BRIEFING

For the ITRE Committee

European Parliament

European Biotech Act I

Scope, Regulatory Framework, Market Landscape and Competitiveness Context

KEY FINDINGS

Latest available aggregated data show that the EU **biotech sector accounts for EUR 75.1 billion in total economic footprint** in 2022, providing nearly one million jobs.

Health R&D is the second-largest EU sector by corporate R&D investment (EUR 46 billion in 2024), underlining biotech's strategic importance.

The European Biotech Act I, proposed in December 2025, is the first standalone EU legislation regulating health biotechnology as a distinctive sector, covering the full lifecycle from research to market placement.

The **high-risk, capital-intensive nature of biotechnology**, combined with lengthy development cycles and low commercialisation rates, **makes access to funding across all development stages one of the sectors' principal bottlenecks**.

Despite its economic weight, the EU faces a **structural competitiveness gap on commercial clinical trials**.

The financing gap between the EU and US in late-stage biopharma R&D increases the **risk of EU biotech start-ups choosing to IPO abroad**.

National biotech strategies focus on ecosystem building and investment priorities, while the EU Biotech Act aims to tackle regulatory friction.

Geographical concentration in the EU is pronounced: leading biotech clusters are predominantly located in Northern and Western Europe, while CEE countries are emerging.

Market failures are structural barriers to EU biotech competitiveness, while regulatory fragmentation is secondary to the capital gap.

Background and Objectives

In the March 2024 Communication 'Building the future with nature'[1], the European Commission (EC) acknowledged the importance of biotechnology and biomanufacturing and their critical role in the EU's competitiveness, economic security and sustainability. Following the Life Science Strategy released in July

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2025, EC President Ursula von der Leyen announced in the Political Guidelines a proposal for a new European Biotech Act to address the challenges biotech companies face in scaling-up their technologies and bringing them to market.[2] The Bioeconomy Strategy and the announcement of a Biotechnology Act in the Competitiveness Compass position the EU's expanding bioeconomy market in the spotlight. The EC underlined the importance of biotechnology in a 2040 scenario: "[…]biotechnology, boosted by the Biotech Acts, becomes the engine that makes bio-based solutions affordable, competitive, and deployable at industrial scale".[3] Furthermore, "[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".[4]

On 16 December 2025, the EC proposed a broad package of measures aiming to improve the innovative prowess, competitiveness and resilience of the EU health sector. The proposal for a **European Biotech Act I** forms part of the package, focusing on (i) health; (ii) revised rules for medical devices and; (iii) Safe Hearts Plan. The European Biotech Act I therefore establishes a framework for the health biotechnology sector. The Commission has also announced a second European Biotech Act for 2026, which will address biotechnology beyond health.[5]

The main objectives of the proposed European Biotech Act I and the measures to achieve them are listed in Table 1.

Table 1: Objectives, Pillars and Measures

	OBJECTIVES	PILLARS	MEASURES
1	Improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector, from research to production.	I, II, III	• Recognition of health biotechnology strategic projects • Support of health biotechnology strategic projects and high impact health biotechnology strategic projects • Single points of contact • Priority status • Access principles and strategic mapping • EU health biotechnology support network • European Health Biotechnology Steering Group • Access to funding • Extension of the supplementary protection certificate • Enhancing competitiveness in biosimilars
2	Creating the conditions for the development and timely placing on the EU market, of biotechnology innovations, products and services.	IV, V	• Artificial intelligence and data as biotechnology enablers • Regulatory tools for novel health biotechnology products • Support in determining the regulatory status of novel health biotechnology products • Foresight on emerging health innovation • Regulatory sandboxes

3	Safeguarding high standards for the protection of human health, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity.	VI	• Biodefence and preventing biotechnology misuse
			  ○ EU Biothreat Radar
			  ○ Biodefence capability
			• Prevention of biotechnology misuse

Enabling the three objectives		VII	Amendments to Regulation (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938

Source: Authors' own elaboration.

Definition of biotechnology in the EU economy

Identifying terms and definitions is challenging in modern, innovative fields such as biotechnology. The definition has evolved over several decades, with the Organisation for Economic Co-operation and Development (OECD) frequently updating its key biotechnology indicators to keep pace with the technological progress. The World Health Organization (WHO) does not work with "health biotechnology" as a defined term, but provides a definition of biotechnology in the context of its work on biotherapeutics (cytokines, growth factors, hormones, interferons, monoclonal antibodies, etc.): "Biotechnology describes biological processes that have been manipulated or modified in some way through modern science".[6]

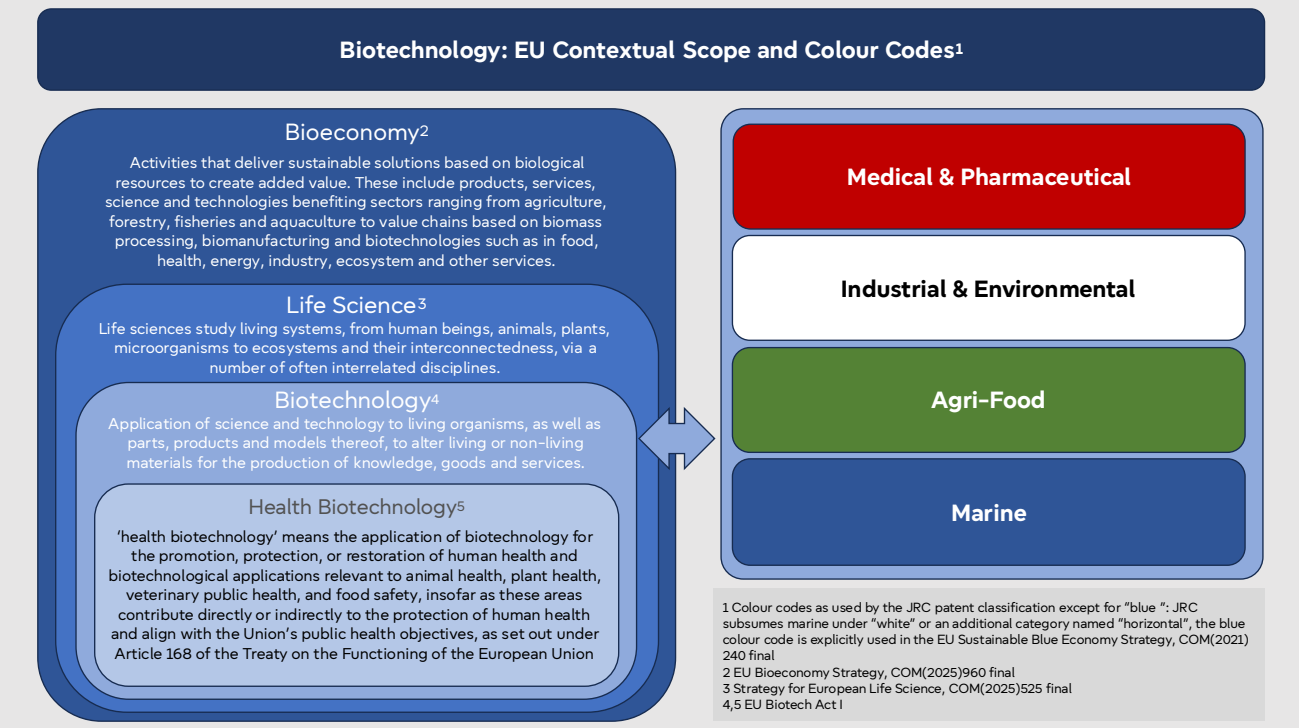
In **the EU Biotech Act I, EC uses the exact OECD wording, defining 'biotechnology'** as '*the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services*.'[7] It encompasses a wide range of advanced technologies aimed at various application areas: industrial and environmental ("white" biotechnology), agri-food ("green" biotechnology), and medical and pharmaceutical ("red" biotechnology). In addition, further colour codes cover emerging technologies, of which marine biotechnology ("blue" biotechnology) is gaining increased attention. In 2025, **a parliamentary resolution drafted under the auspices of the ITRE committee raised concerns on the scope of future legislative proposals** and called EC to ensure that any future legislative initiative has a sufficiently broad scope to capture the breadth of the biotechnology and biomanufacturing industry and its full range of applications.[8]

The proposed European Biotech Act I focuses mainly on the "red" biotechnology. It **defines 'health biotechnology'** as the '*the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union'*. The scope covers the entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities. While "green" biotechnology is covered under the condition that it contributes directly or indirectly to the protection of human health. A second Act announced for 2026 shall cover "white" and "green" biotechnology.

