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By José Montegu, Nunzia Francesca Saporito and Zofia Polakiewicz

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This paper analyses the biotechnology sector in the European Union (EU), with a focus on trends in small and medium-sized enterprises (SMEs) and foreign direct investment (FDI). It presents two foresight exercises that explore four plausible scenarios for red and green biotechnology, and examines the challenges and opportunities shaping the EU's ability to compete in a rapidly evolving global economy. The analysis aims to inform policy by highlighting the role of SMEs and investment in driving innovation, sustainability, and resilience across the biotechnology value chain.

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Executive summary

This paper examines the evolution of the biotechnology sector in the European Union (EU), with a focus on the role of small and medium-sized enterprises (SMEs) and foreign direct investment (FDI). It explores how FDI–SME linkages develop within broader innovation ecosystems, and how their performance influences the EU's competitiveness in an expanding global market. Despite a global plateau in biotechnology patenting since the early 2000s, Europe has consistently generated a substantial share of high-value inventions, reflecting the strength of its scientific base. However, Europe continues to lag the United States and China in private investment, particularly in venture capital. This investment gap poses a strategic risk, as insufficient capital inflows could undermine Europe's long-term capacity for innovation.

Growth trajectories in European biotech differ significantly across subsectors. Red biotechnology, focused on medicine and healthcare, attracts the majority of cross-border investment, benefiting from relatively mature markets and more harmonised regulatory frameworks. In contrast, green biotechnology, encompassing agriculture and environmental sustainability, remains less developed, often constrained by fragmented regulation and uncertainties surrounding genetically modified organisms (GMOs). SMEs in this sector frequently face disproportionate compliance costs and depend heavily on public support for R&D and innovation partnerships. While industrial or white biotechnology is an important and growing area, it is not the focus of this analysis.

At the global level, competition is intensifying. The United States retains a leading role in biotechnology innovation and commercialisation, underpinned by a consistently high share of global investment and research output. Its robust venture capital ecosystem, strong university-industry links, and streamlined regulatory frameworks enable faster translation of discoveries into market solutions. China is catching up rapidly, leveraging structural cost advantages, rising patent activity, and a large, skilled research workforce. Europe, while home to world-class research and biotech clusters, struggles to match the speed and scale of investment available elsewhere. This is compounded by regulatory and policy fragmentation across Member States, which creates uncertainty, delays market access and deters cross-border investment.

FDI plays a growing role in shaping the global biotech landscape. Although biotech still represents less than 1% of total global greenfield FDI, its share has more than tripled since the early 2000s, with a notable peak during the COVID-19 pandemic. Increased demand for manufacturing and R&D capacity has reinforced long-term trends, particularly in OECD and EU countries, where innovation and production-related FDI have grown significantly. Cross-border M&A activity also rose sharply during the COVID-19 pandemic, accelerating longer-term consolidation trends in biotechnology and increasing the sector's share of global M&A, particularly in OECD countries. Although activity moderated after the pandemic, deal levels have remained structurally above their pre-pandemic baseline.

Biotech FDI remains geographically concentrated, but signs of diversification are emerging. The United States leads both as a source and destination of greenfield investment, followed by the EU and China. While intra-EU investment is increasing, extra-EU investors – especially from the United States, Brazil and Japan – continue to dominate capital inflows. High-value biotech FDI is increasingly oriented towards R&D and advanced manufacturing, generating skilled jobs and facilitating knowledge transfer. However, the impact varies across EU Member States, shaped by their position in biotech global value

chains, the maturity and robustness of regional innovation ecosystems, and the strength of local capabilities, from research institutions and human capital to digital and physical infrastructure. Regions with well-developed biotech clusters, supported by targeted policies, are better positioned to attract R&D-intensive investment and record higher job creation per euro invested than those focused primarily on capital-intensive manufacturing.

Unlike traditional sectors, where FDI often seeks scale or cost advantages, biotech relies on FDI to bridge the high-risk gap between discovery and commercialisation. SMEs typically lead early-stage innovation, while multinationals provide the capital, regulatory expertise and infrastructure needed to bring products to market. These linkages take varied forms – equity stakes, licensing, acquisitions and manufacturing partnerships – and are often concentrated in specialised clusters near research institutions and hospitals. While R&D-focused FDI generates fewer but more skilled jobs, manufacturing-related investment anchors long-term infrastructure.

Reinforcing the strength of EU biotech clusters requires strategies tailored to both mature and emerging hubs. Central to this is deepening FDI-SME linkages, where clusters act as matchmakers that connect multinationals with local innovators and embed investment through supply chains and shared infrastructure. In mature ecosystems, foreign investment can anchor long-term supplier relationships and retain R&D activities locally, supported by dense networks and shared capabilities. Emerging clusters can attract strategic investments by leveraging EU research networks, accelerators and digital supply chains, enabling local firms to plug into global value chains as testbeds or early adopters. Access to pilot facilities, niche technologies and incubation services helps SMEs overcome scale-up challenges and attract specialised investment. Sustained competitiveness also depends on developing hybrid talent, improving regulatory navigation, and supporting cross-border collaboration through interoperable data and streamlined mobility.

The European biotech landscape is being reshaped by geopolitical, technological and socioeconomic shifts. Strategic autonomy is driving efforts to reduce reliance on foreign suppliers, with firms reconfiguring supply chains and governments tightening controls on sensitive technologies. At the same time, biotech is entering a new growth phase fuelled by the convergence of biology and digital technologies, including AI-driven drug discovery and synthetic biology. These trends are set against a backdrop of ageing populations and growing demand for sustainable solutions such as bio-based materials.

To assess how these emerging trends could shape Europe's biotech landscape, this paper uses strategic foresight to explore plausible futures for red and green biotechnology, projecting scenarios through 2040. Rather than predicting a single outcome, it applies scenario planning based on two critical uncertainties – the degree of globalization and the pace of technological progress – mapped into a 2x2 matrix generating four contrasting scenarios: one where technological advancement and international openness reinforce each other; one where innovation remains strong but global cooperation is limited; one with low levels of both innovation and global integration; and one where markets remain open but technological progress is slow and incremental. These scenarios are designed to explore and test how sector dynamics, investment flows and SME performance might evolve under different circumstances.

For red and green biotechnology, possible futures range from rapid innovation in an open global context to slower, more incremental progress under fragmented conditions. Depending on how geopolitical and technological forces interact, red biotechnology in the EU could see faster development and greater access to therapies, or face heightened pressure on SME participation, affordability, and capability retention. Across all scenarios, the completion of the Single Market, support for SMEs, and sustained investment in core infrastructure and regulatory science emerge as critical enablers of a dynamic ecosystem. Similarly, green biotechnology in the EU could evolve along different paths. In globally connected and innovation-driven scenarios, sustainable solutions might scale rapidly, though such

developments could also amplify competition and supply-chain dependencies. More inward-looking or slower-moving futures could shift focus toward resilience and incremental gains. Regardless of the trajectory, preserving Single Market coherence, investing in enabling capabilities, and ensuring inclusive SME participation in the value chain appear central to realising the industry's potential for environmental and economic benefit.

Closing the scale-up gap must be a central priority for EU biotech policy. Despite a strong scientific base, many European SMEs struggle to grow due to fragmented capital markets, limited access to late-stage financing, and uneven regional capabilities. A coordinated strategy is needed, structured around four interrelated objectives: expanding access to finance, enhancing connectivity, building capacity and improving policy coherence.

First, expanding access to finance requires targeted measures to address the shortage of growth-stage capital in Europe. This includes increasing the size and number of EU-based funds, strengthening public-private investment vehicles, and encouraging greater participation by institutional investors in high-risk, innovation-driven ventures. Second, enhancing connectivity involves improving SME access to global value chains, strategic partners and international capital, helping firms gain visibility and credibility beyond their local ecosystems. Third, building capacity means supporting SMEs with the infrastructure, skills and advisory services needed to scale, such as incubators, demonstration facilities and managerial expertise, particularly in regions that lack mature innovation ecosystems. Fourth, improving policy coherence across Member States, especially in regulation, data interoperability and intellectual property (IP), would reduce uncertainty, lower transaction costs and enable smoother cross-border collaboration.

1 Introduction

Biotechnology is a rapidly evolving field at the intersection of biology and technology, supporting solutions in health, agriculture, environmental protection and industry. It plays a central role in addressing major societal challenges, from pandemics and ageing populations to climate change and food security, with innovative applications ranging from vaccines and therapies to bio-based materials and genetically modified crops. These diverse uses are typically grouped into three major subsectors: *red biotechnology*, focused on medicine and healthcare; *green biotechnology*, encompassing agriculture and environmental sustainability; and *white biotechnology*, concerned with industrial and manufacturing processes. Box 1 provides working definitions and examples for each category.

This paper analyses the development of the biotech sector in the European Union (EU), with a particular focus on the role of small and medium-sized enterprises (SMEs), foreign direct investment (FDI), and the linkages between them. It uses strategic foresight – a method for exploring plausible future developments under conditions of uncertainty – to outline scenarios for red and green biotech and assess the challenges and opportunities that may influence the EU's global competitiveness. The analysis prioritises these two subsectors as they operate in rapidly evolving, tightly regulated environments, allowing for more targeted insights within a manageable analytical scope. The aim is to provide a foundation for exploring how SMEs and cross-border investment may advance key policy objectives, such as innovation, sustainability and resilience.

The global biotech market is growing rapidly amid intensifying international competition. Estimates valued the market at approximately USD 1.6 trillion in 2024, with projections indicating growth to around USD 4 trillion by 2030 and potentially above USD 5.7 trillion by 2034 (Grand View Research, 2024[1]; Precedence Research, 2025[2]). However, market value remains heavily concentrated in pharmaceuticals, which generate the majority of sector revenues and attract most investment. Agri-environmental and industrial biotechnology applications are expanding as well, though from a considerably smaller base.

Although Europe's biotech sector has expanded in recent years, it continues to lag the United States in both market share and private investment. As of 2025, the United States accounts for about 35% of the global biotech market, compared with 31% for Europe and approximately 5% for China (MERICS, 2025[3]). However, when it comes to venture capital investment, Europe significantly trails both countries. In 2023, European biotech firms raised about USD 11.5 billion (just over 7% of the global total) while the United States secured USD 56.8 billion and China attracted USD 20.6 billion, despite its smaller market share (Drug Discovery Trends, 2024[4]). While modest in scale relative to the global market, VC funding is critical for supporting high-risk R&D and helping SMEs bring innovations from lab to market.

The EU also trails the US in attracting FDI, and although it is the second-largest destination globally, much of this investment is heavily reliant on extra-EU sources, with the US alone accounting for nearly half of projects. This reinforces a structural imbalance: the EU draws substantial capital for scaling and production, but remains undercapitalised in early-stage, high-risk segments, where long-term innovation is most at stake.

Major economies are deploying biotechnology and biomanufacturing strategies as instruments of national competitiveness and resilience, aiming to secure first-mover advantages in the emerging global bioeconomy. This entails aligning mission-oriented research and development (R&D) agendas, establishing predictable lab-to-market scaling pathways, and embedding enforceable standards and

biosecurity protocols to govern emerging biotechnologies. While institutional arrangements and funding timelines vary across countries – and remain exposed to political developments – the underlying strategic trajectories are likely to persist. This persistence is driven by structural factors, such as public health and climate adaptation, and reinforced by long investment horizons, established infrastructure, and accumulated capabilities that lock in trajectories beyond electoral cycles.

Box 1. Defining biotechnology subsectors: red, green and white

Biotechnology is defined by the OECD as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living and non-living materials for the production of knowledge, goods and services" (Friedrichs and van Beuzekom, 2018[5]) In line with common usage across policy, industry and academia, this paper uses the term "biotech" as shorthand for biotechnology and groups the main biotechnological applications and areas of research into three colour-coded subsectors: "red", "green" and "white".

- **Red biotechnology** involves the application of biological technologies in medicine and healthcare, focusing on the prevention, diagnosis, and treatment of disease. It includes the development of biopharmaceuticals such as monoclonal antibodies, vaccines, gene and cell therapies, and tissue-engineered products, as well as diagnostic technologies that enable personalised medicine. Underpinning these advances are enabling platforms like mRNA delivery systems, viral vectors, and genome editing tools, including clustered regularly interspaced short palindromic repeats (CRISPR) technology.
- **Green biotechnology** applies biological techniques to agriculture and environmental sustainability, aiming to enhance crop productivity, reduce chemical inputs, and mitigate ecological impact. It includes genetically engineered and genome-edited crops, microbial inoculants such as biofertilisers and biostimulants, and biological pest control strategies. Beyond agriculture, green biotech supports environmental services such as soil restoration, bioremediation, and methane mitigation in livestock.
- **White biotechnology**, also known as industrial biotechnology, involves the use of biological organisms, enzymes, and metabolic pathways to produce materials, chemicals, and energy in environmentally sustainable ways. It relies on fermentation, biocatalysis, and metabolic engineering to convert renewable feedstocks (such as sugars, biomass, and organic waste) into a wide array of products including industrial enzymes, bio-based polymers, platform chemicals, biofuels, and specialty ingredients like surfactants, fragrances, and solvents.

While these labels offer a useful framework for describing biotech applications, their boundaries are increasingly fluid. Enabling technologies such as synthetic biology, genomics, and bioprocess engineering often cut across categories, highlighting converging platforms.

Sources: (Barcelos et al., 2018[6]) (European Commission, 2025[7]) (European Commission, 2018[8])

The EU grounds its policy approach in the principle of open strategic autonomy, seeking to strengthen resilience while remaining open to international collaboration and investment. In March 2024, the European Commission published a strategy on biotechnology and biomanufacturing aimed at boosting competitiveness and scale-up capacity (European Commission, 2024[9]). It includes measures to streamline regulation, support scale-up and skills development, promote standardisation, and establish coordination platforms such as the Biotech & Biomanufacturing Hub (European Commission, 2025[10]). The forthcoming *EU Biotech Act,* expected in 2026, has evolved into two separate initiatives focused on industrial and health-related biotechnology. These aim to introduce horizontal regulatory reforms that

support innovation and international alignment, tailoring oversight to the risk associated with different applications.

Complementing these efforts, the Commission has adopted a new Strategy for a Competitive and Sustainable EU Bioeconomy (European Commission, 2025[11]). This updates earlier strategies and reinforces support for bio-based innovation and scale-up. Beyond the EU and other advanced economies, more than 50 governments worldwide have adopted national bioeconomy strategies that place biotechnology and bio-based solutions at their core (Gardossi et al., 2023[12]). This underscores both the growing global recognition of the sector's potential and the urgency for the EU to sustain its leadership amid intensifying competition for investment, talent and technological advantage.

The EU enters the global biotechnology race with strong foundations. A robust research base, a growing pool of specialised scientists, and a dense network of internationally recognised institutions and centres of excellence provide a solid platform to support scientific advancement and cross-sector collaboration. These strengths are reinforced by expanding infrastructure for piloting and scaling-up innovations (Hillson et al., 2019[13]; European Strategy Forum on Research Infrastructures, 2024[14]), including biofoundries, industrial demonstration facilities, and pan-European data infrastructures such as ELIXIR (Drysdale et al., 2020[15]). These assets are reflected in tangible innovation outcomes, with OECD patent data confirming the depth of EU capabilities across all biotech subsectors (OECD, 2025[16]). Despite a global plateau in biotechnology patenting since the early 2000s, the EU has consistently generated a substantial share of high-value inventions. In 2020, the EU accounted for 18% of global biotechnology patents, second only to the United States with 39% (Grassano et al., 2024[17]).[1]

SMEs are central to the EU's biotech innovation model but face significant challenges in scaling up. Many are early-stage start-ups or university spin-outs focused on a specific innovation or platform technology. In 2024, individual inventors and SMEs accounted for about 22% of European patent applications (European Patent Office (EPO), 2025[18]). However, their ability to scale and expand across borders is often constrained by fragmented capital markets, regulatory complexity and limited access to late-stage investors (European Investment Bank, 2024[19]). University spin-outs, in particular, frequently emerge from grant-funded research and struggle to secure follow-on capital for commercialisation. These scale-up barriers are not unique to biotech, affecting other strategic sectors such as clean technology and advanced manufacturing.

FDI and cross-border partnerships help bridge the biotech scale-up gap through two complementary channels. First, multinationals invest directly in SMEs through equity stakes, licensing deals, contract R&D, joint ventures or acquisitions. These arrangements provide targeted firms with critical resources such as capital, regulatory expertise and international market access, helping them move from early-stage innovation to commercial scale. Second, FDI contributes to broader ecosystem development, indirectly benefiting SMEs by creating demand, knowledge spillovers and strengthening supply chain linkages beyond bilateral deals. Investments in production facilities, research infrastructure or clinical trials often stimulate local service markets and foster collaboration. For example, many industry-sponsored trials across the EU engage local SMEs such as diagnostic firms and contract research organisations (CROs), offering commercial opportunities and enabling knowledge transfer. More broadly, FDI-SME linkages embed firms in global value chains and research networks, supporting innovation and raising productivity, particularly where absorptive capacity is strong (OECD, 2023[20]).

Clusters play a central role in amplifying the benefits of FDI-SME linkages by concentrating research institutions, multinationals, SMEs and specialised infrastructure in one location. Examples such as BioValley in the Upper Rhine and Medicon Valley in Copenhagen and Southern Sweden illustrate how such ecosystems can accelerate clinical development, embed firms in global value chains and raise international visibility. However, these benefits and spillovers are neither automatic nor uniform. They depend on local conditions such as the availability of specialised skills, research infrastructure, and innovation networks, as well as effective governance and supportive policy frameworks.

To ensure more inclusive outcomes, biotech investment strategies should reflect regional differences and support the EU's cohesion and resilience goals. Realising this potential requires place-based policy approaches combining inward investment with coordinated public support, such as shared infrastructure, workforce development, innovation funding and incentives for public-private partnerships. Complementary EU-level efforts to align regulation, harmonise standards, improve cross-border operability and streamline data governance are also essential to reduce fragmentation and support integration across regions. Green biotech, in particular, offers opportunities in rural and less-developed areas with strong agricultural or marine value chains, helping regions move up the value chain and contributing to EU priorities. In this context, clusters are not only centres of innovation but also platforms for delivering place-based industrial policy and public-private collaboration.

Looking ahead, strengthening the links between SMEs and FDI will be essential to unlocking the full potential of the EU's biotech sector to scale innovation and compete globally. The following sections explore recent developments and emerging trends in the biotech landscape, with a focus on FDI-SME dynamics, and discuss policy levers to better align investment flows with the EU's long-term goals of open strategic autonomy, innovation-driven growth and sustainability.

