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European Federation of Pharmaceutical Industries and Associations

A comparative analysis of biopharmaceutical strategies in 10 countries

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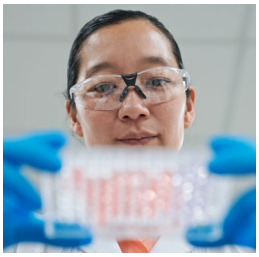
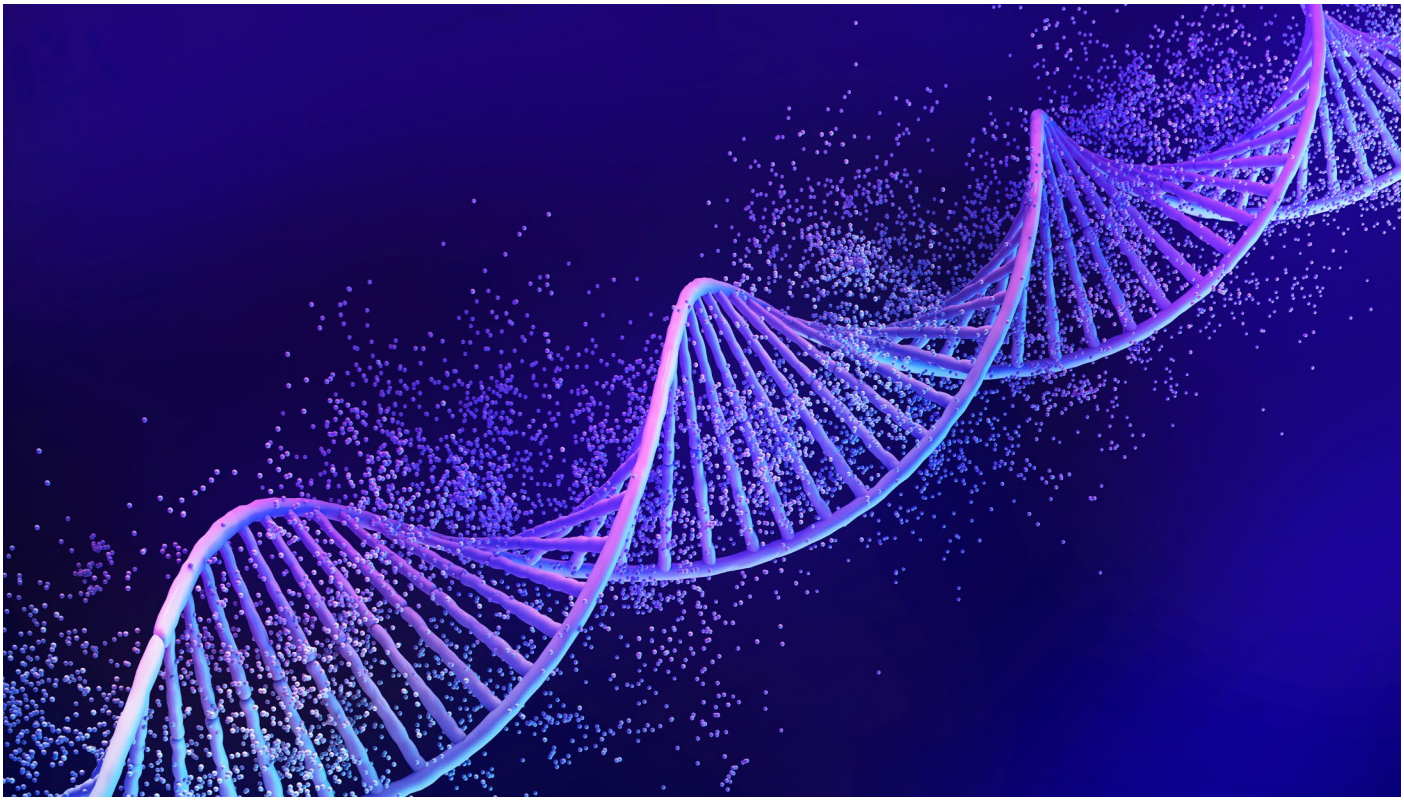


Biopharmaceutical support measures post-COVID-19 reflect the growing strategic interest in the sector. The sector is part of the global race for innovation and industrial competitiveness, alongside areas such as artificial intelligence (AI) and quantum technology. Countries compete for talent, investment, manufacturing and positioning in future global value chains.

The biomedical industry is a high-risk, high-investment, technology-intensive sector. These characteristics make it uniquely challenging to achieve innovation, attract investment and translate innovation into globally significant leadership. A supportive policy environment and finance are crucial prerequisites for converting innovation into leadership.

The urgency for Europe is driven by shifting geopolitical and economic pressures:

- The countries reviewed in this analysis view biotech and biopharma as a key strategic sector. They develop policies that support innovation and are willing to invest public funds into drivers for its growth. Convergence of technologies (AI, biotechnology, quantum technology) are deliberately sought in integrated policy frameworks. Governments are increasingly orienting R&D and industrial policy around economic and national security. In China and the US, the national security dimension is becoming more central to their policies, and this dynamic is contributing to capital flows and investment.
- Cost pressures are increasing – for example, US pricing reforms – while competition from China is shortening asset lifecycles. Industry pipelines are expanding, but considerable pressure points will further drive focus on R&D productivity and cost efficiency. National biopharma support policies will become even more important, both to address the pressure points and generate cutting-edge technology leadership.
- Barriers to entry into biotech are lowering with the combination of biotech, digital and AI technologies. Asia is emerging as a major driver for global pipelines. Multiple datasets indicate that the Asia–Pacific (APAC) region now accounts for roughly one-third to approaching one-half of the global innovative-drug pipeline, with China alone contributing around 23% of the total. While the US and China dominate, the hub landscape is diversifying.

Government measures span the value chain from early research to biomanufacturing and post-launch activities. While market access and pricing policies are not within scope of this analysis, demand-side measures matter. Varying degrees of state intervention mix between innovation incentives, drug pricing and public access openness in different and often contradictory ways. Complementarity between measures to attract investment with access to medicines and technologies remains one of the most challenging areas for genuine reform. In some countries, such as the UK, the contrast between favourable industrial strategies and cost-driven pricing policies is particularly stark, with longer-term consequences for the country's attractiveness.

Countries want to build a 'homegrown' industry that keeps headquarters, jobs and IP within their borders, in addition to attracting foreign direct investment. This is harder in today's risk-averse capital markets, and hinges on investor confidence in local firms' ability to grow to global commercial success.

Post-COVID-19, countries are also reevaluating how to make biopharma resilient to shocks (for example, pandemics, geopolitical fragmentation). The analysis looks at structural policies (such as supply-chain localisation, stockpiles, flexible regulatory regimes) that best supported resilience. The report identifies specific elements in the strategies that respond to the changing geopolitical landscape, such as supply-chain risk mitigation, strengthening of manufacturing, preparedness and talent retention.

Health policy and regulation are important levers that shape attractive business environments and strengthen Europe's position as a preferred global-launch market for biopharma innovation. However, they are by far not the only levers. In today's geopolitical environment, policy predictability, and quality and stability of key institutions such as regulatory agencies, are becoming key.

Comparison across countries to identify patterns and best practices is useful, but not all measures can simply be 'translated' into a European context. The EU can learn from them while playing to its unique strengths: scientific excellence and high-quality research centres, values-driven governance, public sector scale, collaborative spirit and vast high-quality data, which can be powerful levers when combined with political urgency and coordination. Closer collaboration between the EU and its European neighbours, notably Switzerland and the UK as significant centres for biopharmaceutical innovation, will further amplify impact.

If European countries do not manage to seize the current momentum, there is a tangible risk of losing the innovation curve in a more permanent way. It will mean an acceleration of the shift towards the US and China, plus strong regional pockets, notably in the APAC region. The two member states analysed in this report – France and Denmark – could further reinforce their respective strengths if they brought these to bear in a coherent European biotech and biopharma strategy.

While this report looks specifically at life sciences strategies, it is important to recognise that the most critical actions the EU and Member States can take is to make Europe a place that **values innovation** – by strengthening IP and including wider societal benefits in value assessments. And make Europe a place that **invests in innovation** by removing clawbacks and making a firm commitment to increase spending on innovative medicines as an investment in our collective health and economic future.

Conceptual framework

The report is descriptive and does not aim to rank countries. It recognises that national ecosystems reflect distinct histories, industrial strategies, institutional processes, and design and policy choices. While each of the countries selected are in upper income brackets, there are significant differences in their political and socio-economic systems and regulatory frameworks, as well as governance and innovation models.

The analysis can help understand specific combinations of public investment, regulation and industrial policy that are most effective under the institutional conditions of each country, while identifying core drivers of support that are less context-dependent, to advance a set of recommendations for Europe. For example, all countries in this analysis have public-private partnerships (PPPs), but the intensity of these partnerships and the modalities with which each is set up will be a function of things such as entrepreneurial culture, centralised vs decentralised government and political ambition. Some countries excel in scaling advanced biomanufacturing, others in translating research into venture-capital (VC)-backed startups. Each has strengths and structural limitations. The purpose is to understand how different models of innovation function and what they might learn from one another. Further analysis is recommended.

Structure of the report

1. **Recommendations for Europe**

   With Europe seeking to develop a biotechnology act – and given that the report by Mario Draghi has already made a number of important recommendations that are still fully valid – this section discusses the potential for reinforcing Europe's strengths in the six metrics (R&D intensity, public-private collaboration, clinical trials uptake, regulatory framework efficiency and agility, VC and financing dynamics, translational ecosystem and startup generation) highlighting each time the balance of efforts between the EU specifically (for example, through its R&D funding programme, the new Competitiveness Fund, but also existing legislation) and member states. This should provide a discussion basis to identify which measures explored through the country examples can be brought into the EU and where the balance of effort lies for each.

2. **Who does what well: six-pillar framework based on key markers with attention to translational efficiency to qualify the composition of a country's biopharma support strategy**

   This section will seek to position each of the 10 countries analysed within the framework, highlighting each time stand-out countries with particular strengths in each of the identified markers.

3. **Short individual country descriptions, which will include a particular description of biomanufacturing support measures**

   This section will give a one-page description of each of the 10 countries' key strategic frameworks, including a short section on a country's biomanufacturing focus and specific support measures.

Key recommendations

Increased global competition for biopharmaceutical leadership is coming at a challenging period for Europe in today's context of threats to Europe's security, and geoeconomic and macroeconomic challenges.

Over the past two decades, the share of pharmaceutical R&D spend between Europe, US, Japan and China has decreased from 37% in 2010 to 32% in 2020, with projections indicating a further decline to 21% by 2040 if no countermeasures are taken[2]. EU member states have underestimated the impact that different drivers of investment in other third countries is having on Europe's own attractiveness as a region (for example, the lack of sense of urgency in improving Europe's clinical trials ecosystem considering the rapid rise of China in this field over the past few years), combined with underinvestment in the structural issues that are eroding its biopharma ecosystem and are at risk of eroding it further.

The European Commission's 2024 Communication on Biotechnology and Biomanufacturing acknowledges these gaps: it lists regulatory hurdles, technology transfer bottlenecks, financing gaps[3]. The impact of incomplete and under-resourced implementation of EU legislation is well documented (such as the Clinical Trials Regulation), and Mario Draghi's report 'The future of European competitiveness' (September 2024) highlighted the impact of Europe's fragmented regulatory and national pricing and reimbursement systems on investments and on access delays to new treatments.