Biotechnology is often conflated with bioeconomy. The EC definition is as follows: '*The bioeconomy covers all sectors and systems that rely on biological resources (animals, plants, micro-organisms and derived biomass, including organic waste), their functions and principles*'. Biotechnology is a subset of bioeconomy where biological resources (biomass) are processed or treated by biological (biotechnology), chemical, or physical means (technologies). The definition and key indicators cover a broad range of technologies including nanobiotechnology, bioinformatics, cell and tissue culture and engineering, biomanufacturing etc.

The bridging element is provided by the EU Life Science Strategy, which lists the EU Biotech Act I as one of eleven flagship actions. It defines life sciences as studying living systems, and biotechnology as applying science to them. Biotechnology is therefore a subset of the life science sector, while the Life Science Strategy does not define it, thus avoiding the risk of conflicting definitions.

Figure 1: Biotechnology: EU Contextual Scope and Colour Codes



Source: Authors' own elaboration.

EU Biotechnology Policy Landscape and Regulatory Framework

The current regulatory framework that recognises and integrates biotechnology at both the EU and national level is very complex. In its resolution 'Future of the EU biotechnology and biomanufacturing sector', the Parliament recommended facilitating fast and efficient uptake of biotechnology and biomanufacturing through clear regulatory frameworks, thereby establishing criteria for a comprehensive Biotech Act.[9][10] The Member States also urged the Commission to unlock the potential of biotechnologies, by reducing fragmentation and simplifying the EU regulatory framework across policy areas.[11]

The European Biotech Act I is the first legislation outlining and regulating the biotechnology sector as a standalone field, despite its many sub-fields (e.g. New Genomic Techniques, synthetic biology, biofoundries, biocomputing, AI, drug discovery, and nanotechnology), which create a complex policy landscape. Numerous legislative acts and strategies at the EU level shape biotechnology's integration into the EU market, with the dedicated bioeconomy and life science strategies – and now the Biotech Act I – as the main drivers.[12]

The EU Biotech Act I is best understood as a sector-specific framework regulation (health biotech) legislation, combining targeted regulatory streamlining with the aim of strengthening the sector's competitiveness and its internal market functioning, to ensure high standards of protection and to prevent misuse.[13]

Specifically, the Biotech Act I sets out to amend the regulations on clinical trials (CTR), advanced therapy medicinal products (ATMPs), standards of quality and safety for substances of human origin intended for human application (SoHO)[14] and Veterinary Medicine Products (VMPs), and the General Food Law. Labelled as 'accompanying' instrument, EC proposed amendments to the directive on the placing on the market of genetically modified micro-organisms and the processing of organs[15]. While this directive is the

biggest drag on the white/green biotechnology, it will not be dealt with in this briefing as it is subject to a separate legislative procedure.[16]

Table 2: Main amendments proposed by the EU Biotech Act I[13]

Regulation to amend	Reasons for proposed amendments	Summary of amendments
Regulation (EC) No 178/2002 on General Food Law	Innovators need broader pre-submission support and more flexible testing environments. EFSA procedures are currently seen as too rigid for some emerging products and study designs.	• Introduces definitions for regulatory sandbox (plan) and participants. • Broadens EFSA's pre-submission advice so it can cover applicable rules, required content, study design and testing strategies. • Amends the Scientific Committee/Panel structure and EFSA chairing arrangements. • Softens some procedural consequences linked to missing study notifications. • Creates a new chapter on **regulatory sandboxes** covering food, feed, food-contact materials and certain non-food/non-feed GMO products, while excluding areas such as **novel foods** where a specific framework already exists.
Regulation (EC) No 1394/2007 on advanced therapy medicinal products (ATMPs)	The ATMP framework is being updated because the existing categories and interfaces with GMO law no longer fit parts of the advanced therapy pipeline, especially investigational products used in trials.	• Adds a definition of **"viral vector".** • Allows the Commission to update definitions of gene therapies, cell therapies, and tissue-engineered products through delegated acts, after consultation with EMA and the SoHO Coordination Board. • Inserts a new **Article 4a** exempting certain low- or negligible-risk GMO-containing ATMP investigational products from submitting an environmental risk assessment; Instead sponsors have to submit a declaration explaining why their product qualifies as low-risk to the Committee for Medicinal Products for Human Use (CHMP). • The same products are also exempted from certain GMO-related manufacturing/import requirements for the duration of the trial.
Regulation (EU) No 536/2014 on Clinical Trials (CTs)[17]	The Commission argues that the current framework remains too cumbersome for multinational trials, combined studies and AI-enabled research, and that legal uncertainty around data protection and emergency procedures reduces the EU's attractiveness for clinical research.	• **Cuts approval times** from 106 to 75 days for multinational clinical trials, including validation and ethical review. • Cuts approval times from 75 to 46 days, when there is no request for information to the sponsor. • Eliminates the additional 50 days for assessment of ATMPs given the growing expertise on these. • Cuts approval times for substantial modifications (SMs) from 96 to 47 days with options for parallel SMs. Cuts approval times for SMs from 64 to 33 days, when there is no request for information to the sponsor. • **Fosters greater collaboration across borders** by strengthening the role of the reporting Member State (RMS). The RMS will be able to lead the assessment. Also, communication between MS and sponsors will be improved via an enhanced EU-portal. • Simplification and regulatory efficiency, without compromising standards, by applying **a single core dossier** and by **introducing a new category of 'minimal-intervention CTs'** for low-intervention CTs. • Harmonization using **mandatory EU harmonized templates** and **a single assessment process** defined for combined studies and a harmonized legal basis for processing personal data. • Accelerated and simplified procedures in cases of **public health crises.** • Increases regulatory efficiency through the **uptake of AI systems and digitalization** via non-binding guidance on the deployment and use of systems based on advanced technologies, including AI systems in the authorization of medicinal products. • Testing of innovative approaches using **regulatory sandboxes.**

Regulation to amend	Reasons for proposed amendments	Summary of amendments
		• Efficiency through a **more risk-proportionate approach towards investigational ATMPs that contain GMOs**, which present a negligible risk to human health and the environment.
Regulation (EU) 2019/6 on Veterinary Medicinal Products (VMPs)[18]	The Commission considers that, for biotech-derived veterinary products, the coexistence of veterinary and GMO regimes can duplicate risk assessment and slow innovation, especially for products relevant to zoonoses.	• Cuts administrative burden for innovations by placing assessment of VMPs containing GMO solely under the ERA. • Also, clarification that administering VMPs does not place treated animals nor their products under the GMO legislation. • To support their development, **an extra year of SPC** for VMPs developed by means of biotechnology processes. • Fostering innovation in veterinary medicine by introducing **regulatory sandboxes for animal health innovation.**
Regulation (EU) 2024/1938 on substances of human origin (SoHO)	The SoHO framework is amended to make room for innovation in products and therapies that sit close to, or across, existing categories and to reduce delays in regulatory-status clarification.	• Introduces regulatory sandbox to create a controlled testing environment within the SoHO framework for new and innovative products. • Introduces a new rule allowing the Commission to adopt implementing acts that set **time limits for replies on regulatory-status consultations**. • The proposal also uses the SoHO framework to support experimentation with innovative or regulatorily difficult products and to feed lessons back into future legislative updates.
Regulation (EU) 2024/795 establishing the Strategic Technologies for Europe Platform (STEP)	The proposal seeks to ensure that strategically important biotech projects can more easily connect to EU funding and platform support.	• Health biotechnology strategic projects deemed to contribute to the STEP objectives *or* safeguard and strengthen their respective value chains, including shortages of labour and skills.

Source: Authors' own elaboration.

Clinical Trials in the EU

A clinical trial is understood as a study performed to investigate the safety or efficacy of a medicine.[19] For medicines intended for human use, these studies are carried out in people who volunteer. A legally binding definition is provided by the Clinical Trials Regulation. Clinical trials are a decisive gateway between investments in R&D and market readiness.