2 Biotech value chains: Trends and policies in FDI and SME ecosystems

Industry and SME trends in the biotechnology sector

The EU's biotechnology sector is expanding rapidly, but with uneven patterns across subsectors

Over the past decade, the EU's biotechnology sector has grown across several dimensions, including international trade and employment. According to a study by WifOR/EuropaBio (Haaf and Sale, 2025[21]), extra-EU exports of biotech goods reached EUR 87 billion in 2022, representing approximately 3.4% of all extra-EU goods exports. This generated a trade surplus nearly seven times larger than in 2008 and allows the sector to rank among the EU's leading high-technology export categories. While this increase partly reflects the EU's pivotal role in the COVID-19 vaccine response, it also signals structural gains in R&D and industrial capacity. In 2022, the sector directly employed about 238 000 people across Europe, accounting for approximately 0.11% of total EU employment, and supported over 900 000 jobs when indirect and induced effects are included (Haaf and Sale, 2025[21]).[2] Direct employment, particularly in healthcare biotechnology, is characterised by exceptional labour productivity – generating EUR 160 000 in gross value-added per worker – and requires advanced technical skills, while the expansion of industrial biotechnology is associated with more labour-intensive supply chains and a broader skills base, aligning with a wider segment of the European workforce.

Investment and collaboration patterns differ by subsector, with red biotech displaying significantly higher levels of cross-border deal activity. This reflects its greater market scale and maturity (European Federation of Pharmaceutical Industries and Associations (EFPIA), 2025[22]), as well as the existence of centralised authorisation pathways that reduce regulatory fragmentation and facilitate EU-wide market access (European Medicines Agency, 2025[23]). Large firms dominate late-stage development and commercialisation, while SMEs typically focus on early discovery and proof-of-concept stages, often leading to partnerships or acquisitions by larger companies.

In contrast, green biotech remains a comparatively nascent industry. Investment and commercialisation are hindered by restrictive and fragmented legislation governing genetically modified organisms (GMOs) (European Commission, 2025[24]). Over the past decade, several leading agri-biotech multinationals have scaled back their EU GM-crop activities (e.g. BASF, Monsanto, Syngenta). SMEs, facing disproportionate regulatory costs and uncertainty, often depend on public R&D support and EU partnership programmes, such as the Circular Bio-based Europe Joint Undertaking (CBE-JU), a public-private partnership supporting sustainable innovation in Europe's bioeconomy (Circular Bio-based Europe Joint Undertaking, 2025[25]).

The scale and pace of the United States and Chinese advances are reshaping the global biotech landscape

The United States retains a leading position in biotech, supported by deep capital markets, an innovation-oriented financial environment and strong university-industry linkages. In 2023, US biotech start-ups raised approximately USD 57 billion, far exceeding totals in Europe and China (Drug Discovery Trends, 2024[4]). Investment is concentrated in clusters such as in Massachusetts and the San Francisco Bay Area. Massachusetts alone hosts more than 1 000 life-science companies and a dense network of investors and specialised service providers.

US biotech leadership also reflects streamlined and predictable regulation. The FDA's expedited designations (Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review) provide developers with rolling reviews, intensive regulatory engagement and fast approval timelines (U.S. Food and Drug Administration (FDA), 2024[26]). These features reduce development frictions and partnering costs, supporting cross-border collaborations between SMEs and larger firms.

China has become an increasingly important partner for pharmaceutical companies in the United States and Europe. By July 2025, Chinese biotechs were involved in 18% of multinational licensing deals (Financial Times, 2025[27]). US drugmakers alone signed 14 China-sourced in-licensing agreements worth up to USD 18.3 billion in the first half of 2025, including 3SBio's USD 6 billion agreement with Pfizer to develop a cancer drug. Other major US pharmaceutical companies (e.g. AstraZeneca, AbbVie, Merck, Regeneron) also announced multibillion-dollar agreements with Chinese partners during the same period (Financial Times, 2025[27]).

China now ranks second globally in commercial trial activity and is rapidly closing the gap in biotech-related intellectual property (IP). Its share of industry-sponsored clinical trials has doubled since 2018 (from approximately 9% to 18% in 2023), while the European Economic Area's share fell from around 22% in 2013 to just 12% by 2023 (Financial Times, 2024[28]). China now accounts for about 10% of global biotechnology patent filings, up from negligible levels a decade ago (Grassano et al., 2024[17]). However, this growth includes a substantial and fast-growing share of bioequivalence studies, which may reflect less innovation-intensive activity.

Chinese biotech firms benefit from structural cost and human capital advantages that are reshaping their role in global innovation networks. Lower wage levels reduce operating costs, while large patient pools, faster recruitment and consolidated hospital networks help keep clinical trial expenses below US or EU benchmarks. The National Medical Products Administration (NMPA) has introduced expedited review pathways and shortened application timelines, accelerating development (Financial Times, 2025[29]). Combined with a research workforce exceeding 2.6 million full-time equivalent (FTE) researchers (Eurostat, 2024[30]) and a steady inflow of internationally trained returnees, these conditions make Chinese SMEs increasingly attractive partners for multinationals.

Nonetheless, several structural challenges continue to limit the broader attractiveness and reliability of China's biotech ecosystem for both domestic and foreign actors. Execution and compliance burdens persist, and foreign IP owners continue to report limited predictability and transparency in IP protection and market access, including in life sciences (European Commission, 2025[31]). Enforcement risks, including counterfeit trade, impose significant costs on IP-intensive sectors such as pharmaceuticals (OECD and European Union Intellectual Property Office, 2025[32]). Concerns also persist around non-discrimination in government procurement and limited transparency regarding state support (World Trade Organization, 2024[33]).

Europe's biotech clusters anchor global competitiveness

Biotechnology activity in Europe is highly **concentrated, with a few regions hosting a critical mass of firms, research institutions and infrastructure.**[3] Key hubs include the United Kingdom's Oxford–

London–Cambridge “Golden Triangle”, Medicon Valley in Denmark and Sweden, and BioValley in the Upper Rhine region of France, Germany and Switzerland. These areas bring together thousands of companies, numerous science parks, and many world-class universities and research institutes. Europe’s biotech landscape is further reinforced by dense clusters and established networks in countries such as the Netherlands and Belgium (e.g. Leiden Bio Science Park, BioWin Wallonia), as well as emerging nodes in cities such as Manchester (Financial Times, 2025[34]).

These clusters attract strategically important FDI–SME collaboration in biotechnology and related fields. Key functions, such as process and scale-up development, Good Manufacturing Practice (GMP)-compliant production, clinical trial operations, and co-development or licensing of new products, are particularly concentrated in these hubs. By co-locating start-ups, academic researchers, scientists and specialised infrastructure, clusters provide both foreign and domestic investors, as well as multinationals and SMEs, with access to facilities, operational capacity and innovation pipelines. These environments encourage collaboration, investment, knowledge exchange and technology transfer across the ecosystem.

Cluster organisations and EU instruments further reinforce these agglomeration effects. By reducing search, coordination and scaling costs, they support a cumulative process of capability upgrading and renewed investment. Cluster organisations – that is, dedicated entities supporting the strategic development of these regional ecosystems – facilitate these dynamics through networking platforms, incubators, investor matchmaking and joint R&D initiatives. At the EU level, policy instruments also promote these mechanisms: the European Cluster Collaboration Platform (ECCP) connects over 1 200 cluster organisations, Joint Cluster Initiatives (Euroclusters) fund cross-border cooperation, while programmes such as ClusterXchange facilitate SME internationalisation (European Commission, 2025[35]).

Box 2. Large and established European biotech clusters

Several European biotech clusters illustrate how FDI and SMEs interact on the ground, shaping regional innovation ecosystems.

BioValley (France-Germany-Switzerland)

BioValley is a tri-national life-sciences cluster centred on the Upper Rhine region, spanning Alsace (France), Baden-Württemberg (Germany), and Northwestern Switzerland around Basel. Established in 1996 as one of Europe’s first cross-border clusters, it brings together more than 700 life-science companies and several dozen research institutions, including major universities and specialised research centres. The region hosts global industry leaders such as Novartis, Roche, Syngenta and Lonza, alongside a dense population of SMEs active in pharmaceuticals, diagnostics and medtech.

BioValley supports technology transfer, start-up creation and international partnerships through a range of cross-border networking and innovation-support initiatives. These include mechanisms linking early-stage firms with private investors and regional funding sources, typically providing access to seed-stage capital. The cluster’s integration across three countries and its world-class academic and industrial base make it a leading destination for foreign investment and a conducive environment for collaborations between SMEs and multinational companies.

Medicon Valley (Denmark-Sweden)

Medicon Valley is a bi-national life sciences cluster spanning Copenhagen (Denmark) and Southern Sweden, including Malmö and Lund. Recognised as the strongest life sciences hub in the Nordics, it hosts more than 500 companies and a deep talent pool of around 60 000 private-sector employees and 15 000 researchers. Anchored by 12 universities, 11 university hospitals, and world-class research infrastructures such as the European Spallation Source (ESS) and the MAX IV Laboratory, the cluster

integrates cutting-edge research with industrial capacity. It is home to leading Danish and Swedish firms, including Novo Nordisk, Lundbeck, LEO Pharma, Ferring, Genmab and Novonesis, as well as major international players like AbbVie, Pfizer and Amgen. Medicon Valley also has the highest concentration of contract development and manufacturing organisations (CDMOs) in Europe, with firms such as AGC Biologics, Fujifilm Diosynth Biotechnologies and Sever Pharma Solutions providing strong linkages between FDI and local SME suppliers.

Between mid-2023 and mid-2024, companies in the cluster raised more than USD 3 billion in financing, much of it from international investors. The region also hosts the highest concentration of contract development and manufacturing organisations (CDMOs) in Europe, creating strong linkages between foreign capital and local SME suppliers. Dedicated incubators, such as the BioInnovation Institute (Copenhagen) and SmiLe Incubator (Lund), nurture dozens of start-ups annually, while the Medicon Valley Alliance (MVA) fosters cross-border collaboration, runs specialised networks (e.g. oncology, microbiome, medtech) and supports SME growth through initiatives like the Life Science Academy for Start-ups. This dense ecosystem brings together world-class research institutions, multinational anchors and dedicated support structures, making Medicon Valley a prominent example of interaction between FDI, SMEs, and global pharmaceutical firms within an international cluster.

Note: This characterisation draws on official information published by the relevant cluster organisations, regional investment and economic development agencies, and major research infrastructure providers, which collectively provide authoritative data on the clusters' structure, scale and activities.
Sources: (BioValley Basel Association, 2025[36]) (BioValley France, 2025[37]) (Medicon Valley Alliance, 2025[38])

Smaller EU countries and regions are also using the cluster model to connect local SMEs to international networks. These platforms expand opportunities for SMEs to participate in collaborative EU projects that explicitly aim to embed them in global value chains and new markets. For example, in Horizon Europe, SMEs account for roughly one-third of participants and over one-fifth of total funding (European Commission, 2024[39]).

Examples in Central and Eastern Europe illustrate how the cluster model is being implemented to strengthen regional ecosystems and lay the groundwork for investment and cross-border collaboration. *Tartu Biotechnology Park* in Estonia provides physical infrastructure, incubation services and business development support, and serves as the national contact point for the cross-country *ScanBalt BioRegion* network (ScanBalt, 2025[40]). In southern Poland, the *LifeScience Kraków Cluster* facilitates collaboration through infrastructure, commercialisation support, Special Interest Groups, and participation in EU initiatives such as EIT Health and CE4BIG (Trade.gov.pl, 2022[41]). In Hungary, the University of Debrecen has established multiple accredited clusters in different industries, including the *Pharmapolis Innovative Pharmaceutical Cluster* and the *Pharmapolis Innovative Food Industry Cluster* (University of Debrecen, 2024[42]). In Romania's North-East region, the bioROne biotechnology cluster, founded in 2011, is active in biotech and pharmaceutical value chains, though still in an early stage of development. A more mature example is the ROHEALTH cluster, established in 2015, which connects companies, universities and public institutions across health and bioeconomy sectors, and actively supports SME participation in international funding programmes and cross-border networks (European Cluster Collaboration Platform, 2025[43]).

These examples illustrate several mechanisms through which clusters mediate the strength and direction of FDI–SME linkages within innovation ecosystems. First, foreign acquisitions or exits are more likely to leave R&D activities and talent embedded locally, supported by dense academic-industry ties, spinout pathways and shared infrastructure. Second, in mature industrial clusters with strong manufacturing capacity, foreign investment often anchors long-term supplier relationships and SME integration, driving demand for process innovation and subcontracting. This can lead to the emergence of

"hidden champions" in local supply chains. Third, smaller or emerging ecosystems can attract strategic FDI by leveraging EU research networks, sector-specific accelerators and digitally connected supply chains that link local firms to global manufacturers and customers, enabling them to "plug into" global innovation value chains, often as testbeds or early adopters. Overall, public policy and cluster governance play a critical enabling role, though their effectiveness depends on institutional density, absorptive capacity and alignment with long-term industrial strategy.

Box 3. Smaller and emerging European biotech clusters

Tartu Biotechnology Park (Estonia)

Based in Estonia's second largest city, Tartu Biotechnology Park (TBP) is a national centre for genetics, biomedicine and digital health anchored by the University of Tartu. The cluster brings together more than 80 organisations, including biotech, health tech and food tech companies, research institutes and laboratories across Southern Estonia. It provides essential infrastructure such as laboratories and offices, incubation services like Sparkup, and business development support ranging from partner-matching to guidance on funding applications. The cluster also fosters visibility and collaboration through initiatives such as Estonian HealthTech Week and targeted market access webinars.

With Estonia's domestic market size limiting opportunities for firm-level scale-up, Tartu has adopted a networked internationalisation strategy. It plays an active role in alliances like ScanBalt BioRegion, EIT Health and EIT Food, which connect it to more than 60 clusters and organisations across the Nordic-Baltic region. Through these networks, local start-ups gain access to EU-funded programmes including Horizon Europe and Interreg, as well as opportunities to engage with international investors and partners. As a cluster located in a small, open economy, Tartu illustrates how public and EU-level support mechanisms can help emerging SMEs build capacity and integrate into global innovation ecosystems.

Sofia Tech Park (Bulgaria)

Launched in 2015 as the country's first large-scale science and technology park, Sofia Tech Park (STP) is located in the capital and anchored by partnerships with the Bulgarian Academy of Sciences and leading universities. Its Biotech and Health cluster brings together early-stage life sciences SMEs, research groups and medtech entrepreneurs. The park offers an incubator programme (South-East European Innovators Programme, SEEIP), laboratory facilities, office space and event venues. Its Lab Complex houses 11 specialised laboratories, covering molecular biology, 3D bioprinting, biopharma and bioinformatics, while the "Discoverer" petascale supercomputer provides advanced computational capacity for bioinformatics and related fields.

Sofia Tech Park also acts as Bulgaria's main entry point into EU-level innovation networks through platforms such as the European Cluster Collaboration Platform, as well as regional initiatives. A major development came in March 2025, when STP, together with the INSAIT institute, was selected to host one of the EU's new AI Factories (Brain++), a EUR 90 million project that will expand its role as a hub for AI applications, with construction planned to start in 2026. This initiative has the potential to position the park at the frontier of AI-driven biotech R&D, from drug discovery to diagnostics, and to attract specialised FDI while creating new opportunities for SMEs. Although still at an early stage compared to Western European hubs, Sofia's biotech ecosystem is beginning to integrate into global value chains, with EU funding, network effects and pilot collaborations with multinationals providing pathways to sustained growth.

Note: This characterisation draws on publicly available information from official cluster organisations, research institutions and EU-level innovation programmes, which provide authoritative data on cluster structures, infrastructure and SME activity.
Source: (Tartu Biotechnology Park, 2025[44]) (ScanBalt, 2025[40]) (Interreg Baltic Sea Region Programme, 2025[45]) (Sofia Tech Park, 2025[46]) (Sofia Tech Park, 2025[47])

Finance and skills gaps still limit growth and push SMEs abroad

Despite growing international engagement, the EU's biotech sector continues to face significant funding gaps. Venture capital raised in the EU remains substantially below US levels, with seed-, early- and later-stage investments in 2024 approximately 80% lower across the board (European Commission, 2025[48]).

Beyond overall volumes, structural features of the European financial system continue to hinder biotech scale-up, including fragmented capital markets and a persistent reliance on debt over equity (European Investment Bank, 2024[19]; Böninghausen et al., 2025[49]; European Investment Fund, 2025[50]). These constraints are compounded by a late-stage financing gap, reflected in the limited size of EU-based venture and growth funds, a shortage of lead investors able to anchor large Series B and C+ rounds, and comparatively shallow public equity markets. As a result, many European SMEs are pushed to seek growth capital abroad (European Federation of Pharmaceutical Industries and Associations, 2024[51]).

Financing biotechnology is inherently challenging due to long, costly and uncertain development cycles. Clinical trials take years and often yield binary outcomes, meaning that a setback or failure can jeopardise an entire project. Regulatory approvals may be slow or unpredictable, adding timing risk. Even when efficacy is proven, scaling production to GMP standards can fail or face delays. Post-approval, reimbursement decisions by health systems can further delay or limit commercial returns. These risks drive investors to favour safer, later-stage assets, leaving many promising early-stage projects underfunded. Bridging this gap requires patient, risk tolerant capital that can support ventures across trials, regulatory review, manufacturing and market access.

Beyond finance, execution capacity and ecosystem conditions are critical to success. While the EU produces a strong supply of researchers (2.15 million FTEs in 2023), translating scientific advances into commercial ventures is often constrained by limited experience in four key execution domains to move ideas to market: clinical development; regulation; manufacturing and quality; and market access (WorkInHealth Foundation & European Investment Fund, 2024[52]). These gaps are compounded by systemic frictions, including uneven university-industry links, varying knowledge-transfer capacity across Member States, fragmented scale-up infrastructure and inconsistent procedures and timelines. Together, these factors increase execution risk and slow progress even when the underlying science is robust.

In response, EU policymakers are deploying measures that combine finance, capacity-building and clearer adoption pathways. On financing, instruments such as the EIC Accelerator, InvestEU and EIF vehicles – alongside reforms under the emerging Savings and Investments Union (SIU) – aim to mobilise more risk-tolerant capital and support cross-border expansion. On capacity building, the EU's "Knowledge Valorisation" guidance and codes of practice promote common approaches to IP management, spin-outs and co-creation between industry and academia. To address scale-up and biomanufacturing bottlenecks, EU actions and shared platforms, such as IBISBA (European Strategy Forum on Research Infrastructures, 2024[14]), are working to expand pilot-to-GMP capacity and reduce fragmentation. For improved market-access predictability, phased implementation of the EU Health Technology Assessment (HTA) Regulation, including Joint Clinical Assessments, seeks to align clinical evidence requirements across Member States.

Complementary efforts aim to strengthen entrepreneurial capabilities and expand the talent pipeline. For instance, the EIT Health Accelerator and related programmes across Europe support biotech, medtech and digital health start-ups by bridging science and business readiness (EIT Health, 2025[53]). The SPARK network, originally modelled on Stanford's SPARK programme and now active in multiple European institutions, provides mentoring and translational support to academic inventors developing therapeutics, diagnostics and medical devices (SPARK Global, 2025[54]). The EU Blue Card Directive (European Commission, 2025[55]) is designed to attract and retain highly qualified non-EU nationals and simplify intra-EU mobility, potentially enabling non-EU graduates and postdoctoral

researchers to join or collaborate with innovative firms and SMEs in sectors such as life sciences. While these instruments are not tailored specifically to biotech or business creation, they contribute to the broader ecosystem supporting talent and entrepreneurship.