Recent global developments, notably US tariffs on pharmaceuticals and the introduction of most-favoured-nation pricing in the US, will impact the dynamics of accelerating global competition, investment flows and global launch incentives. These developments further reinforce the need for building Europe's geopolitical resilience in biopharmaceuticals, derisking supply

2 Dolon (2023): Revision of the general pharmaceutical legislation: impact assessment of the European Commission and EFPIA proposals, November 2023
3 European Commission. (2024, March 20). Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU (COM(2024) 137 final).

chains, safeguarding incentives and reinforcing Europe's ability to leverage its strengths in the biopharmaceutical value chain.

Competition from China and its growing strengths in several key segments of the biopharma value chain reflects today's importance of speed and cost effectiveness to address lagging R&D productivity. The Draghi report's assessment that innovation and R&D are non-negotiables for global tech leadership will require that all member states pull in the same direction with a much greater sense of urgency (keeping in mind that a recently launched report highlights a lack of action on Draghi's recommendations[4]). Europe should focus on what it already does well and scale its own unique model through joined-up efforts by its member states, many of which run their own national biopharmaceutical policies. It should also agree on key objectives and core metrics for performance, just like many national strategies do. This also requires a much better understanding of the link between the value added drawn from more biopharma activity and supply-side measures (R&D, skills, biomanufacturing) in Europe and demand-side incentives (faster, more predictable market access) to further advance investment.

1. Treat single-market completion as a top priority

Enrico Letta's report 'Much more than a market' (April 2024) was very clear on the imperative of completing the single market. Other countries analysed here play to their strengths. Europe's strength is the single market. Europe's lower competitiveness vs the US and, increasingly, China is partly due to the lack of all member states pulling in the same direction with a strong political will to invest the required resources. As in other sectors, there are still many areas of underperformance in biopharmaceutical competitiveness that are caused by an insufficient level of implementation of existing EU legislation.

Investors are very clear on this: **faster and predictable routes of access to innovation for patients in Europe will pull in investment and impact location decisions for various stages in the biopharma value chain (for example, location of clinical research)**[5]. This is not only a question of how much financing is available. Speed to patients should be a measurable investment incentive (with measurements along, for example, clinical trials, regulatory processes, health technology assessment [HTA] processes).

The EU and member states should double down on efforts to address those areas where a strong foundation has already been set through agreed legislation or EU policies:

- **Uniform implementation of the Clinical Trials Regulation, with necessary targeted adjustments:** remove bottlenecks and administrative burden created through fragmented implementation and duplicative requirements, ensuring faster and more predictable reviews through harmonised timelines. Optimise the Clinical Trials Information System, strengthen infrastructure for multi-country trials, and establish coordinated ethics reviews and cross-border patient participation to reduce delays and enable more rapid access to innovation.
- **Accelerate regulatory processes** (to address the gap with other regulatory agencies).
- **Move towards a more coherent European cutting-edge innovation access pathway, that ensures that emerging technologies, for example cell and gene therapies, can be adopted more efficiently.** This requires more flexible and adaptive regulatory responses, supported by the implementation of the EU HTA Regulation, in a way that delivers EU-added value and system coherence[6]. The objective should be reduction of access delays, for example through the use of managed entry agreements and outcomes-based contracts.
- **Invest in health data and AI:** operationalise the European Health Data Space with data access for trials and real-world evidence (RWE) under strong governance; create European Medicines Agency (EMA)/HTA sandboxes for AI/machine learning in discovery, trial design and labelling; connect biotech/biopharma with the Commission's AI factories roll-out (for example, consider biopharma use cases); and create health-specific infrastructure in AI capacity to succeed in the biotech-AI nexus, leveraging existing national strengths, such as Denmark's Gefion supercomputer.
- Facilitate the administrative, compliance, financing and scaling-up processes for smaller biotechs.

2. Excel at cutting-edge science

Leverage cross-border scale building on existing expertise: this should draw on practices and learnings from public-private (PP) consortia that operate within the EU, and on the learnings from non-EU countries. The EU's biotech/biomanufacturing strategy rightly highlights the need for investment into regulatory sandboxes, standards, skills and test-bed access – ie, the translational infrastructure. Efforts should leverage what is already happening in countries, fix cross-border frictions and couple finance with translational infrastructure (such as good manufacturing practice (GMP) testbeds/pilot facilities, such as exist in the UK with the Cell and Gene Therapy Catapult's Stevenage Manufacturing Innovation Centre).

4 European Policy Innovation Council (2025). Draghi Observatory & Implementation Index (September 2025)

5 European Confederation of Pharmaceutical Entrepreneurs & FTI Consulting. (2024). The Economic Lens: Understanding What Makes the EU Attractive for Life Sciences Investments (Investor insights into the Pharma Package), EUCOPE, November 2024

6 See for example: Alliance for Regenerative Medicine. (2024, December 12): Call to Action of Concerned Stakeholders on the Implementation of the EU Joint Clinical Assessment for ATMPs, which argues that 'joint clinical assessment' processes under the HTA Regulation, should not introduce requirements beyond what regulators already assess, and that HTA coordination should promote convergence across Member States.

It is encouraging that the EU Life Sciences Strategy supports cross-border cluster collaboration and the scaling from national towards pan-European bioclusters. This analysis has shown the significant role played by clusters in every country analysed, and the existence of a comprehensive and complementary ecosystem composed of bigger pharma companies, biotech startups and a rich network of research centres for attracting talent and creating a positive financing dynamic (which will require public funding support). Therefore, scale what works, fund multi-country bioclusters with shared platforms (for example, imaging, biobanks) and ensure efficient governance. Tie EU funding to industry use and private co-investment, as well as to supporting the drivers on key shared objectives, such as, for example, clinical trials timelines. This action should also have an international component, through the EU's international partnership strategy, to connect the EU's leading hubs with hubs in partner countries.

Taking inspiration from South Korea, **leverage Europe's biomanufacturing strength**, including in vaccines, fast-track variations for process intensification and greener bioprocessing. Make 'clean biomanufacturing' a European brand (energy-efficient plants, greener solvents etc), where countries such as France and Denmark can take leadership and develop appropriate incentives, while ensuring that the regulatory framework remains fit for purpose.

Ecosystem thinking, not just sector policy frameworks: The biopharmaceutical sector depends on the interaction of multiple capabilities and technologies, upstream and downstream industries, suppliers, data infrastructure, skills, investors. The OECD's 2025 STI Outlook argues that industrial policy should move from narrow "sector" approaches to ecosystem-based strategies to design more effective industrial policies[7]. An ecosystem approach helps identify and coordinate the full set of enablers required for innovation to translate into investment, clinical development and production. This should come paired with more strategic intelligence and foresight, to anticipate areas where Europe can have a leading role in the value chain and address potential vulnerabilities and pressure points in supply chains, and guiding investment and regulatory action accordingly.

Integrate the international dimension in Europe's biotech strategy: the challenges for the biopharmaceutical sector and risks to a country's health security extend beyond a narrow supply chain and manufacturing scope. Countries analysed show an increasing awareness of the geopolitical risks and the need to adapt to these through more investment into various parts of the biopharma value chain, with tariffs and non-tariff barriers, data-localisation obligations and investment-screening regimes becoming a more frequent feature across geographies. A European international partnership strategy should include, for example, considerations such as health-data flows, standard-setting covering the interaction between AI and biotech and securing supply chains for biomanufacturing.

3. Financing at scale – unlock late-stage capital and anchor it in Europe

Move quickly on enabling startup and scaleup finance: It is encouraging to see that the EU now explicitly acknowledges the startup-to-scaleup financing gap and exploring action on several levers: the role played by public catalytic finance through the instruments of an expanded InvestEU and strong European Investment Bank (EIB) role in life sciences, alongside proposals to free up insurer/pension capital, advance a potential evolution of the European Innovation Council into a European Advanced Research Projects Agency (ARPA)-type agency.

Europe needs to offer an attractive early-stage environment for VC funds: the EU's Biotech Communication of 2024 ties finance to scale-up infrastructure (such as biomanufacturing, standards, skills), mirroring what successful hubs (for example, the US, Denmark, Singapore) already do. The proposals for the next Multiannual Financial Framework include ambitious objectives for R&I. The EU should use InvestEU, the Competitiveness Fund, the EIB and the European Investment Fund to crowd in private capital for scaleups and biomanufacturing testbeds. Public co-investment can bridge Europe's weaker late-stage VC pool. Even small increases in VC allocations (via dedicated vehicles) could materially change late-stage availability and reduce leakage. International Monetary Fund (IMF)/EIB analyses highlight this lever.

EU policymakers need to continue pushing for pan-EU-scale mechanisms so as to create new levers that Europe can use to compete on a global scale: these include co-investment, InvestEU-style funds, pension reforms, establishing a guarantee fund for biopharma SMEs to minimise their losses through lower hurdle rates and risk-sharing harmonised incentives, and the structural reforms needed to mobilise long-term capital. Together these measures target the same bottlenecks that push EU founders abroad and pair risk capital with scaleup infrastructure. Politically, the climate also calls for industry to reflect on its acceptance of approaches that tie these measures to manufacturing and/or trial commitments in the EU.

Europe needs to scale its own model: world-class science and talent, cross-border clusters, industrial-grade translation and credible, faster routes to market, backed by serious capital and geopolitical realism.

7 OECD (2025), OECD Science, Technology and Innovation Outlook 2025: Driving Change in a Shifting Landscape, OECD Publishing, Paris.

Part 1: Who does what well?

What distinguishes countries that convert science into medicines is not just how much they spend, but how fast ideas move through trials and regulation, how reliably capital can be provided at scale, and whether there is an attractive ecosystem to build modern biomanufacturing capacity, digital infrastructure (for example, for running digital remote trials) and efficient data flows. The six indicators below are chosen because they are both **comparative and policy-responsive** within a two-to-five-year window. They emphasise translational efficiency in addition to a country's ability to build and/or maintain a strong science ecosystem. Countries should not only fund basic science, but also derisk development phases through incentives, shared infrastructure and faster review cycles. While more difficult to measure, political commitment and consistency (in funding, support, willingness to reform) with clear objectives is often a key contributor to achieving set objectives and should underlie national frameworks. Where possible, the comparisons use normalised measures (per capita/per € GDP) to keep small and large countries comparable, or use metrics such as the Global Innovation Index (GII) by the World Intellectual Property Organization (WIPO).[8] The aim is to show which levers each country pulls well. The following key ecosystem performance indicators have been selected, each contributing to success in global biopharma innovation, and in most cases included in national efforts.