The EU faces a structural challenge on clinical trials. Despite a 38% increase in global clinical trials over the last decade[20], the European Economic Area's (EEA) share of commercial clinical trials (sponsored by a pharmaceutical company) has declined from 22% in 2013 to 12% in 2023, effectively halving the EEA's position in global clinical research. Over the same period, China's share rose from 5% to 18%.[21] This is problematic, since clinical trials constitute a pillar of the European economy, generating EUR 35,7 billion of added value across the Union every year.[22]

At macro-regional level, **the Spanish region Catalonia stands out as a clinical trial hub**. In 2025, Catalonia was home to 5,768 active clinical trials (92% of trials in Spain).[23] Catalonia attracts clinical trials due to a high-performing healthcare system, especially in oncology[24], a dense innovation ecosystem and 80% of startup financing being venture capital, including international capital.[25] Strong public-private integration is exemplified by Biocat[26], a public-private foundation aiming to scale and consolidate the life science sector in Catalonia. France (4,200 clinical trials in 2025) and Germany (3,700 respectively) are also leading European countries in conducting clinical trials.[27]

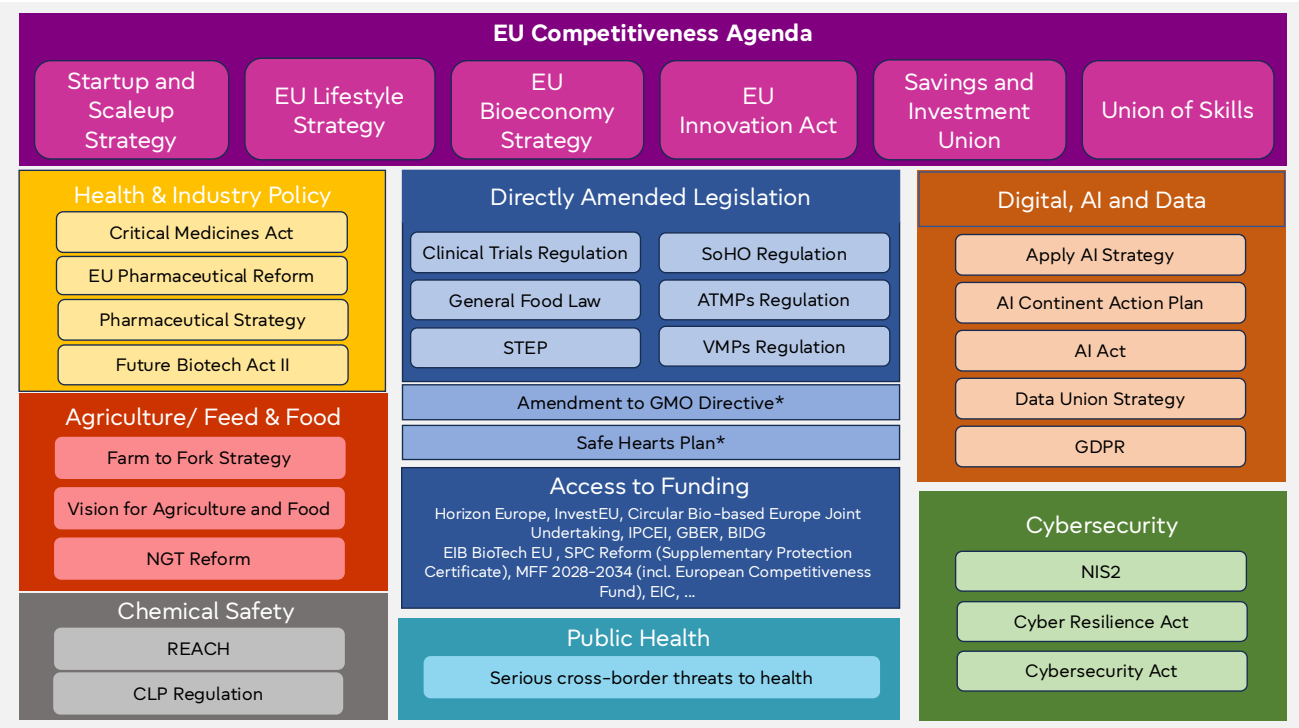
EC argues that complex and time-consuming regulatory barriers explain the decline.[28] The EU Biotech Act I therefore sets out to cut approval times, foster greater collaboration across borders and simplify procedures, among other measures.

Biotech Booster, a Dutch biotech incubator, endorses the EU Biotech Act's focus on cutting approval times, noting that **speed is a decisive factor in clinical trials**: until Europe accelerates, sponsors will favour the US and China. EuropaBio, the industry association for European biotech, points to both EMA and national regulatory agencies having been underfunded and understaffed for years, prolonging approval times, and calls for adequate budget allocation in the MFF or the ECF. In line with the Draghi report, EuropaBio welcomes a streamlining of the procedure for multinational, clinical trials.[29] According to Biotech Booster, there is a need for a pan-European one-stop shop for researchers and companies wanting to carry out clinical trials, though they point to the difficulty of establishing one due to the European fragmentation.

EU (health) biotechnology policy landscape

Further to its inherent complexity, the EU Biotech Act I is embedded in a range of existing laws, policies and strategies.

Figure 2: EU (health) biotechnology policy landscape



Source: Authors' own elaboration.

* Amendment to GMO Directive and Safe Hearts Plan have been published together with (and in the context of) the EU Biotech Act I, but are not subject to this briefing.

The EU Biotech Act I aims to align with the **EU's health and industrial policy framework**. The proposed Critical Medicines Act[30] is designed to improve the availability, supply and manufacturing of critical medicines in the Union[31], while the Pharmaceutical Strategy for Europe and the ongoing reform of the pharmaceutical legislation seek a more future-proof, innovation-friendly and simpler regulatory

framework[32]. In that context, the Biotech Act I focuses on the early stages of developing and testing biotech products. It aims to make it easier to develop and test biotech products, especially through faster clinical research pathways, streamlined ATMP/GMO interfaces and better support for strategic projects. There is also a clear synergy with the EU's broader **competitiveness agenda**. For more details, see below the textbox 'The European Biotech Act I: Competitiveness, Technological Leadership and Strategic Autonomy'. As briefly mentioned in chapter "Background and Objectives", the EC's Life Sciences Strategy explicitly announced the Biotech Act as the **instrument intended to enable more rapid market access for life-science innovation**, and the strategy is itself presented as part of the Competitiveness Compass. The same logic runs through the Startup and Scaleup Strategy, the Savings and Investments Union and the Union of Skills: Together they address financing, firm growth and workforce bottlenecks, including in the biotech sector. The upcoming European Innovation Act, announced for 2026, will focus on improving the functioning of the innovation ecosystem.

The EU Biotech Act I also interacts with the **EU's digital and AI policy stack**. The Apply AI Strategy and the AI Continent Action Plan aim to integrate AI into strategic sectors, including pharmaceutical and biotechnology applications; the Data Union Strategy is intended to increase access to data and simplify data rules; and the AI Act provides the Union's horizontal risk framework for AI systems. The Biotech Act does not create a parallel AI regime; instead, it inserts sector-specific operational rules, for example for AI in clinical trials, into this wider architecture.

Because modern biotech is also digitally intensive, the proposal should be read alongside the EU **cybersecurity framework**. The NIS2 establishes a common cybersecurity framework across critical sectors and requires national cybersecurity strategies and cross-border cooperation[33]; the Cyber Resilience Act sets lifecycle security requirements for products with digital elements[34]; and the Cybersecurity Act provides an EU-wide certification framework. For AI-enabled labs, digital biomanufacturing and connected health-biotech infrastructures, these instruments complement the Biotech Act I and set out security provisions.[35]

On the **public health** side, the connection with the Regulation on serious cross-border threats to health is particularly important. That regulation strengthens the Union framework for prevention, preparedness, surveillance, risk assessment, early warning and response[36]. The Biotech Act I complements it by creating faster pathways for clinical trials in public health emergencies and emerging serious cross-border threats.

The European Biotech Act I: Competitiveness, Technological Leadership and Strategic Autonomy

The European Biotech Act I needs to be seen in the context of the EU's competitiveness agenda. The Act is proposed at **a time of fierce global competition over technological leadership**. The World Economic Forum estimates that the European bioeconomy contributes EUR 614 billion to the economy annually and has the potential to create 1 million new, 'green' jobs by 2030,[37] while synthetic biology alone is projected to account for value creation across nearly USD 30 trillion of global manufacturing output by the end of this decade.[38] The McKinsey Global Institute puts the direct annual global economic impact of the **"Bio Revolution"** (convergence of rapid advances in biological science with breakthroughs in data science, AI and computing, with economic consequences similar to the "digital revolution") at USD 2 to 4 trillion by 2030-2040 (approximately EUR 1.8 to 3.6 trillion).[39] Both the US (2022 National Biotechnology and Biomanufacturing Initiative[40]) and China (14th Five-Year Plan[41]) have designated biotechnology as a strategic priority. The Draghi Report identifies life science and deep technology segments as precisely where the EU's innovation gap with the US is the most severe, and where horizontal capital market instruments alone are insufficient to close it.[42]

The proposal for a European Biotech Act I aims to translate Competitiveness Compass' first strategic imperative: closing the innovation gap. It targets **three structural failures:**

1) the financing gap that drives EU biotech start-ups to IPO abroad,

2) regulatory fragmentation that eroded the EU's position in global clinical research, and

3) the absence of a clear pathway to integrate AI into innovation governance.