The EU's biotech ecosystem is shifting towards more open, collaborative models

A dual dynamic of consolidation at the top and specialisation at the bottom is reshaping the EU's biotech landscape, creating both opportunities and challenges for SMEs. Large-scale mergers and acquisitions, such as AstraZeneca's USD 39 billion purchase of Alexion (Reuters, 2020[56]), reflect a trend towards concentration within a shrinking pool of global firms. While consolidation can open new pathways for partnerships and investment as large incumbents seek to expand innovation pipelines, it also raises scale-up barriers in markets increasingly dominated by a few global players.

At the same time, the sector is undergoing growing technological specialisation, as emerging firms and investors focus resources on subfields such as synthetic biology and advanced cell and gene therapies. Venture activity is increasingly organised around domain-specific capital markets, often supported by specialist funds and accelerators. In this context, experimental policy tools – such as the Digital Sandbox Accelerator piloted by EIT Health in the early 2020s – can help SMEs access biobanks, data infrastructures and regulatory guidance in controlled test environments.

The relationship between large biopharmaceutical companies and SMEs is evolving towards open innovation models. Innovation is now distributed across networks rather than confined within individual firms. Whereas pharmaceutical companies once relied primarily on vertically integrated, in-house R&D, they increasingly manage portfolios of acquisitions, partnerships, licensing deals and co-development agreements. "Emerging" biopharma firms, as defined by IQVIA based on thresholds for R&D spending and prescription-drug sales, now account for over 65% of molecules in active development globally, and the majority of newly approved drugs originate from these smaller players (IQVIA Institute, 2022[57]).[4]

This shift highlights the central role of SMEs as drivers of early-stage innovation, valued for their scientific creativity, agility and risk tolerance. Conversely, large firms provide the capital, regulatory expertise, infrastructure and market access needed to scale and commercialise new technologies. The rise of corporate venture funds and incubators has further institutionalised this partnership model. For instance, dedicated units within multinational companies such as Roche, Novartis and Sanofi now act as intermediaries, connecting start-ups with established players and aligning early-stage investment with corporate strategic priorities, thereby preserving their influence over the direction of technological development. While this model can accelerate translation and scale-up, empirical studies have found that some acquisitions of innovative start-ups by large incumbents can lead to reduced R&D activity and lower patenting by the acquired firms, raising questions about their longer-term effects on competition and innovation pathways (OECD, 2020[58]; Cunningham, Ederer and Ma, 2021[59]).

The growing emphasis on collaboration is also reflected in the evolving role of industry associations. Organisations such as the European Federation of Pharmaceutical Industries and Associations (EFPIA), EuropaBio and CropLife Europe have expanded beyond advocacy to play more operational roles in shaping networks and facilitating participation in cross-border initiatives and global value chains. For instance, EuropaBio's SME platform provides a structured interface between small firms, established industry players and policymakers, supporting knowledge exchange and international visibility. CropLife Europe, while retaining its focus on crop protection, has broadened its agenda to include digital agriculture and plant biotechnology, aligning with emerging priorities around sustainability and innovation.

Public-private partnerships (PPP) have likewise expanded in both scope and ambition. The Innovative Medicines Initiative (IMI), launched in 2008, was Europe's flagship PPP for pharmaceutical R&D (Laverty and Meulien, 2019[60]). Its 2021 successor, the Innovative Health Initiative (IHI), reflects a broader orientation towards cross-sector collaboration, pooling EU and industry resources across biopharma,

medtech, biotech and digital health (Innovative Health Initiative, 2025[61]). These initiatives increasingly engage SMEs, academic institutions and non-European partners in pre-competitive consortia that distribute risk, accelerate knowledge transfer and support regulatory learning. Other programmes such as the European Lead Factory (ELF) – which provided shared compound libraries and screening platforms for early-stage drug discovery between 2013 and 2023 – and the AMR Accelerator – which coordinates research on microbial resistance across public and private actors – illustrate the maturation of the PPP model towards more open, distributed and collaborative approaches (European Lead Factory, 2025[62]; Fernow et al., 2025[63]).

The EU is building a more supportive biotech ecosystem, but complex rules could still deter investment

The EU's policy and regulatory framework is evolving to address internal constraints and respond to intensifying global competition. The European Commission's 2023 *Communication on biotechnology* calls for a more coherent and supportive ecosystem, combining efforts to close financing gaps, reduce regulatory fragmentation and strengthen scale-up capacity. These measures also aim to position the EU more strategically in global biotechnology value chains by attracting capital, deepening international collaboration and aligning innovation with sustainability and security objectives under shifting global conditions.

Funding and incentives are central to shaping the pace, direction and geography of biotech investment at the EU level. Instruments such as Horizon Europe SME schemes, the European Innovation Council (EIC), and the forthcoming Biological Manufacturing initiative under the Strategic Technologies for Europe Platform (STEP) channel resources into biotech production and high-risk ventures. These initiatives support not only start-ups and scale-ups, but also collaboration with international partners.

National strategies and policies play a decisive role in attracting investment. Across the EU, a variety of bioeconomy and health-innovation strategies, tax incentives and support schemes have been introduced. For example, France's *Healthcare Innovation 2030* allocates over EUR 7 billion to health and bioproduction, including dedicated support for biotherapies and biomanufacturing, while Germany's *Bioeconomy Strategy* (2020) offers a whole-of-government R&D and innovation framework guiding federal funding and coordination. Ireland combines start-up grants from IDA and Enterprise Ireland with an R&D tax credit to support firm growth. Other Member States also offer fiscal incentives such as Belgium's R&D Innovation Income Deduction, the Netherlands' WBSO R&D wage-tax credit, and Denmark's enhanced deduction and refund scheme for R&D expenditures.

Efforts to streamline regulation are under way, but complexity persists. Firms continue to face layered procedures, inconsistent national implementation and overlapping compliance obligations that extend time-to-market (OECD, 2025[64]). The EU Clinical Trials Regulation seeks to simplify multi-country approvals and make the EU more attractive as a unified market. The European Medicines Agency (EMA) offers SME-specific support, such as scientific advice and fee reductions, recognising the unique challenges smaller firms face. The phased implementation of the new EU HTA Regulation from 2025, introducing joint clinical assessments for selected medicines, could further improve investment conditions by reducing duplication and increasing predictability in market access. Similarly, the proposed EU framework on "new genomic techniques" (NGT) introduces a two-tier system that could improve predictability around data, timelines and labelling (Council of the European Union, 2025[65]). "Category 1" new genomic techniques (NGT) plants, deemed equivalent to conventional breeding, would follow a simplified notification process and be listed on a public EU register, while "Category 2" plants would undergo proportionate risk assessment under genetically modified organism (GMO) legislation. Recent EU trade agreements also support regulatory alignment by including provisions such as mutual recognition of GMP inspections, notably with the US.

Across the global landscape, numerous jurisdictions have already modernised their regulatory frameworks, often well ahead of the EU's current pace. Countries such as Argentina, Australia, Brazil, Canada, Chile, Japan, New Zealand, the United Kingdom and the United States have introduced product-based or case-by-case approaches for NGTs, typically exempting certain gene-editing plants from GMO legislation where no foreign DNA is present. Many have also accelerated pathways for advanced therapies (e.g. Japan's conditional approval system), streamlined clinical trial approvals (e.g. the UK's combined review model), and simplified rules for environmental field trials, scaling facilities or the approval of low-risk biological products. These reforms have generally created clearer, faster and more predictable routes to development and commercialisation.

IP remains a core consideration for biotech firms and investors. Europe offers strong protections, including 20-year patents and regulatory data exclusivity (of approximately 8+2 years) for new medicines. Ongoing reform of EU pharmaceutical legislation, with new rules expected to start applying towards the end of this decade, may lead to adjusted data exclusivity provisions aimed at encouraging broader market launches across the EU. At the same time, emerging technologies such as AI and gene editing are raising new legal questions; for instance, regarding the ownership and patentability of AI-generated compounds and whether current IP frameworks remain fit for purpose.

Looking ahead, the regulatory treatment of emerging technologies will continue to shape the EU's global competitiveness. In red biotech, this includes AI-driven drug discovery, adaptive trial designs and advanced therapies. In green biotech, the 2023 Commission proposal would exempt certain NGTs from traditional GMO rules where they mimic natural mutations, potentially accelerating approvals by 2027. In white biotech, the European Chemicals Agency (ECHA) is exploring regulatory approaches for bio-based chemicals. How regulators balance safety and innovation will remain under scrutiny, particularly given that the COVID-19 pandemic demonstrated that faster, co-operative pathways are possible when conditions align.

The EU's biotechnology outlook will depend on how effectively new policy tools translate into predictable, timely and scalable support for innovation. Recent measures mark an important shift towards a more coherent framework, yet regulatory complexity and fragmented implementation can still create uncertainty and deter cross-border investment, as suggested by the EU-US gap in biotech venture capital and innovators' concerns about approval timelines. As highlighted in recent OECD analysis, jurisdictions that combine agile, product-focused regulation with de-risking finance instruments tend to attract more private capital and scale emerging technologies (OECD, 2025[64]). Further strengthening the alignment of efforts across finance, talent, regulation and IP could help the EU convert its strong scientific base into global industrial leadership, and reduce the incentives for projects and investment to gravitate towards other ecosystems.

The EU's biotech sector is being reshaped by geopolitics, technological change and societal demands for health and sustainability

Macro-trends are projected to influence the EU's biotech landscape over the coming decades, altering **how SMEs and foreign investors connect.** These include the evolving trajectory of globalisation, the pace and scope of technological change, and the rising societal demand for health and sustainability solutions.

The pursuit of strategic autonomy is challenging the sector's deep global interdependence

Biotech innovation has long been global in reach. Knowledge circulates rapidly across borders, and global challenges such as pandemics or climate change demand international responses. This openness is reflected in trade agreements, cross-border clinical trials and scientific consortia. Large EU programmes like Horizon Europe encourage international participation, while organisations such as the International

Coalition of Medicines Regulatory Authorities (ICMRA) promote harmonised standards that facilitate global drug development.

However, recent geopolitical tensions and the COVID-19 pandemic have intensified concerns about concentrated supply chains in biotech and other strategic sectors. In response, many firms are adopting "China+1" strategies, which involve diversifying production beyond China by establishing operations in alternative locations. Others are adopting "Europe for Europe" approaches, whereby manufacturing intended for the European market is located within it. This has led to new facilities across the EU, such as Moderna's analytical and fill-finish hub in Spain and BioNTech's expanding vaccine manufacturing operations in Germany.

Policy responses in the EU include efforts to boost local production of vaccines and active pharmaceutical ingredients (APIs), as well as to reduce reliance on imported seeds and fertilisers. While these moves may strengthen self-sufficiency, they could also redirect FDI. Some multinational firms may near-shore manufacturing and clinical operations to remain close to the EU market and regulatory framework, whereas others may delay or abandon planned investments if overlapping regulations or subsidy requirements increase complexity and cost.

The EU's ability to attract and retain global talent will be critical for biotech competitiveness**.** International and interdisciplinary teams are associated with higher innovation output, and investors often favour businesses capable of mobilising high-skilled researchers with minimal friction. However, administrative fragmentation, inconsistent recognition of qualifications and uneven implementation across Member States may continue to raise hiring and relocation costs. Moreover, administrative complexity and uncertainty around migration policies may create barriers to talent attraction and retention, while streamlined and predictable regimes could enhance the EU's appeal as a leading destination for R&D and innovation.

Taken together, these dynamics illustrate the tension between the EU's objective of strategic autonomy in critical biotech capabilities and the need to remain open and globally connected. How this balance evolves will strongly influence the nature of future partnerships, investment patterns and innovation flows. Targeted programmes may attract trusted partners and foster co-investment in EU projects, whereas more restrictive approaches could reduce external participation and limit SMEs' access to global opportunities.

Scientific breakthroughs are confronting the hard limits of scalability and governance

Alongside geopolitical forces, technological change is redefining the contours of biotech and opening new avenues for FDI-SME collaboration. Driven by the convergence of AI, synthetic biology and automation, biotech is entering a rapid growth phase of what many describe as a new "S-curve" of innovation. This integration streamlines the Design-Build-Test-Learn cycle, reducing experimental timelines and costs (OECD, 2025[66]). These transformations may expand the sector's potential, positioning agile SMEs as potential partners in global value chains and enabling foreign investors to access emerging applications.

AI is rapidly transforming biotech by accelerating discovery and enabling new forms of collaboration. Beyond identifying promising candidates ("needle-in-a-haystack" problems), Generative AI tools and Large Language Models (LLMs) are now facilitating "biodesign", predicting molecular structures (e.g. AlphaFold) and creating de novo genetic sequences with optimised properties (King, 2025[67]; Mazheika et al., 2022[68]; Merchant et al., 2023[69]). In Europe, a growing cohort of AI-focused biotech start-ups is attracting global investors, including technology funds entering life sciences for the first time (Dealroom.com and MTIP, 2024[70]). Meanwhile, federated cloud-based platforms such as the European Health Data Space are enabling SMEs to collaborate virtually across borders, reducing barriers to international partnerships and investment (European Commission, 2025[71]).

Synthetic biology is opening a new frontier in biotech by making biology programmable. This is increasingly supported by biofoundries; that is, highly automated modular facilities that integrate robotics and AI to democratise access to high-throughput experimentation (OECD, 2025[66]). Globally, the field is attracting significant investment as a general-purpose technology with implications for health, agriculture, industry and climate.

The future of biotech is becoming increasingly data-driven, with access to large, high-quality datasets emerging as a key competitive differentiator and a driver of cross-border collaboration. However, robust AI models require a steady "data supply chain" (OECD, 2025[66]). In red biotech, initiatives such as the "1+ Million Genomes" coalition and the UK Biobank are critical for overcoming data fragmentation. In green and white biotech, progress relies on agricultural, environmental and industrial datasets to improve processes and measure sustainability outcomes. Robust and interoperable data governance will be essential to build trust, clarity and investment-readiness.

While these technological advances offer transformative possibilities, their full impact remains uncertain. Potential bottlenecks include a shortage of multidisciplinary talent capable of navigating both biology and computer science, as well as evolving biosecurity concerns regarding "dual-use" applications. Furthermore, cost reductions may occur more slowly than anticipated, manufacturing yields may fall short, and ensuring consistent product quality and performance during scale-up can be challenging. Similarly, some technologies may fall behind if others prove more effective, safer or more affordable to develop and scale.

Furthermore, societal acceptance and regulatory frameworks do not always evolve at the same pace as scientific and technological developments. For example, governance of gene-edited crops in the EU continues to be shaped by long-standing public concerns (European Parliamentary Research Service (EPRS), 2021[72]). Similarly, cultivated proteins such as cultured meat, while progressing rapidly in terms of technical development, have yet to be authorised for the EU market (European Parliament Research Service (EPRS), 2024[73]). Biotech's next wave of innovation is underway, but its trajectory will be shaped as much by scientific breakthroughs as by governance capabilities, external risks and enabling conditions, without which investment and research may stall or shift elsewhere.

Demographic and climate shifts drive robust demand expectations, but regulatory timing and social license remain uncertain

Market demand and societal megatrends are powerful long-run drivers of biotech investment. Demographic change is foremost: people aged over 65 already account for more than one-fifth of the EU population and this proportion is expected to rise to nearly one-third by 2050 (Eurostat, 2020[74]), fuelling sustained demand for medicines, diagnostics and care technologies. Meanwhile, climate change and environmental awareness are driving growing consumer and business demand for sustainable biosolutions, which could save up to 2.5 billion tons of CO2 equivalent per year by 2030 by replacing fossil-based products (European Commission, 2025[75]). In agriculture, farmers face pressure to reduce chemical inputs, creating rising demand for bio-based fertilisers, biostimulants and microbial crop technologies. Together, these demand-side forces are broadening biotechnology's scope from healthcare into industrial and environmental applications.

The EU's policy frameworks increasingly position biotech within a broader industrial and sustainability agenda. The Clean Industrial Deal, together with the new Strategy for a Competitive and Sustainable EU Bioeconomy, emphasise the contribution of bio-based solutions to a circular and climate-neutral economy. Financial norms are also evolving, with the EU Sustainable Finance Taxonomy and broader ESG requirements helping to steer capital towards activities that demonstrate clear societal and environmental value. This is reflected in the growth of ESG-labelled assets in Europe and the expansion of green and sustainability bond markets. At the same time, green finance markets are gradually expanding their offer of SME-oriented instruments, reinforcing the potential for smaller biotech innovators to benefit

from sustainability trends (OECD, 2025[76]). However, ongoing simplification efforts and the recalibration of sustainability rules introduce uncertainty about timing and scope.

The "social license to operate" remains a decisive variable. In Europe, the biotech sector still carries the legacy of public resistance to GMOs, which contributed to restrictive regulation and slowed the deployment of certain biotechnologies. Public sentiment, however, is differentiated: medical and pharmaceutical applications tend to benefit from higher levels of trust, and growing environmental concerns are fostering greater openness to certain bio-based solutions. At the same time, skepticism around agri-food applications remains strong. As more complex innovations, from precision fermentation to NGTs, move from lab to market, their adoption will depend heavily on whether businesses and policymakers can build long-term trust.

These transformations are not only reshaping the sector's innovation landscape, they are also changing global value chain configurations and investment patterns. FDI, particularly through greenfield projects and cross-border mergers and acquisitions, provides a concrete lens through which to assess these shifts. FDI trends highlight how countries and regions position themselves in the global biotech race, how value is distributed across manufacturing and R&D activities, and which ecosystems are most successful in attracting and retaining international capital. The following section presents a quantitative analysis of the role of FDI in the biotech sector, focusing on structural trends, regional patterns and implications for the EU and other OECD economies.