Indicator	Rationale – what it captures	Why it matters
R&D intensity	Measures sustained capacity to generate new knowledge and commitment to innovation (public and private)	Demonstrates value given to science
Public-private collaboration	Shows openness to collaboration and is essential for translational research; strong clusters ecosystem with excellent academic institutions	PPPs, shared IP rules and joint infrastructure help bridge between grants and phase I/II
Clinical trials uptake	Indicates system agility, strong health infrastructure (clinical centres, hospitals) and willingness to adopt innovation	Time to first patient and enrolment speed drive direction of pivotal programmes; trial density correlates with earlier access and local skills
Regulatory framework efficiency and agility	Regulatory agencies' efforts at streamlining and simplifying processes, and their openness to novel regulatory approaches and international alignment	Regulatory barriers impact speed to market; shorter and reliable high-quality regulatory review lowers costs and attracts pivotal clinical trials
VC and financing dynamics	Depth and availability of private risk capital provide ability to scale and commercialise; public financial instruments can help derisk private investment	Balanced early- and late-stage funding is key to enable a rich and dynamic pipeline of biotech startups
Translational ecosystem and startup generation	Conversion rate from science to investable companies and from companies to products	Indicates ecosystem maturity, density of qualified biotech entrepreneurs and managers, and quality of clinical networks

8 The WIPO GII is the annual benchmark of innovation performance in countries, based on around 80 indicators capturing both 'inputs', such as institutions, human capital, research, infrastructure and market and business structures and 'outputs', such as knowledge and technology, and creative outputs. It provides a comparable score and rank for each economy, enabling cross-country and year-over-year tracking of innovation capacity and results.

Countries at a glance

Country	R&D intensity	Public-private cooperation	Clinical trials uptake	Regulatory framework efficiency	VC and financing	Startups/ translational ecosystem
 **China** State-driven combining large R&D scale with speed in clinical trials, rapid clinical trials and biomanufacturing expansion, aiming for self-sufficiency and for global scope, pricing/ market dynamics in domestic market can have dampening effect	Strong and driven by large-scale state funding	State-orchestrated, cluster-based	Rising global share of trials	Improving but complex, with unique national rules	Sizeable but cyclical VC base, increasing number of licencing deals with US/European companies	More domestic initial public offerings (IPOs) than global exits
 **Denmark** High PPP density with integrated life-sciences hub and world-class clusters, and high per-capita trial productivity; data/AI infrastructure focus	Very high for size of economy	Integrated academic–industry collaboration	High trial activity per capita	Highly efficient and aligned with the EU	Strong niche VC, global investor appeal	Strong in merger and acquisition (M&A) exits in specialty niches
 **France** End-to-end strategy and strong public science base and state-industry partnerships, but hampered by administrative complexity and late-stage scaleup challenges	High in public sector, moderate in private	Well-developed, cluster-based with several clusters across France	Mid-to-high, but slower patient recruitment	Solid but bureaucratic	Strong public financing, private VC is improving	Good early-stage pipeline, fewer global-scale exits
 **Japan** Established scientific leader with strong niches, but slower to translate innovation to market at global speed; drug-lag/ drug-loss context but increased efforts to foster structured dialogue with industry	High on R&D intensity	Structured, with clear efforts to strengthen this	Mid-level, strong domestic focus	Stable, predictable, some novel pathways	Mature but conservative VC base	Gradual growth in cross-border exits

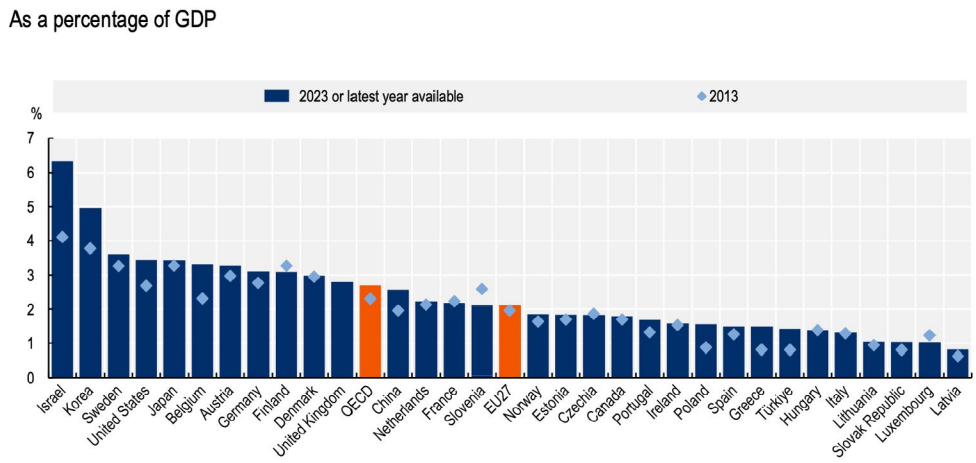
 **Saudi Arabia (KSA)** Ambitious, state-led biotech builder rapidly creating capacity from a low base to align with national diversification goals	Growing rapidly from low base	State-led partnerships with global firms	Limited but expanding	Regulatory reforms underway	Heavily state-backed funds, limited private VC	Early stage, few exits
 **Singapore** Highly coordinated and agile regional hub, leveraging strong state-industry co-location and attractive incentives to attract global players	High for size	Strong, government-facilitated collaboration	High trial density	Efficient, internationally harmonised	Strong public funding, targeted private VC	Global-first commercialisation focus
 **South Korea** High-intensity R&D and advanced manufacturing hub, rapidly expanding global clinical and contract development and manufacturing organisation (CDMO) footprint	Very high, especially in biologics	Strong, advanced manufacturing-linked clusters	Rising global trial share	Efficient, export-oriented	Growing VC depth, strong corporate backing	Strong IPO pipeline domestically
 **Switzerland** Key hub with strong R&D, patenting performance and education system and focus on clusters and public-private (PP) collaboration	Very high R&D intensity	Strong, cluster-driven PP cooperation	High quality, smaller absolute scale (vs China, US)	Predictable, transparent, fast-track pilot underway	Solid VC environment, strong corporate partnerships	Strong spin-off base
 **UK** Science-rich with strong PP links and ambitious Medicines And Healthcare Products Regulatory Agency (MHRA) reforms, but hampered by late-stage capital gaps, and pricing constraints within commercial market	Ranks highly on government R&D funding, but declining global share of private R&D	Strong clusters with international reputation, and translational institutes	High trial participation in non-commercial trials. However, the UK's slow trial set-up times and limited research capacity are constraints on competitiveness in trials	Performance showing signs of recovery, with strong potential for reform	Strong early-stage VC, weaker scaleup finance	Good licencing/ M&A record, fewer domestic IPOs
 **US** Leading, deep and mature biotech ecosystem, blending capital, research depth and commercialisation capacity, though facing strategic coordination gaps	Very high, with both public and private leadership	Highly networked clusters with academia-industry-government ties	Leading centre for global trials	Strong, adaptive, internationally influential	Most mature VC market globally	High rate of IPOs and strategic M&A

1. Overall R&D intensity and pharmaceutical R&D

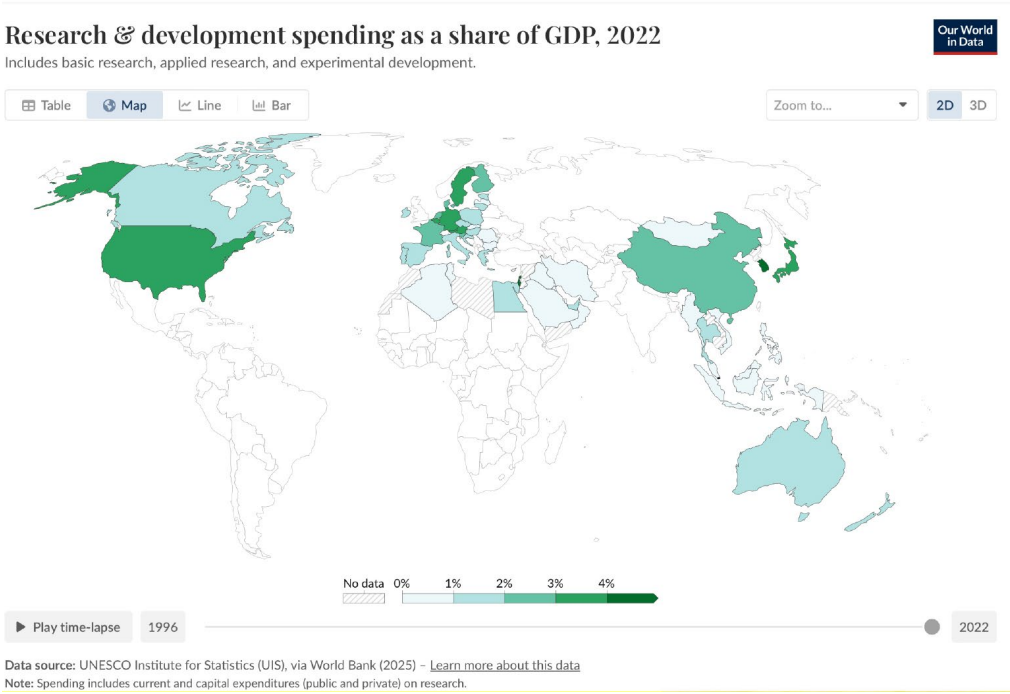
Relevance for Europe:

In his report 'A Competitiveness Strategy for Europe' Mario Draghi frames innovation and R&D as non-negotiable drivers of Europe's future economic strength. The report calls for an additional €750–800 billion per year in investment to meet the overall objectives set out in the report. In pharmaceuticals, the gap between Europe and other global leaders is stark: EU pharmaceutical R&D spending grew on average 4.4% per year between 2010 and 2022, from €27.8 billion to €46.2 billion. Over the same period, R&D spending growth in the US was 5.5% and in China 20.7% (EFPIA figures), highlighting a significant competitiveness gap in innovation capacity. Without this, Europe risks losing ground in advanced therapies, clinical trial leadership, and biomanufacturing capacity – areas where the US and Asia are rapidly consolidating their lead. The shortfall also threatens the EU's ability to deliver on the Pharmaceutical Strategy for Europe's goals of securing supply chains, reducing import dependency and strengthening strategic autonomy in health.

R&D intensity, selected economies, 2013-2023



Source: OECD. (2025). OECD Science, Technology and Innovation Outlook 2025: Driving Change in a Shifting Landscape. Paris: OECD Publishing.



South Korea leads on intensity. According to the latest OECD STI Outlook 2025, with a GERD as percentage of GDP of 5% in 2023, South Korea remains one of the leading countries in R&D intensities. Japan (with 3.44%), the US (with 3.45%) and Denmark (with 2.99%) form a solid mid-range. In absolute terms, the US is the world's largest R&D investor and China is second, which matters for sustaining very large, global-scale research systems. South Korea combines very high, sustained intensity with mission-oriented programmes that attract private R&D into scale production. Denmark's business R&D intensity is high relative to its size and Japan's R&D also remains predominantly business funded. China continues to raise both intensity and total spend from a lower per-GDP base. Funding mixes differ across Europe, East Asia and the US, but in most of these economies the business sector finances the majority of national R&D.

Stand-out country:
South Korea – translating spending into tangible industrial advantage

South Korea: South Korea ranks second in the world for R&D intensity (at around 4.9-5% of its GDP) and combines strong corporate investment with significant state-led strategic funding. The government uses R&D budgets to drive targeted industrial transformation, including in biopharma and advanced manufacturing, often through long-term technology roadmaps. Public programmes focus heavily on mission-oriented challenges, such as vaccine sovereignty and biosimilar leadership, while chaebols (large conglomerates) channel private R&D into high-scale production capabilities. The combination of sustained high-intensity investment and vertically integrated industrial policy means R&D spending directly supports South Korea's ambition to become a top five global biopharma producer.