Regarding strategic autonomy, the European Biotech Act I aims to **address vulnerabilities that go beyond supply chain resilience**. Europe depends on China and India for between 60% and 80% of its active pharmaceutical ingredients and approximately 40% of finished medicines.[43] The WHO's World Health Statistics[44] and the 2025 Pandemic Agreement[45] underscore that **domestic biomanufacturing and clinical research capacity are pre-conditions for health security**, not merely economic assets – a lesson learned from the COVID-19 pandemic when the EU faced acute shortages despite being home of world-class research institutions.

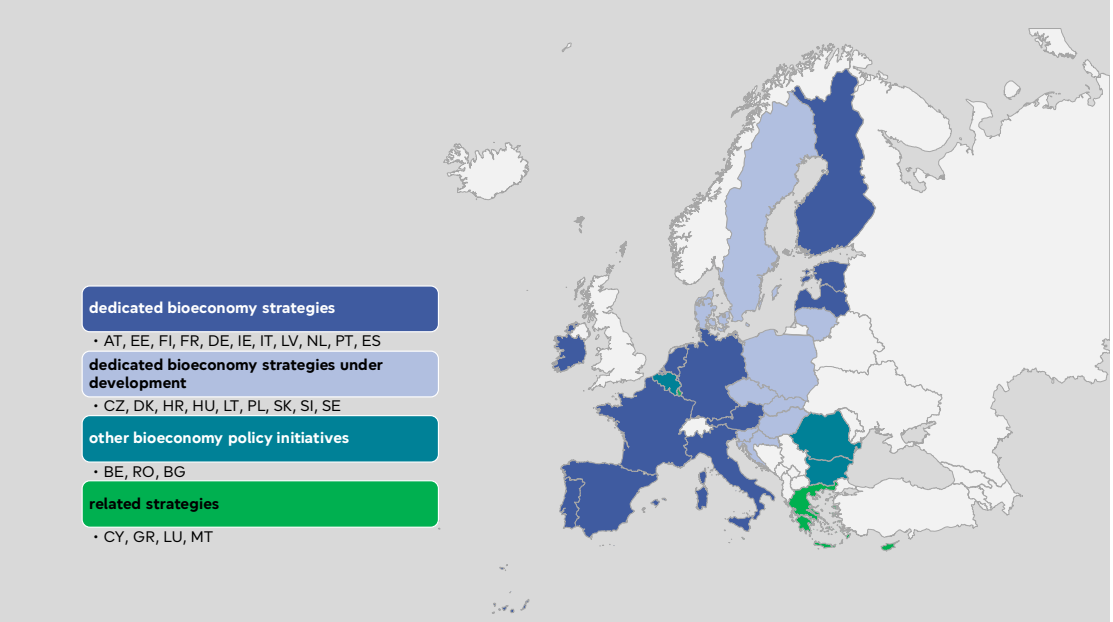
On the **cybersecurity dimension**, data from the European Agency for Cybersecurity (ENISA) show that ransomware accounts for 54% of incidents in the health sector, supply chain attacks on pharmaceutical infrastructure are an accelerating vector, and operational technology threats – directly relevant to AI-enabled biotech labs and digital biomanufacturing – represent 18.2% of all identified threat categories in 2025.[46]

AI in biotech settings introduces a distinct dual risk: by lowering the technical barrier for designing harmful biological agents, it gives the Act's EU Biothreat Radar and biodefence provision a rationale that extends beyond conventional cybersecurity governance and into the prevention of biological misuse.[47]

National biotechnology strategies in Member States

At Member State level, biotechnology is usually embedded in a bioeconomy strategy or related innovation strategies, rather than being organised through stand-alone biotechnology legislation. According to the JRC's September 2025 state-of-play, eleven EU Member States had dedicated national bioeconomy strategies in force; a further nine Member States had dedicated bioeconomy strategies under development; three Member States were among the countries with other bioeconomy policy initiatives; and four Member States were among those with related strategies. With the exception of Estonia in some biomass-processing categories, biotechnology is explicitly covered in the existing national bioeconomy strategies[48].

Figure 3: National EU-27 strategies



Source: Authors' own elaboration.

These national strategies are not identical, but they show a common structure. The JRC identifies **three recurring policy actions** across them: (i) encouraging investment in research, innovation and market development; (ii) supporting circularity, cascading use and resource efficiency; and (iii) promoting awareness and communication. Many also include governance reforms, education and skills measures, public procurement, standards/labelling and monitoring systems. In other words, national strategies are mainly about building ecosystems and industrial transition, not about the detailed authorisation and procedural issues that the Biotech Act I targets at EU level.

National strategies tend to focus more on defining investment and development priorities, research agendas and industrial opportunities. The EU Biotech Act I, by contrast, focuses on EU-level regulatory frictions: clinical-trial authorisation, GMO interfaces for ATMPs and veterinary products, SoHO innovation pathways, and access to STEP recognition for strategic biotech projects. In that sense the Act is intended to complement the Member States' national strategies by enabling them to implement their biotech development plans more efficiently through simplified regulatory procedures.

Access to funding

The high-risk, capital-intensive nature of biotechnology, combined with lengthy development cycles and low commercialisation rates, makes access to funding across all development stages one of the sectors' principal bottlenecks. Compared to the US and China, stakeholders indicate fragmented funding schemes, limited early-stage financing, public R&D under-investment and low EU venture capital share as the main contributing factors. The financing gap between the US and EU in late-stage R&D investment of biopharma start-ups – approximately ninefold – is a key driver behind the majority of EU Biotech start-ups choosing to IPO abroad, predominantly in the US.[49] Since 2016, EU biotech IPOs have raised only EUR 5 billion, roughly one tenth of their US counterparts.[50]

Stakeholder interviews indicate that EU financing strategies are quite risk-averse: grants are scarce and public seed investment is limited compared to the US, while private co-investment requirements are high. The European Investment Bank (EIB) and European Investment Fund (EIF) play a role here, though uptake

among early-stage biotech companies remains limited. Due to the lack of lead investors with enough capital needed in the initial stages of biotechnology development, start-ups rapidly accumulate debt and face dilution in early funding rounds (series B).[51] This is reflected in the EU investment landscape, where some of the largest funds award only a very small number of biotechnology projects. The funding gap is even more substantial in the scale-up stages where the absence of cross-border capital impedes access to financing. The Savings and Investments Union addresses this gap, but the industry emphasises the need for a further push towards an effective model that combines EU, national and private investments in order to strengthen the biotech ecosystem.

The position of biotechnology as a strategic sector in the EU has changed in recent years, as reflected in the evolving approach to its financing. Previously fragmented across several technologies within Pillar II of the **Horizon Europe** 2021-2027 programme, biotechnology has been prioritised in the new Horizon Europe 2028-2034 programme proposal as a strategic sector positioned in the Pillar II - Health, Biotech, Agriculture, and Bioeconomy policy window (under the ECF). The proposed policy window design and budget allocation[52] (currently under negotiation) for this window is EUR 20.4 billion. Alongside Horizon Europe, several EU funds have been announced to target the scale-up phase, the largest bottleneck in this sector: **Scaleup Europe** (EUR 5 billion, biotech/life sciences are one of several eligible sectors), **European Investment Fund** (EUR 15 billion aggregated annual deployment target 2025-2027 for all sectors), and **BiotechEU** – the European Commission and EIB initiative introduced in the EU Biotech Act I as the investment pilot. It aims to mobilise EUR 10 billion in 2026-27 specifically for the biotech and life sciences sector.

