and carbon-neutral production chains, such as the bio-based sector, for disease prevention in the context of the One Health concept). The contribution of bio-based industries to decarbonization should be recognized through specific incentives and facilitations.
2. **Reduction of persistent toxic pollutants in the environment** through sustainable bioremediation of contaminated sites using microorganisms and replacing conventional pollutants, plastics, pesticides, etc., with equivalent biodegradable biobased products (biofertilizers, biopesticides, biodegradable bioplastics for agriculture, compostable bioplastics, etc.). These products

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<https://www.epicentro.iss.it/antibiotico-resistenza/documentazione-italia>

should be promoted where they can contribute to solving environmental challenges.

3. **Restoration of biodiversity and terrestrial and hydrosphere ecosystems** (for health and productivity, but also to prevent future zoonoses and pandemics).
4. **Production of healthier and more nutritious foods** to better combat obesity and aging through targeted food biotechnology processes and the use of biofortified crops.
5. **Conversion of lignocellulosic biomass** and by-products and agri-food, forestry, and marine waste into new or innovative bio-based chemicals, materials, and fuels. Improvement of biomass productivity, resilience to biotic and abiotic stresses, and nutritional value through gene editing and hybridization.
6. **Production of biomolecules** (basic and biologically active chemicals) through fermentation and biotransformation following the principle promoted by the European Commission of Safe and Sustainable by Design<sup>8</sup>.
7. **Sustainable production** of Active Pharmaceutical Ingredients (APIs), nutraceuticals, and personal care compounds (cosmetics).
8. **Synthetic biology** for the production of molecules of industrial and pharmaceutical interest.

## 5.2. EMERGING BIOTECHNOLOGIES

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### Precision and Advanced Medicine

NWTIB has mapped and identified emerging biotechnologies that are best suited to address the indicated priorities in the therapeutic field. This analysis considered the most promising and innovative technologies in the scientific and technological landscape, assessing their ability to tackle critical health challenges and improve industrial processes.

1. **RNA-based therapies:** treatments that use RNA to target and modify genetic instructions within cells. These therapies can help correct or modulate gene behavior, offering potential treatments for a range of diseases, including genetic disorders, some types of cancer, and infections (interfering RNA (RNAi), messenger RNA (mRNA), mRNA-based vaccines, mRNA-based CAR-T, mRNA-based monoclonal delivery).
2. **Gene and cell therapies:** cell and gene therapy involves altering the genes within a person's cells to treat or halt the disease, while cell therapy involves transferring live cells into a patient to replace damaged or diseased cells, improving their function and health.
3. **Immunotherapies:** treatments that enhance or restore the immune system's

<sup>8</sup> [https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials/safe-and-sustainable-design\\_en](https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials/safe-and-sustainable-design_en)

ability to fight infections and diseases, often used to target various types of cancer (checkpoint inhibitors, CAR-T, targeted therapies...), and often associated with the study of the human microbiota..

4. **Monoclonal antibodies:** lab-produced proteins that mimic the immune system's ability to fight harmful pathogens like viruses. They are designed to bind to specific targets in the body and can play a therapeutic role in treating various diseases, including some forms of cancer and autoimmune disorders.
5. **Antivirals:** drugs designed to treat viral infections by inhibiting the development or replication of the virus within the body. New classes of antivirals are being tested to treat a variety of viral infections with a single drug.
6. **Neuroscience Biotechnologies:** biological, mechanical, and computational technologies for studying the functioning of the nervous system and treating neurological disorders; technological solutions that analyze the mechanisms of natural and artificial cognition, as well as brain-machine interactions (digital twin), also leveraging AI.

### Industrial and Environmental Technologies

1. **Microbiome-based technologies:** to improve soil productivity, the hydrosphere, and the ecosystem, as well as the productivity of bioprocesses.
2. **Genetics and selection:** to improve productivity, adaptation to biotic and abiotic stresses, and the nutritional value of primary biomass. Gene editing offers improvements in accuracy and precision for the reproduction of plants and animals, with the additional benefit of accelerating component processes at a reduced cost.
3. **Precision fermentation** for the sustainable production of better and more nutritious foods.
4. **Synthetic biology** to improve the efficiency, selectivity, and sustainability of bioprocesses. Biotechnologies and bioprocesses for the conversion of organic waste and CO<sub>2</sub> into bio-based molecules and materials, as well as CO<sub>2</sub> capture and storage.
5. **Micro and nano technologies:** nanomaterials, such as nanoparticles, nanofibers, and nanotubes, offer unique properties and functionalities that can be used in specific biotechnological applications.
6. **Bioconversions** to support the sustainable production of active pharmaceutical ingredients (APIs), nutraceuticals, and personal care compounds (cosmetics).

### 5.3. SPECIAL LIST OF EMERGING BIOTECH COMPANIES (SLEBC)

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The Special List of Emerging Biotech Companies (SLEBC) is established through the call for expression of interest mechanism, to identify, using a set of precise parameters, only those companies based in Italy that are engaged in research and development of emerging technologies in the fields of the diseases of national interest and biotechnological industrial priorities, including biomanufacturing.

#### Admission Criteria:

- Emerging Biotechnology Companies (SMEs and Start-ups) operating in the field of precision and advanced medicine must declare that they invest at least 2 million euros per year in Research and Development (R&D).
- Industrial and environmental Emerging Biotechnology Companies must declare that they invest or have received at least 700,000 euros per year in R&D through projects financed by the EU Commission or through international grants.
- Emerging Biotechnology Companies must demonstrate that they possess, either directly or through licensing, patents.
- Emerging Biotechnology Companies must be resident in Italy, both in terms of legal headquarters and main office, and that the R&D activity must be carried out predominantly in Italy.