2. Public-private collaboration

Relevance for Europe:

The strength of collaboration between various public and private actors in the biopharma ecosystem is a key driver for increased knowledge sharing and transfer and innovation generation, and hence contributes to attracting investment, talent and scientific excellence, and generating new business opportunities and economic value. Countries have developed a broad range of instruments and policy measures to encourage knowledge transfers (for example, tax incentives, direct financing of collaborative projects, joint research labs) and are investing into creating clusters. The increasing importance of knowledge and innovation in gaining leadership in critical technologies such as biotech and biopharma, both for competitiveness and to address socio-economic challenges, requires strong public and private research, and the ability to effectively use research to innovate and to translate that innovation into scalable products, globally competitive companies, and measurable health and economic impact. The strength of PP collaboration is key. There are significant differences in the degree of development, concentration of expertise, maturity and diversity. Europe has several strong clusters but is not sufficiently leveraging the **combined** strength of its rich science and its excellence in national research centres. Europe is now at a crucial point. While it is facing growing competitive pressures and declining share of global biopharma R&D, several multinational pharmaceutical and technology companies continue to make long-term R&D and infrastructure commitments in Europe, and recent data show a revival of venture and growth capital into European biotechs.

Metrics for PP collaboration:

- Co-authored scientific publications (public and industry) show the extent of scientific collaboration between academia and the private sector, using the GII ranking (data based on OECD science, technology and innovation scoreboards.
- Jointly funded university-industry R&D projects, reflecting a direct financial collaboration between government/academia and industry (GII scoring from the WIPO GII is used).
- Number of formal PP consortia or clusters (for example, Genomics England) and/or support to PP consortia and collaborations (for example, US National Institutes of Health [NIH] funding); existence of major biotech/biopharma clusters.

Country	Co-authored publications*	University-industry R&D collaboration/ projects**	Public private consortia and clusters***
 **China**	2.7% Rapid growth in co-authored R&D publications with industry partners	GII score: 83.8% Huge scale of state-supported academic-industry programmes, but limited global integration/inward-facing collaborations	National science cluster networks, eg, China National Center for Biotechnology Development
 **Denmark**	5.3% High level of co-production thanks to clusters and shared labs	GII score: 80% Based on structured and co-funded PP programmes that strengthen collaboration, notably via the Innovation Fund Denmark, which finances large university-industry consortia (eg, minimum of DKK 145.8 million call); the BioInnovation Institute, which supports academic-industry spinouts; Trial Nation (single entry point for companies, to coordinate clinical trials)	Medicon Valley plus public clusters Trial Nation – national PPP for clinical trials; Lighthouse Life Science – PP platform; BioInnovation Institute with Novo Nordisk Foundation backing
 **France**	4.6% France ranks 15 on the GII score for public-industry co-publications, produces solid public-industry publications	GII score: 60.6% System complexity and funding fragmentation with multiple overlapping institutions (Société d'Accélération du Transfert de Technologies [SATT] and Inserm Transfert) and complex/lengthy administrative processes still stand in the way of efficient collaboration uptake	Increasing investment in PP clusters, France 2030 bioclusters (eg, Paris-Saclay Cancer Cluster €80–100 million over 10 years; GenoTher biocluster) Alliance Nationale pour les Sciences de la Vie et de la Santé public-private coordination (members include major research bodies, eg, Centre National de la Recherche Scientifique [CNRS], Institut Pasteur). Industrial counterpart: Alliance pour la Recherche et l'Innovation des Industries de Santé, links public and private/PPP interface
 **Japan**	9%, very strong public-private co-publication activity, ranked in first place for this indicator in the WIPO GII 2024 ranking	GII score: 66.8% Mid-tier; universities, while top-tier, have not prioritised translational science and academic career progression did not reward industry partnerships	Fewer large-scale, cross-sector R&D consortia in biopharma than in countries like the US or Denmark, more focus on government/thematic programmes The Agency for Medical Research and Development (AMED) CiCLE – JPY55 billion, supports industry-academia collaboration across drug development; AMED budget, around JPY140.5 billion (FY2025); PRISM public-private R&D initiative in AMED framework; regenerative medicine division programmes
 **Saudi Arabia (KSA)**	1.1%	GII score: 60.3%	Nascent, but ambitious programmes with the Saudi Human Genome Program (national genomics PPP); National Biotechnology Strategy (Vision 2030) – PPP enabler; Public Investment Fund (PIF)-backed biotech/manufacturing initiatives
 **Singapore**	3%	GII score: 84.9% High level of activity, with Singapore's lead public sector agency for Science, Technology and Research (A*STAR) funding public-private partnership projects, and effective at partnering global multinationals with local R&D structures. Scope of activities includes bioimaging, clinical analysis, computational biology, biologics discovery and development[9].	Emerging through A*STAR consortia, open innovation units, A*STAR Industry Alignment Fund, with the Industry Collaboration Project designed to support industry-driven R&D projects and collaboration between companies and A*STAR research institutes etc; Diagnostics Development (DxD) Hub & translational consortia; ACCESS/Project Orbis participation (regulatory collaboration)

9 About A*STAR research: www.a-star.edu.sg/Research/overview

South Korea	6.6% Notable co-authorship of technical papers and patents, ranks among top 10 on GII 2024 for co-authorship in scientific publications	GII score: 69% Mid-to-strong performance, government actively promotes collaboration between universities and private sector through Leaders in Industry-University Collaboration 3.0, Korea Drug Development Fund (KDDF) and Korea Health Industry Development Institute (KHIDI); however, many projects still less focused on cutting-edge novel drug discovery (vs US)	Highly state-supported clusters with co-location of government bodies, companies and academia Osong Bio-Health Valley: both a regulatory hub and an industrial/biomanufacturing cluster, purpose-built, which integrates government agencies, public research institutes, companies and infrastructure with an objective of shortening translation to market through co-location of regulatory, public R&D and industry Innopolis Daedeok: science and technology innovation cluster with more than 1,500 research institutes, labs and startups across several critical tech areas (biotech, advanced materials, ICT, and nanotech) KDDF – historical, around $1 billion; plan to support 1,200 projects with KRW2.17 trillion by 2030; K-Bio/Vaccine Fund (from KRW500 billion to KRW1 trillion)
Switzerland	8% (which puts Switzerland in second place after Japan for this indicator in the GII ranking)	Switzerland ranks second on the university-industry R&D collaboration score of the WIPO GII ranking Switzerland's innovation agency, Innosuisse, co-funds joint R&D projects between companies and non-profit research institutions, with health/life sciences a key thematic area through several instruments Impact assessment of Innosuisse indicates that around 70% of the supported researchers found a startup or spin-off after the funding (startup with formal IP licencing); and three years after the funding ended, more than half of the funded innovations (57%) had either been launched on the market, implemented in the company or were scheduled to be launched in the next two years	Benefitting from a rich presence of multinational pharma companies and smaller biotechs/healthtech companies, Switzerland has several main biopharma clusters, notably The Basel BioValley, the Life Science Zurich Business Network, and the Swiss Health Valley around Geneva Example Basel: significant density and diversity of players (big pharma, startups, institutes, investors), leading to very high per-capita research output and partnerships: only 784 stakeholders yet the highest stakeholder density (1,352 per million residents); high clinical-trial density, patents per capita, and pipeline assets per capita (figures from EY[10]). Focus on late-stage strength, with 59% of trials in phase III, showing strong capabilities in advancing assets toward market. Research-intensive universities attract international talent
UK	13% High rate of co-authored publications	GII score: 82.4 Strong university-industry ties through strategic research partnerships, such as with University of Oxford, Cambridge/Cambridge Biomedical campus (eg, launch of a joint AI drug discovery centre), UCL whole genome sequencing of UK Biobank	Attractive world-leading clusters ('golden triangle' of Oxford, Cambridge, London) with strong 'crowding-in' effect Various examples of PP consortia such as Our Future Health (put in reference in footnotes) – more than 1.5 million participants

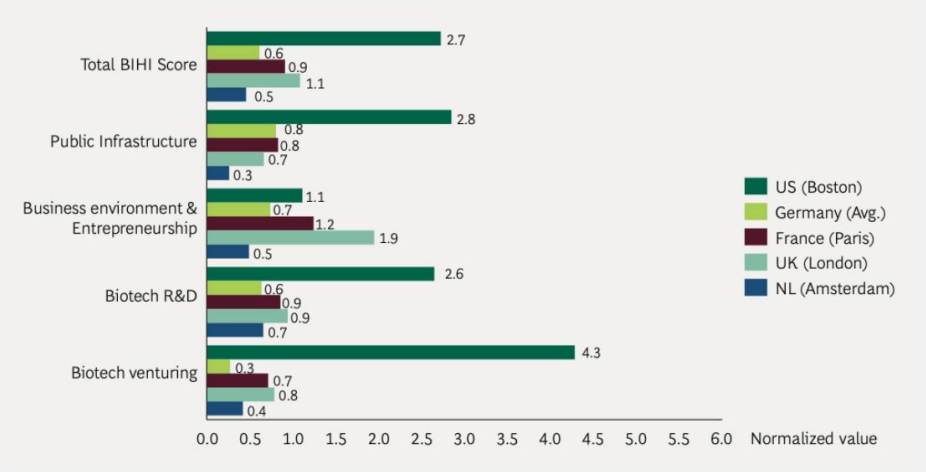
10 Weissbäcker S, 'The Basel area life science ecosystem in a global landscape', EY, 21 January 2025

US	7.9%	GII score: 91.3 Top tier globally; strong collaboration reported via the GII rankings	Major biotech clusters Funding through NIH, Advanced Research Projects Agency for Health (ARPA-H) Large flagship PPPs: Accelerating Medicines Partnership (AMP) with around $360 million, including in-kind; AMP Bespoke Gene Therapy Consortium – $104 million/five years; NIH All of Us Research Program – national data platform (broad academic/industry access)

Stand-out performers: US, UK and Denmark

US: global gold standard for scale, breadth and diversity of public-private collaboration. The US leads with a strong, mature public-private ecosystem. The US has the scale and breadth of institutionalised public-private collaboration frameworks (for example, NIH, National Centre for Advancing Translational Sciences, Biomedical Advanced Research and Development Authority [BARDA], ARPA-H, Department of Defense–DARPA biotech programmes), world-class biotech/biopharma clusters (Boston, San Francisco, San Diego) and a dense network of academic-industry consortia, including pharma-led innovation hubs. There is a high rate of co-patenting, university spinouts and large-scale federal grant programmes that encourage public-private ties. In a study published in February 2024,[11] Boston Consulting Group highlighted that the US's Boston cluster consistently outperformed all other hubs in Europe in all sub-indices used, apart from business environment and entrepreneurship.

Total BIHI score* and sub-index scores per country:



Source: Institute for Deep Tech Innovation (DEEP) at ESMT Berlin & Boston Consulting Group. (2024). Biotech Innovation Hubs in Germany – Divided and Conquered?