Table 3: EU funding for (health) biotechnology

Fund/Programme	Instrument	Amount in EUR Biotech/Life Science	Overall fund volume	Remarks
Horizon Europe – Cluster 'Health'	Grants	6 billion	8.24 billion (2021-2027)	New proposal 2028-2034 currently under negotiation
Innovative Health Initiative (IHI)	PPP (EU grants and industry co-funding)	239 million*	2.4 billion (2021-2027)	1.2 billion EU contribution from Horizon Europe, 1.2 billion from life science industry
EIC Fund (European Innovation Council)	Venture Capital	≈ 4 billion		35 companies from the health biotechnology sector have already received investment from the EIC Fund; Executes through Accelerator and STEP Scale up
EIC Accelerator	Grants, blended or equity only	634 million (414 million 'open' and 220 million 'challenges' No dedicated biotech budget line, but 'health biotech' and 'medical technologies' listed in the portfolio categories		Main EIC instrument for individual start-ups and SMEs
EIC STEP Scale-Up	Equity	300 million (2026)		Biotechnology is one out of three technologies under scope
EIC Scale-Up Europe Fund	Equity	5 billion		Finalizing of the Fund's legal and governance structure ongoing Biotech explicitly under scope

Fund/Programme	Instrument	Amount in EUR Biotech/Life Science	Overall fund volume	Remarks
BioTech EU Scale-Up	Venture debt, lending, blended finance (InvestEU guarantee)	10 billion (2026-2027)	EIB Group's current life sciences venture debt portfolio: 3.5 billion	Targets at biotechnology and life sciences. Announced in December 2025. The amount is a mobilisation target, not a committed budget line.
EIF	Equity, guarantees and technical assistance	EUR 15 billion aggregated annual deployment target 2025-2027 for all sectors		EIF does not directly fund SMEs, but invests in venture capital funds and provides guarantees to banks; generates on average a 5x leverage of public money
InvestEU	Guarantee	26.2 billion (2021-2027)		No direct applications, biotech companies benefit indirectly via banks and funds that use InvestEU
ERC	Grants	16 billion (2021-2027)		Funded from Horizon Europe, part of pillar 1 'Excellent Science' (no sector preference)
CBE JU	2 billion (2021-2031) under Horizon Europe 2026: EUR 170.7 million funding for call for project proposals			Partnership between the European Union and the Bio-based Industries Consortium (BIC), target: shift to circular bio-based production processes
STEP	red existing funds across 11 existing EU programmes to projects in the development and manufacturing stages in STEP sectors			Biotech is one out of 4 STEP sectors

Source: Authors' own elaboration.

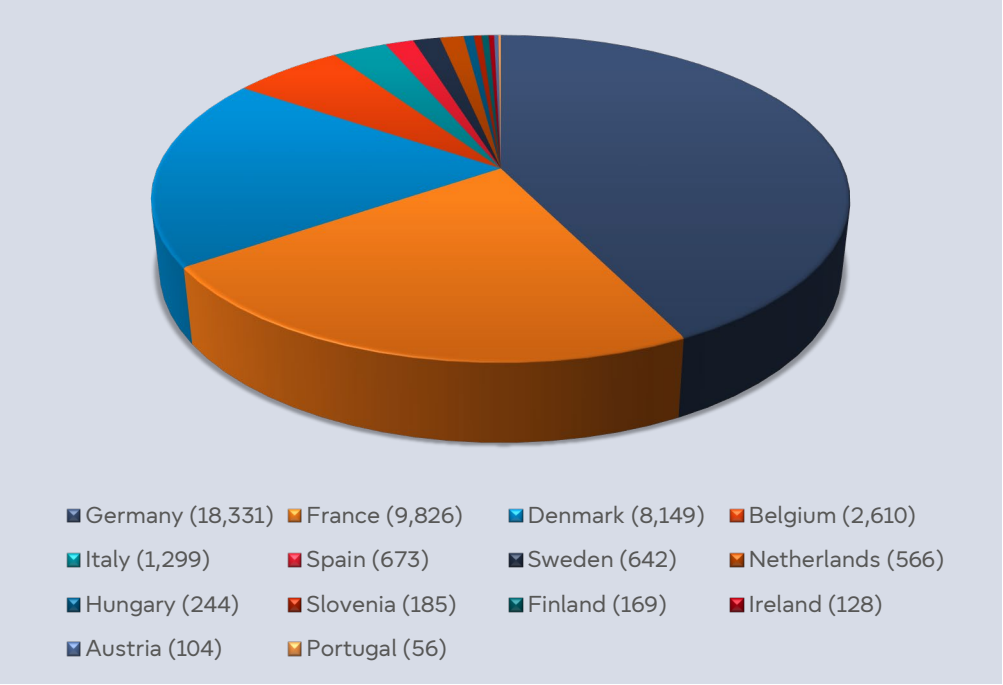
* Total commitment appropriations of EUR 239 million consist of fresh credits (EUR 185 million) and carry overs (EUR 53 million).

Please note: In the absence of aggregated data provided by the institutions, the table lists a variety of committed budgets and fund capitalisation that should not be aggregated; unless stated otherwise, there is no specific data on 'biotechnology' or 'health biotechnology'.

Health biotechnology – R&D

The JRC EU Industrial R&D Investment Scoreboard, the primary source corporate R&D benchmarking, classifies companies under a broader 'health sector', which includes healthcare equipment and services as well as pharmaceuticals and biotechnology. Unless otherwise indicated, figures therefore refer to this broader sector. Disaggregated health biotechnology data from future scoreboards would support a more granular understanding of the sectors' dynamics.

Figure 4: EU Industrial R&D Investment in health (top 800 EU companies) in million EUR



Source: Authors' own considerations based on JRC EU Industrial R&D Investment Scoreboard data.

The **health sector is the second-largest sector in terms of R&D investment among EU companies**, with over €46 billion invested in 2024. EU Health R&D grew by 13% in 2024 (US +7.1%, Japan +9.1%, China +0.1%). EU companies in the pharmaceutical and biotechnology sectors are internationally oriented, allocating around 40% of their R&D investment to the United States (US) and Canada, partly to comply with regulatory requirements for product approval in those markets. Sanofi is the leading European company in health sector R&D, with €7,394 million invested, and ranks 10th among health sector companies globally. In comparison, the global health sector R&D leader Johnson & Johnson (US) invests approximately 2.4 times more in R&D than Sanofi. The top 10 EU pharmaceutical and biotechnology companies are concentrated in just four countries - Germany, France, Denmark, and Belgium - and together account for 76.8% of the sector's total R&D investment in the EU.

The health sector is characterised by a **high number of young, small, and R&D-intensive biotech firms**, mostly based in the United States. Indeed, as of 2024, a vast majority of SMEs among the top 2,000 R&D-investing companies operated in the health sector, most of them in biotechnology.[53]

Europe relies on China and India for up to 80% of active pharmaceutical ingredients and around 40% of finished medicines, a dependence that has weakened its capacity to produce these substances domestically and may pose risks to public health.[54]

Biotechnology Market Landscape in the EU

The economic footprint and spillover effects of the biotech industry are recognised in the Biotech Act I and have been extensively reported on. In 2022, the EU biotech sector generated **38 billion euros in direct gross value added, with a total economic footprint of 75.1 billion euros supporting nearly one million jobs**.[55]

The biotechnology sector is highly concentrated in EU, with large companies and biotech hubs present in a few countries in the EU, mostly in the Northern and Western Europe. The entire industry has been

working in close proximity to draw talent and capital through large and dynamic biotech ecosystems consisting of start-ups, SMEs and universities. Global companies form part of these ecosystems as well, using the well-established infrastructure and knowledge for their R&D development. Historically, the ecosystems have emerged through health biotechnology in the leading Member States, with hubs of start-ups and SMEs emerging over the past 40 years. However, the landscape has been changing over the past 10–15 years, with some countries specialising in specific technologies, usually based on existing industry.

Leading Members States

The largest biotech clusters are in Denmark and Sweden (Medicon Valley), BioValley Basel (France, Germany and Switzerland), Spain (BioRegion Catalonia), France (Ille-de-France), Germany (BioM Munich and Heidelberg–Rhine-Neckar) and Netherlands and Belgium (Leiden BioSciencePark, Biowin Wallonia). While all types of biotechnologies are represented in each hub, some **distinct competences can be observed in specific regions due to the existing industry and established economic base**. Medicon Valley leads in R&D of small molecules and metabolic diseases, Germany in platform technologies and Spain (Catalonia Bioregion) in cell therapy, digital health and clinical trials.

Table 4: Biotechnology in leading Member States

Country	Number of Companies	Dominant Biotech	Specialisation
DE	≈ 1,000	Red White	Platform tech, mRNA, industrial biotech
FR	895	Mixed	Digital health, AI-biotech convergence
ES	1,119	Red	Clinical trials, oncology, ATMPs
IT	5,869* 436 (health)	Green	Agri-food and livestock (65%), healthcare
DK	707	Red	Metabolic diseases, weight-loss
SE	850	Red	CRISPR, pharma manufacturing
NL	>500	Red	Therapeutics, diagnostics, pharma manufacturing

Source: Authors' own elaboration.

* The Italian national association works with a very broad definition of biotechnology, of which agri-culture and livestock is by far the largest share (65%).