The role of FDI in the biotechnology sector

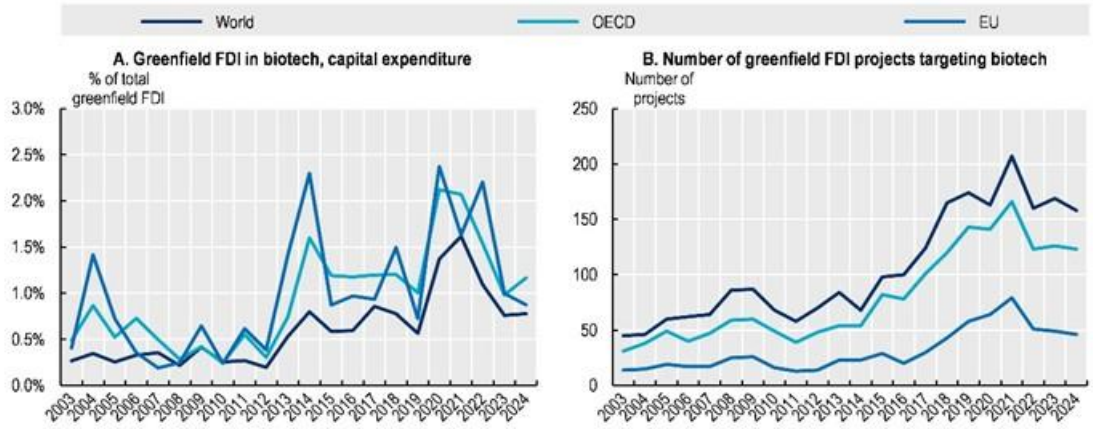
The biotechnology sector attracts less than 1% of global greenfield FDI, but its relevance has increased over the last decade

Greenfield FDI in the biotechnology sector has increased since 2003, peaking during the COVID-19 pandemic and accounting for almost 1% of total greenfield FDI in recent years. Between 2003 and 2024, biotechnology's share of total global greenfield FDI (i.e. the establishment of new foreign companies or the expansion of existing ones) rose from 0.27% to a peak of 1.62% in 2021 (Figure 1, Panel A). This increase was driven largely by the COVID-19 pandemic, which increased the demand for biotechnology, underscoring the strategic importance of the sector. Most of the growth came from investment in non-diagnostic biological products, which accounted for 87% of greenfield FDI in biotechnology. However, investment in in-vitro diagnostic substances also grew significantly in the early stages of the pandemic. The expansion was led by increased manufacturing and R&D activity, as firms responded to urgent demands for innovation and production capacity. The number of biotechnology projects rose from 45 in 2003 to a high of 207 in 2021, before declining to 158 in 2024 (Figure 1, Panel B). In the same year, capital expenditure in biotechnology represented around USD 10 billion, equivalent to 0.8% of global greenfield FDI and spread across 158 projects.

Biotechnology has become a relatively more prominent area of greenfield FDI in both the OECD and the EU, outpacing global trends. Figure 1 shows that even before the COVID-19 pandemic, the biotech sector accounted for a larger share of total FDI in these regions than elsewhere. The post-pandemic rebound was particularly strong, with biotechnology's share rising from 1.01% to 2.12% in the OECD and from 0.73% to 2.37% in the EU between 2019 and 2020 (Figure 1, Panel A). This sharp increase reflected strong public investment to expand manufacturing capacity, advanced R&D capabilities, and the strategic focus on health-related industries. However, in both the OECD and EU steady growth in biotechnology FDI is recorded since the early 2000s, with particularly strong momentum between 2013 and 2022. The EU outperformed the OECD average in several of these years, peaking in 2014 and again during the pandemic. By 2024, however, the sector's share had declined to 1.17% in the OECD and 0.87% in the EU, returning to pre-pandemic trends (Figure 1, Panel A).

Figure 1. The biotechnology sector accounts for almost 1% of total global greenfield FDI

Greenfield FDI in biotechnology, capital expenditure as a share of total greenfield FDI and number of projects

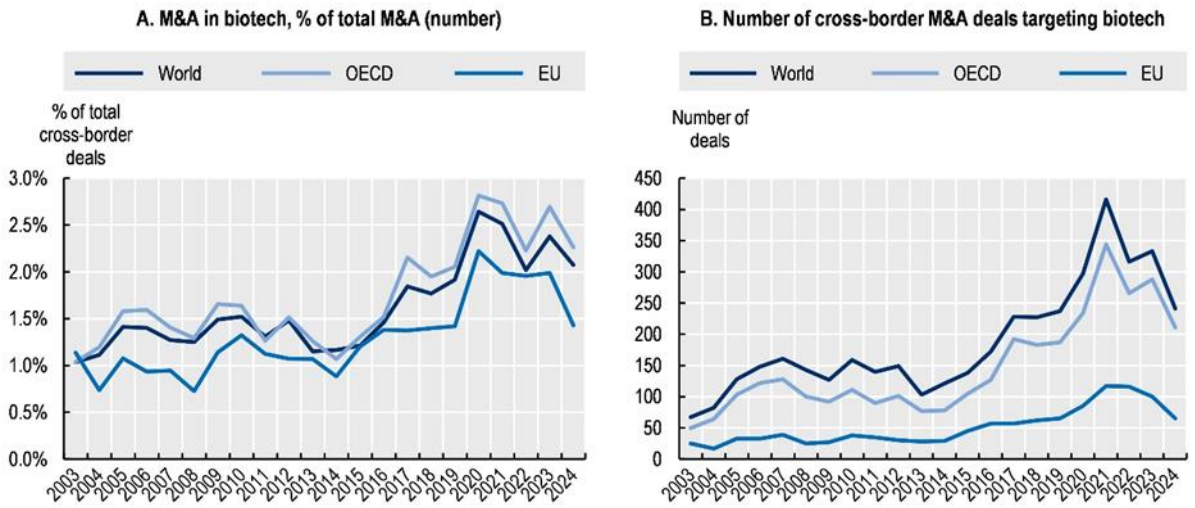


Source: OECD based on (Financial Times, 2024[77])

Cross-border M&A activity in the biotech sector has also experienced a significant upward trend worldwide, representing almost 3% of all M&A deals in 2020-2024. Starting from modest levels in the early 2000s, deal numbers increased steadily through the 2010s, with a notable acceleration from 2016 onward. This growth culminated in a peak during 2021, when global deals reached 416, with 344 in the OECD and 117 in the EU, more than triple their 2003 levels (Figure 2, Panel B). This surge aligns with the COVID-19 pandemic, which drove investor interest and cross-border consolidation. Biotech's share of total M&A also rose significantly during this period, peaking in 2020 at 2.6% globally and 2.8% within the OECD, compared to just around 1% in the early 2000s (Figure 2, Panel A). Post-COVID, while the number of deals has declined from their 2021 highs, they remain well above pre-pandemic levels, suggesting a structural shift in the sector's role within global M&A. The EU, while showing growth, has lagged in both absolute deal numbers and share gains, indicating more modest cross-border integration or possibly tighter regulatory conditions. Overall, the pandemic acted as a catalyst, accelerating longer-term trends in biotech consolidation, particularly in the OECD, and reinforcing biotech's strategic importance in the global M&A landscape.

Figure 2. Cross-border M&As in biotech have expanded in the aftermath of the COVID-19 pandemic

Cross-border M&A deals in the biotechnology sector, % of total cross-border M&A (Panel A) and number of deals (Panel B)



Source: OECD based on (LSEG Refinitiv Database, 2025[78])

High-profile M&A deals have driven M&As growth during the last decade. M&As enable firms to quickly access new technologies, enter strategic markets, and diversify their operations. This mode of entry has become central to industry growth during the COVID-19 pandemic, with many firms shifting from specialised expertise to managing a portfolio of activities across different segments (McKinsey & Company, 2021[79]). High-profile deals such as Pfizer's acquisition of Seagen (USD 43 billion), AstraZeneca's purchase of Alexion (USD 39 billion), and Amgen's acquisition of Horizon Therapeutics (USD 27.8 billion) illustrate the dominance and strategic value of M&A in recent years. In the aftermath of the pandemic, the wider investment environment began to shift. Several countries reviewed restrictions on cross-border investment in health and other strategic sectors. The pandemic also accelerated the trend toward investment screening, particularly among EU member states and other OECD economies (OECD, 2020[80]). Venture capital became a key source of funding during this period, helping to fill financing gaps and support innovation. While the post-pandemic surge has eased, venture capital remains a major driver of early-stage biotechnology development (McKinsey & Company, 2023[81]). However, greenfield investments play a distinct role in supporting local employment, transferring knowledge, and enhancing innovation ecosystems in host countries.

Box 4. Measuring FDI in the biotech sector

Biotechnology is not classified as a standalone industry in major statistical systems such as ISIC or NAICS, making sector-specific measurement difficult. In ISIC, biotechnology-related activities are classified across pharmaceutical manufacturing, R&D, and agriculture-related categories, while NAICS provides a dedicated code for biotechnology R&D but classifies production and service activities under broader pharmaceutical or life sciences industries.

To address these gaps, the OECD uses a functional definition of biotechnology based on key techniques (Friedrichs and van Beuzekom, 2018[5]) and encourages firm-level surveys to capture biotech activity across sectors.

Consequently, internationally comparable biotechnology statistics often rely on surveys, patents, or project-level datasets rather than official sectoral statistics.

This lack of a dedicated industry classification also affects the measurement of foreign direct investment (FDI). Official FDI statistics are reported at broad manufacturing or services levels, preventing the isolation of biotechnology-specific investment trends.

To approximate biotechnology-related FDI, this paper combines two complementary data sources:

- Greenfield FDI data capture the establishment of new facilities or the expansion of existing ones, including production plants, R&D centres, and commercial subsidiaries. These data shed light on new market entry, investors' long-term commitments, and control over local operations, but are based on announced projects rather than realised flows and cannot be disaggregated by biotechnology subsector (e.g. red, white, green).
- Brownfield FDI data (mergers and acquisitions) capture cross-border equity purchases or reinvestments in existing firms, enabling rapid access to markets, technologies, and talent pools, especially in mature biotechnology hubs. However, M&A data seldom provide detailed classification of biotech activities, limiting their usefulness for granular analysis.

Overall, measuring FDI in biotechnology remains challenging due to the absence of a dedicated statistical category and the inability to break down data by subsector. Combining greenfield project information with M&A data offers only a partial but valuable picture of foreign investment dynamics in the sector.

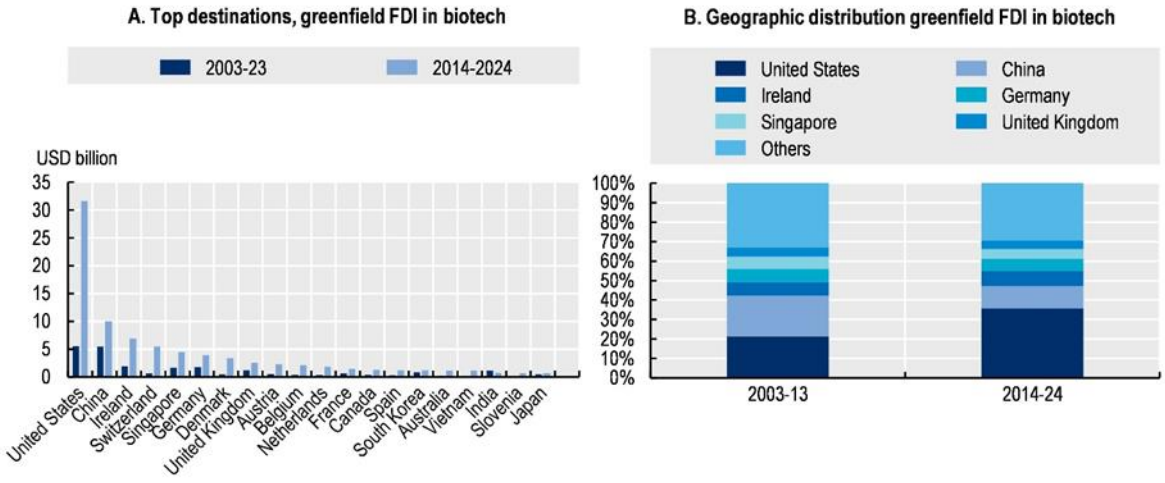
Biotech greenfield FDI is concentrated in a few countries, but its distribution has shifted over the past decade

The United States, the EU, and China have remained the three largest destinations for biotechnology greenfield FDI during the last two decades, although their relative shares have shifted significantly. Between 2003 and 2024, the United States attracted 31% of global biotech FDI, followed by EU Member States (28%) and China (13%). The United States and China were the top two destinations in both 2014-2024 and 2003-2013 (Figure 3, Panel A). However, over the last decade, China's share fell from 20% in 2003-2013 to 11% in 2014-2024, while the US share increased from 20% to 35% (Figure 3, Panel B), receiving USD 32 billion of the USD 92 billion announced worldwide. The EU's aggregate share remained stable at 28%, although the distribution within the bloc shifted. Countries such as Austria, Belgium, Denmark and Switzerland, recorded notable gains.

Despite the continued dominance of a few destinations, investment in biotechnology has become less geographically concentrated. The share of greenfield FDI to the sector declined from 88% in 2015 to 74% in 2024. The COVID-19 pandemic contributed to this diversification, prompting projects in new markets. Canada and Singapore, in particular, attracted investments in the first two years of the pandemic. Biotech FDI in Canada rose from USD 7 million in 2019 to USD 390 million in 2021, while Singapore saw an increase from USD 7 million to USD 330 million over the same period (Figure 3, Panel A).

Figure 3. The United States alone accounts for more than one third of total biotech greenfield FDI

Greenfield FDI in biotechnology, by destination, 2003-2013 and 2014-2024



Source: OECD based on (Financial Times, 2024[77])

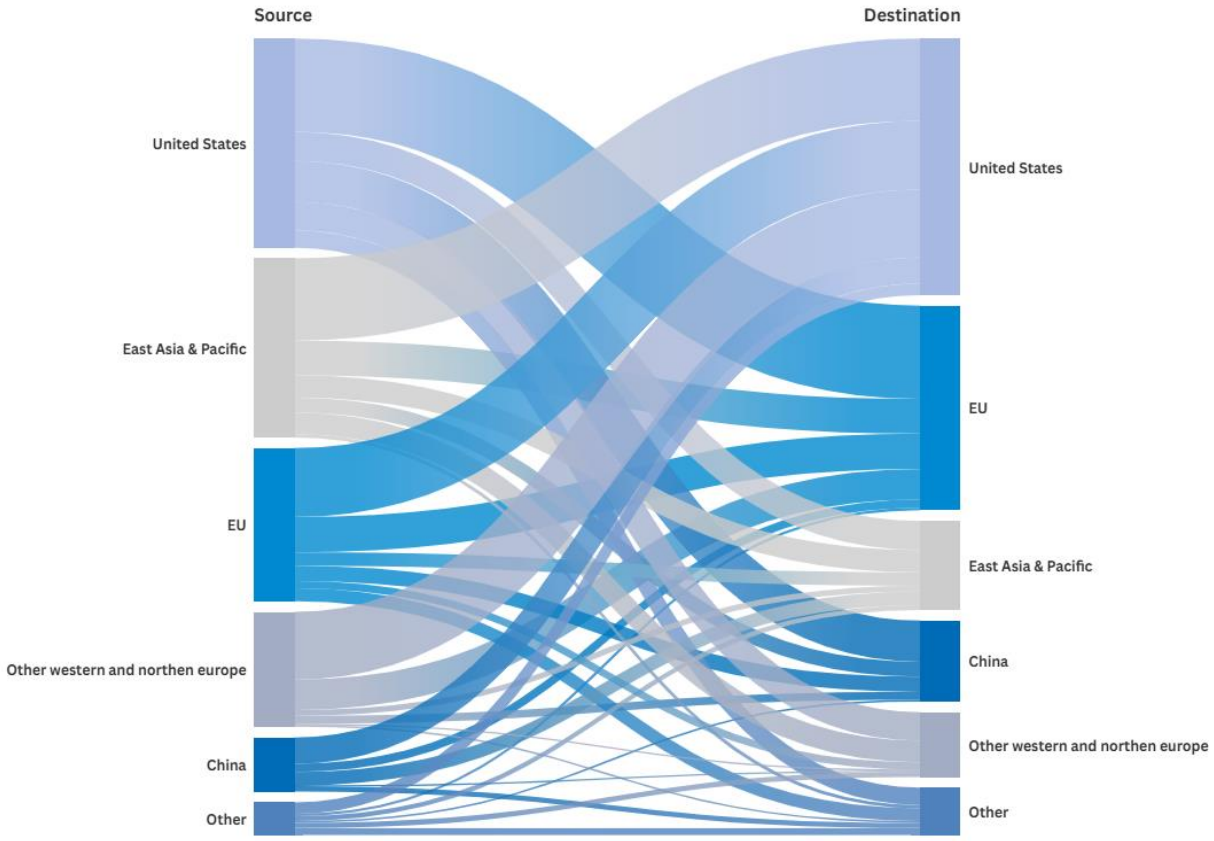
The United States has long been a leading source of greenfield FDI in the biotechnology sector. Between 2003 and 2013, it was the dominant investor, accounting for approximately USD 11 billion in announced projects. The United States was followed by investors from Europe and Central Asia. During 2014–2024, the United States remained a key player, announcing more than USD 25 billion and accounting for around 28% of total announced investment (Figure 4).

However, companies based in East Asia and the Pacific have emerged as a major source of greenfield FDI in the biotechnology sector, accounting for 31% of global greenfield FDI in 2014-24 (Figure 4). Firms from East Asia and the Pacific announced almost USD 30 billion in new projects, led by Japan, China, and Korea. China alone accounted for about 7% of global biotech FDI. This marks a sharp increase from 2003-13, when East Asia and the Pacific contributed less than 8% of global biotech FDI, with around USD 2 billion announced, well behind the United States and Europe.

Regional value chains remain significant across all regions, with nearly 14% of greenfield biotech FDI staying within the investor's region. Nevertheless, North America, driven by the United States' role as a global biotechnology innovation hub, has been the main destination for investors from all other major regions (Figure 4). In most cases, either East Asia and the Pacific or North America is the leading source of biotech FDI inflows. The EU is the top source for the Middle East and North Africa region.

Figure 4. Investors from East-Asia and North America dominate greenfield FDI in biotechnology

Greenfield FDI in biotechnology, by source and destination country/region, USD billion, 2014-2024

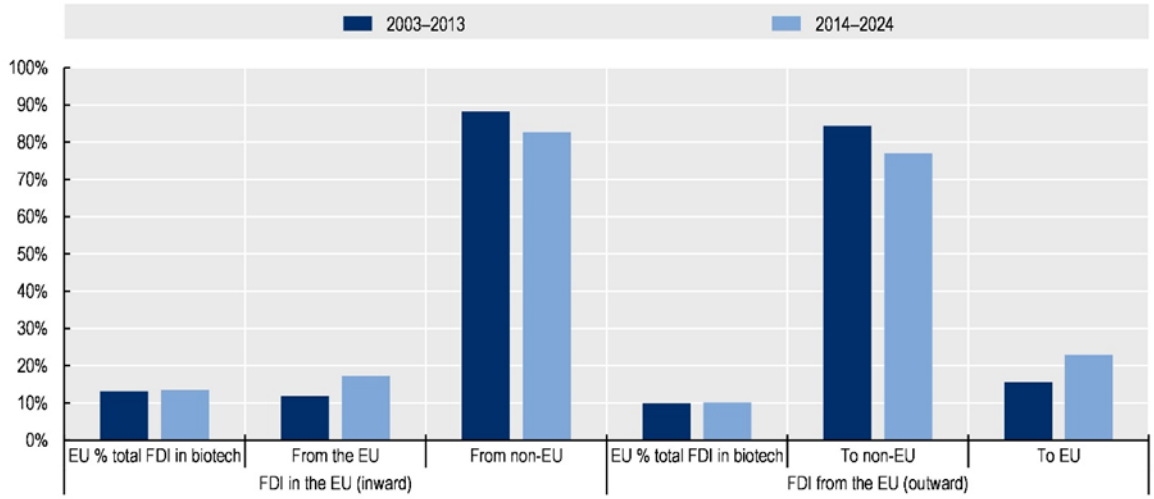


Source: OECD based on (Financial Times, 2024[77])

More than 20% of EU greenfield FDI were directed toward the internal market in 2014-2024. While the share of biotechnology in total EU FDI has remained broadly stable over the past two decades, at around 10% of both inward and outward flows, EU investors are showing a growing preference for other Member States (Figure 5). Between 2014 and 2024, 23% of greenfield FDI announced by EU companies was located within the EU, up from 16% in 2003-2013. A similar pattern is seen on the inbound side. EU Member States are receiving a greater share of investment from within the bloc: the proportion of inward greenfield FDI originating from other EU countries rose from 12% in 2003-2013 to 17.3% in 2014-2024 (Figure 5). Nonetheless, extra-EU investors still account for about 80% of total greenfield FDI. The United States remains the largest external source, accounting for 46% of biotech FDI announced in the EU in 2014-24, followed by Brazil (25%) and Japan (15%).