**BIHI stands for 'Biopharma Innovation Hubs Index', and is used by BCG as a composite metric to rank biopharma clusters, using metrics such as scientific publications, clinical trial activity, venture capital inflows etc.*

UK: the UK's biotech strength is anchored in solid university-industry links, concentrated in the Cambridge-Oxford-London triangle, one of the world's leading life-sciences clusters. Universities like Oxford and Cambridge consistently produce high-value spinouts through vehicles such as Oxford Sciences Innovation and Cambridge Enterprise,

11 Nisslein M and others, (2024). 'Biotech innovation hubs in Germany – divided and conquered?' ESMT Berlin, February 2024

*The GII score refers here to GII 5.2.1: public research-industry co-publications (in % share of total research output, representing a five-year average).
**The GII score refers here to GII 5.2.2: university-industry R&D collaboration score, extracted from the WIPO GII Index 2024 – NB: scoring is industry-wide, not only health/biopharma. For more information on the GII Index: www.wipo.int/web-publications/global-innovation-index-2024/en/appendix-i-conceptual-and-measurement-framework-of-the-global-innovation-index.html
*** Largely based on known national initiatives (eg, Global Health Innovative Technology Fund, AION Labs, A*STAR, Medicon Valley).

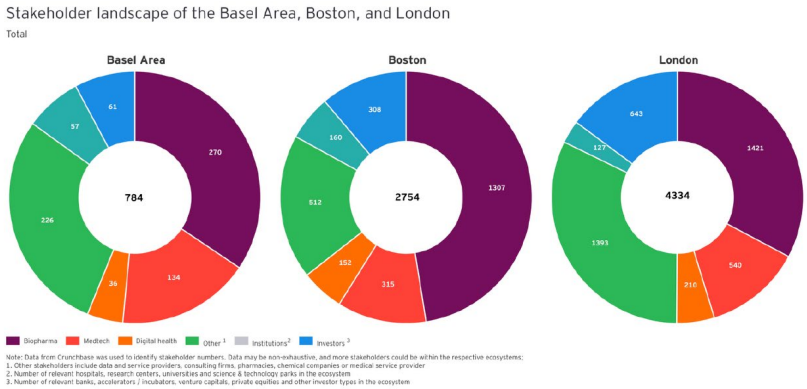
supported by a strong culture of co-authored research between academia and industry. National programmes such as the Medicines Discovery Catapult and the Cell and Gene Therapy Catapult provide a structured translational backbone, embedding public-private collaboration from discovery through to clinical application. London's role as a hub for venture capital and capital markets gives the ecosystem additional financial depth, while the NHS offers a leading real-world data (RWD) integration, making the UK still an attractive location for clinical trials (though its lead has weakened) and translational research. However, the UK's ability to scale biotech companies into global leaders is constrained by persistent funding gaps at the growth stage, limiting the transition from strong early-stage science to sustained commercial success.

Denmark: Denmark's life-sciences ecosystem is anchored by strong institutionalised public-private platforms such as Trial Nation, the BioInnovation Institute, Medicon Valley and the Greater Copenhagen Bioscience Cluster. Medicon Valley alone hosts more than 1,100 life-science companies employing more than 60,000 professionals, with particular strengths in neurology, inflammatory diseases, oncology and diabetes research. High rates of co-authored publications, a proactive government role in strategic life-science planning, and advanced health-data integration underpin a collaborative research environment. Denmark exemplifies a fully integrated model linking universities, hospitals, startups and multinationals through a steady pipeline of co-funded biotech initiatives and robust public-private funding mechanisms. While positioned for stronger performance, Denmark's relatively small scale limits the volume of collaborations compared to larger competitors.

Honourable mention: South Korea

South Korea: South Korea's biopharma ecosystem is underpinned by sustained state investment in large-scale translational research institutes such as the Korea Research Institute of Bioscience and Biotechnology (public research/translational institute), the K-BioX clusters and the KDDF. The country ranks highly in co-publication metrics and has built tightly coordinated biopharma clusters with strong infrastructure, particularly in advanced manufacturing and convergent technologies. A prominent state role in developing biocluster infrastructure has positioned South Korea as a leader in biomanufacturing and biosimilars. However, to transition towards a more innovation-driven ecosystem, South Korea will need to strengthen startup density, expand risk-capital availability and enhance late-stage development and commercialization capabilities to complement its biomanufacturing base[12].

Breaking down the building blocks of biopharma clusters:



Source: EY: The Basel area life-science ecosystem in a global landscape, January 2025

12 Kim Ji-hye. (2024). Korean biotech startups face tough road ahead without early investment support. Korea Biomedical Review, 7 November 2024; Korea's biotech startups face tough investment climate, Maeil Business Newspaper / Pulse News, 9 March 2023

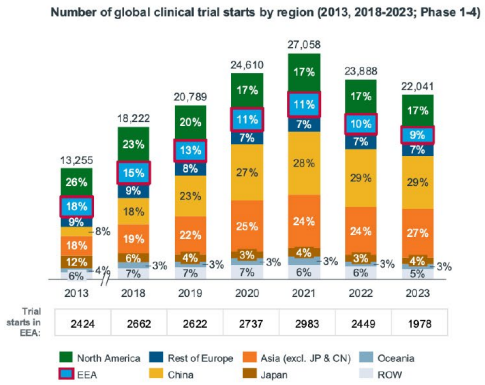
3. Clinical trials

Relevance for Europe:

Clinical trials are an essential enabler for driving innovation and strengthening the research ecosystem in a country. Increased trial innovation will be essential in a context that is becoming ever more competitive and where first-mover advantage is critical. Innovations such as decentralised clinical trial (DCT) methodologies will become part of most trial processes and operational decisions. Countries that want to attract clinical trials will need to rapidly adapt to these shifts.

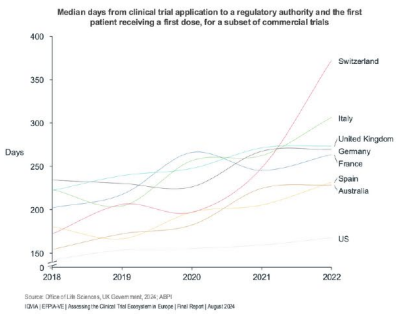
The APAC region is becoming a serious competitor for the US and Europe. According to some figures, between 2017 and 2022 the region posted growth in clinical trials of around 10%, ahead of growth in other major regions including the US, Europe and the rest of the world.[13] Growth exceeded the overall average figure of 5.3% per year. As of 2023, the number of trials reached 14,346.[14] APAC's rising appeal can be explained by several factors, among which the fact that many countries, including Japan, South Korea and China, require local data for drug approval (though also accepting non-local data). Leading biopharma countries in APAC identified for this study have well-established medical infrastructures, high regulatory standards and streamlined application processes, are exploring the use of DCTs and digital health technologies in clinical research, and, in the case of China, can offer lower costs.[15] As highlighted in one recent article: "Throughout the region, regulatory bodies are looking at how real-world data (RWD) complements traditional development approaches, leveraging technology solutions to enable decentralised gathering of participant data, where appropriate, and what role patient advocacy should have in clinical trial design."[16]

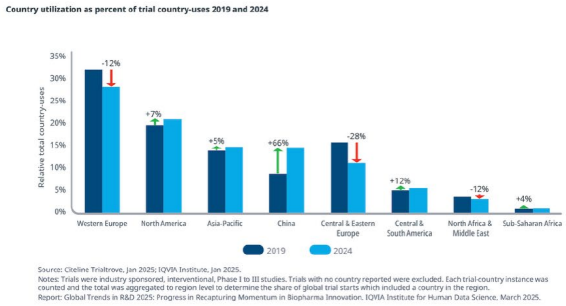
Maintaining Europe's strength as an attractive hub for clinical trials will be critical in any biotech/biopharma policy, national and EU policies need to move forward in a joined-up manner, and member states must double down on efforts to implement EU legislation. This is well recognised by the European Commission, the European Medicines Agency and the Heads of Medicines Agencies, which have jointly defined new targets for clinical trials, such as an additional 500 multinational clinical trials are added to the current average of 900 that are already authorised each year. The EU still has a considerable number of strengths in its ecosystem, though there are significant differences between member states on several performance markers. As the EFPIA-commissioned IQVIA study has shown, Europe's share in clinical trials is declining, with countries in Asia becoming more significant locations for new clinical trials, and with China moving from 8% of trial starts in 2013 to 29% in 2023.



Top countries holding the highest number of commercial trials (2018-2023, Phase 1-4)

Country	2018	2023	CAGR
US	1850	**1719**	-2%
China	727	**1412**	14%
Japan	472	**546**	3%
Spain	491	**485**	0%
South Korea	491	**444**	-2%
Australia	436	**444**	0%
UK	566	**437**	-5%
Canada	473	**429**	-2%
Germany	618	**417**	-8%





Source: IQVIA. 'Assessing the clinical trial ecosystem in Europe', October 2024

13 Siddiqui A, 'What's APAC's recipe of success in clinical trials market?', BioSpectrum Asia Edition, 1 May 2024
14 Bejer G, 'Diversity in Asia-Pacific region's clinical trials pushed', Healthcare Asia Magazine, 14 October 2024 (citing GlobalData and NovoTech reports)
15 Life Science Connect Editorial Staff, 'Reasons why APAC leads the world in clinical trials', Clinical Leader, 21 September 2023
16 Siddiqui A. 'What's APAC's recipe of success in clinical trials market?', BioSpectrum Asia Edition, 1 May 2024,

Country	Key data
 **China**	China's share in clinical trials sponsored by companies has risen from 8% in 2013 to 29% in 2023 (IQVIA data[17]). The capacity to launch trials quickly and at less cost than in the US and Europe is widely considered one of the reasons for China's rise, alongside a substantial urban patient pool and a large hospital network. Rapid regulatory reform and strong domestic sponsorship have been put in place; however, approval delays (nine to 12 months) and lingering IP/systems concerns persist. To match FDA timelines, China's regulatory authority, the National Medical Products Administration (NMPA), seeks to cut the clinical trial review waiting period for novel medicines to 30 working days down from the current 60 working days. This is proposed to apply to key medicines with clear clinical value that are supported by the Chinese government and paediatric drugs for cancers and rare diseases, as well as global studies that are simultaneously conducted in China and multinational trials led by Chinese investigators.[18]
 **Denmark**	High per-capita trial activity, placing it among the top three countries in Europe when measured as number of trials per million inhabitants, as highlighted by Trial Nation. Trial Nation is a public private partnership which serves as a single entry point in Denmark for conducting trials and which seeks to increase Denmark's attractiveness for clinical trials. Denmark has the ambition to process phase I approvals in just 14 days (Denmark launched a 14-day expedited assessment for mono-national phase I/integrated phase I–II trials on 14 Aug 2025, an initiative developed in collaboration with the Danish Medicines Agency (DKMA) and the Danish National Center for Ethics[19]. Denmark has demonstrated leadership in the EU with the adoption of one of the first DCT-specific guidance.
 **France**	France remains in third place in Europe for multinational clinical trials conducted domestically (Les Entreprises du Médicament [LEEM] barometer figures) and in the top three for single country commercial trials in the EEA (IQVIA/ EFPIA data). Solid oncology trial base (around 41% of active trials), reduced time to first patient (160 days in 2024 vs 204 in 2019), and supportive R&D strategies under Health Innovation 2030. However, its share is slipping. A large patient population and universal healthcare system enable broad access to trials. However, it has slower regulatory timelines than leading APAC hubs, though implementation of the EU Clinical Trials Regulation has improved this.
 **Japan**	Comprehensive strategy presented in March 2025 to strengthen the clinical research ecosystem. This includes support to decentralised clinical trials, incentivise research participation, promote centralized Institutional Review Boards (IRBs). IRB approval can take four to eight weeks; Pharmaceuticals and Medical Devices Agency (PMDA) response is provided in approximately 30 days.
 **Saudi Arabia (KSA)**	The Saudi Food and Drug Authority (SFDA) requires trials to be registered in the Saudi Clinical Trials Registry and sets defined administrative timelines (for example, review response windows and appointment-based submissions); updated guidance and priority review processes were refreshed in 2024.
 **Singapore**	Benefits from highly developed research infrastructure and significant government-funded life-sciences hubs. Singapore has introduced streamlined regulatory review pathways to accelerate approval process. Through the Singapore Clinical Research Institute – Singapore's national coordinating body to implement the national clinical trial strategy and enhance Singapore's clinical trial ecosystem – it coordinates and supports 12 multi-country networks across the region.
 **South Korea**	South Korea benefits from streamlined regulatory processes that have significantly accelerated trial startup times. Under the Clinical Trial Authorisation (CTA) system, trials are approved within 30 days of submission, with sponsors empowered to file simultaneously to institutional review boards (IRBs), ethics committees, and the Ministry of Food and Drug Safety (MFDS), minimising delays[20]. Heavy investment in biopharma and early-phase trials, supported by government R&D backing and fast-growing trial ecosystem. South Korea has built a strong reputation for speed, efficiency and regulatory support in clinical research, distinguishing it from other APAC regions.[21] The country's advanced healthcare infrastructure, strong government backing, and well-established research ecosystem enable it to attract a high volume of global clinical trials. However, it still needs to improve flexibility in adopting innovative approaches and novel trial designs. Adoption of DCTs also remains limited/patchy as regulatory challenges have slowed their implementation.[22]
 **Switzerland**	Robust clinical trial ecosystem, with Swissmedic as the key regulatory authority and parallel ethics committee review structure at cantonal level. Launch of a pilot fast-track procedure in July 2025 to reduce standard review times from 30 to 20 days and for first in human/new active substance (NAS) from 60 to 40 days (conditional on certain criteria, for example, serious/life-threatening disease). Fee reduction of 80% for academic trials. Some updates made recently to strengthen transparency, allow for digital tools such as e-consent and improve alignment with international norms[23].