Germany

Germany is among the EU's leading biotechnology countries with roughly 1,000 companies in 2024. It invests heavily in R&D, recording **the highest biotech R&D expenditure in the EU** at EUR 4.4 billion, and generating EUR 11 billion in biotech revenue. Germany is also strong on patents, with 2,371 relevant patents in the period of 2022 – 2024.[56]

Biotech companies in Germany raised €1.9 billion in 2024, up 78% from 2023, while venture-capital funding rose from €533 million to €898 million. Funding in the first quarter of 2025 fell to €130 million, down 78% compared to the first quarter of 2024. The number of employees fell by five per cent to 56,093. However,

higher early-stage investment and a growing number of phase 2 and phase 3 assets are signs for improvement[57]. The BIO Deutschland 2025 trend survey shows modest improvement in business sentiment, hiring plans and planned R&D investment after the decline caused by the pandemic[58].

Germany's biotech sector includes major players alongside mid-sized companies such as Evotec, Miltenyi Biotec, Qiagen, Rentschler Biopharma and IDT Biologika. At regional level, Roche, Daiichi Sankyo and Sandoz are located in Bavaria; the Rhine-Neckar region combines BioNTech with AbbVie, Boehringer Ingelheim and Merck and NRW.Global Business includes Bayer, Qiagen, UCB and Evonik[56].

Germany's cluster structure connects universities, research institutes, hospitals, investors and firms, allowing for faster interactions between science and clinical development and making shared infrastructure easier to access for start-ups and SMEs.

In the 'metropol-region' of **Hamburg**, around 80 companies employ approximately 8,200 people in biotechnology research, with a further 70 companies in the pharmaceutical industry. Core competencies cover drug discovery, molecular diagnostics and platform technologies, including nanotechnologies and marine biotechnology.[59]

In **Berlin-Brandenburg**, biotechnology is driven by red biotech and clinical translation of innovations. The cluster consists of 303 biotech companies with approximately 7,200 employees, with almost 80% active in biomedicine. The regional focus is on therapeutic and diagnostic innovation for cancer, cardiovascular disease and diabetes, supported by strong clinical-trial infrastructure and major research institutions such as Charité, BIH and MDC.[60]

The **Bavarian biotechnology cluster** has more than 500 biopharma companies and a strong investor landscape. Recent Bavarian innovation has been driven by gene therapy, radiopharmaceuticals and the integration of AI and big data into drug development, alongside major corporate investment by Roche, Daiichi Sankyo and Sandoz[61]. Hotspots are located in Munich, Regensburg, Würzburg, Straubing and Nuremberg/Erlangen. The **Munich-Martinsried** biotech cluster includes 450 life science companies, as well as several universities, university hospitals, research institutes, and start up centres. It focuses on drug development, therapeutics and diagnostics, personalised medicine and immunotherapy.[62]

The **Rhine-Neckar/Heidelberg cluster** is most clearly translational of the German hubs, combining major biopharma companies with research institutions such as DKFZ and EMBL, and focusing on personalised medicine, molecular diagnostics and cancer therapies. The presence of BioNTech makes this region especially important in advanced therapeutics and mRNA-based innovation [56,63]. Founded in 2023, the Life Science and Biotechnology Hub in **Mainz** already comprises around 25 life science companies, among them BioNTech, the German company that developed the first approved mRNA COVID-19 vaccine. Relevant institutions in the cluster include the Institute of Biotechnology and Drug Research (IBWF), the Translational Oncology Centre TRON and the curATime Cluster for Cardiovascular Medicine, also founded in 2023, which promotes research and translation.[64]

North Rhine-Westphalia is more diversified than the southern hubs and is especially important for industrial biotechnology and the bioeconomy. BIO.NRW presents the region as active across bioeconomy, industrial biotechnology and pharmaceutical biotechnology, with concrete emphasis on bioplastics, biosurfactants, biofuels, biopharmaceuticals and gene therapy.[65] NRW.Global Business adds that the region has more than 500 life-science companies, more than 100 companies focused on biotechnology, 56 universities and universities of applied sciences with biotech relevance, and a large network of technology and start-up centres.[66] In policy terms, NRW is where Germany's health-biotech strength most clearly overlaps with industrial biotech and bioeconomy applications.

France

Biotech is **a young, dynamic sector: one-third of companies are under five years old**, with an average age of 10 years and 29 employees per firm. Over 60 new biotech companies are created each year.[67]

France hosts seven competitiveness clusters focused on the pharmaceutical and biotechnology sector: Lyonbiopôle, Medicen, Alsace BioValley, Atlantic Biotherapies, Cancer Bio Santé, Eurobiomed, and Nutrition Santé Longévité[68]. There is strong growth in the number of digital health companies operating at the intersection of biotechnology, medical devices, and digital technologies. Within this landscape, AI-biotech convergence is emerging, with around twenty French companies clustered around France Biotech, France Deeptech, and Future4Care[69].

According to "The Panorama France HealthTech 2026 report", the health innovation sector (Biotech, Medtech, digital health/AI and TechBio) comprises 2,738 companies in 2025 (895 Biotech companies). All companies are SMEs, half of them micro SMEs (<10 employees).

'France 2030' is a major pillar of state support for biotech innovation in France. It is a EUR 54 billion investment plan aimed at driving economic and environmental transformation through disruptive technologies. The plan allocates 50% of funding to decarbonisation and 50% to innovative emerging players, while avoiding environmentally harmful investments. In the health sector, it has supported a community of over 1,000 funded projects. France 2030 includes ten major objectives, including the production of at least 20 biomedicines, particularly for cancer and chronic diseases, and the development of innovative medical devices. This ambition is embedded in the Health Innovation Plan (Plan Innovation Santé 2030), which led to the creation of the Health Innovation Agency (Agence de l'Innovation en Santé), responsible for coordinating the national health innovation strategy and managing a EUR 7.5 billion budget. France 2030 is implemented by key public agencies, with Bpifrance (Public Investment Bank) as the main operator. BpiFrance has invested over EUR 1 billion in the health innovation sector in 2025 alone. It is also deploying a dedicated Health Plan focused on four strategic areas: medical treatments, digital health, care delivery, and prevention, with a total of EUR 10 billion expected to be allocated by 2030[70].

Spain

Spain hosts 1,119 dedicated biotech companies (an increase of 10.4% compared to the previous year), of which the vast majority are SMEs (52%) or micro SMEs (43.6%). Catalonia is home to the largest cluster (23.3% of the companies) followed by Madrid (18.7%), Andalusia (12.3%), the Basque Country (9.7%) and Valencia (8.9%). In terms of total turnover, Catalonia is also in the lead with 43.05%, followed by Madrid (32.84%) and the Basque country (5.65%).[71]

In terms of application areas of biotechnologies, **human health leads** with 52.1%, followed by food (30.2%), agriculture and forestry production (26.3%), environment (20.9%), animal health and aquaculture (20.8%) and industry (15.7%).[72]

According to the national statistical office, the last available data show an R&D investment of EUR 3,144 million in 2024 (a 14% increase), financed mainly by business (45.4%) and Public Administration (38.6%).[73]

Grifols, a global leader in essential plasma-derived medicines and transfusion medicine, is by far the dominant figure in the Spanish biotech and pharma sector. In 2025, the company generated EUR 7,524 million in revenue, representing a 7% rise, while net profit more than doubled to EUR 403 million.[74]

Spain is the **European leader in clinical trial authorisation**, with 92% of their clinical trials taking place in Catalonia.[75] The Spanish Agency of Medicines and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios – AEMPS) reports sustained growth over the past decade. In 2025, AEMPS authorised 962 clinical trials, of which 758 were multinational studies. Within therapeutic areas, oncology

accounts for the largest share (39.3%), followed by rare diseases (22.5%) and advanced therapy medicinal products (4.2%).[76]

The Spanish sector benefits from a network of almost 1,000 hospitals, high patient recruitment rates and an agile regulatory framework, exemplified by introducing the first EU-wide fast-track procedure (FAST-EU) for multinational trials in 2025.[77]

Italy

Italy, one of the largest pharmaceutical producers in the EU, is home to 5,869 biotech companies. 89% are SMEs or micro SMEs. **While healthcare biotech only represents roughly 7% of the sector, it accounts for EUR 20.8 billion in turnover**. Most companies are active in agri-food and livestock biotechnology (65%) with approximately EUR 27 billion in revenue.[78]

The majority of biotech companies are in Northern Italy (47%), followed by the South and Islands (28%) and the centre (25%), in particular in Lombardy (16%), Tuscany (11%), Veneto (10%), Campania (9%), Emilia-Romagna (8%), Apulia (7%) and Lazio (7%).[79]

Italy's largest pharma company by revenue, the Menarini Group in Florence, has a dedicated Menarini Biotech division specialised in process development and manufacturing of biopharmaceuticals.[80] Other companies that have been recognised beyond borders include Chiesi Farmaceutici in Parma (respiratory disease focus, active in ATMPs), Dompé farmaceutici in Milan (developer of 'Oxervate', the first recombinant human nerve growth factor, based on the 1986 research of Italian Nobel Prize winner Rita Levi-Montalcini), Milan based Recordati (disease focus) and AAVantgarde Bio (gene therapy) and Swiss-Italian cancer treatment developer Philogen.