### 5.4. STRATEGIC SUPPORT FOR EMERGING BIOTECHNOLOGICAL INDUSTRIES

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Emerging Biotechnology Companies (IBEs) included in the Special List (ESIBE) will be the subject of strategic support through an international **promotion program** in collaboration with the Ministry of Foreign Affairs and International Cooperation (MAECI) and the Italian Trade Agency (ICE), through their networks and Innovation Centers abroad (such as INNOVIT in San Francisco), in order to establish a **presence in key international biotech markets** (ICE Agency Appendix V). International Promotion Program for ECBs in collaboration with MAECI and the ICE Agency, through their foreign networks including Embassies, Consulates, ICE Agency Offices, and Italian Government Innovation Centers abroad (such as INNOVIT in San Francisco), to establish a presence in key markets (*EU, USA, Asia, Middle East. Annex IV-V*).

- **“Montalcini Global Biotech Tour:”** a promotional activity organized by ICE for companies in the biotech sector that allows IBE to participate, upon subscription to individual initiatives, in a path that includes the major global biotech events, with actions that support networking and high-value

relationships with potential investors and institutions. Below is the list of events planned for 2025:

1. JP Morgan Health Conference - San Francisco, January 13-16;
  2. Arab Health - Dubai, January 27-30;
  3. BIO-Europe Spring - Milan, March 17-18;
  4. Qatar Forum - Doha, April 16-17;
  5. Swiss Biotech Days - Basel, May 5-6;
  6. BIO USA - Boston, June 16-19;
  7. BIO ASIA - Singapore, September 9-10;
  8. IFIB 2025 - Turin, September 25-26;
  9. BIO EUROPE - Vienna, November 3-5.
- **Institutional Relations:** MAECI and ICE will promote exclusive meetings for IBE with top managers of the main pharmaceutical and biotechnology companies, as well as with international scientists and investors in the sector.
  - **Government Relations:** MAECI will promote government-to-government (G-to-G) contacts to strengthen international collaborations (bilateral and multilateral) in order to increase the credibility of the Italian biotech ecosystem (for example with ARPA-H and NSCEB in the USA).
  - **Support for Internationalization:** measures and facilitated financing should be created for IBE to support internationalization and R&D investments. (*Appendix VI – France case*).
  - **Communication campaign** on biotech themes both in Italy and abroad to increase awareness of the importance of the sector from both a scientific and economic point of view.

## 5.5. STRATEGIC ROLE OF RESEARCH INFRASTRUCTURE AS A BRIDGE BETWEEN COMPANIES AND THE MARKET

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Research infrastructure plays a crucial role in the development of emerging biotechnologies, as it provides the necessary support for advanced research, innovation, and the practical application of scientific discoveries. The main roles of research infrastructure:

1. Support for research and development (R&D): research infrastructure, such as specialized laboratories, cell culture facilities, and high-capacity sequencing platforms, are essential for performing complex experiments and analyzing large volumes of data. These tools are crucial for testing new ideas,



- developing prototypes, and validating technologies.
2. Access to advanced data and technologies: infrastructure allows researchers to access advanced tools such as next-generation sequencers, electron microscopes, bio-pharmaceutical production plants, and supercomputers for the analysis of complex genomic data. These technologies are fundamental for the design and production of new therapeutic or biotechnological solutions.
  3. Intersectoral collaborations: research infrastructure promotes collaboration between universities, research institutes, private companies, and public entities. These interactions are essential for translating scientific discoveries into concrete commercial or therapeutic applications. Shared platforms also offer opportunities for joint experiments, accelerating the progress of emerging biotechnologies.
  4. Education of startups and SMEs on the themes of opening up to the public capital market (listing on the stock exchange) which allows to maintain control of the company with access to risk capital aimed at financing late-stage phases, strengthening at the same time management and internal control processes of accountability towards institutional investors and disclosure.
  5. Support for training and skill creation: research infrastructure acts as advanced training centers, offering researchers and students access to advanced techniques and methodologies. This promotes the creation of a highly qualified workforce, capable of managing the technological and scientific challenges in emerging biotechnologies.
  6. Application and scalability of technologies: research infrastructure is fundamental for the scalability phase of many biotechnological technologies. For example, the production of therapeutic proteins or vaccines requires biotechnological production plants, which can only be optimized with adequate structures. Industrial infrastructure can also test and implement solutions developed in the laboratory.
  7. Sustainability and safety: biotechnology-dedicated infrastructure must also address the challenges of sustainability and safety. For example, it must ensure rigorous compliance with ethical and safety standards when working with genetically modified organisms, experimental drugs, or industrial biotechnologies.
  8. Access to funds and investments: often, research infrastructure is supported by public and private funding, which allows for the development of new technologies, conducting clinical trials, and validating solutions. Having access to high-quality infrastructure also makes it more likely to attract investments and commercial partners.

## 6. FINANCE IN SUPPORT OF STRATEGIC GROWTH AND INTERNATIONALIZATION

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- The finance is the engine of every economic-productive system, and the Working Group has deepened the themes of investments in the sector. Since government resources are limited, it is believed that they should be primarily directed towards advanced technologies and research projects oriented towards internationalization. Public finance choices must be bold and (while respecting budget constraints) adopt priorities consistent with the country's future growth. By concentrating investments on IBE of national interest, a robust and attractive Italian biotech ecosystem will be favored for international investors and multinationals. The venture capital system must recognize the difference between countries with consolidated technological leadership and follower countries. In the former, venture capital stimulates innovation and internal growth, while in the latter, like Italy, it risks becoming a means for the transfer of technologies towards leading countries rather than supporting the local ecosystem. It is therefore necessary to reform the strategy of support for venture capital to create an environment that attracts capital for technological development and incentivizes companies to root and grow in their own country, avoiding the so-called phenomenon of Company Flight. This can be achieved by strengthening and creating new growth and large funds to finance larger operations (funds that in turn have a greater chance of attracting financing from foreign institutional investors, starting with sovereign funds). This result is possible by mobilizing public and private financial resources (managed savings, deposits, pension and insurance provisions) in a higher measure and guaranteeing a de-risking based, for example, on tax advantages.
- Therefore, it is urgent to reformulate the strategy and strengthen government investment agencies both for the component of direct investments in companies, to be preferred for strategic sectors, and for the indirect component in other private investment funds. All this also requires a rethinking of public financing, promoting policies for the long-term sustainability of local innovation and the creation of a self-sufficient technological ecosystem. Technological transfer not only requires financing, but also structures and systems for preclinical and clinical experimentation and industrial research and related applications, fundamental for the development of innovations. Here are some of the key points to start this process:
- Government agencies should prioritize direct, strategic, and large investments, while third-party funds supported by the same agencies, through indirect investments, should focus more on Tech Transfer, Proof of Concept, and Series A investments, which are more numerous and complex and justify outsourcing to third parties and recognition of management fees.