17 IQVIA & EFPIA. (2024). Assessing the Clinical Trial Ecosystem in Europe (Final report, August 2024).

18 Liu A, 'China proposes shorter clinical trial reviews in efforts to accelerate drug development', Fierce Biotech, 16 June 2025

19 https://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/expedited-processing-for-phase-i-and-integrated-phase-iii-trial-applications/

20 BioSpectrum Asia, citing GlobalData/Clinical Trials Arena

21 Chmielewska I, 'Spotlight on South Korea: innovation, clinical trials, and market trends shaping 2025', Norstella, 4 March 2025

22 Miseta E, 'Why South Korea is the hottest growth spot for clinical trials', Novatech, 30 November 2017; see also: Armellini J and others, 'Seizing opportunities: overcoming the challenges of decentralized clinical trials in Asia-Pacific', IQVIA, 27 December 2023

23 Swissmedic. (2025). Clinical trial application and fast-track pilot project for clinical trials in Switzerland. Bern: Swiss Agency for Therapeutic Products.

UK	The ABPI clinical trials report published in December 2024[24] highlights that the UK is now ranked eighth in the world on commercially-led phase III clinical trials, with enrolment in the UK dropping by 44% between 2017/18 and 2021/22. The UK currently still has one of the longest clinical trials set-up times among peers and lags other countries in Europe on several key metrics. The UK Prime Minister has set a March 2026 target to address this and reduce commercial trial start up times to 150 days. Based on a government review[25] in April 2025, the new Clinical Trials Regulations were adopted, bringing harmonisation with EU regulation and international legislation standards. This was meant to streamline the process and increase flexibility through: changes to the application and review process to reduce duplication, publication and reporting requirements; and updates to good clinical practice provisions. The MHRA aims to "realise the opportunity of being a sovereign regulator" and meet its obligation to complete a combined regulatory and ethics review for each new trial in 60 days, within just 40 days (effectively 30 plus 10).[26] A combined review will occur within a maximum of 30 calendar days, and a decision will be granted after responses have been received to any request for further information (RFI) within a maximum of 10 calendar days (reduced from 16). The new legislation also aims for greater flexibility for sponsors and increases the time sponsors must respond to an RFI from 14 days to 60 days. A 2025 government-led pilot of an mRNA norovirus vaccine trial reduced initiation time from nearly nine months to 70 days. The MHRA is to launch a pilot aimed at refining the approval process for amendments to clinical studies. Pilot to run from October 2025 to 31 March 2026, ahead of the forthcoming clinical trials regulation, which is to be implemented in April 2026.[27]
US	Strong clinical trial infrastructure, diverse patient access and regulatory clarity. The Food and Drug Administration (FDA) adopts an objection-based method towards clinical-trial review. The FDA finalised DCT guidance in September 2024 ("Conducting Clinical Trials with Decentralized Elements"). With the rise of China, the US's ability to improve on what is perceived as long and costly approval processes for phase I studies are increasingly under scrutiny,[28] with China's processes seen as more cost-efficient and faster.

Stand-out performers: China, Singapore and South Korea

China: China is making clinical trial speed and costs an integral part of its biopharma strategy. Clinical development in China can rapidly move from startup to trial. It uses an 'implied approval' system: if no issues are raised, the sponsor may start the trial after 60 working days. In a draft policy posted by China's NMPA, authorities are proposing a 30-day clock for certain innovative drugs (2024-2025 drafts).[29] Clinical trials are estimated at 30–40% lower cost than Western counterparts,[30] accelerating throughput and commercial feasibility. While China has significantly aligned with international standards in recent years, early-phase clinical trials may still vary in methodological rigour. In addition, regulatory decisions regarding clinical trials can lack full transparency, with less frequent publication of detailed reviewer comments or full clinical trial data, compared with regulatory agencies such as the FDA and EMA. While the Center for Drug Evaluation **does** publish approval lists, detailed review rationales and clinical datasets are generally not made public like in the EMA's European public assessment reports or FDA's drug labels and approval packages.

Singapore: Singapore is a reliable country for conducting clinical trials with high review-performance reliability. The Health Sciences Authority (HSA) reports approval timing metrics, with approximately 98–100% of trials approved within published review timelines in recent years. Submissions in 2023 were heavily multinational; around 80% multinational trials, which shows high level of cross-border research and consistent regulatory performance for cross-border studies.[31] Singapore actively participates in regional and international clinical research networks. It is strong in data governance, trial logistics and co-location of industry with academic research (Biopolis, translational platforms). High regulatory credibility and IP protection make Singapore attractive for industry-sponsored, high-value studies, with an increase in oncology trials to over 50% of trials approved in Singapore in 2023, considered a reflection of Singapore's focus on high-impact research areas.[32]

South Korea: South Korea is in a strong position among APAC countries for sponsor-initiated trials. It has implemented a comprehensive five-year plan for the advancement of clinical trials in 2019 to establish the country as a leading research and clinical trials destination regionally and globally. It included the creation of a clinical trials review division to expedite pre-investigational-new-drug (IND) reviews, electronic informed consent and expanded treatment opportunities including for rare diseases. The country offers fast study startup and efficient patient recruitment and patient availability due to high population density, backed by tech-enabled and accredited hospitals with qualified trial sites. South

24 ABPI, 'The road to recovery for UK industry clinical trials,' 10 December 2024
25 UK Government, 'Commercial clinical trials in the UK: the Lord O'Shaughnessy review – final report', 26 May 26, 2023
26 Kuchler H, Neville S, 'UK drugs agency outsources 40% of applications after Brexit turbulence', Financial Times, 20 July 20 2025
27 Clinical Trials Arena, 'UK MHRA to initiate pilot for clinical trials', 29 August 2025
28 Gottlieb S, 'How to stop the shift of drug discovery from the US to China,' Stat News, 6 May 2025
29 ibid
30 According to some estimates, as quoted in: Hipp R and others, 'China's rise in biopharma', Porsche Consulting, May 2025
31 Clinical Trials Singapore, 'Statistics and infographics' (nd)
32 Parliamentary Q&A, 'Reasons for decline in clinical trial approvals despite increase in biomedical investments', Ministry of Health Singapore, 4 February 2025

Korea processed 711 IND approvals in 2022 (49% global, 35% local), reflecting high throughput. This speed is driven by an efficient CTA/IND workflow and increasing use of central/expedited IRB procedures.[33] Despite a global 5.5% decline in clinical trial activity in 2023, South Korea experienced a 9% increase, signalling resilience and continued growth.[34]

4. Regulatory framework and development efficiency

Relevance for Europe:

Both the Draghi and Letta reports and the Competitiveness Compass highlight the need for simplification of regulation, and speed and flexibility. In pharmaceutical R&D, for every 100 drugs that begin human testing, only around 10 will make it to patients.[35] In consequence, R&D productivity, cost efficiency and speed are major drivers of companies' business development decisions. A key factor for a competitive ecosystem that attracts first-wave new product launches and quality in medical care is efficient access to innovative pharmaceuticals. The regulatory system plays an integral part in enabling that through incentives and innovation in regulatory systems and practices while ensuring only safe, efficacious and quality medicines are authorized[36].

Regulatory agencies can support efforts to increase R&D productivity and success rates for compounds in development through providing high standards of safety and efficacy while keeping pace with the development of science.[37] Expedited regulatory approval pathways, performance of early advice and scientific advisory committees, competitive assessment and approval timelines, qualified expertise and openness to regulatory sandboxes, and the use of rigorous analytics, including AI-driven methods to generate evidence, are playing an important role in determining the overall attractiveness of a country and its investment-friendly ecosystem.[38] The increased use of expedited pathways and other flexibilities, and the use of reliance mechanisms by various regulatory authorities are illustrative trends. With rapidly changing science, regulatory agencies are increasingly looking at building structures for dialogue and partnerships, such as the FDA's Centre for Clinical Trial Innovation, the Center for Real-World Evidence Innovation and the Rare Disease Innovation Hub.

The EU has a world-class regulatory system and high standards for drug approval. It delivers real-world evidence with DARWIN EU, its data analysis and real-world interrogation network, and launched a multi-annual workplan on AI as well as a reflection paper on AI development and deployment within the medicinal-product lifecycle. However, evidence suggests that there still is slower adoption of real-world evidence, innovative pathways and digital methodologies compared to more agile agencies such as the FDA[39]. Overall, the prevailing trend indicates that most pharmaceutical companies currently will still chose to submit in the US before considering Europe.[40] Given the ongoing review of the general pharmaceutical legislation and the EU's competence over the EMA and the European regulatory process, as well as other areas of relevance to enable greater development efficiency, this is an area where the EU can improve.

What is clear from recent developments across the countries studied is that competition to attract more clinical trials and first regulatory applications is driving regulatory agencies' reform efforts. APAC countries still feature jurisdiction-specific regulatory authorities, with varying frameworks and guidance. However, political dynamics are likely to further strengthen efforts towards greater regional collaboration.