Specific clusters include the flagship life science and innovation hub 'Milan Innovation District' (MIND)[81], the OpenZone campus in Bresso (greater area of Milan), The Bio Industry Park Silvano Fumero in Turin, the Tuscany Life Sciences in Siena (vaccine and biotech), Be Factory in Trento, the Cluster Scienze della Vita Friuli Venezia Giulia in the Trieste/Udine region and the Research Centre 'Sviluppo di terapia genica e farmaci con tecnolgia a RNA' in Padua. In addition, the Ministry of Health recognises and promotes more than 50 research hospitals,[82] among them the Vatican-owned 'Bambino Gesù' that is well-known for its paediatric CART-T cell therapy.[83]

Denmark

Denmark has a dynamic biotech sector: the number of biotech companies increased from 483 in 2010 to 707 in 2020. 71% of these companies are small, having 0-9 employees. The number of employees in the biotech sector increased 33% from 2010 to 2020. In 2020, the turnover from the Danish biotech sector was EUR 28.3 billion[84]. Most of the companies are located in the Capital Region, which together with Southern Sweden constitute the Medicon Valley.[85]

In Denmark, biotech dates back over a century, to when Novo Nordisk started producing insulin[86]. Novo Nordisk is the largest company in Denmark. In 2024, the market value of Novo Nordisk was EUR 369,2 billion, making the company larger than the other nine largest Danish companies put together[87]. Most recently, its success is driven by the development of weight-loss drugs.[88] Danish life sciences exports have increased 182% from 2010 to 2024, amounting to EUR 24.3 billion, of which EUR 22.4 billion derived from biotech.[89] However, Novo Nordisk suffered a decline in 2025, with its market value falling to EUR 193.3 billion in 2025.[90] Other major Danish companies are Lundbeck, LEO Pharma, Bavarian Nordic and ALK, as well as smaller, emerging pharma innovators such as Genmab, Zealand Pharma, Gubra and Muna Therapeutics[91]. The added value of the red biotech sector has almost quadrupled from 2008 to 2022,

amounting to approximately EUR 11 billion.[92] The red biotech sector is dominant in Denmark, whereas the added value of the white sector amounted to EUR 2.5 billion and the green to EUR 3 billion in 2022[3].

A new Life Science strategy (2026-2030)[93] aims to place Denmark at the forefront of the European Life Sciences industry through several initiatives. The first initiative strengthens the growth ecosystem through the Danish Life Science Cluster (established in 2020) with hubs in the largest cities and partners such as regions, knowledge centres and business organisations and EIFO investments to improve access to venture capital. The second initiative aims to strengthen research through better use of AI and health data, alongside a stronger framework to support more clinical trials. Thirdly, healthcare system will be strengthened through the establishment of a National Centre for Health Innovation, which seeks to increase dissemination and availability for healthcare professionals and citizens. A new framework seeks to attract foreign investment, including a focus on international cooperation and health diplomacy. Finally, a Life Science Council has been established to strengthen the public-private dialogue.

Sweden

In 2022, there were 850 biotech companies in Sweden and 1,305 pharma companies. Most of the companies are in the Stockholm area as well as in Southern Sweden. In 2022, Sweden exported EUR 17.1 billion worth of life science; 22% of the life sciences was biotech. [94] Emmanuelle Charpentier carried out foundational CRISPR-Cas9 work at Umeå University, recognised with the 2020 Nobel Prize in Chemistry; CRISPR-Cas9 is a gene scissor with the potential to treat serious diseases. Global pharma innovators such as AstraZeneca, Pfizer and Novartis are located in Sweden, and larger Swedish biotech firms include Camurus, Sobi, Bonesupport and Calliditas.[95] In 2025, the market value of AstraZeneca was EUR 247 billion[96] and the market value of Camurus was EUR 3.3 billion[97]. **The red biotech sector dominates in Sweden**, amounting to an added value of EUR 7.3 billion in 2022, whereas the green sector amounted to EUR 5.8 billion and the white sector to EUR 3.4 billion.[98] Sweden adopted a national life science strategy in 2019, updated in 2024,[99] aiming to make the country a biotech leader through initiatives similar to those in the Danish strategy, with additional emphasis on skills supply, talent attraction and lifelong learning.

Netherlands

As **one of Europe's biggest and most connected hubs for life sciences and biotechnology innovation**, the Netherlands is home to nearly 2,000 life sciences companies and research organisations, with over 500 registered biotech companies. Therapeutics (19.8%) and Diagnostics and Analytical Services (19.3%) are the key focus areas of the sector, with Genomics and Proteomic (6%), Agro-Bio (6%) and Food and Nutraceuticals (7%) being highly represented as well.[100] It has established itself as a crucial hub for pharmaceutical manufacturing, hosting a number of manufacturing facilities across the country.[101]

On an EU level, the Netherlands is one of the leaders (behind France and Germany) when looking at the number of companies and amount of funding raised on a per capita basis. Biotech companies raised more than 400 million euros in private equity rounds, most of it coming from the US private investment. The sector maintained a steady level of activity between 2023 and 2024, with venture financing increasing by 10%, though a recent report showing a mixed picture.[102] The number of newly founded biotech companies has been declining since 2018, reflecting a global trend where the growth capital is increasingly concentrated among a few large companies across a broader funding landscape and not only in the early-stages of the funding rounds.

Several factors underpin the success of the biotech ecosystem in the Netherlands: strategic location (home of EMA in Amsterdam), high levels of interconnected infrastructure, and comprehensive, integrated approach to talent and skill development in the entire sector, across all levels. The biotech landscape is concentrated in several key innovation hubs, each with its own competences. Leiden Bio Science Park – the oldest and the largest cluster – hosts over 200 companies (including the international leaders such as

Johnson and Johnson) and employs more than 27,000 people, making it one of the largest biotech ecosystems in the world. Rotterdam Square (focusing on health tech and medical devices), Utrecht Science Park (sciences and health) and Groningen campus (healthy ageing and sustainable chemistry) are among other, smaller ecosystems.

The Netherlands biotech funding landscape and regulatory environment reflect similar challenges to other Western European Member States. While the sector does benefit from some national programmes such as Biotech Booster (EUR 250 million fund by the Dutch National Growth Fund) and well-established Dutch venture capital firms (LSP, Forbion, Bio Generation Ventures), the gap between early-stage and scale-up phase remains the main driver behind R&D start-ups and SMEs relocating to the US at an early stage.

Mindful of this trend and its own capabilities in the rapidly developing biotech sector, the Netherlands is closely following the EU's Competitiveness agenda. The caretaker government has commissioned Peter Wennink (former ASML CEO) to publish advice on the future earning capacity of the Netherlands – the Dutch Draghi report. The Wennink report, published in December 2025, recognises biotechnology as one of the four key deep tech innovation sectors and an important domain for the Netherlands to remain a relevant global player.[103] The report points out that more investment is needed in red biotechnology (medical and biopharmaceutical innovation and emerging technologies) to strengthen the country's healthcare system alongside its competitiveness. Generating just over 1.1% of GDP, the red biotechnology sector lags behind Belgium (2.7%) and Switzerland (5%). Several project proposals have been released to tackle the challenges in the scale-up of the Netherlands' biotech sector. One of the projects is the creation of a national programme (Biotech Nexus) intended to accelerate the path from lab to patient for innovative medicines. Another is the establishment of a DARPA-like government agency (NADI – Nationaal Agentschap voor Disruptieve Innovatie) tasked with fostering higher-risk, high reward R&D in areas such as AI, security, digitalisation and biotechnology.

Emerging Member States

The gap between the Western and Central and Eastern European (CEE) countries is pronounced, and the challenges that CEE biotech companies face are well documented: lack of venture capital and private investment, skilled experts, managerial experience and administrative support.[104] [105] **However, the landscape is shifting**, with several countries accelerating in the biotech owing to lower operating costs, high rates of STEM education, significant agricultural sectors producing biomass, and recent increases in EU funding.