- Reach thresholds of government investments in line with the main global ecosystems. For example, in the Boston area in 2023, the average startup investment was \$10 million and the Series A average was \$53 million per company.
- Speed of use of government capital: research is a competition, who arrives first wins; and patients need care.
- Government capital should be patient, with a time horizon aligned with the development times of the sector: for example, 15 years, as in the case of the investment policy of the NATO Innovation Fund.
- Support the growth of companies through the stock market (IPO) to keep companies in Italy (asset protection) and leave leadership to the founders or professional and competent managers. In this context, it could be useful to accelerate the project of the union of the EU capital markets, the only one able to offer sufficient pools of capital for the listing of biotech companies with global ambitions and thus able to compete with international biotech, balancing national interests and those of the EU.
- Provide that VC funds can invest in IBE that are also listed through interventions on the secondary market.
- Support the development and birth of independent third-party funds with the co-investment of government agencies, not only seeking to multiply investments in Italy, but also favoring managers who have demonstrated or aim to develop the national ecosystem, exits through the stock market and control of the founders.
- Attract foreign investment funds both by co-investing through government agencies and by favoring those funds able to bring new resources from abroad.
- Encourage **corporate ventures** to allow the inclusion in the SLEBC of corporate-backed companies, even if they do not qualify as SMEs under EU definitions.

## 7. RESHORING OF PRODUCTION AND ENHANCEMENT OF LOGISTICS

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### A. Reshoring is strategic for:

- **Ensuring supply chains:** bringing the production of specific APIs (active pharmaceutical ingredients) back to Italy from countries like India and China.
- **Quality and reliability:** improving product integrity and reducing risks by controlling the quality of critical components, leveraging the renowned excellence of “Made in Italy.”

### B. Strategic importance of pharmaceutical logistics:

- **Feasibility of biotechnological production depends on logistics:** seamless logistics are essential for timely delivery and maintaining the efficacy of biotechnological products.
- **Product quality:** the promise of “Made in Italy” requires sophisticated logistics to ensure adherence to product conditions and standards (from production to delivery).

### C. How to enhance logistics:

- Expand **Special Economic Zones (SEZ)**: create more privileged economic zones for the biotech and pharmaceutical sectors, with fast approvals and one-stop-shop services for all regulatory and setup needs.

### D. Importance of local supply chains in the context of industrial biotechnology:

- Local supply chains are essential for the availability of feedstock and local biomass storage.

## 8. ATTRACTION OF TALENT

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The Working Group supports current regulations to attract and retain talent, including researchers and professionals in the scientific and academic fields, entrepreneurs, and international experts in the managerial field.

It is necessary to adopt targeted strategies to avoid the loss of strategic assets (“company flight”), but it is equally important to remember that innovations generated abroad by Italian talents - whether it be scientific publications, products or services - enter the sphere of interest of the countries in which they are developed. As a result, Italy will have to reacquire these innovations, supporting not only the increased cost of foreign production, but also the price of the lost intellectual capital. This capital, remaining outside national borders, will continue to generate innovation and form new generations of researchers in another country.

Italy can and should reverse the so-called “brain drain” and transform it into a competitive advantage, by incentivizing the return of those who have acquired specific skills abroad.

The Working Group suggests, as a non-exhaustive list:

- creating a “brain mapping” of Italians abroad shared among universities and research institutions, also using reports from a virtual network of biotech industry professionals to initiate targeted actions to encourage return to Italy;
- launching a campaign to promote “Working in Italy” and the Italian Biotech ecosystem, following the example of the French “Key indicators of French economic attractiveness”<sup>9</sup>;
- investing in the creation of advanced research infrastructure, such as world-class laboratories and campuses, capable of attracting the best talent;
- simplifying research grants: streamlining bureaucratic procedures for accessing research funds, making Italy more competitive compared to other countries;
- providing targeted tax incentives for highly qualified researchers and professionals and for technology entrepreneurs willing to bring or establish their businesses in Italy. Both employees and self-employed workers who have spent at least 3 years abroad will have access, for a maximum of 5 years, to a tax incentive regime with a 50% reduction in taxes up to 600 thousand euros in income. Currently, this incentive allows for an extension up to 10 years and no income limit;
- encouraging priority access to R&D poles: for IBE and to support international

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<sup>9</sup> <https://en.media.businessfrance.fr/news/key-indicators-of-french-economic-attractiveness-a8fe3-aba4d.html>

development, a facilitated access to the structures of the Italian ecosystem will be proposed (e.g. Human Technopole, Italian Institute of Technology, network of IRCCS, etc.).

- supporting participation in the Talent Booster Mechanism EU<sup>10</sup> program “This initiative aims to support regions in training, retaining, and attracting people with the necessary skills and competences to mitigate the impact of demographic transition. The Talent Booster Mechanism is part of the broader efforts of the European Year of Skills and emphasizes tailor-made solutions for various regions, utilizing existing EU funds and initiatives.”

## 9. USE OF DATA: HEALTH AND ENVIRONMENTAL

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The Working Group supports all actions that may allow for greater use of health data (including properly anonymized public data) and the reform of current legislation so that data can be used to improve treatment of diseases of national interest (See Appendix VII, Human Technopole). Furthermore, it is considered necessary to carry out a complete mapping of marginal areas and available biomass. It is suggested to strengthen the sharing of clinical and industrial data through the creation of dedicated national networks to accelerate diagnoses and treatments on one hand, and the analysis of environmental issues on the other.

## 10. PROTECTION OF INTELLECTUAL PROPERTY

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The Working Group supports the importance of protecting intellectual property through specific political actions, to counteract the low propensity to protect intellectual property in Italy compared to other countries, primarily the United States and Germany, as also emerged from recent studies<sup>11</sup>. The table also supports the need to clarify the application of legislation on intellectual property rights on TEA<sup>12</sup> plants and the development of specific studies to assess the impact of all possible intellectual property scenarios on the European and international market of the agri-food sector, considering the impact on the seed world, on agricultural products and on the food system.