33 Ormandy H, (2024). 'How South Korea became a leading destination for clinical trials', Precision for Medicine, 5 September 2024

34 Siddiqui A, (2024). 'What's APAC's recipe of success in clinical trials market?', BioSpectrum Asia Edition, 1 May 2024

35 Tran B. (2025). 'Clinical trial success rates: how many drugs make it to market? (Latest approval stats)', Patent PC, 16 July 2025

36 Heikkinen, I. et al. (2023). Role of innovation in pharmaceutical regulation: A proposal for principles to evaluate EU General Pharmaceutical Legislation from the innovator perspective, Drug Discovery Today, Volume 28, Issue 5, 2023,

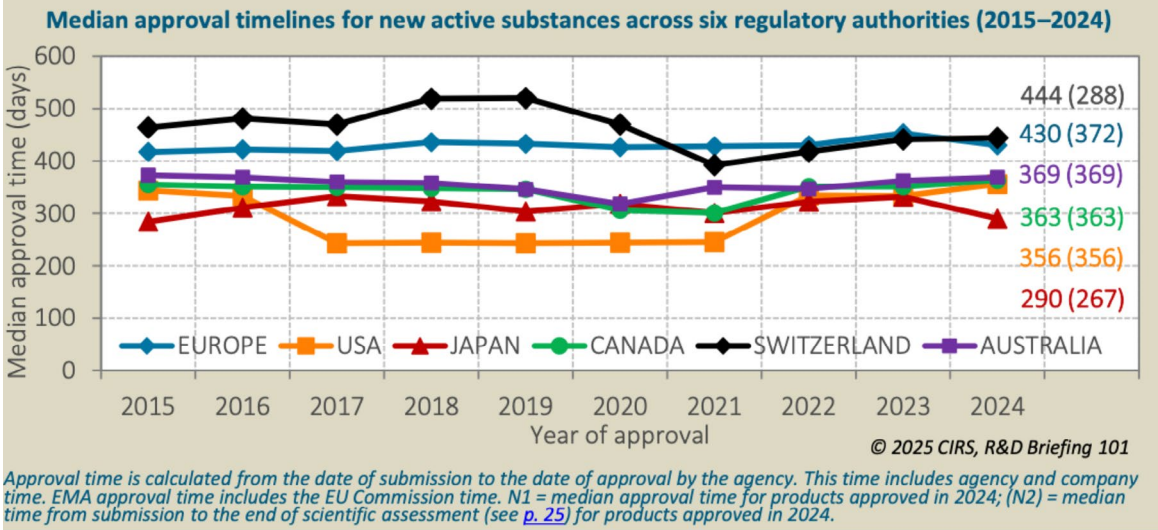
37 Franco P, Haefliger S, 'Competition of regulatory ecosystems in approving medicines: policy implications in the case of Europe', Drug Discovery Today, 2 February 2025

38 Lara, J., Kermad, A., Bujar, M., & McAuslane, N. (2025). R&D Briefing 101: New drug approvals in six major authorities 2015–2024: Trends in an evolving regulatory landscape. London: Centre for Innovation in Regulatory Science (CIRS).

39 See for example: Bachinger M, Jankowski MA, Kesselheim AS, Krüger N. (2025). Real-World Evidence in Drug Approvals at the European Medicines Agency. JAMA Netw Open. 2025; Zong J, Rojubally A, Pan X, et al. A Review and Comparative Case Study Analysis of Real-World Evidence in European Regulatory and Health Technology Assessment Decision Making for Oncology Medicines. Value Health. 2025; Charles River Associates for EFPIA. The Root Causes of Unavailability and Delay to Innovative Medicines in Europe.2025.

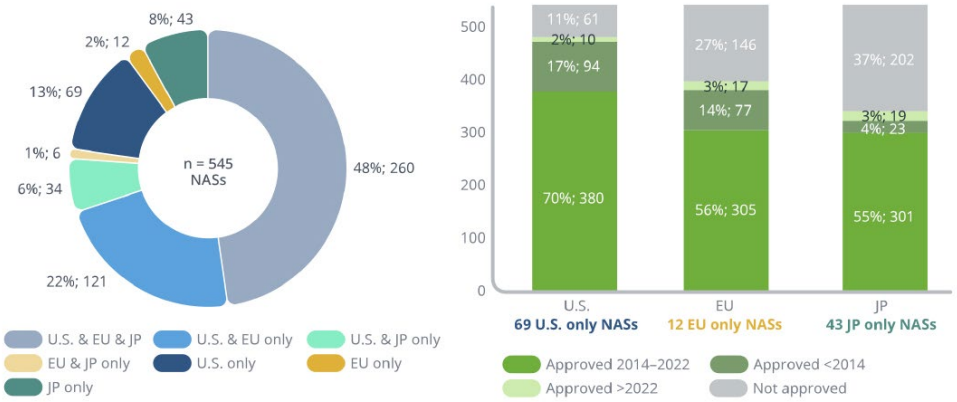
40 Franco P, Haefliger S, 'Competition of regulatory ecosystems in approving medicines: policy implications in the case of Europe', Drug Discovery Today, 2 February 2025

Median approval timelines for new active substances across six regulatory authorities (2015-2024):



Source: CIRS R&D Briefing 101: New drug approvals in six major authorities 2015–2024: Trends in an evolving regulatory landscape. London: Centre for Innovation in Regulatory Science (CIRS).

New drug approvals: regional overlap and exclusivity across US, EU and Japan:



Source: IQVIA Institute, Oct 2024.
Notes: Approvals in the <2014 and >2022 category (in the bar chart) are NASs that were approved by one or both of the other two governing bodies within 2014–2022.
Report: Assessing Availability of New Drugs in Europe, Japan, and the U.S. IQVIA Institute for Human Data Science, December 2024

Source: IQVIA Institute for Human Data Science. (2024, December). Assessing Availability of New Drugs in Europe, Japan, and the U.S. IQVIA.

Country	Key characteristics of the regulatory system
 **China**	**Speed of approvals:** • Overall, the approval timelines for new drugs in the US, the EU and Japan have been earlier than those in China. However, compared to pre-2021, China has significantly narrowed the gap in new drug approval dates with the US and the EU from 2021 onwards.[41] Post-2021, the approval date gap between China and the US shortened by 351 days. Similarly, the gap decreased by 663 days with the EU.[42] • Review and approval lead time for seasonal flu vaccines will be reduced from 60 to 45 working days or less. **Flexible/accelerated pathways:** • China's 2025 Pharmaceutical Regulatory Roadmap: the General Office of the State Council issued a policy in January 2025, known as the 2025 Opinions,[43] in which it outlined reform measures to attract foreign innovative drugs and biologics through streamlined, expedited review timelines and priority approval pathways for certain categories of drugs (for example, CGTs, overseas approved drugs, combination vaccines). In tandem with growing alignment to International Council for Harmonisation (ICH) standards, broader support for global multi-centre trials, and segmented biologics manufacturing models. The proposals optimise the review and approval for supplemental drug applications requiring inspection/testing, from 200 working days to 60 working days. • China's NMPA offers expedited pathways for drugs addressing critical or unmet medical need and seeks to accelerate timelines for orphan drugs and medical devices. **Digital and data-driven innovation:** • RWE guidelines issued to enable more rapid approvals by leveraging RWE to bridge global data and reduce drug lag.
 **France**  **Denmark**	**Speed of approvals:** • Average EMA timelines are 210 days plus clock stops (approximately 12 months), around 430 days end-to-end from submission to final approval (CIRS data 2025). **Flexible/accelerated pathways:** • PRIME designation and adaptive licencing processes are in place but not frequently used. The EMA had no NAS approvals via accelerated assessment during 2024 (CIRS data, 2024). **Digital and data-driven innovation:** • The EMA is moving towards a broader regulatory framework for AI, with more guidance expected in the coming years, incorporating AI and RWE (EMA's June 2023 RWE framework) into regulatory assessments as part of the EMA's multi-annual workplan (2023-2028). • The EMA's DARWIN EU federated network connects healthcare data from across Europe, offering a federated pathway enabling routine use of RWD for safety monitoring and supplementary efficacy data. • **France:** pilot programme launched in 2024 with the French regulatory agency, Agence Nationale de Sécurité du Médicament et des Produits de Santé, together with the Commission Nationale de l'Informatique et des Libertés (data protection authority) and the Ministère des Solidarités et de la Santé (Ministry of Health); up to 20 decentralised clinical trials are being supported in a structured and experimental phase aimed at integrating digital elements like e-consent, remote drug delivery and at-home procedures, while ensuring general data protection regulation compliance. • **Denmark:** in its National Strategy for Digitalization 2022-2026, Denmark allocated DKK17 million specifically for a national AI regulatory sandbox (2023 strategy), which fosters supervised testing of AI solutions with authorities, complementary to EMA-level work.

41 Yan Y and others, 'New drug approvals in China: an international comparative analysis, 2019-2023', Drug Design, Development and Therapy 19, 2629–39, 2025

42 ibid

43 Source: General Office of the State Council (Circular 53), as translated and analysed by Bird & Bird, 2025

Japan	Japan's drug approvals are managed by the PMDA under the Ministry of Health. Measures have been taken to address Japan's 'drug lag' and 'drug loss' (approval of a drug in other locations but not Japan) and align Japan's regulatory frameworks with global best practice. **Speed of approvals:** • Median approval time for marketing authorisation applications of 332 days (in 2023) • Accelerated pathways for Sakigake-designated products targeted at 6 months. Overall timing of approval remains however slower than the FDA, according to IQVIA data[44] ,across 285 NASs approved in both the US and Japan (2014-2022), the mean and median time to approval is 2.8 years faster and 1.3 years faster in the US, respectively. **Flexible/accelerated pathways:** • The PMDA supports conditional approvals, priority review (approx. 9 months instead of 12) and early consultation services. • Introduction of the SAKIGAKE (pioneer) system, which is similar in concept to the Breakthrough designation in the US or PRIME designation in Europe, and targets novel medical products first developed in Japan[45] • Dedicated approval pathways for investigational cell and gene therapy (CGT) product candidates on a case-by-case basis (through Japan's Act on the Safety of Regenerative Medicine). As of 2025, Japan's Ministry of Health, Labour and Welfare has authorised the use of 21 new regenerative medical products, including 17 regenerative medical products and four gene therapy products.[46] **Digital and data-driven innovation:** • Regulatory authority is still developing key principles but has been investing in RWD and digital health regulation, and has used RWD for post-marketing safety studies since 2018; the Real-World Data Working Group (2021-2024) was tasked with defining principles for data reliability. • Gradually building tools and policies for AI-enabled medical devices, with a pilot for priority review of Software as a Medical Device.
Saudi Arabia (KSA)	Saudi Arabia's SFDA is a maturing regulatory framework (WHO ML4; aligned with ICH, Pharmaceutical Inspection Co-operation Scheme standards), globally aligned regulator with robust processes, tiered approval speeds, and modern oversight mechanisms. Its use of reliance pathways and conditional approvals demonstrates adaptability, while its pharmacovigilance initiatives and policies governing in vitro diagnostics, including companion diagnostics tied to targeted therapies, reflect forward-looking scientific governance.
Singapore	Singapore's HSA (spell out) holds a top-tier regulatory maturity designation – maturity level (ML) 4 – from the WHO. **Speed of approvals:** • Singapore uses a verification (reliance) pathway for NAS approvals, allowing streamlined review based on approvals from trusted regulators. The total review typically targets around 110 working days. • Singapore is carving out a place as a regional testbed and is part of the Access Consortium, which promotes regulatory collaboration with Australia, Canada, Switzerland and the UK –enhancing efficiency in advanced therapy (for example, ATMP) assessments. **Flexible/accelerated pathways:** • Integrates AI regulatory preparedness, provides a digital health sandbox, and supports priority review and conditional pathways.
South Korea	South Korea's Ministry of Food and Drug Safety (MFDS) oversees drug approvals, GMP inspections, post-market surveillance. **Speed of approvals:** • The overall median review time was around 315 days, with biologics taking around 353 days and orphan drugs around 191 days (data based on a 2022 report[47]), and a drug lag, with a median approval gap vs EU and US of around 551 days. Recent reforms aim to shorten review times, with the MFDS targeting an average of about 295 days through modernizing its processes, increase number of experts, adapting to international benchmarks, and strategies like parallel review processes. **Flexible/accelerated pathways:** • South Korea seeks to accelerate review speed through expedited programmes like the Global Innovative products on Fast Track programme, which applies to breakthrough therapies, orphan drugs or urgent treatments and within which approvals aim to take less than 90 days. **Digital and data-driven innovation:** • South Korea is starting to invest in digital/regulatory innovation through targeted programmes (for example, AI sandbox, digital health pilots). • MFDS guidelines since 2019 and 2021 permit RWD in risk-management plans and observational research. The Comprehensive Plan for Drug Safety (2020-2024) and hosting of a global symposium on use of AI across the medical product lifecycle reflect South Korea's ecosystem building for data infrastructure and regulatory science training.