Several CEE countries are investing in physical infrastructure through the cluster ecosystem model: Estonia (Tartu Biotechnology Park), Poland (Life Science Krakow Cluster), Romania (bioRONE), Bulgaria (Sofia Tech Park) and Hungary (Pharmapolis Innovative Pharmaceutical Cluster and the Innovative Food Industry Cluster). Rather than building large independent ecosystems, the hubs connect local SMEs and start-ups to existing ecosystems in Western Europe to participate in collaborative EU projects and use their networks and knowledge to join global innovation value chains as testbeds or early adopters. The macroregional BIOEAST initiative illustrates this strategy.

Baltic States

Determined to close the innovation gap with Western Europe, Lithuania, Latvia and Estonia have joined forces. Building on the success of the Horizon-funded BIOCONNECT project which aimed to strengthen the Baltic biotech ecosystem by connecting academia, industry, policymakers and investors across the region (and Finland), these countries proposed a **Baltic Biotech Action Plan** at the end of January 2026, comprising more than 40 initiatives aimed at strengthening the sector. [106] The plan's central aim is the creation of the Baltic Biotech Hub where each country contributes unique knowledge in different biotechnology areas.

Receiving strong national support for life sciences innovation and investment, **Lithuania** is the regional leader in biotechnology, with more than 550 companies. The country's life sciences sector grew by approximately 80% during the COVID-19 period and now accounts for approximately 2.7% of national GDP, with a target of 5%. The most active area is gene editing and CRISPR technologies, driven by leading companies such as CasZyme. Currently, two large construction projects are underway: Tech Zity – R&D for deep tech innovations and Bio City – a project worth 7 billion euros, dedicated entirely to biotech development with facilities for virology, stem cell, gene therapy and 3D bioprinting R&D (projected to be Europe's largest biotech campus).

Chemical and pharmaceutical industries are the main areas where biotech applications are found in **Latvia.** The success of the sector rests primarily on R&D capabilities in organic synthesis and pharmaceutical manufacturing (Institute of Organic Synthesis of Latvia, Latvian Biomedical Research and Study Centre, Grindeks and Olpha). Pharmaceuticals account for 38% of all sector exports. [107]

Extensive experience and knowledge in digital health anchors the health ecosystem in **Estonia**. The country is known for its expertise in biobanking and data-powered personalised health; most biotech innovation is concentrated in this area. The country has built a hub as well - Tartu Biotechnology Park (TBP), a national centre for genetics, biomedicine and digital health. The park hosts more than 80 organisations, including biotech, health tech and food tech companies. Biotech companies emerging from this hub have built successful networks and interfaces with Western European ecosystems. Industrial technology is also being developed through Important Projects of Common European Interest (IPCEI), together with Germany and Finland. Food and feed biotech is one of the areas discussed, where Estonia will be the lead partner due to the country's expertise in alternative proteins, cell-based agriculture, and solutions that enhance food safety.[108]

Bulgaria

Identifying biotechnology as one of the key economic sectors in its Innovation Strategy for Smart Specialisation 2014-2020, Bulgaria paved the way for innovation in pharmaceuticals and biotech. The Bulgarian pharmaceutical industry today comprises around 90 companies, contributing to 2.2% of its GDP in 2022.[109] It is **one of the fastest-growing sectors of the Bulgarian economy**, in part due to economic growth and high pharmaceutical prices and spending. According to its Health and Life Sciences Cluster (HLSC), Bulgaria hosts 128 medical centres engaged in biotechnology research and 56 companies as part of this cluster. Offering affordable and efficient clinical research, the country has created **a thriving clinical trials sector** valued at around EUR 280 million and ranking among the top 20 countries globally in terms of the number of trials conducted.[110]

Unlike the Baltic States, Bulgaria is building its infrastructure from the ground up. In 2015, it opened Sofia Tech Park, the country's first large science and technology park, offering an incubator programme (South-East European Innovators Programme), laboratories, office space and event venues, alongside several Centres for Excellence in the biotech sector (Genomic Centre, PERIMED, Phantasies). Many initiatives in the country are based on collaborations between the clusters, such as the establishment of the BioCenter in Bulgaria. The Health and Life Sciences Cluster Bulgaria collaborates directly with AI Cluster Bulgaria, with an explicit focus on integrating artificial intelligence (AI) into biotechnology from the earliest stages of ecosystem development. In March 2025, the Park was selected to host Brain++, EU's new AI factory. The EUR 90 million project opens an opportunity for the hub to position itself at the frontier of AI- integrated biotechnology R&D, especially drug discovery. The development of the sector is still in the early stages but following a progressive model.

Poland

Like other CEE countries, Poland is a latecomer to biotechnology, the sector having begun to develop only after 1990, lagging about 15 years behind Western Europe.[111] Having since experienced significant expansion, it is now one of the fastest-growing sectors in the Polish economy. According to the latest report by the Central Statistical Office, in 2024 there were 246 companies conducting biotechnology activities, an increase of 26.2% on 2023, with the sector employing 6,408 people (43% more than the year before). R&D in biotech also increased, with 15.1% more entities in 2024 than in the previous year, 8,424 employees and an expenditure increase of 7.1%.[112] A further indicator of growth is clinical trials: 26 non-commercial trials were registered in 2018, rising to 220 in 2025, supported by 35 Clinical Research Support Centres and 19 Regional Digital Medicine Centres.

Recent growth in the biotech sector owes much to Poland's pharmaceutical market – the largest in CEE and sixth largest in the EU.[113] The strength of the sector lies in the established domestic production base, focusing on generics and OTC products, with growing interest in genetic engineering techniques. The biggest players include Selvita, Celon Pharma and Mabion closely followed by Oncoarendi Therapeutics, Pure Biologics, and Captor Therapeutics. Strategic location within the EU, a highly educated workforce and cost-competitive manufacturing make Poland a hub for pharmaceutical production and distribution and one of the most dynamic Life Science centres in Europe. In more than 600 entities operating in biotech and medical clusters across the country (Life Science Krakow Cluster, Warsaw Health Innovation Hub, Gdańsk Science & Technology Park, Kutno Agro-industrial Park, Wrocław Technology Park, Łódzki Regionalny Park Naukowo-Technologiczn etc.), academia-business interlinkages are being forged.

Despite the potential and high interest of foreign investors, the government has identified the need for increased coordination and better resource management to transform the country into a regional leader in biotech. In March 2022 it announced a Government Development Plan for the Biomedical Sector. The substantial governmental funding of PLN 2 billion (approx. EUR 470 million) dedicated exclusively to the development of biomedical sector for 2022-2031 comes from the National Reconstruction Plan and the Medical Research Agency.[114] The strategy is to create a more investor-friendly ecosystem and promote R&D through new laws and financing programmes.

In addition to public funds, Poland has been very active in securing international partnerships and EU programmes such as BBI JU, CBE JU, and STEP. Niche biomedical therapies are at the centre of attention, with recent examples such as Parkinson's gene therapy project (EUR 46.1. million) and new generation RNA-based medicines (EUR 7 million) putting Polish companies at the frontier of biotechnology innovation.[115, 116]

Factors of Success

Six factors of success appear across all leading EU biotech ecosystems:

1. **Physical Cluster Co-Location** - geographically concentrated hubs linking companies, universities and hospitals
2. **Triple Helix Integration**[117] - structured coordination between academia, industry and government
3. **Specialisation around Existing Comparative Advantage** – focus on areas of comparative advantage (e.g. oncology, metabolic diseases, gene editing)
4. **Public De-Risking of Early-Stage Capital** – state-backed instruments providing early-stage capital or guarantees to crowd in private investment

5 **Clinical Infrastructure as a Competitive Asset** – density of trials capacity, research hospitals and patient cohort access

6 **Talent, Skills and International Openness** – STEM pipeline depth, international recruitment and cross-border mobility

Success factors are not independent, the strongest ecosystems such as Medicon Valley combine all six of them. To fully understand their impact, further analysis is needed to understand their depths and their interconnection. However, the **success factors are not primarily regulatory**.

Success factors reveal that physical co-location is a baseline, not a differentiator. Triple helix integration, public de-risking of early-stage capital and talent openness are present in every mature ecosystem but largely absent in CEE countries.

The market landscape shows that **market failures are structural barriers to EU biotech competitiveness, while regulatory fragmentation is secondary to the capital gap**.

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