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<sup>10</sup> [https://ec.europa.eu/regional\\_policy/policy/communities-and-networks/harnessing-talent-platform/talent-booster-mechanism\\_en](https://ec.europa.eu/regional_policy/policy/communities-and-networks/harnessing-talent-platform/talent-booster-mechanism_en)

<sup>11</sup> <https://www.euipo.europa.eu/en/publications/2023-startup-finance>

<sup>12</sup> <https://www.crea.gov.it/-/le-tea-le-nuove-tecniche-genomiche-per-l-agricoltura-italiana-servono-davvero->



## **11. REGULATORY SUPPORT**

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Dedicated regulatory support for ESIBE (Innovative Biotech Startups and SMEs) on aspects related to the pharmaceutical development of innovative biotechnological products. Compliance with regulatory requirements from the early stages of development of a pharmaceutical product is a relevant aspect for the valorization of research and its translation into clinical use products. Regulatory agencies must be considered an integral part of the innovation ecosystem, as in the case of AIFA (Italian Medicines Agency).

## ANNEX I



Ministero degli Affari Esteri  
e della Cooperazione Internazionale

### WORKING GROUP FOR THE INTERNATIONALIZATION OF INDUSTRIES IN THE BIOTECHNOLOGY SECTOR

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#### Members

- Coordinators: **Min. Plen. Mauro Battocchi**, General Director for the Promotion of the Country System & **Council. Amb. Massimo Carnelos**, Head of the Technological Innovation and Startup Office, Italian Ministry of Foreign Affairs and International Cooperation.
- Moderator: **Pierluigi Paracchi**, CEO, Co-Founder and Chairman Genenta Science; Member of the Federchimica Assobiotec Executive Committee, the National Association of biotech companies.
- **Sergio Abrignani**, Professor of Immunology and Immunopathology University of Milan and Scientific Director of the National Institute of Molecular Genetics (INGM) of Milan.
- **Giovanni Caforio**, Former Executive Chairman Bristol Myers Squibb.
- **Fabio Fava**, Professor of Industrial and Environmental Biotechnology University of Bologna, National Delegate for the Bioeconomy at the DG RTD of the European Commission and Coordinator of the National Bioeconomy Coordination Group (CNBBSV) of the Presidency of the Council of Ministers (representative of the Ministry of University and Research).
- **Maurizio Forte**, Central Director for Export Sectors, ICE Agency
- **Giuseppe Gigli**, Director Institute of Nanotechnology CNR-Nanotec.
- **Anna Lambiase**, Chairwoman CDP Venture Capital SGR and CEO IR TOP Consulting.
- **Pierluigi Petrone**, Vice-Chairman Farmaindustria and CEO Petrone Group.
- **Maria Cristina Porta**, General Director Fondazione Enea Tech and Biomedical.
- **Rino Rappuoli**, Scientific Director Fondazione Biotechnopolo of Siena.
- **Gianmario Verona**, Chairman Human Technopole.
- **Teresa Rinaldi**, Professor Biology and Biotechnology at La Sapienza University, Rome.

#### Institutional observers:

- **Claudia Biffoli**, “**Biotech and Pharmaceutical**”, new enabling technologies, Department for Digital, Connectivity and new Technologies - Ministry of Business and Made in Italy.
- **Gabriele Altana**, Diplomatic Advisor to the Ministry of Health.

## **ANNEX II - A - B**

- A. *“Building the future with nature: boosting biotechnology and biomanufacturing in the EU”*. Brussels, 20.3.2024 ([https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT\\_24\\_1610](https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_24_1610))
- B. Press Release: *Commission takes action to boost biotechnology and biomanufacturing in the EU* ([https://ec.europa.eu/commission/presscorner/detail/en/ip\\_24\\_1570](https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1570))
- C. **Executive Summary** annex II-A: *Building the future with nature: boosting biotechnology and biomanufacturing in the EU*
- **Simplified Regulatory Framework and Faster Market Access:** initiate a study to analyze how biotechnology legislation can be further simplified. This study could lay the groundwork for a possible European Biotechnology Law.
  - **Encourage More Investments:** launch a study to identify barriers and ways to support funding consolidation by mid-2025. Promote the inclusion of biotechnology and biomanufacturing in the 2025 work program of the European Innovation Council (EIC) Accelerator.
  - **Better Support for Scale-Ups and Easier Navigation of Regulations:** establish an EU biotech hub to help companies navigate the regulatory framework and identify support for expansion by the end of 2024.
  - **Foster a Broader Market for Biotechnology and Biomanufacturing:** deepen cooperation with international partners, such as the United States, on biotechnology research within the scope of scientific and technological agreements by the end of 2024.
  - **Review the EU Bioeconomy Strategy by the End of 2025:** taking into account current social, demographic, and environmental challenges; strengthen the industrial dimension of the bio-economy and its links with biotechnology and biomanufacturing to contribute to a stronger EU economy.
  - **Accelerate the Adoption of AI in Biotechnology Together with Stakeholders:** support structured exchanges with biotech and biomanufacturing companies and industry within the GenAI4EU initiative. Raise awareness among AI startups and the scientific and innovation community about facilitated access to EuroHPC supercomputers. Support the development of advanced generative AI models for healthcare, leveraging existing data, tools, and EuroHPC supercomputing capabilities.
  - **Enable Fair Comparison with Fossil-Based Products:** further develop methodologies to ensure a fair comparison between fossil-based and bio-based products in 2025, including reviewing the environmental footprint of

products.