Figure 5. The internal market is playing a growing role for EU investors

Outward and inward EU greenfield FDI, % of total greenfield FDI in biotechnology, 2003-2013 and 2014-2024



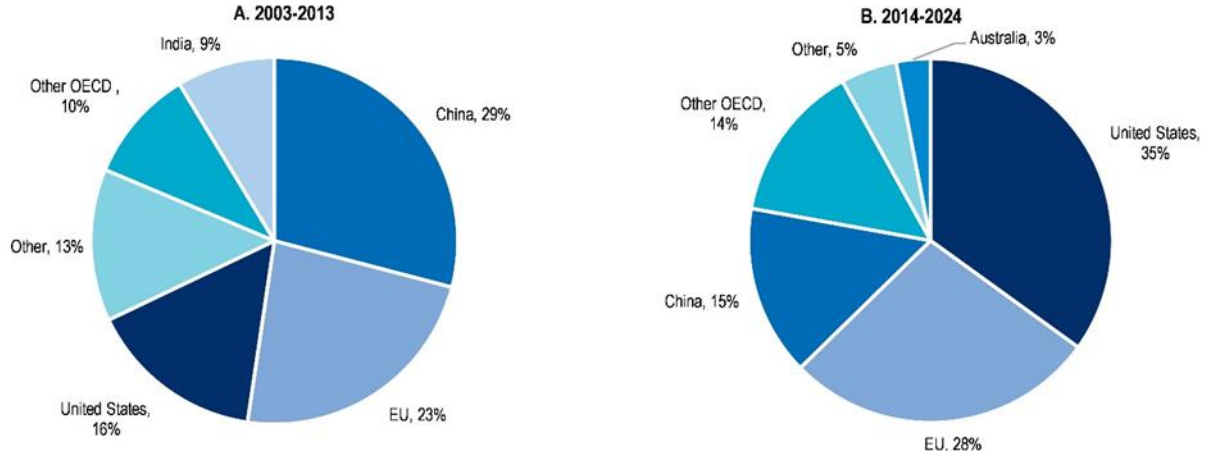
Source: OECD based on (Financial Times, 2024[77])

Biotechnology greenfield FDI can be a strong driver of innovation, but the impact depends on the host country's value chain positioning

Biotechnology greenfield FDI has been strongly anchored in innovation, with 23% directed to R&D activities during 2014–2024. Biotechnology announcements into R&D have been mainly concentrated in OECD countries, which accounted for 78% of total R&D investment between 2014–24, an increase compared to 58% in 2003-2013. The OECD increase was largely driven by R&D investment in the United States, which alone accounted for 35% of FDI in R&D in 2014-2024 (Figure 6). The EU also increased its share of global biotech R&D FDI over this period, though more modestly, from 23% to 28% (Figure 6). It is not surprising that most R&D investment targets OECD countries, and particularly the United States, as these economies have long been leaders in innovation and remain key hubs for research capacity, talent, and advanced infrastructure. However, the global landscape is diversifying, with new actors gaining importance. OECD economies still hold a dominant but declining share of global biotechnology patents, falling from 97.0% in 2001 to 81.5% in 2021. This decline has been driven mainly by reductions in the shares of the United States (from 43.5% to 37.2%) and Japan (from 14.0% to 9.5%). At the same time, non-OECD economies are increasing their role in innovation, most notably China, which expanded its share of global biotechnology patenting from 3.8% to 14.2% between 2011 and 2021 (OECD, 2025[82]).

Figure 6. OECD countries account for 78% of biotech greenfield FDI in R&D activities

Biotechnology greenfield FDI in R&D activities, by source country, % of total biotech R&D investment

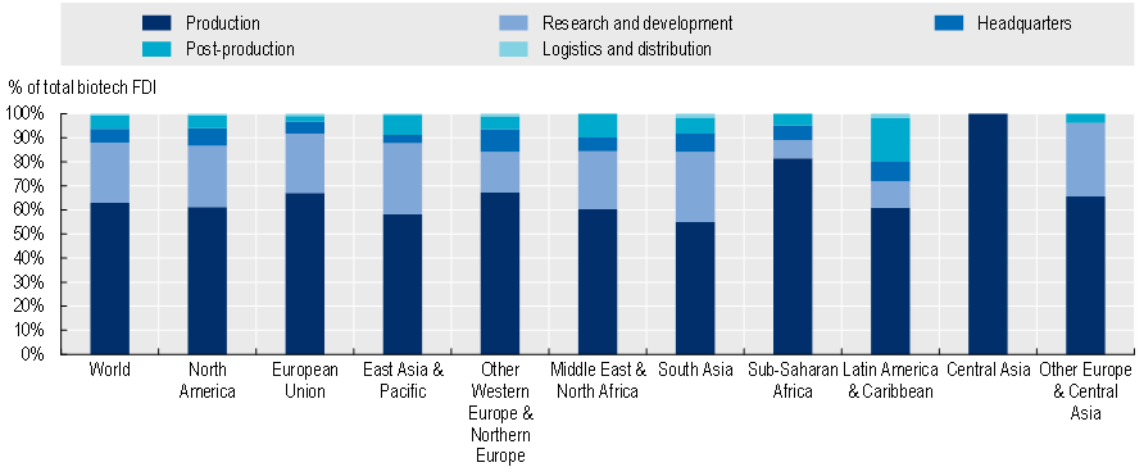


Source: Based on (Financial Times, 2024[77])

While greenfield FDI in the biotechnology sector remains predominantly concentrated in core production activities, differences exist across regions. From 2014 to 2024, core production activities accounted for no less than half of greenfield FDI in biotechnology across all regions (Figure 7). However, the share of R&D-oriented FDI was generally higher in regions where stronger innovation ecosystems, skilled talent pools, and established research infrastructure supported such investment. For example, East Asia & Pacific recorded the highest R&D share (29%), with North America and the European Union also reporting relatively high levels (25% each) (Figure 7). In contrast, many developing regions showed a much smaller proportion of biotech greenfield FDI in R&D, as investment often focused on scaling manufacturing capacity or meeting local market needs rather than advancing innovation. R&D accounted for only 8% of projects in Sub-Saharan Africa and 11% in Latin America & the Caribbean, and was absent in Central Asia, where investment exclusively targeted production activities.

Figure 7. More than 50% of biotechnology greenfield FDI targets production-core activities

Biotech greenfield FDI, by value chain activity and world region, % of total biotech FDI, 2014-2024



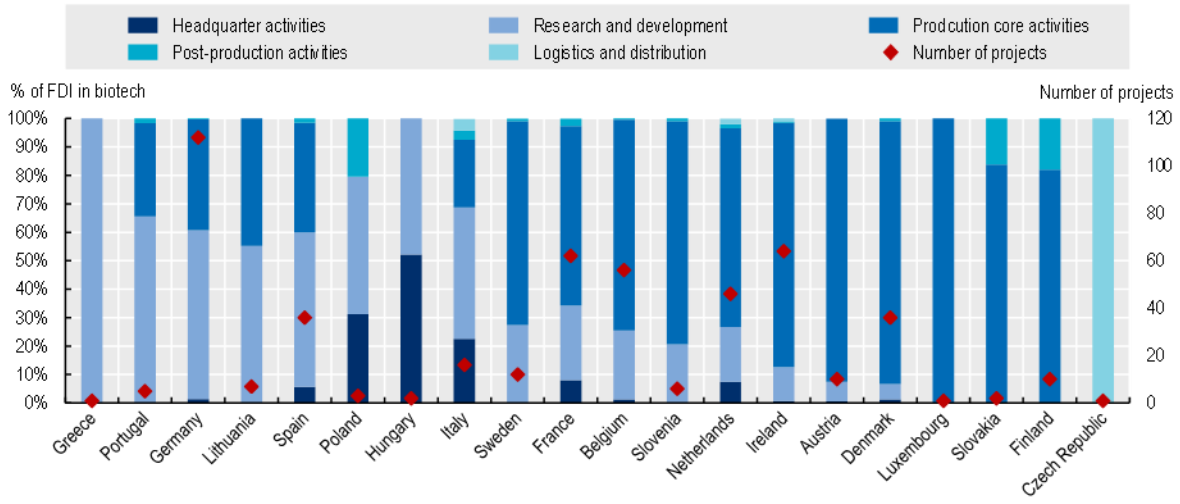
Note: Regions are ordered according to the total capital expenditure they received in the biotech sector in 2014-2024.
Source: Based on (Financial Times, 2024[77])

Countries face varying challenges and opportunities in leveraging FDI to strengthen their positioning in the biotechnology value chain. Outcomes depend on the stage of industry development, the technological sophistication of the economy, and the size of domestic or regional markets. Additional factors such as the availability of skilled labour, the quality of the innovation system, and the capacity of the domestic supplier base, including SMEs, also play a critical role. Together, these elements shape investor decisions on where to establish biotechnology manufacturing, conduct R&D, and provide related services such as sales, marketing, and customer support.

In the EU, biotech greenfield FDI patterns showed marked variation in the role of R&D relative to other activities. In 2014-2024, some countries, including Portugal (66% of biotech FDI in R&D), Germany (59%), and Lithuania (55%), stood out for the strong focus of FDI on innovation (Figure 8). Others, including Italy and Poland, displayed a more balanced profile, with substantial investment in R&D complemented by notable production and post-production activity. By contrast, in much of Northern and Western Europe, FDI was concentrated in production, with relatively modest R&D shares, as in Sweden (27%), France (26%) and Belgium (24%) (Figure 8). Ireland, Austria and Denmark recorded minimal R&D investment, reflecting a stronger specialisation in manufacturing. A few member states, including Luxembourg, Slovakia, Finland and the Czech Republic, reported no biotech R&D investment, with activity focused entirely on production, post-production or logistics (Figure 8). These patterns illustrate the diverse roles EU countries play within the biotech value chain, ranging from R&D hubs to manufacturing and downstream service centres.

Figure 8. Biotech greenfield FDI in the EU reflects country-specific roles along the biotech value chain

Greenfield FDI in biotechnology, by value chain activity, EU countries, 2014-2024



Source: Based on (Financial Times, 2024[77])

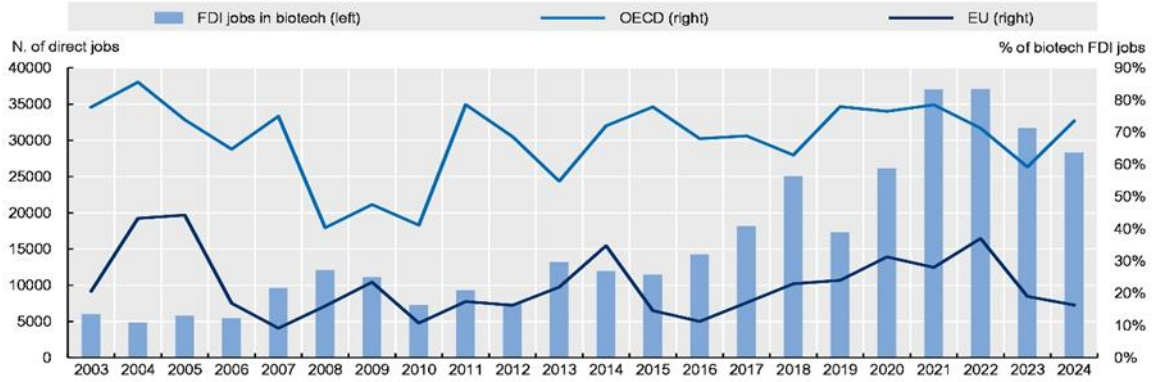
Greenfield FDI in biotechnology can contribute to the creation of high-skilled jobs

Between 2014 and 2024, biotechnology greenfield FDI generated almost 130 000 jobs globally, with employment increasingly concentrated in advanced economies. OECD countries accounted for over 71% of these jobs, and the EU alone accounted for about one-quarter (Figure 9). Although biotechnology represents a relatively small share of total greenfield FDI-related job creation (0.5% globally, 1% in the OECD and EU), it often generates high-quality, knowledge-intensive employment as many positions within the sector require advanced expertise in areas such as molecular biology, bioinformatics, and regulatory

science. Between 2014 and 2024, almost 60% of biotech greenfield FDI direct jobs in OECD and EU economies were created in manufacturing activities and almost 17% in research and development.

Figure 9. More than 70% of biotech greenfield FDI jobs were generated in OECD countries

Greenfield FDI jobs in biotechnology, number of jobs (left) and share of total biotech jobs (right), 2003-2024



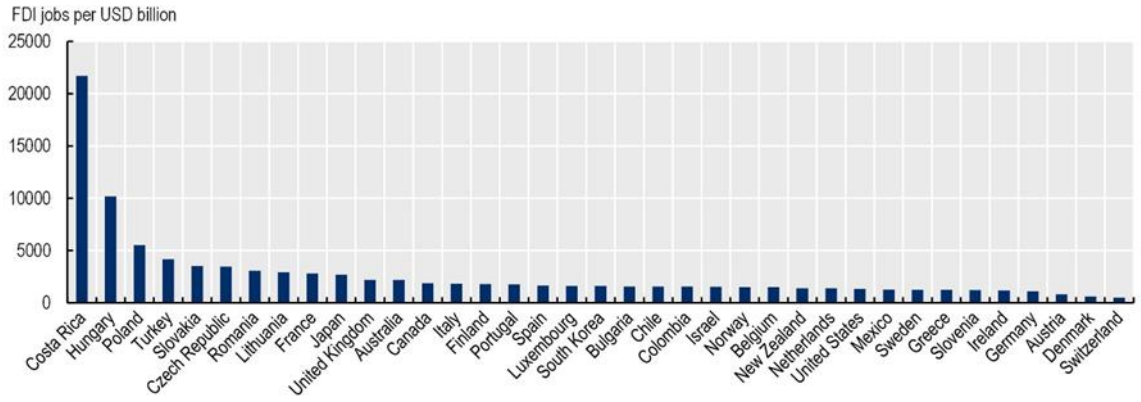
Source: Based on (Financial Times, 2024[77])

Beyond direct job creation, biotechnology FDI may also deliver important indirect impacts. Foreign investors often engage local firms and institutions through supply chains, research partnerships, and clinical trial networks. These linkages support the transfer of knowledge and technology, encourage skill development, and can raise local firm productivity. In regions with strong research and innovation systems, such spillovers may strengthen domestic capabilities and reinforce the broader life sciences ecosystem. Moreover, the sector itself generates substantial indirect employment effects, magnifying the impact of each direct job created. Estimates from a study prepared for EuropaBio illustrate that the biotechnology sector directly employs around 223 000 people in the EU and the UK and supports an additional 710 500 jobs through indirect and induced impacts (Haaf and Sale, 2025[21]).

To understand how biotech greenfield FDI may shape labour market outcomes, it is equally important to examine the job creation potential of foreign investment projects. The intensity of direct job creation from foreign investment projects varies widely across countries. Between 2014 and 2024, biotech greenfield FDI generated an average of 1 300 jobs per USD billion invested, below the OECD cross-sectoral average of 1 900 jobs (Figure 10). This may reflect the capital- and knowledge-intensive nature of biotechnology, where high-technology activities tend to rely on smaller numbers of highly qualified workers (OECD, 2022[83]).

Figure 10. Biotech greenfield FDI generated an average of 1 300 jobs per USD billion invested across OECD countries

Job intensity of greenfield FDI, number of jobs per USD billion invested, OECD and EU countries, 2014-2024

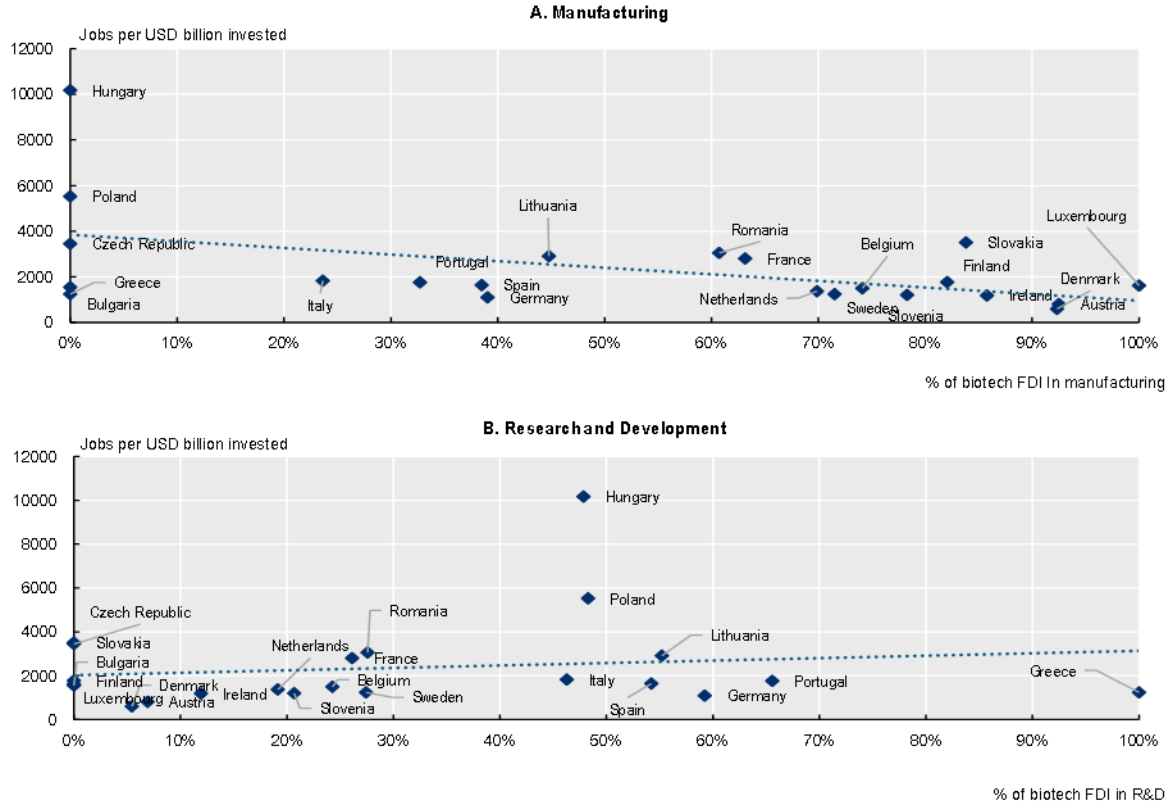


Source: Based on (Financial Times, 2024[77])

Disparities in job creation intensity can be explained by variations in the value chain activities targeted by investors. These activities range from R&D and headquarters activities at the beginning of the product lifecycle to manufacturing, marketing, training, logistics or maintenance and servicing. As these activities differ in their labour intensity, investments within the biotech sector have a different job creation potential depending on the value chain segment that is targeted. The characteristics of the biotech sector in host economies and countries' integration into biotech GVCs are important determinants in this context. On average, R&D-related FDI in biotech tends to be more labour-intensive and create proportionally more jobs, while biotech manufacturing FDI relies more on physical capital and automation, resulting in fewer jobs per dollar invested. These trends are clear in the EU, where countries attracting a larger share of R&D-intensive biotech FDI tend to generate more jobs per unit of investment, as seen in Hungary and Poland, where close to half of biotech FDI was directed into R&D and job creation intensity was among the highest in the EU. By contrast, countries where biotech FDI is concentrated in manufacturing, such as Austria, Denmark, or Ireland, recorded much lower job creation intensity, reflecting the capital- and automation-intensive nature of production activities.