### **ANNEX III - A - B**

- A. A: Bold Goals for U.S. Biotechnology and Biomanufacturing: Harnessing Research and Development to Further Societal Goals (<https://www.whitehouse.gov/wp-content/uploads/2023/03/Bold-Goals-for-U.S.-Biotechnology-and-Biomanufacturing-Harnessing-Research-and-Development-To-Further-Societal-Goals-FINAL.pdf>)
- B. B: Report U.S. National Security Commission on Emerging Biotechnology (<https://www.biotech.senate.gov/>)

#### **Executive Summary Annex III A “Bold Goals for U.S. Biotechnology and Biomanufacturing: Harnessing**

#### **Research and Development to Further Societal Goals”**

The document provides insight into how advancements in biotechnology and biomanufacturing can be used to build greater resilience in the United States’ supply chains. Recent global production disruptions, geopolitical conflicts, and climate events have highlighted the vulnerability of critical supply chains for U.S. industrial production. New biotechnologies and biomanufacturing processes offer the potential to mitigate the risks and impacts of supply chain disruptions, creating opportunities to diversify production pathways and alleviate bottlenecks.

**Executive Summary Attached III B:** after its first year of work, the U.S. National Security Commission on Emerging Biotechnology has publicly shared its first report, attached here, which will culminate in a comprehensive report to be presented to Congress in December 2024. Biotechnologies have the potential to strengthen and support economic development in every sector and country. A thriving biotechnology industry will enhance the national security of the United States, strengthen and diversify the U.S. economy, and support a growing workforce. The Commission’s recommendations, once implemented, will ensure that the United States continues to lead the world in the development and implementation of biotechnology.

## ANNEX IV

### MAPPING ECOSYSTEMS: EMERGING BIOTECHNOLOGIES AND LIFE SCIENCES

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#### COMPILED WITH INFORMATION PROVIDED BY THE MINISTRY OF FOREIGN AFFAIRS AND INTERNATIONAL COOPERATION AND THE ICE AGENCY.

**GERMANY.** The landscape of the German biotech sector in 2022 includes 750 companies, with a total of 47,000 employees, generating revenues of 25 billion euros, of which 3.7 billion are invested in research and development. Since 2019, the sector's revenue has grown, from 7 billion in 2020 to 26 billion in 2021, before settling at 25 billion in 2022. The sector's financial size is mainly due to the success of BioNTech, a German biotechnology and biopharmaceutical company active in the research, development, and commercialization of drugs, which achieved revenues of 19 billion and 17.4 billion in 2021-2022 respectively—a success that seems to show the characteristics of a bubble. Currently, production levels in the sector are experiencing a downturn; for 2023, the forecast is around 11 billion in revenue, reflecting a decline in optimism among the major players in the sector. The main reasons for this decline include the war, the energy crisis, inflation, the shortage of qualified labor, and the lack of financing opportunities.

**FRANCE.** France ranks third in Europe, after the United Kingdom and Germany, in the number of biotech companies, employing a total of 5,500 individuals, more than half of whom are engaged in research and development. The COVID-19 pandemic gave a boost to the sector as biotech companies and venture capital firms were heavily capitalized. However, the French industry was unable to position itself among the leading vaccine developers; thus, the French Government led by Emmanuel Macron launched the Healthcare Innovation Plan 2030 in 2022, aiming to transform France into the leader of the European health innovation sector by 2030. Strategies implemented by the government include the creation of biotech innovation hotspots, streamlining the organization of clinical trials, and simplifying the market access system for new treatments. France is home to leading research institutes in the life sciences sector, including the Institute Curie and CNRS, as well as emerging companies supported by major venture capital firms such as Sofinnova Partners, Jeito Capital, and Kurma Partners. France currently has the potential to become the leading attraction hub for EU talent in the sector in the future, due to its greater critical mass compared to most European countries.

**SPAIN.** In 2022, biotech companies in Spain generated about 1.1 billion euros, accounting for about 1% of the country's GDP, an increase of about 8% from the previous year. R&D investment in the sector amounted to 1,063 million in 2021, making it the fifth largest sector for R&D investments in Spain, after services, pharmaceuticals, automotive, and education sectors. About 10% of this comes from public funding,

and 11% from abroad. More than 64% comes from own funds, 13% from investment funds, and about 1% from non-profit private organizations. As for the education and research segment in the biotech sector, in about 21 of the 24 public universities where it is offered, biotechnology is one of the ten disciplines with the highest average admission scores for enrolled students, who are thus remarkably well-prepared. Biotechnology is also within the scope of the Spanish Recovery, Transformation, and Resilience Plan (PERTE), with at least three of the twelve lines of investment connected to biotech sectors (health, agri-food, circular economy), thus opening new public and private funding opportunities, with considerable room for further growth. In conclusion, Spain is emerging as a country active in the biotechnology sector, capable of attracting investments and young talent, supported by institutions and a solid research base.

**QATAR.** In Qatar, the biotech sector is considered an emerging sector, in which the government has shown signs of interest. Examples include the Qatar Science and Technology Park, a special economic zone dedicated to the sector, the Sidra Medicine Hospital and Research Institute, and the Qatar Biomedical Research Institute, a national center of excellence for biomedical research.

Noteworthy is also the financial commitment to the sector. Since 2020, the Qatar Investment Authority (QIA) has been involved in significant sector funding, financing various biotech industries worldwide, such as in the United States and Germany. In addition, QIA has also initiated partnerships and collaborations within the biotech industry, concluding agreements with academic institutions, national research centers, and companies in the sector, both in Qatar and around the world. Also worth mentioning is the inauguration of EXPO Doha 2023 “Green Desert Better Environment,” which will address, among other things, the issues of environmental sustainability and innovation applied to agriculture, paving the way for further exploration of the biotech sector.

**CHILE.** In Chile, the biotechnology and life sciences sector is experiencing significant growth. Since the 1980s, the country has made scientific and technological efforts to support the expansion of key sectors of the economy, such as fruit growing and forestry, in addition to applications in livestock and medicine. In 2003, the country defined a National Policy for Biotechnology Development, outlining four main objectives: business development; development of scientific-technological capabilities and human resources training; creation of a regulatory framework for the sector; institutional coordination of regulatory institutions and ensuring citizen participation and information. According to the latest available data, 93% of entities/companies active in the biotech sector are also engaged in R&D activities, mainly in the field of human health. Examples include the development of a vaccine against the Respiratory Syncytial Virus (RSV), one of the main causes of bronchiolitis and pneumonia in children under two years of age; the aquaculture sector, particularly



the study of cellular and molecular mechanisms of fish stress response, resulting from climate change, which is relevant to the productivity of fish industry companies.