Figure 11. R&D-related FDI tends to be more labour-intensive and create proportionally more jobs

Correlation between biotech FDI in manufacturing (Panel A) and R&D (Panel B) and number of direct FDI jobs in the biotechnology sector per USD billion, EU countries, 2014-2024



Source: Based on (Financial Times, 2024[77])

3 Foresight scenarios for the EU biotechnology sector

In the foresight exercises, the two most consequential drivers of change for red and green biotech were identified as the degree of globalisation and the pace and scale of technological progress (see Box 5 for a detailed description of the methodology). These dimensions form the axes of the scenario matrix, producing four coherent yet contrasting futures. This structured framework enables decision-makers to evaluate how these subsectors might evolve and to test the robustness of EU policies under varying conditions.[5]

Box 5. Exploring plausible futures for EU biotechnology through strategic foresight

Objectives and context

This section draws on insights from a foresight workshop, desk research and interviews with experts to explore the future of the biotech sector and its implications for FDI-SME linkages across the EU. Convened in Paris in June 2025, the workshop brought together a diverse group of representatives from international organisations, national governments, investment promotion agencies, business networks and academic institutions. The discussions centred on red and green biotech (see Box 1.1 for definitions), examining the forces and trends set to reshape their global value chains. Looking ahead to 2040, the analysis considers how these shifts could influence investment flows, SME performance and emerging policy priorities across the EU. While the scenarios consider global trends, they are anchored in the position of the EU biotech sector and examine how Europe may advance, keep pace with or fall behind leading regions.

What is strategic foresight?

Strategic foresight is a structured method for scanning the horizon, identifying early signals of change and exploring how these could reshape the future. Its goal is not to predict or forecast what will happen, but to open thinking about what could happen. By adopting a 2040 time horizon, the workshop considered how short-, medium- and long-term shifts might disrupt current trajectories and create new pathways. In an increasingly complex and fast-moving world, strategic foresight equips policymakers to anticipate a range of futures, enabling them to design institutions and policies that are resilient, adaptive and fit for uncertainty, not just for what seems most likely.

Why red and green biotech?

Red and green biotech stand out as subsectors particularly suited to strategic foresight. Both are critical in the delivery of public goods (such as public health, food security, and environmental sustainability) and closely aligned with EU strategic priorities. Yet, they also operate in volatile environments, marked by scientific breakthroughs, evolving regulations and the constant threat or promise of disruption.

Method

To explore the long-term and distant future, the workshop employed scenario planning, a well-established and widely used method in the foresight toolkit. Unlike other approaches, scenario planning is explicitly exploratory, helping to structure thinking and visualise multiple plausible futures. It begins with a provocative question – "what if?" – and develops divergent narratives about how events might unfold. By juxtaposing these narratives, scenario planning challenges assumptions and expand the range of options that decision-makers must consider, particularly regarding the EU's position in global biotech value chains.

Scenario planning begins by identifying two critical uncertainties that are likely to shape future developments. These drivers are mapped onto a 2x2 matrix, with each axis representing opposing extremes. The resulting four quadrants define distinct scenarios, each describing a plausible future that may reveal risks, opportunities and strategic considerations that predictive or normative approaches might overlook. In this case, the matrix looks ahead to 2040, while also integrating near-term developments that could accelerate or alter these trajectories.

Workshop participants split into two breakout groups – one for each subsector – to build and discuss the four scenarios. They examined implications for FDI, SMEs and EU policy, among other sectoral implications. The workshop followed the Chatham House Rule, which encourages open dialogue by ensuring that comments and contributions are not attributed to specific individuals or organisations.

These scenarios are not forecasts but tools to stretch strategic thinking. They help inform forward-looking policies and strategies that can be implemented now or phased in over the next decade. The goal is not only to prepare for multiple futures, but to help shape them by fostering the right conditions and incentives for innovation and investment aligned with EU priorities. This demands attention to the deeper forces reshaping the biotech landscape.

Globalisation, both in its scope and direction, will be a decisive factor in the evolution of the biotech sector. As a structuring force of the global economy, it shapes how capital, talent, technology, goods and services flow across borders. Shifts in trade policy, investment regimes, data governance and mobility can either deepen integration or fracture markets, profoundly influencing FDI-SME dynamics. Recent geopolitical tensions and evolving public attitudes towards free trade and migration underscore how fluid and consequential this variable has become.

Equally important is the pace and scale of technological progress. Technological innovations can spark new markets, reduce costs and drive productivity, but may also widen gaps if only large companies can keep up with scale and compliance demands. Slower technological progress, conversely, may favour incremental improvements and broader adoption among SMEs. In the scenarios that follow, "fast" and "slow" technological progress refer mainly to the relative speed at which red and green biotechnologies diffuse, scale and are adopted in the EU compared with leading global regions. These developments hinge not only on science but on finance, regulation, infrastructure and public trust, all of which influence the transition from laboratory to market.[6]

The next subsections apply strategic foresight to red and green biotech. Each subsector is examined through the lens of the four scenarios and structured around three analytical layers. *Key trends* outline possible contextual shifts and sector dynamics. *Sectoral implications* explore the potential impacts on businesses, investors, regulators and other stakeholders. *Policy considerations* identify possible responses, including short- and longer-term measures that could guide EU actions.

Red biotechnology

Scenario 1: High technological progress, high globalisation

Key trends

In this scenario, the EU could operate in a world where scientific progress and international openness reinforce one another. New medical and pharmaceutical techniques may emerge rapidly, and open global markets might support their swift diffusion. Research, clinical trials and manufacturing could be increasingly organised across borders. Regulators may reduce duplication by recognising one another's decisions, while international standards could facilitate the movement of products, data and skills. These developments might shorten and make more predictable the path from laboratory to patient for new medicines, tests and therapies.

International research partnerships may become more common. SMEs could benefit from shared laboratories and production facilities, working alongside larger firms and universities. Investment pools might deepen as venture capital and corporate investors syndicate across borders, offering more reliable exit opportunities. Larger contract research and manufacturing providers may expand, enabling SMEs to scale by "renting" infrastructure. However, expectations might also rise: health systems could demand stronger evidence and sustainability standards might increasingly influence product design.

Data governance could serve as the system's connective tissue. Secure and interoperable data spaces, aligned with international norms, may enable reuse of evidence across jurisdictions. Regulators might accept "real-world" data from outside clinical trials, while common taxonomies for outcomes and traceability could reduce costs and uncertainty. With easing geopolitical tensions, global standards bodies might regain traction, and plurilateral agreements could lower trade barriers for medicines and therapies.

Sectoral implications

Patients might see faster access to new treatments and broader opportunities to take part in international clinical trials. Pooled data and evidence across borders could improve regulatory decisions. However, fairness and equity concerns may intensify. As advanced therapies expand, health systems might need to ensure affordability and guard against a "two-speed" Europe in which some Member States and under-served populations lag behind.

SMEs may find new opportunities, but also face greater pressure. Access to international partners, shared infrastructure and high-quality data might grow, yet competition could intensify and compliance demands increase. Skills shortages in areas such as manufacturing quality and regulatory science might become a constraint. SMEs combining scientific strength with disciplined operations (e.g. quality systems) might scale successfully, while others risk being squeezed between faster multinationals and well-financed mid-caps.

Larger firms could build global R&D and production networks, and may increasingly seek to shape international standards (for data, quality and safety) to reduce transaction costs. Investors might favour scalable and resilient models. Regulators, payers and hospitals would need to enable faster approvals while managing risks. Coordination challenges may persist, including SMEs' equitable access, public trust in cross-border data use, and timely reimbursement decisions.

For society, ethical governance becomes a competitive advantage. Transparent data-use practices, robust cybersecurity and public engagement on the use of genetic and health data are needed to maintain legitimacy and avoid backlash that could slow innovation. Governments and industry are likely to increase investment in secure digital infrastructure and harmonised privacy frameworks that go beyond compliance to strengthen public trust. Bioethics also comes to the fore, as debates over gene editing, personalised

therapies, and AI-guided diagnostics call for inclusive dialogue to reconcile technological progress with societal values.

Policy considerations

To keep Europe's red biotech sector open, dynamic and safe while ensuring fast diffusion of innovation, the EU could pair near-term supports with longer-term reforms. In the near term, compliance helpdesks might guide SMEs through ethics approvals, clinical trial activation, and regulatory or export requirements. Public reference assets, such as standard trial templates, sample datasets and libraries of operating procedures, could help lower entry costs. Shared or leased facilities (e.g. manufacturing suites, quality-control laboratories, access to regulatory expertise) may allow SMEs to scale without heavy fixed costs.

Over the medium term, Europe could expand master protocols and multi-country clinical trial networks, and co-fund shared pilot manufacturing and testing facilities with explicit SME-access conditions. Blended-finance tools, such as guarantees, convertible loans and revenue-based instruments, might underwrite first commercial runs and help SMEs secure production capacity. Talent bottlenecks could be addressed through fast-track visas, industrial PhDs and aligned curricula in areas such as manufacturing and regulatory compliance.

Structural reforms may be needed to build durable long-term advantage. Priorities could include trusted, interoperable health-data spaces, harmonised risk-tiered approval pathways, broader reliance agreements for inspections and quality systems, and joint clinical assessments within the EU. Policy options to encourage SME participation in standards development and to promote local linkages could include reserved SME access to shared pilot or GMP facilities, co-funded training and upskilling initiatives, joint testing and quality systems with larger firms, and transparent partnership or procurement criteria that value SME involvement. These approaches might help ensure that inward FDI and public support generate broader benefits across local ecosystems.

Policymakers might strengthen public trust and innovation by advancing data-sharing frameworks that are transparent, interoperable, and aligned with public expectations. Key elements include clear safeguards for privacy and security, consistent standards across Member States, and mechanisms for citizen engagement to maintain social license. Targeted support can also help SMEs meet compliance requirements without creating disproportionate administrative burdens.

Taken together, these approaches suggest how high technological progress and high global integration could serve as a springboard for EU leadership in red biotech. By anchoring discovery and regulatory expertise in the EU, scaling production through trusted international partnerships and delivering measurable patient outcomes – such as faster treatment times, improved survival and quality of life, and fair access across Member States – public investment can build and sustain long-term trust in the EU's biotech ecosystem.

Scenario 2: High technological progress, low globalisation

Key trends

Rapid scientific progress in red biotech could continue, but it might unfold within increasingly fragmented health economies. Rising geopolitical tensions, supply-chain disruptions and sovereignty concerns may lead governments to prioritise domestic control over openness. Export restrictions, investment screening and nationally focused procurement could become more common. Regulatory standards and data rules might diverge by region, making it harder to move evidence, products and services across borders. Scientific capability might advance, but approvals, inspections and data requirements would likely remain less portable, raising the fixed costs of international operations.

Europe could respond with mission-oriented, state-backed research and investment programmes aimed at strengthening capacity closer to patients. Public procurement and long-term contracts might support local biomanufacturing and diagnostic testing. This could attract talent back to Europe and help build resilience in critical capabilities. However, without strong coordination inside the EU, these investments might risk creating duplication of infrastructure, fragmented datasets and inconsistent rules across Member States. Policies designed to reinforce sovereignty may unintentionally lengthen timelines and limit knowledge spillovers.

Sectoral implications

For patients, new therapies might become less accessible even across Europe. Diverging rules for approvals, health technology assessment (HTA) and reimbursement could mean that patients in some countries gain faster access while others wait longer. Data-localisation requirements and limited recognition of evidence generated abroad may slow learning and raise evaluation costs. Hospitals and clinical networks might face higher administrative burdens when national processes are not aligned, making multi-country studies more difficult to coordinate. As a result, advanced therapies could reach different populations at varying speeds, with inconsistent monitoring and oversight once in use.

For firms and investors, both opportunity and friction might increase in parallel. SMEs may benefit from local pilot projects, procurement opportunities and targeted grants, yet might struggle to secure permits, inspection slots or skilled staff. Multinationals and mid-caps may need to duplicate compliance processes and production footprints across regions while relying more heavily on local suppliers to sustain quality and cost control. Investors may favour staged, co-funded deals linked to regulatory or procurement milestones, as traditional exit routes might narrow.

Academic institutions and clusters could specialise at the regional level, sharpening comparative advantages. However, without EU-level coordination, this might lead to under-used infrastructure and duplication. With appropriate frameworks, such specialisation could support complementary centres of excellence that share facilities, data and expertise across borders; for example, through joint platforms for clinical trials or GMP-scale manufacturing. FDI might help address capability gaps, particularly if policies encourage SME participation and local knowledge transfer through incentives or requirements for local partnerships, training and shared facilities.

For innovation ecosystems, fragmentation could reduce opportunities for cross-border collaboration and knowledge exchange. Clinical data and trial results might be less likely to circulate internationally, making it harder for SMEs and researchers to build on global evidence. Clusters could become more inward-looking, with less exposure to international competition and weaker incentives to scale internationally.

For the workforce, demand might grow for regulatory specialists, quality assurance professionals and manufacturing talent able to meet divergent national requirements. Training could become more localised, with qualifications and curricula increasingly shaped by domestic rules. Cross-border mobility of experts could be constrained by inconsistent compliance regimes, slowing the diffusion of best practices.

Policy considerations

In the near term, the completion of the Single Market would represent a priority. One-stop regulatory and health technology assessment (HTA) helpdesks might guide SMEs through complex procedures. Publishing service-level targets for approvals and inspections could increase predictability. Outcome-based procurement pilots, rather than prescriptive technical specifications, may reduce fragmentation. Standard templates for intellectual property and data collaboration, together with simplified reporting and predictable fees, can ease administrative burdens. Where cross-border data sharing is constrained, trusted EU-level data spaces with strong privacy protections might preserve validation and monitoring capacity.

Over the medium term, the EU could expand EU-wide clinical trial networks and co-fund pilot manufacturing and testing facilities with clear SME access rules. Blended-finance tools, such as guarantees, convertible loans and revenue-based instruments, might bridge the scale-up gap, supported by predictable offtake or value-based contracts. Skills bottlenecks could be addressed through academies, mobility schemes and industrial PhDs in manufacturing and regulatory science.

At a structural level, Europe might seek greater coherence through mutual recognition of inspections, quality systems and traceability. Shared centres of excellence could pool scarce equipment and expertise, while pooled procurement of critical inputs might reduce costs and strengthen supply security. FDI regimes could remain open, complemented by support instruments that foster knowledge transfer and SME integration into local value chains (for example, through collaborative R&D projects, workforce training and upskilling programmes).[7] In the longer run, EU-level training and mobility schemes for critical biotech skills might be reinforced through common curricula and mutual recognition of qualifications. Support for cross-border apprenticeships, short-term exchanges and digital training platforms could help ensure that expertise continues to flow even in a more fragmented regulatory environment.

Taken together, these options treat high technological progress under low globalisation as a potential opportunity for the EU to build resilience and leadership from within. Preserving Single Market coherence, anchoring critical research and production capacity in the EU, and encouraging public and private investments that generate spillovers for SMEs and patients alike could help strengthen internal capabilities. Progress might be reflected not only in faster and fairer access to therapies across Member States, but also in sustained trust and in keeping options open for future reintegration into wider global networks.

Scenario 3: Low technological progress, low globalisation

Key trends

In this scenario, red biotech would evolve in a world of prolonged geopolitical tension, recurrent crises and entrenched protectionism. Cross-border trade in health products might contract, data flows could become increasingly localised, and international agreements on standards or mutual recognition may be rolled back. Public budgets might shift away from frontier research towards preparedness and continuity of essential services, while private capital could recede. With fewer international clinical trials and limited access to global research platforms, breakthrough pipelines may stall. Health systems might prioritise reliable, low-complexity solutions and local manufacturing basics over advanced therapies.

Within Europe, policy could become more inward-looking as Member States emphasise security of supply and cost containment. Procurement nationalism may raise barriers to shared capacity, and clinical research networks could become increasingly fragmented. Evidence generation might be siloed as cross-border data use is restricted. Hospitals could face rising administrative costs, with limited interoperable standards to ease the burden. Talent mobility may narrow, worsening geographic mismatches between where specialised skills exist and where they are most needed. Without strong EU-level coordination, expensive equipment could be duplicated, utilisation might fall, and the scale advantages of the Single Market could erode.

Sectoral implications

For patients and health systems, access may depend increasingly on local capacity rather than EU-wide networks**.** Availability of essential medicines and basic diagnostics could improve where procurement is managed effectively, but novel therapies may reach markets unevenly or not at all. Divergent standards across Member States raise evaluation costs and weaken monitoring of safety and

effectiveness. Equity gaps widen as some fiscally constrained economies struggle to maintain capabilities, while patient participation in research narrows as multi-country trials decline.

For policymakers, a sustained focus on national resilience may become costly and less efficient over time. Maintaining parallel stockpiles, production lines and emergency infrastructure absorbs significant public budgets, diverting resources from frontier research. This could reduce the EU's capacity to compete globally on innovation and create a path-dependence that proves difficult to reverse.

For the EU's innovation ecosystem, fragmentation could erode competitiveness. As development pipelines slow and clinical trial participation declines, the EU risks losing ground to regions that maintain larger and more coordinated markets for innovation. Limited sharing of evidence and international benchmarks may increase uncertainty for investors, discouraging risk-taking and the scaling of new technologies.