**POLAND.** The biotechnology sector in Poland began to develop between 2005 and 2010. The strengths of the sector are its qualified personnel and good scientific facilities. About 200 companies are active in the sector, more than half of which are micro and small enterprises. The Polish market is the largest in Central and Eastern Europe, and although the value of investment and research spending is still far from the benchmarks of the continent's leading countries, it is constantly increasing, now reaching about 1.4 billion PLN per year (approximately 320 million euros at the current exchange rate). Companies that have been active for more than three years are concentrated in six biotech clusters: Krakow, Łódź, Poznań, Warsaw, Wrocław, and the Tricity area (Gdynia, Gdańsk, and Sopot). About twenty companies are listed in this sector, mainly related to the pharmaceutical, diagnostic, and laboratory industries. The report of the Polish National Statistical Institute (ISNP) on the state of biotechnology in the country in 2022 provides a representation of the sector's structure: experimental research and development activities; company sizes; expenditures; personnel. Among the critical issues are the funding of activities, the frequent migration abroad of many promising companies; the demand for increasingly specialized personnel; and the alignment between academic research and commercial needs.

In 2022, the previous government launched the "Government Plan for the Development of the Biomedical Sector 2022-2031," aimed at promoting a favorable ecosystem, universities, start-ups, and funding to support innovative projects.

**MALAYSIA:** Biotechnology and life (and health) sciences are key sectors for the growth of Malaysia's manufacturing industry, which totaled nearly €17 billion in 2022, encompassing total approved investments and 801 new projects. Of this amount, 78.3% came from foreign investments (€13.2 billion), while the remaining 21.7% was from domestic investments (€3.66 billion). In line with the New Investment Policy (NIP), the Malaysian government's objective is to achieve sustainable economic growth in this sector, creating high-value and highly skilled job opportunities, thus optimizing all national policies regarding investments, and promoting high-quality investments for equitable growth. Pharmaceutical Sector: Malaysia's pharmaceutical industry is a key sector (in 2019, it generated revenues exceeding \$1 billion) and includes over 100 companies categorized into three groups: generic drug manufacturers, research-based pharmaceutical companies, and over-the-counter (OTC) producers. In 2021, approximately €84 million was invested in the pharmaceutical sector. Malaysian pharmaceutical products include new pharmaceuticals, biological products, generic drugs (both prescription and over-the-counter), health and nutritional supplements, traditional and complementary medicines (TCM), and veterinary products. Local pharmaceutical companies can produce most dosage forms, including sterile preparations, injections, and soft gelatin capsules. Many Malaysian manufacturers

also conduct contract manufacturing for multinational companies. The government has identified seven potential growth areas in the pharmaceutical sector: new pharmaceuticals, biologics (vaccines, hormones, monoclonal antibodies), generics (both prescription and OTC), health supplements (vitamins, enzymes, probiotics), traditional and complementary medicine (nutraceuticals, herbal supplements), veterinary products (vaccines, hormones, vitamins), and services (clinical trials, R&D services). Bioeconomy: in 2021, total investments in the bioeconomy sector in Malaysia amounted to €2.2 million, highlighting growth potential in bio-agricultural, biomedical, and bio-industrial sectors. Malaysia's rich biodiversity provides a solid foundation for growth in this sector, especially in R&D projects for breakthroughs in agricultural productivity, healthcare innovations, and the adoption of sustainable industrial processes.

**HONG KONG.** Hong Kong has the highest life expectancy in the world, thanks to its advanced healthcare services. Industry studies predict that, similar to many developed economies, the number of elderly people aged 65 and above will increase from 20% of the total population in 2021 to 32% in 2041. An aging population and increased health awareness among the public are driving the demand for healthcare services and products. According to the Food and Health Bureau, total public and private healthcare spending in Hong Kong was approximately HK\$243.2 billion (US\$31.2 billion) in 2020-2022, representing 8.5% of GDP. Hong Kong's medical and healthcare equipment sector primarily targets the domestic consumer market. Hong Kong's total exports of medical and healthcare equipment decreased by 14.9% in 2022; however, the decline narrowed to 2.2% in 2023. Technology plays a crucial role in the healthcare industry. Innovations such as smart hospitals and telemedicine provide sustainable solutions to the challenges posed by the growing demand for services. The HKSAR government is creating an InnoLife Healthtech Hub in the Hong Kong-Shenzhen Innovation and Technology Park (HSITP) to better leverage Hong Kong's strengths in life and health sciences. In the 2023 Policy Address, the government introduced a new \$10 billion industrialization acceleration scheme to promote downstream development of new industrialization and provide financial assistance to companies in the life and health technology fields. Hong Kong is a popular destination for biotech IPOs. According to Hong Kong Exchanges and Clearing Limited (HKEX), Hong Kong was the largest IPO center in the Asia-Pacific region for biotech companies and the second-largest in the world, after the United States. The development of the Greater Bay Area (GBA) Guangdong-Hong Kong-Macao presents numerous opportunities for Hong Kong's healthcare companies. Designated healthcare institutions operating in the GBA are authorized to use drugs and medical devices registered in Hong Kong in public hospitals, subject to approval by Guangdong Province. By January 2024, 28 drugs and 28 medical devices had been authorized for use in 19 designated healthcare institutions through this measure. To promote medical cooperation between Hong Kong, mainland China, and abroad,

following the Chief Executive's proposal to improve the drug registration system in the 2022 Policy Address, the Pharmacy and Poisons Board of Hong Kong added the regulatory authorities of four countries (mainland China, Brazil, South Korea, and Singapore) to the list of specified reference locations under secondary evaluation as of November 1, 2022, to allow for the registration and use in Hong Kong of drugs registered in mainland China and other relevant locations. Following the 2023 Policy Address, a new "1+" mechanism was established to accelerate the approval of new drugs and promote the development of clinical trials and drug R&D in Hong Kong.

**USA.** North America remains the global leader in the biotechnology sector, with a market share of 41.6% out of a global market value that was approximately \$1.37 trillion in 2022, and which is expected to grow at a compound annual growth rate of 13.9%, reaching \$3.879 trillion by 2030.