For firms and investors, opportunities may cluster around maintenance and incremental services rather than breakthrough innovation. SMEs could pivot towards quality-control, equipment servicing and low-risk digital tools, but margins may remain thin and working capital stretched. Start-ups focused on advanced therapies might face long and uncertain pathways, leading some to shut down or relocate. Larger firms may narrow their global R&D footprints to focus on securing supply for local markets. FDI could continue to play a role, especially in basic manufacturing, but without policy incentives to promote knowledge transfer and local linkages (e.g. supplier development, workforce training), it risks creating enclaves with limited local benefit. Academic institutions and clusters might specialise narrowly, with less knowledge exchange or staff mobility, causing capabilities to erode over time.

Policy considerations

In this constrained environment, a central policy priority would be to secure essential services while maintaining the coherence of the Single Market. Governments could publish procurement playbooks centred on outcomes such as faster diagnostic turnaround and predictable release-to-patient timelines, enabling SMEs to compete on performance rather than navigate fragmented technical rules. Regulatory helpdesks could support approvals, compliance and ethics processes, while simplified procedures for low-risk uses could reduce administrative burdens. Shared and leased facilities could lower fixed costs for SMEs and hospitals, and baseline interoperability across Europe could be preserved through common standards for traceability, identifiers and quality systems, supported by open operating procedures and reference datasets.

Over time, policy could shift to building shared capacity and reinforcing local resilience. Municipal or cluster-level pilot facilities, pooled metrology services and regional laboratories could give SMEs access to infrastructure otherwise out of reach. Public finance could play a stabilising role, with working-capital and guarantee facilities smoothing cashflows, and targeted support to upgrade and adapt existing infrastructure to maintain high safety and reliability standards. Long-term service contracts and advanced market commitments could secure provision of essentials, with training and supplier-development obligations attached to ensure spillovers to SMEs and hospitals. Workforce redeployment programmes could allow staff to move between operations, maintenance, compliance and regulatory roles, while industrial PhDs help retain talent.

At a structural level, Europe could invest in preserving a minimum viable research and regulatory base while preparing for future reintegration into global networks. Regional centres of excellence could be networked to avoid duplication and share scarce expertise. Investments could prioritise essential, decentralised capabilities (such as basic biomanufacturing and diagnostic infrastructure) and promote circular supply models for critical inputs, including measures to reuse, recycle and locally source key materials. Modular, leased equipment could reduce capital intensity and obsolescence risk. Minimal trusted data spaces could be maintained to enable safety monitoring and portability of evidence, ensuring that systems can reconnect quickly when conditions improve. Pooled procurement and template contracts

could help stabilise prices and guarantee SME participation, while EU-wide interoperability frameworks could be refreshed regularly to prevent internal fragmentation.

Taken together, these measures would treat a low-tech, low-globalisation environment not as an endpoint but as a period of resilience-building and risk management. By keeping the Single Market coherent, securing access to essential services and preventing the erosion of core capabilities, Europe could preserve the foundations needed for future recovery. The task would not be to chase breakthroughs under adverse conditions, but to maintain equity of access, sustain SMEs through shared infrastructure and predictable contracts, and avoid irreversible capability loss. If Europe succeeded in delivering tangible improvements in reliability, safety and fairness, it would be better positioned to pivot back to a more dynamic innovation trajectory when external conditions ease.

Scenario 4: Low technological progress, high globalisation

Key trends

In this scenario, global markets for health products, services and data would remain open and rules-based, yet the pace of scientific progress in red biotech could remain modest. High costs, technical complexity and political caution around advanced therapies may dampen breakthrough pipelines. Regulators and health technology assessment bodies might default to conservative pathways, which would slow the uptake of novel modalities. As a result, most value creation could come from incremental improvements such as biosimilars, smarter diagnostics, better delivery mechanisms and more efficient manufacturing processes. Contract development and manufacturing organisations might expand their capacity for established technologies, while advanced know-how is often imported. Public funding may shift away from frontier research towards diffusion, prioritising affordability and reliability over high-risk bets.

Open trade and investment might continue to channel capital into the EU, but primarily for market access and operations rather than discovery. Multinationals could concentrate their research in regions of the world where costs are lower and approvals are faster, while maintaining European footprints for manufacturing, distribution and servicing. International clinical trials may persist, but they would likely reinforce existing technologies. Data could move more freely across borders, but it might be used mainly for monitoring and cost-effectiveness assessments rather than for generating new scientific insights.

Sectoral implications

The immediate benefits could be tangible but bounded for patients and health systems. Broader access and affordability might improve as biosimilars and efficiency gains spread, while predictable approval processes may provide stability. Yet, without breakthroughs, public health impact might remain limited in areas with unmet medical needs. Over time, the opportunity cost could grow. Negotiations between payers and suppliers might focus on incremental improvements rather than transformational outcomes, and fewer high-impact therapies may originate in Europe. Hospitals and clinical networks could optimise operations but might rarely host frontier trials, reinforcing a cycle of incrementalism.

Incentives might reward operational excellence rather than discovery for firms and investors. SMEs could find steady demand for services such as compliance, quality assurance, validation and digital integration, but margins might remain thin and competition could intensify. Startups pursuing advanced therapies may face long timelines and weak exit options, often pivoting to safer niches like retrofits or integration. Multinationals might maintain European production capacity but shift early-stage R&D elsewhere, while investors may concentrate on low-risk, scalable models and consolidation strategies. Linkages from foreign investment to local SMEs could focus mainly on supplier upgrading and service contracts, with limited knowledge spillovers. Talent might increasingly follow opportunities abroad, leaving Europe with strong compliance and operations but weakening research pipelines.

Over time, the EU could risk being seen primarily as a service and manufacturing hub rather than an innovation leader. This could affect bargaining power in global partnerships, reduce attractiveness for frontier talent, and limit influence in shaping international standards. The cumulative effect may weaken Europe's ability to respond to future scientific or public health opportunities. Clusters and research networks could increasingly specialise in operational excellence rather than scientific discovery**.** While efficiency and reliability might improve, the lack of breakthrough projects would likely reduce opportunities for cross-fertilisation of ideas, spinouts, and new business models. SMEs may remain trapped in low-margin niches, limiting long-term growth and scaling potential.

Policy considerations

In the short term, policy may centre on diffusion and predictable compliance. Navigation hubs could help SMEs manage recurring filings, clinical approvals and payer-evidence requirements. Grants and vouchers might reduce the cost of certification and quality upgrades, while reference datasets and template procedures could limit duplication. Public procurement could be used strategically, with outcome-based tenders so firms compete on performance without being locked into specific technologies. Regulatory sandboxes for low-risk improvements might lower evidentiary costs and speed adoption of incremental upgrades.

Over the medium term, attention could turn to unblocking the pilot and demonstration stage, which remains a bottleneck. Funding top-ups for incremental upgrades in production settings, paired with blended-finance tools such as guarantees or convertible loans, might help SMEs reach first commercial runs. Uptake could be supported through long-term contracts and anchor customers, particularly in diagnostics or sterile production. Skills programmes that rotate staff across operations, quality assurance and scale-up roles may address bottlenecks in compliance and production capacity.

In the longer term, the EU may seek to modernise its industrial base while keeping the Single Market coherent. Standardised, modular equipment, supported by leasing and shared-asset models, could reduce capital intensity and obsolescence risk. Shared services for metrology, quality control and regulatory science in regional clusters might lower fixed costs for SMEs. Real-world testbeds could help translate incremental innovations into practice. Preserving interoperability in traceability, identifiers and quality systems may sustain scale advantages. FDI could remain open and play an important role in strengthening domestic capabilities. Targeted policy measures and incentives might encourage local linkages by supporting workforce training, promoting supplier-development initiatives and facilitating SME access to manufacturing capacity.

These dynamics suggest an open but incremental pathway for red biotech in the EU. Openness to trade and investment may secure access to capital, talent and markets, while operational efficiency and high standards remain comparative strengths. However, without renewed efforts to support technological innovation, the EU risks becoming primarily a service and compliance hub rather than a driver of breakthroughs. The challenge ahead may be to use openness to maintain patient access and systemic resilience, while laying groundwork for a future return to frontier innovation.

General assessment for red biotechnology

The four scenarios sketched for red biotech outline contrasting futures shaped by two fundamental uncertainties: the levels of technological progress and globalisation. Each scenario reveals different strengths and vulnerabilities for the EU's red biotech sector, especially with respect to SMEs, investment flows and the coherence of the Single Market.

Table 1. Alternative futures for the EU's red biotech ecosystem

Summary of core conditions, opportunities and risks

	Low Globalisation	High Globalisation
High Technological Progress	**Scenario 2: Strong science amid fragmented global conditions** • Bloc-based rules drive local capacity near patients, supported by public finance and procurement. • Duplication, siloed data and higher compliance costs limit scale efficiencies. • SMEs benefit from pilot and procurement opportunities, but scale-up is constrained by divergent approvals and uneven demand.	**Scenario 1: Rapid innovation with open cross-border exchange** • Cross-border trials, interoperable data and shared manufacturing shorten time to patient. • The EU leverages research depth, market scale and regulatory credibility. • Risks include SMEs being squeezed by intense competition and rapid technology turnover.
Low Technological Progress	**Scenario 3: Stalled innovation under low integration** • Cross-border trials and investment decline; focus shifts to security of supply and basic services. • SMEs pivot to maintenance, retrofitting and contract support; patient access varies by national capacity. • A central challenge is avoiding irreversible capability loss in research, regulation and production.	**Scenario 4: Openness without major breakthroughs** • The EU remains embedded in trade and investment networks; innovation is slower and incremental. • Emphasis shifts to biosimilars, diagnostic upgrades and operational efficiency. • SMEs find steady demand in compliance and quality services, but risk becoming a service or manufacturing base for others' discoveries.

Across all four futures, several cross-cutting lessons emerge. First, the coherence of the Single Market is a critical foundation. Whether the world is open or fragmented, Europe's internal integration determines whether SMEs can scale, investments generate local benefits and strengthen regional ecosystems, and patients benefit evenly. Second, SME inclusion is essential for system health. If smaller firms retain access to trials, manufacturing slots, data spaces and procurement, ecosystems remain dynamic; if not, consolidation can erode innovation. Third, capability preservation matters in every scenario. Even in difficult conditions, investments in skills, regulatory science, shared infrastructure and trusted data must continue, as they form the basis for recovery when external conditions shift.

Taken together, the four scenarios show that the EU's strategic choices are not just about predicting which future will emerge, but about shaping how the system responds under different conditions. The immediate priority is to secure access, fairness and trust across Member States; the long-term imperative is to keep options open for a return to frontier leadership. In every pathway, the ultimate measure of success will be whether red biotech delivers tangible benefits for patients while sustaining a vibrant, competitive and resilient European ecosystem.

Green biotechnology

Scenario 1: High technological progress, high globalisation

Key trends

In this scenario, the global economy might remain open and rules-based, while biotechnology accelerates due to advances in synthetic biology, AI-enabled design, and modular plant bioprocessing. For instance, synthetic biology platforms could allow the rapid reprogramming of crops, drastically reducing fertiliser needs, and AI-driven protein design might be used to engineer enzyme cocktails allowing crops to tolerate drought, high salinity, or fungal infections.

Trade, investment and talent mobility could intensify, enabling the EU to participate actively in international R&D networks, standard-setting organisations and value chains. For example, Europe could engage in global plant-genome editing consortia and contribute to open-source seed banks, while helping to shape standards for GMO and CRISPR-based crops. Europe's position could strengthen through its large agri-food Single Market, its strong research base in plant molecular biology, and agile policies that could shift emphasis from the laboratory to the field, accelerating cross-border trials and commercial deployment of crops.

This trajectory could be supported by easing international tensions, which might allow for greater regulatory reliance and mutual recognition of biotech crops. For example, a wheat variety edited for climate resilience in one European country could be certified and exported to other continents without duplicating approval processes. Non-tariff barriers could be reduced, allowing soil, crop, and biotech trial information to circulate safely and efficiently across borders.

Major economies might pursue ambitious bio-economy strategies, expanding global markets and collaboration opportunities for engineered microbial fertilisers, bio-remediating plants, and next-generation GM seeds, among others. Within the EU, the upcoming Biotech Act, DARPA-like initiatives, and funding choices under the Multiannual Financial Framework could shift public policy towards translational research and mission-driven programmes, accelerating cross-border commercialisation.

Technology platforms for green biotech could become more interoperable, compressing development cycles and enabling faster, safer collaboration across institutions. Trusted data and clearer intellectual property frameworks might underpin this progress. At the same time, converging eco-label schemes could certify crops grown with biofertilisers and biopesticides, lowering transaction costs and improving global market access.

Sectoral implications

Firms could benefit from harmonised regulation of GM and CRISPR crops, lowering compliance burdens, but the pace of change may increase competitive pressures. Large seed corporations might deploy globally distributed R&D networks and secure diverse gene libraries. SMEs could initially thrive thanks to open testbeds for trials and global demand, but they may face challenges in capital intensity and rapid turnover of biotech platforms (e.g., new CRISPR precision tools could make older strains obsolete every few years).

Investment dynamics might shift as green-biotech platforms become highly valued. Corporate venture capital could grow as agribusiness incumbents hedge by buying stakes in synthetic biology startups. Investors could demand proof of scalability, regulatory resilience, and sustainability metrics. University spin-outs might get better licensing pathways, but they will need to demonstrate field-readiness and cross-border certification compliance. Regulators may face pressure to approve new seeds faster,

using adaptive pathways, such as conditional approvals for urgent climate-resilient crops. Civil society, more familiar with biotech, might push for transparency and a fair distribution of benefits.

The FDI-SME nexus could become central. As foreign investors back EU startups developing bio-based solutions, risks of IP leakage and over-dependence on multinational input suppliers may grow. Mitigation might come from performance-based incentives requiring that multinational seed companies reinvest locally.

Policy considerations

In the near term, policy could aim to keep the green biotech market both open and dynamic while enabling rapid diffusion of innovation. Cross-border compliance helpdesks might guide companies through certification for precision-bred crops developed using CRISPR-based genome editing and for genetically modified plants, easing administrative burdens across jurisdictions. SMEs could benefit from export-readiness programmes that help them meet certification for biofertilisers and biopesticides in multiple markets. Publicly accessible datasets of field trials may lower entry costs by allowing smaller firms to draw on validated evidence rather than duplicating experiments. Equipment-leasing and shared-asset schemes could enable farmers and SMEs to access advanced technologies without bearing the full cost of fast-moving infrastructure.

Over the medium term, the EU and Member States could expand pan-European pilot farms and soil-**health laboratories, with reciprocal access for international partners when appropriate.** These demonstration environments may accelerate testing of climate-resilient crops and bio-based inputs under real conditions. Complementary financing mechanisms might help firms move from proof-of-concept to large-scale production, for example through support that facilitates construction of biomanufacturing facilities able to produce engineered seed varieties or biofertiliser strains at scale.

Structural measures may also be important for long-term advantage. Interoperable and trusted data spaces could provide common standards for data sharing and validation among researchers and regulators. Harmonising risk-tiered frameworks for precision-bred crops might reduce fragmentation at market entry, and adaptive approval pathways could allow urgent climate-resilient traits, such as salinity-tolerant rice or drought-resistant maize, to reach farmers faster without compromising safety. SME participation in rule-making may help ensure local businesses are considered alongside multinational firms.

These developments could position high technological advancement and growing global integration **as potential drivers of progress in EU green biotech**. Emerging approaches may focus on anchoring more R&D activity in the bloc, scaling production through trusted international partnerships and demonstrating environmental outcomes that strengthen public confidence. In this context, the EU might gradually evolve to play a wider role in shaping sustainability standards.

Scenario 2: High technological progress, low globalisation

Key trends

In this scenario, the EU would operate within a globally fragmented environment, even as technological progress accelerates. Geopolitical tensions, protectionist trade policies and diverging regulatory frameworks may constrain cross-border flows of goods, capital, talent and data. Green biotech R&D and innovation could continue to advance within major regional blocs, supported by strategic autonomy agendas, public and private investment, and the drive to build more resilient value chains in food, energy and materials. The result might be a technologically dynamic but regionally concentrated biotech landscape, in which breakthroughs emerge but remain largely confined to domestic or regional markets due to limited mutual recognition of approvals.

Several factors could push the EU in this direction. Persistent supply shocks, such as volatility in energy and input prices, may encourage localisation of production and tighter control over strategic technologies. Regulatory divergence could deepen as countries adopt distinct standards for green biotech applications, while EU governments place greater emphasis on sovereignty and resilience in the biotechnology and energy sectors. Investment patterns might shift toward public banks and state-backed instruments, reflecting a more risk-averse model than private venture capital systems elsewhere. Firms could increasingly regionalise operations to align with available feedstocks and to mitigate exposure to vulnerable supply-chains.

Sectoral implications

Rapid technological progress may continue through advances in bioinformatics, AI-enabled design and platform biotechnologies, but collaboration could become more guarded. Data-sharing and IP protection might be constrained within geopolitical blocs. Infrastructure may cluster near feedstock sources and stable energy supplies, with major biomanufacturing plants for engineered crop seeds and microbial biofertilisers established close to Europe's cereal belts. Emphasis grows on ensuring interoperability within the Single Market to prevent internal fragmentation. Talent dynamics may also shift, and Europe could experience a "reverse brain drain" as scientists return from less stable research environments elsewhere to contribute to flagship EU projects. However, insufficient coordination might risk duplicating efforts across Member States and under-utilising shared assets.

Investor behaviour could adjust accordingly, with international capital becoming more selective and favouring regional champions and co-investment with public banks. Exit options might narrow, while due diligence could broaden to assess regulatory alignment and long-term standards evolution. Multinational firms may restructure operations to comply with varying regulatory regimes, deepen engagement with local suppliers and hedge input risks. For SMEs, the outlook could be mixed: agrifood and environmental startups might benefit from public pilot farms testing engineered microbial coatings for seed resilience and from demand linked to climate adaptation, but they may face tighter labelling rules and permitting bottlenecks when expanding across borders. Scale-ups could enjoy access to capital grants, yet growth might remain constrained by market fragmentation and uncertainty around securing long-term buyers for their products.

Policy considerations

In this context, policy could focus on lowering non-technological barriers and building coherence across fragmented systems. Short-term options include one-stop regulatory helpdesks to guide SMEs through approval processes, clear and harmonised processing-time targets for permitting bioprocessing facilities, risk-proportionate sandboxes for field-testing and outcome-based public procurement pilots (e.g. for climate-resilient crop varieties). Templates for IP-safe collaboration and data sharing might de-risk partnerships between universities, SMEs and larger firms, and could support private co-investment.

Medium-term priorities might include expanding regional (i.e. subnational) pilot and demonstration facilities with transparent access for SMEs and strategic investors. Blended-finance instruments could bridge funding gaps for scale-ups seeking to commercialise bio-based crop inputs at market scale. Trusted data spaces and sharing protocols may help protect sensitive information while enabling regulators and researchers to generate robust evidence.