**California.** In California, about 23% of biotech facilities are located, thanks to its large population, availability of skilled labor, above-average income levels, and the presence of major research universities (Stanford, University of California Berkeley, UC San Francisco, UC Davis, etc.) with active interests in biotechnology. Stanford is one of the leading holders of biotech patents. California's biotech companies generate more revenue than any other state. Two globally significant biotech clusters operate in California: one in San Diego and the other in the Bay Area. These two regions are among the most attractive for venture capital investments. California provides significant funding for biotech research, through established companies and existing infrastructure within the state.

Silicon Valley and Bay Area. the biotech sector in Silicon Valley continues to grow significantly. Numerous groundbreaking discoveries in life sciences originated in the Silicon Valley and San Francisco Bay Area, including Genentech's pioneering work in recombinant DNA technology and the involvement of Stanford University and the University of California (UC) Berkeley in the Human Genome Project and the development of checkpoint inhibitors. Recently, Bay Area innovators are integrating artificial intelligence into drug discovery and development. The Bay Area represents a thriving ecosystem where talent, academic research, and entrepreneurial spirit converge, including within the universities themselves. Universities, research institutes, and various industrial sectors create a pool of dynamic and synergistic talent spanning disciplines like biology, medical engineering, and data science. San Francisco also hosts the J.P. Morgan Healthcare Conference (the most important investor conference in the sector, in which Italy participates annually with a delegation and a side-event organized by the Consulate General, ICE Office of Los Angeles, and, most recently, INNOVIT) and the Biotech Showcase. These two events bring together leaders and innovative companies from around the world to create connections, partnerships, and investments. Researchers, venture firms, and companies have fostered innovative startups, including giants like Genentech/Roche, Chiron/Novartis, ALZA/J&J, DNAX/Merck, Syntex/Roche, Gilead, and BioMarin. Notably,

there are also Italian biotech companies present, including Tr1X Inc., founded in 2022 by Maria Grazia Roncarolo to treat autoimmune and inflammatory diseases; Solaris Biotech, founded by Raffaello Porro, specializing in fermenters, bioreactors, and filtration systems for R&D and production purposes; Dorian Therapeutics, a leading company founded by Maddalena Adorno based in San Carlos, California, working on senoblockers, a new class of drugs capable of rejuvenating cells and tissues.

**New York.** The city, the second-largest tech ecosystem in the world after Silicon Valley, is now a true innovation hub with thousands of startups in fields like AI, clean technology, biotechnology, and life sciences, along with numerous coworking spaces, accelerators, and incubators. The sector's development has been encouraged by various initiatives from the city government and universities, aimed at attracting, developing, and enhancing the city's tech sector in a comprehensive manner. The New York metropolitan area is also the country's primary life sciences hub, with nearly 150,000 jobs and 5,100 companies operating in the sector, which last year alone generated salaries exceeding \$23 billion. Finally, regarding Italian biotech companies already operating in New York, it's worth mentioning Genenta Science, a young company in the sector that has established itself in the dynamic environment of the Big Apple. Founded in 2015 as a spin-off of San Raffaele, Genenta Science—since its launch, has raised over €30 million from Italian and foreign investors—was the first all-Italian company in the sector to be listed on the NASDAQ in New York (2021). The company is developing therapies against solid cancers based on hematopoietic stem cells.

**Texas.** With over 5,400 research and life sciences companies and more than 106,000 workers in related sectors, Texas is one of the leading states in the life sciences industry. Fortune 500 companies like Kimberly-Clark, Celanese, and McKesson have their headquarters in Texas, while global industry leaders such as Galderma, Novartis, Abbott, Allergan, Lonza, Johnson & Johnson, and Medtronic, among others, have significant operations in the state. A highly skilled workforce, top-tier research institutions, and a business-friendly climate consolidate Texas's status as a global leader in the life sciences industry, particularly in biotechnology innovation and cancer research, thanks to its impressive size, workforce, and institutional strength. The state is home to over 5,200 manufacturing and R&D companies related to biotechnology and life sciences.

**Arkansas.** Positioned in the heart of America, Arkansas is a promising location for new or expanding biotechnology companies. Arkansas boasts a long history of entrepreneurial energy now being applied to the biosciences. Arkansas is committed to organically building its bioscience industry by supporting growing research clusters throughout the state. The University of Arkansas for Medical Sciences (UAMS) is the state's largest institution for basic and applied research, with over \$10 million in annual funding for research, grants, and contracts. UAMS BioVentures

provides incubation space, including an FDA-certified “ultra-clean lab” necessary for human testing activities. Two examples of promising biotech companies associated with BioVentures are HealthSpan Solutions, a leader in food safety products and technologies for food manufacturers and processors, and Safe Foods, which specializes in nutritional products designed to combat common diseases in people over 50.

**Louisiana.** The Greater New Orleans region is not only a major provider and employer in the healthcare sector but is also a thriving center for bioscience research. Louisiana is working to develop its biotechnology and life sciences sectors. The state has numerous initiatives and resources aimed at fostering the growth of these industries. Some of the key players in the biotechnology and life sciences ecosystem are: AlfaSigma, ExxoSim, Baton Rouge Health District, Bayou Biolabs, BioInfoExperts, Center for Molecular Imaging and Therapy, and Dr. Reddy’s Laboratories.

**Oklahoma.** Discoveries made by researchers in Oklahoma City have helped make the city a competitor in the biosciences and technology market. Oklahoma City’s bioscience companies boast annual sales of over \$6.7 billion and support 51,000 workers with total wages of \$2.2 billion. There is no doubt that one of the most significant factors in the explosion of biotechnology in this area is the powerful symbiotic relationship between entrepreneurs, clinical researchers, academic scholars, and public and private investors. In recent years, significant medical advances and life-saving drugs have been developed in Oklahoma City’s laboratories and facilities. Recently, a diverse group of community partners collaborated to win a \$35 million grant through the Build Back Better Regional Challenge to boost the emerging biotechnology sector in the region. The grant will fund six key investment projects and the development of ten translational research laboratories dedicated to drug discovery within the OU Health Stephenson Cancer Center.