In the long term, the EU could seek to avoid fragmentation into many initiatives that never reach efficient scale by building shared modular infrastructure, developing circular feedstock markets and supporting mutual recognition of standards across regions. FDI might remain open to diverse investors while incorporating incentives that strengthen local linkages; for example, by supporting SME participation in supply chains, promoting workforce training and upskilling, encouraging collaborative R&D, and facilitating access to shared testing or pilot facilities. Governance could be more integrated and cross-

cutting, aligning industrial, environmental and innovation policy through inter-ministerial coordination and regional one-stop shops. Risk management may be embedded from the outset, using competition policy, pooled procurement and milestone-based funding to limit crowding-out, lock-in and volatility. Monitoring frameworks with clear trigger points, such as widening approval-time variance for biotech crops or evidence of persistent bottlenecks in pilot deployment, could support timely policy adjustment.

This policy stance treats the scenario as potentially manageable, and in some respects advantageous, provided Single Market coherence is preserved, spillovers from public support and FDI are encouraged, and structural investments limit fragmentation and sub-scale outcomes. In such a future, the EU might develop as a regional powerhouse in green biotech, reinforcing food and energy systems while demonstrating public value and attracting sustainable private investment, even in a more fragmented global order.

Scenario 3: Low technological progress, low globalisation

Key trends

In this scenario, the EU would experience a prolonged period of geopolitical tension, repeated crises and resurgent protectionism. These forces may reduce cross-border flows of goods, capital, talent and ideas, undermining international scientific collaboration, dissolving mutual recognition frameworks and deepening standards divergence. Investment in advanced biotechnologies might slow, data-sharing could become more constrained and innovation may stall. Green biotech R&D would no longer advance cutting-edge projects, instead shifting towards incremental improvements in existing crop varieties and temporary solutions for food security. Policy focus could move away from frontier technologies towards immediate security, continuity of essential services and short-term resilience. For example, governments might prioritise support for basic microbial biofertilisers produced through conventional fermentation rather than investing in synthetic biology platforms.

Multiple pathways could lead to this outcome. Global conflicts, pandemics or political shifts towards economic nationalism may entrench trade barriers and export controls, making it difficult to move even conventional seed stocks across borders. Collaboration could freeze, with patterns already evident in some domains widening to encompass additional strands of research. Under these conditions, security-oriented policies might displace green innovation strategies, as governments prioritise stockpiling of conventional fertilisers and pesticides over funding CRISPR-edited drought-resistant crops. Underinvestment in R&D and infrastructure by both public and private actors could gradually pull what might otherwise have been a “high tech, low globalisation” environment into this more constrained, low-innovation scenario.

Sectoral implications

The business environment could become increasingly localised, compliance-intensive and static. Supply chains may contract, certification systems could fragment and access to advanced inputs might become unreliable. Larger incumbents with embedded infrastructure may continue delivering essential services, such as supplying conventional hybrid seed lines and maintaining large-scale fertiliser distribution, but could face weak incentives to modernise. For SMEs and start-ups, innovation opportunities might diminish, prompting many to pivot towards retrofitting older technologies. Payback periods could lengthen, and a thin pipeline of investable green biotech projects may emerge, further dampening sectoral vitality.

The research and talent ecosystem could also deteriorate. Universities and public labs might narrow their focus to national needs. For example, public breeding institutes could concentrate on conventional cross-breeding rather than gene editing. Cross-border collaboration, shared infrastructure and joint training programmes may decline, weakening Europe’s capacity to pursue ambitious international missions. Brain drain could accelerate as leading plant biologists and microbial engineers seek better opportunities abroad.

Regulatory science capacity might lag even modest technological developments, meaning that even relatively simple innovations, such as next-generation bio-based pesticides, could face approval delays. Without coordinated policy, infrastructure may be duplicated across Member States, leading to inefficiencies and underutilised assets, including partially operational plants or fragmented testing facilities.

Policy considerations

In this context, policy could prioritise preserving Single Market coherence while acknowledging tighter global constraints. Proportionate, risk-based approval pathways, transparent permitting timelines and SME-focused regulatory helpdesks could reduce uncertainty. Even if external alignment weakens, minimum interoperability for safety, traceability and conformity assessment might be maintained across the EU. Innovation-oriented public procurement with SME participation and incentives for local linkages could help sustain activity.

Finance tools could focus on stabilising cash flow and preserving core capabilities. Working-capital support and blended finance might underwrite retrofits of existing bioprocessing equipment to capture incremental efficiency gains. Public funding tied to performance milestones could limit misallocation. Industrial policy may prioritise basic research and translational capacity, including support for less-developed regions to limit divergence within the EU. Centres of excellence, shared facilities and open-source tools could diffuse improvements efficiently in a constrained environment. Explicit risk-mitigation measures might target capability decay, technology lock-in, SME attrition and intra-EU fragmentation through pooled procurement, time-bound support, and supplier-development schemes.

A lower-technology, lower-globalisation setting does not preclude progress, but implies different policy approaches. Green biotech innovation may be more modest, focused on low-cost biofertilisers, resilient conventionally bred crops and maintaining basic food security under climate stress. Preserving Single Market coherence, keeping future options open through shared infrastructure and standards, and investing in people and knowledge – at least sufficient to avoid irreversible capability loss – could help deliver tangible environmental and public-service benefits in the short to medium term, while maintaining the foundations for faster recovery when conditions improve.

Scenario 4: Low technological progress, high globalisation

Key trends

In this scenario, global markets would remain broadly open and rules-based, with trade, investment and talent flows continuing at pace. However, technological progress in green biotech may be modest. Most efforts would centre on incremental improvements to established processes rather than breakthrough innovations. Europe might remain attractive for its market scale and operational reliability, yet frontier R&D may increasingly shift to faster-moving global ecosystems such as the United States and China. Within the EU, innovation could tend to focus on practical efficiency gains, such as upgrading fermentation systems for microbial biofertiliser production, improving labelling and traceability tools for CRISPR-edited crops, or scaling waste-to-bioenergy conversion processes.

Several underlying forces could lead to this outcome. Economic pressures and successive crises may delay transformative R&D efforts and push advanced green-biotech manufacturing abroad, particularly to Asian economies with faster regulatory approvals. Funding constraints and risk aversion might tilt both public and private investment towards short-term efficiency and diffusion rather than disruptive innovation. As a result, firms could optimise existing technologies, but systemic advances like synthetic biology platforms for plant engineering or AI-driven gene-editing design would remain rare. Regulatory pathways may remain cautious and under-utilised for novel applications, reinforcing a pattern of safe but incremental gains.

Sectoral implications

The industrial landscape may become increasingly dominated by incumbents. Large agrochemical and seed firms could leverage brand recognition, capital access and established infrastructure to expand global sales. Start-ups pursuing cutting-edge biology may face long validation timelines and narrow exit routes, leading many to pivot towards integration, retrofitting or support services. Operationally efficient SMEs might still find niches, though margins could remain tight and global competition intense. The innovation pipeline may stabilise but become thinner at the frontier, as global capital concentrates on lower-risk, faster-return projects and corporate investment targets incremental improvements rather than disruptive breakthroughs.

Regulatory dynamics could prioritise safety and public trust but at the cost of ambition. Local evidence requirements, stringent labelling and traceability expectations, and the absence of convergent performance-based standards slow adoption even of modest innovations. FDI might continue to flow into the EU, but investment could shift toward market access and established production activities. Greenfield projects may focus on logistics and mature manufacturing, such as biofertiliser distribution hubs or seed-processing facilities. SME linkages may increasingly revolve around compliance services, supply-chain monitoring and eco-label certification, generating limited knowledge spillovers. Without targeted efforts to strengthen innovation capacity and cross-border collaboration, the EU's role in green biotech might increasingly centre on downstream activities – such as adaptation, production and distribution – rather than on frontier R&D.

Policy considerations

In the near term, policy could focus on productivity and diffusion. SME-focused regulatory helpdesks might assist with certification, while micro-grants for eco-label approval could help smaller firms access international markets. Outcome-based procurement may encourage better performance without dictating technology. Low-friction regulatory sandboxes could accelerate adoption of incremental improvements.

Over the medium term, attention could turn to the stage between laboratory validation and full-scale deployment. This is also referred to as the technology readiness levels (TRL) 5–7 bottleneck, where many green biotech projects struggle to advance. At this point, technologies are proven in principle but still face high costs, limited testing environments and uncertain market demand. Funds for demonstration trials, blended-finance tools, and anchor-customer mechanisms (e.g. offtake contracts) might help reduce deployment risks and attract private investment. Skills programmes linking operations, quality assurance and scale-up, particularly in bio-based input manufacturing, could also help embed new practices in mature industrial settings.

Longer-term efforts may aim to modernise the industrial base while preserving optionality. Modular equipment standards and leasing models could mitigate obsolescence risks, while shared validation and regulatory-science infrastructure might lower fixed costs for SMEs. Regional testbeds aligned with practical use cases (such as using agricultural residues for microbial fertiliser production or processing municipal waste into soil enhancers) could translate technical advances into real-world results. Maintaining Single Market coherence would be important: mutual recognition, interoperable conformity assessment and open standards could limit internal fragmentation and preserve scale economies. Competition policy might also help keep market access fair and prevent entrenching dominance by incumbents.

An open but incremental trajectory could yield environmental and operational improvements, though it would involve trade-offs. Global openness may enable the EU to import, adapt and scale available technologies while rebuilding the upstream R&D pipeline to limit dependence on breakthrough innovations made elsewhere. If markets remain contestable, shared infrastructure expands and regulatory cooperation deepens, incremental progress may continue to generate measurable gains, keeping options open for future advances in higher-technology domains.

General assessment for green biotechnology

The four scenarios outlined represent distinct yet plausible futures for the EU's green biotech ecosystem**, shaped by varying levels of globalisation and technological progress.** Each highlights different strategic trade-offs and policy challenges.

Table 2. Alternative futures for the EU's green biotech ecosystem

Summary of core conditions, opportunities and risks

	Low Globalisation	High Globalisation
High Technological Progress	**Scenario 2: Strong science amid a more fragmented global context** • Sovereignty agendas and security concerns drive regional standards and local production. • Duplication of facilities, data silos and compliance costs reduce scale efficiencies and limit cross-border learning. • SMEs find opportunities in regional procurement and demonstration projects, but scale-up is constrained.	**Scenario 1: Rapid innovation with strong international collaboration** • Aligned regulations, interoperable data and open markets accelerate the field-to-market diffusion of crops, inputs and bioprocesses. • The EU leverages its research strengths and sustainability standards to scale climate-smart solutions across value chains. • Risks include SME crowding out and dependence on concentrated global feedstocks and equipment suppliers.
Low Technological Progress	**Scenario 3: Slower innovation and inward focus** • FDI shifts away from frontier biology toward essential inputs and basic resilience measures. • Community-scale applications provide local environmental benefits, but cross-border trials decline. • The main risk is erosion of R&D and biomanufacturing capabilities, making future recovery more difficult.	**Scenario 4: Open trade and investment with incremental improvement** • Global value chains remain accessible, but innovation progresses slowly, focused on cost, quality and compliance. • Incumbents benefit from scale and standards, while SMEs compete in low-margin niches such as validation, traceability and servicing. • Over time, there is a risk of innovation hollowing out, with the EU specialising in adaptation and distribution rather than invention.

Across the four scenarios, three cross-cutting themes shape outcomes for the EU. First, capability investment presents both risks and opportunities. Underinvestment in R&D, infrastructure, talent and institutions constrains every pathway, while steady well-targeted investment can shorten time to scale and retain high-value activities. Second, Single Market coherence is a decisive enabler. Fragmentation raises costs and weakens resilience in all futures, whereas interoperable rules, data and quality systems create scale effects that support faster diffusion, deeper specialisation and stronger crisis response. Third, SME inclusion is critical for system vitality. Exclusion from pilots, procurement, finance and standards concentrates advantage with incumbents, but incentives for SME access can widen innovation sources, strengthen regional linkages and convert foreign and domestic investment into broader spillovers.

The analysis also underscores the importance of thoughtful policy sequencing. Even in favourable scenarios, positive outcomes are not guaranteed. Realising the benefits from disruptive technologies or open global markets may depend on interventions that safeguard competition, promote knowledge

diffusion and manage emerging risk. In constrained environments, adaptive strategies – such as modular infrastructure, open knowledge commons and transparent procurement – could help prevent capability decay and preserve future options.

Monitoring and adaptability may also become central features of governance structures. Scenario transitions are rarely binary; conditions can shift gradually or abruptly. A seemingly open or innovative environment might contract under geopolitical or economic stress, while a fragmented, low-technology baseline could evolve towards greater dynamism with sustained investment and coordination.

From this perspective, the EU's strategy might focus on two parallel objectives: maximising value under prevailing conditions while keeping pathways open to more ambitious futures. Embedding this approach in evidence-based policymaking, institutional resilience and inclusive governance could enhance the EU's ability not only to adapt to change but also to influence its direction.

Conclusions and recommendations

The EU's ability to strengthen its position in global biotechnology will depend on how effectively its policies, industries and institutions align to translate scientific strengths into investment, innovation and growth. Drawing on recent trends and two foresight exercises, this section outlines policy recommendations to enhance FDI–SME linkages in the EU's red and green biotech value chains. Four cross-cutting and interrelated priorities emerge: expanding access to finance, enhancing connectivity, building capacity, and improving coordination.

Expanding access to finance is essential to bridge the scale-up gap. While instruments like the European Innovation Council and the Strategic Technologies for Europe Platform have begun to address early-stage needs, capital markets in the EU remain less deep and dynamic than those in the United States or parts of Asia. Increasing the size and diversity of EU-based growth funds, encouraging participation from institutional investors, and mobilising ESG- and impact-oriented capital could provide SMEs with the resources to grow without relocating. Efforts should also focus on strengthening late-stage financing channels, including scale-up capital and initial public offering (IPO) pathways.

Strengthening international and regional connectivity is critical for a dynamic biotech ecosystem. SMEs benefit most when integrated into global networks of partners, investors and markets. Cluster dynamics across Europe demonstrate how institutional proximity and geographic density attract FDI and support knowledge flows. Established hubs such as Medicon Valley (Denmark-Sweden) and BioValley (France-Germany-Switzerland) already draw global companies, talent and capital. Connecting emerging clusters like Tartu (Estonia) and bioROne (Romania) to wider European and global ecosystems could help spread these benefits more evenly, supporting cohesion objectives while reinforcing Europe's position in global value chains.

Building technical, managerial and workforce capabilities is equally essential to support growth and innovation. Many EU biotech SMEs struggle not only with financing but also with attracting the skills needed to scale. Beyond scientific excellence, greater support is needed for entrepreneurial training, commercialisation expertise and hybrid talent profiles. Access to shared infrastructure – such as pilot facilities, digital platforms, and mentoring networks – can help SMEs overcome capability barriers, especially in less mature regional ecosystems.

Improving policy coordination – across sectors, regions and levels of government – is critical for **creating a more predictable, efficient and attractive investment environment**. Regulatory coherence within the Single Market remains uneven, complicating cross-border operations and deterring investment. Initiatives such as the EU Clinical Trials Regulation and proposals for joint health technology assessment show progress, but further alignment is needed. Areas such as gene editing, advanced therapies, AI-driven drug discovery and bio-based chemicals underline the importance of clear, coordinated and agile

regulatory frameworks, anchored in safety and ethics, to boost investor confidence and reduce transaction costs for SMEs.

Positioning the EU effectively within global value chains also requires aligning inward investment with broader societal goals. FDI can contribute to strategic autonomy by strengthening domestic capabilities while preserving openness to trade, investment and knowledge flows. SME integration into global value chains – as suppliers, R&D partners or service providers – can help retain value locally. Policies that encourage durable partnerships, knowledge transfer and shared infrastructure use can ensure that foreign investment supports long-term resilience and inclusive growth.

To realise the full potential of FDI-SME linkages, policy frameworks should combine openness with strategic direction. Transparent investment conditions, clear risk-management tools and targeted support for knowledge and technology transfer are critical. Instruments that promote collaborative R&D, supplier development, and interoperability of data and standards can accelerate spillovers from foreign investment to domestic firms. By aligning financial, institutional and regulatory levers, the EU can turn its scientific base into a globally competitive, resilient and sustainable bioeconomy.

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Notes

[1] These figures are derived from patent families filed across at least two of the five largest intellectual property offices (IP5: USPTO, EPO, JPO, KIPO, CNIPA), representing high-value international patents. Biotechnology patents are identified using a set of International Patent Classification (IPC) codes defined by the OECD, covering technologies such as genetic engineering, industrial bioprocesses, synthetic biology, and bioinformatics.

[2] Indirect employment effects are estimated using a multiregional input-output (MRIO) framework based on the Leontief production model, which traces how final demand for biotechnology output propagates through their inter-industry supply chains.

[3] Unless stated otherwise, in this paper the term “cluster” refers to a functional agglomeration: co-located firms, research and clinical institutions, specialised providers and shared infrastructure, linked by dense collaboration and labour and knowledge flows. Functional clusters are defined by economic linkages rather than administrative borders and do not require a single coordinating entity. By contrast, a “cluster organisation” is a formally constituted entity with legal status, governance, staff, membership, and defined services.

[4] IQVIA defines “emerging biopharma” based on thresholds for R&D expenditure and prescription drug sales. While this segment largely overlaps with SMEs as defined by EU criteria on firm size and turnover, it is not identical. Specifically, IQVIA classifies emerging biopharma firms as those with less than USD 200 million in annual R&D spending or less than USD 500 million in global prescription drug sales.

[5] In this context, differences in the pace and scale of technological progress primarily capture whether the EU converges towards, tracks or lags behind the global technological frontier, rather than implying a uniform acceleration or slowdown of innovation worldwide.

[6] Beyond the two main drivers, sector-specific shocks could shape outcomes across all scenarios. In red biotech, major health crises, such as pandemics or antimicrobial resistance emergencies, can rapidly shift demand, risk perceptions and regulatory priorities. In green biotech, climate shocks, from extreme weather events to sudden disruptions to agri-food systems, can similarly accelerate or constrain the deployment of new biotechnologies. These shocks may act as accelerators or stressors, opening windows of opportunity for agile SMEs while exposing others to heightened vulnerability. They do not alter the underlying structure of the scenarios, but they offer a useful lens for stress-testing how different futures might unfold. While these shocks were not explored through dedicated scenario variants in the workshop, they provide an extension for applying the framework to analyse how prepared SMEs and policymakers are to respond.

[7] In practice, some Member States have already begun aligning their FDI-screening regimes under the EU's coordination mechanism, encouraging more consistent oversight across borders (White & Case LLP, 2025[85]). The EU has also adopted Codes of Practice on intellectual-asset management, standardisation, and industry-academia co-creation under its valorisation policy (European Commission, 2025[84]).

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