**Chicago.** Although currently Chicago, the third-largest city in the U.S., cannot be defined as the third biotech and life sciences hub in the USA, the current growth trend shows a very interesting reality rapidly emerging in the life sciences sector. With a wide availability and high quality of talent, university facilities, and research spaces—note that from 2016 to 2020, the eight major universities in the Chicago area produced over 1,700 PhDs in life sciences (20% of the total)—there is still room for improvement in terms of investment volume and employment in the sector. Among the most interesting aspects of the research ecosystem in Illinois is the CBC (Chicago Biomedical Consortium), a consortium formed by three universities and national centers of excellence: University of Chicago, University of Illinois-Chicago, and Northwestern University. Finally, it’s worth noting that the states of Minnesota and Wisconsin also have significant university research centers and companies (both Italian and U.S. with Italian interests) in the life science and health science sectors. Examples include: Amplifon, Bracco, Diasorin, Medtronic, and 3M.

**Boston.** Boston and the surrounding area are characterized by the presence of a system of universities and research centers that make it a scientific and technological hub of absolute international relevance. In this region, the various scientific sectors engage in not only basic and applied research but also a high-tech industrial system, rich in technology startups and a particularly active group of investors and venture capitalists. One of Boston's areas of development as a technological hub is biotech and pharma, which can also count on a first-rate hospital system (examples: Mass General Hospital, Brigham Hospital, Children's Hospital). In this context, many Italians are also present, representing academia or research centers; some of them are also active in the startup and investment fund sectors. These include both Italian-trained individuals who have recently moved and second- or third-generation Italians. Examples of investment funds and companies with a strong biopharma focus are: "Riverside Partners," the startups "Alira Health" and "Empatica," "Chiesi Farmaceutica," and "Stevanato," as well as major companies like "Bayer," "Sanofi," and "Thermo Fisher Scientific," where several Italians operate at top management levels.

**North Carolina.** North Carolina is home to 810 life sciences companies that directly employ 75,000 people, plus 2,500 related service providers. The state hosts Research Triangle Park, a research and development sanctuary located between the cities of Raleigh and Durham, which is one of the largest biotech centers in the United States, with numerous renowned companies. The Research Triangle region of North Carolina has been ranked the fourth national hub for biotech activity, behind only Boston, San Francisco, and San Diego. Biogen, Pfizer, and Novartis have facilities here.

**Detroit.** Although there is no definitive ranking of U.S. biotech sectors, some states in the Midwest region have a significant biotech presence. Of particular relevance for the Consulate of Italy in Detroit are Ohio and Indiana, but significant biotech activities also exist in Michigan and Tennessee. While Kentucky is less established in the sector, it is worth noting the focus on the sector in northern Kentucky near the Ohio border.

**Ohio.** In 2021, Ohio's life sciences sector organizations secured \$3.5 billion in funding. Institutional and award-based funding avenues, such as federal grant programs, private foundations, and grant-awarding organizations, have long been valuable funding resources for Ohio's life sciences organizations. In the private investment sector, strong company growth has been driven by angel investors, venture capital, funds from investor exits, and events like public offerings and strategic company acquisitions. Since 2020, after the challenges of the pandemic, Ohio life sciences companies have announced \$2 billion in investments in new facilities and expansions, which are expected to create over 7,350 new jobs.



**Indiana.** Indiana ranks third nationally (preceded by California and Texas) in biosciences, in terms of the number of companies and export value. Indiana's science sector includes 1,689 companies employing 55,000 workers with salaries exceeding \$90,000 annually. The annual economic impact on the state budget is \$78 billion. Indiana ranks 5th in the number of companies and jobs in the science sector and 2nd in the national concentration of jobs in the biopharmaceutical sector, making it one of the few states with specialized employment concentration in four major economic subsectors: agricultural, chemical, pharmaceutical, and bioscientific, with activities in research, medical device, and equipment design. Key players include the Indiana Biosciences Research Institute (IBRI). The founders of IBRI are Lilly Endowment, the state of Indiana, Eli Lilly and Company Foundation, Roche Diagnostics, Eli Lilly and Company, Indiana University Health, Cook Medical, and Indiana University. Regarding the pharmaceutical multinational Eli Lilly, it is worth highlighting the significant investment announced at their Italian plant (where they have been present since 1959) in Sesto Fiorentino of €750 million for the production of innovative drugs (mainly for diabetes and obesity). This further strengthens its ties with Italy, where it has invested €1.4 billion over the last twenty years, making its Tuscan site one of the most innovative and strategic for the production of biotechnology-based drugs in Italy, with 95% destined for export. According to a study by The European House Ambrosetti, Lilly is estimated to contribute €1.5 billion to Italy's GDP, thanks also to the activation of over 6,000 jobs and a multiplier effect on the current 1,500 employees.

**Michigan.** According to a biennial analysis by the national industry association Bio Industry Organization (BIO) conducted in 2022, Michigan ranks ninth in university-conducted bioscience research and development, valued at \$1.62 billion in 2020, a 5.4% increase from 2018. Venture capital investments in the sector grew to \$362 million in 2021 and totaled \$959.9 million over the four years analyzed. Leading Michigan's biotech industry is MichBio, the trade association committed to promoting the growth of Michigan's bioscience industry and its various sectors, including agri-biotech, food and nutrition, bio-based technologies and renewable chemicals, industrial and environmental biotechnology, and more. In February 2023, the city of Detroit announced that Henry Ford Health, Michigan State University, and Detroit Pistons owner Tom Gores had announced a plan to invest \$2.5 billion in a new joint medical research center and related hospital expansions, focused on biotechnology and life sciences.

**Tennessee.** The largest industries in terms of revenue in Tennessee are wholesale trade of pharmaceuticals, cosmetics, and toiletries, hospitals, and health and medical insurance, which generated \$36.3 billion, \$32.0 billion, and \$24.3 billion respectively in 2023. Tennessee ranks third in the USA for exports of medical equipment and supplies, totaling \$4.2 billion in 2022. Exports in this sector have grown by 54% since 2010. Tennessee's major export partners in this sector include the Netherlands,