44 IQVIA Institute for Human Data Science (2023). Assessing the Availability of New Medicines in Europe, Japan and the United States. IQVIA Institute.

45 Laurent, A. (2025). Japan's drug approval process: A guide to PMDA and MHLW, Intuition Labs, 27 November 2025

46 Tan EHP and others, 'Pursuing cell therapy approvals in APAC: your guide to navigating regulations in Japan, South Korea, and Singapore', Cytotherapy 27(9), 1043–59, 2025

47 Choi H and others, 'Changes in the review period of drug application and a drug lag from the FDA and the EMA: An industry survey in South Korea between 2011 and 2020', Therapeutic Innovation & Regulatory Science 57(3), 552–60, 2022

Switzerland	**Speed of approvals:** • Switzerland's regulatory agency, Swissmedic, had the longest overall approval time (447 days) compared to the EMA (428) and FDA (244); the timelines were more comparable when considering only the agency's time spent on the scientific assessment, with Swissmedic at 194 days, the EMA at 218 days, and the FDA at 184 days (based on data regarding new active substances approved in 2019–2021[48]). **Flexible/accelerated pathways:** • Fast-track authorisation for severe/life-threatening diseases with unmet need and high expected benefit, and temporary authorisation process. • Swissmedic authorised a total of 46 NAS applications in 2024, of which 41% were processed in an accelerated authorisation procedure, which includes: fast-track authorisation procedure; procedure with prior notification; the temporary authorisation procedure; and the international procedures through Orbis, started by the US FDA in 2020 for promising oncology drugs, which made it possible to significantly reduce the submission gap (ie, the difference between the submission dates to different authorities) and the duration of assessment for innovative cancer medicines (source: Swissmedic). • Creation of the Swissmedic 'innovation office' in 2022: front door for startups and advanced therapy medicine product (ATMP) developers to get early scientific advice. • Clinical trials fast-track (pilot from July 2025): aim to cut from 30 to 20 days for studies with high medical need. **Digital/data driven innovation:** • Objectives set for AI-supported applications and modern data standards.
UK	**Speed of approvals:** • In 2021, the MHRA authorised 35 novel medicinal products containing NASs, compared to 52 by the FDA and 40 by the EMA.[49] • A system of 'international recognition procedure' (applicable since January 2024) enables reliance on 'trusted-partner' (for example, the FDA, EMA, the Therapeutic Goods Administration [TGA], Health Canada, Japan) approvals alongside national routes; used heavily in early rollout. The MHRA processed 15 out of 16 NAS authorisations via EU reliance (European Commission Decision Reliance Procedure) or the new International Recognition Procedure (IRP). Nearly 40% of applications use the IRP,[50] in order to focus resources on areas of innovation where the UK can take a leadership position, and to improve the UK's global competitiveness as a hub for clinical trials. **Flexible/accelerated pathways:** • Innovative Licencing and Access Pathway (ILAP); key mechanism for faster access, integrates the MHRA, HTA bodies and the NHS, seeks to compress development to access; open to both commercial and pre-commercial developers (UK-based or global) of potentially transformative medicines or drug-device combination products that have a therapeutic aim and evidence of safe use in humans; confirmatory trials have not yet started. • FDA Project Orbis – programme to review and approve promising cancer drugs includes the MHRA **Digital and data-driven innovation:** • Launch of seven Centres of Excellence in Regulatory Science and Innovation (CERSIs) in 2025 to advance areas such as AI, in-silico modelling and pharmacogenomics. • The MHRA's Data Strategy (2024-2027) emphasises RWE and AI integration through initiatives like federated analytics, a data-science network and AI task forces. • RWE Scientific Dialogue Programme (2025) encourages early sponsor-regulator conversations on using RWD in evidence generation.

48 Bujar M and others, 'An evaluation of the Swissmedic regulatory framework for new active substances', Therapeutic Innovation & Regulatory Science, 2023

49 Hofer MP and others, 'Regulatory policy and pharmaceutical innovation in the United Kingdom after Brexit: Initial insights', Frontiers in Medicine 9, 1011082, 2022

50 Kuchler H and Neville S, 'UK Drugs Agency outsources 40% of applications after Brexit turbulence', Financial Times, 20 July 2025

US

Speed of approvals:

- FDA consistently accounts for approximately 45-50% of first global NAS approvals. According to IQVIA data[51], a total of 545 NASs were approved by the US, EU, and/or Japan from 2014-2022, with nearly half (260) approved by all three regulatory bodies and with the US not only approving the most NASs, but also approving them earlier on average than the EU and Japan.
- Margin of exclusive approvals is increasing: US-only NASs are concentrated in the oncology and neurology therapeutic areas, are most often developed by emerging biopharma companies, and nearly half are first-in-class products (all data from IQVIA).
- 2025: launch of the Commissioner's National Priority Voucher (CNPV) pilot seeks to reduce review to one to two months (compared to the usual 10-12 months).[52] In addition, pilot program for split submission, where parts of the application are submitted during the trial (similar to Operation Warp Speed).

Flexible/accelerated pathways:

- Several FDA programmes enabling accelerated review and approval times are in place (priority review, breakthrough therapy, accelerated approval), reflecting adaptive flexibility (such as rolling reviews and surrogate endpoints). The FDA had the highest proportion of expedited review pathways for NASs at 59% (CIRS data, 2024).
- Between 2011 and 2018, 54% of novel drug and biologics approvals in the FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research used at least one expedited development tool, including breakthrough therapy, priority review, fast track, or accelerated approval (data from the FDA). This tallies with a 2023 peer-reviewed study[53] that analysed 367 FDA-approved therapeutics and found that 57% (196 out of 340) used at least one expedited programme (fast track, accelerated approval, breakthrough therapy). There is a clear upward trend: a majority, between 60-70%, of novel drugs approved by the FDA use expedited pathways.
- Specialised tracks: the Real-Time Oncology Review Programme and Project Orbis are signature FDA programmes for speeding cancer-drug approvals and aligning globally.

Digital and data-driven innovation:

- RWE framework aligned with prior guidance and formalising acceptance of RWE in both safety and efficacy contexts.
- Actively deploying AI tools and advanced modelling, for example, a model-informed drug development programme to optimise dose selection, evaluate drug interaction and support development decisions.
- Embracing AI tools (like 'Elsa') and modern testing methods to streamline review.

Stand-out performers: US and Singapore

United States – still an undisputed global leader: the FDA remains the world's most influential and agile drug regulator, accounting for the largest share of first global NAS approvals and consistently acting faster than peers in the EU or Japan. From 2014-2022, it approved more NASs than any other agency, with nearly half of its approvals being first in class and a growing share exclusive to the US, especially in oncology and neurology, often from emerging biopharma. Its hallmark is regulatory agility: a suite of expedited programmes (priority review, breakthrough therapy, fast track, accelerated approval) now used in 60–70% of novel drug approvals, with oncology-specific initiatives like Real-Time Oncology Review and Project Orbis enabling parallel global reviews. The agency has embraced advanced methods, such as model-informed drug development, AI-assisted review, and adaptive submission strategies, culminating in 2025 pilots, such as the CNPV (cutting review to one to two months) and split submissions. This combination of scale, speed and innovation cements the FDA's role as the pacesetter for global regulatory science and a critical enabler of US biopharma competitiveness.

Singapore – a small but high-quality partner: despite lower absolute numbers of new drug approvals (reflecting its smaller biopharma scale), Singapore's regulatory responsiveness and alignment with global standards provides a supportive regulatory environment to the country's ambitions in biopharma. Singapore is the first out of 28 countries assessed to have achieved the highest maturity level (ML4) in the WHO's classification of regulatory authorities for medical products done on the basis of more than 260 indicators. Achieving ML4 brings Singapore closer to becoming a WHO-listed authority of the world's regulators of reference. Singapore maintains efficient regulatory processes, often outperforming peers by leveraging international reliance models (the HSA's reference agencies are Swissmedic, the EMA, the FDA, Health Canada, the MHRA and Australia's TGA). It integrates AI regulatory preparedness, provides a digital health sandbox, and supports priority review and conditional pathways. It participates in work-sharing initiatives like the Access Consortium and Project Orbis, which allows applications to be jointly assessed by multiple regulators (for example, Singapore, Canada, UK, Australia and US), shortening approval timelines while positioning Singapore as a regional hub.

51 IQVIA (2024). 'Assessing availability of new drugs in Europe, Japan, and the US', 11 December 2024

52 Reuters, 'US FDA to shorten review time for drug developers under new voucher program', 18 June 2025

53 Wong A. and others (2023). 'Use of expedited regulatory programs and clinical development times for FDA-approved novel therapeutics', Jama Network Open, 6(8), 31 August 2023

Honourable mention – the UK doubling down on efforts to regain a global position: the UK's MHRA is a leading regulatory agency that is actively repositioning itself as a nimble and innovation-friendly regulator, with signs of early success. The government has sought to manage the post-Brexit impact by focusing on agility through the introduction of the IRP and ILAP to accelerate and innovate drug access. The MHRA is making concerted moves to modernise its regulatory approach, especially in AI, RWE and clinical trial design, positioning itself as a more agile regulator. The Regulatory Science and Innovation Networks and seven CERSIs were launched in 2025 to advance areas such as AI, in-silico modelling and pharmacogenomics. Given resource constraints, nearly 40% of applications in 2024 used IRP or EU reliance, allowing for faster processing and more global convergence. At the same time, it is focusing on innovation areas by prioritising AI, CGT and rare disease therapies. The MHRA's Data Strategy (2024-2027) emphasises RWE and AI integration through initiatives like federated analytics, a data-science network, and AI task forces. Additionally, the RWE Scientific Dialogue Programme (2025) encourages early sponsor-regulator conversations on using RWD in evidence generation.

5. Financing dynamics

Relevance for Europe:

Draghi's report was clear in its assessment that Europe has a structural investment gap and weaker risk appetite than other third countries, such as the US. The call for more investment and real progress on capital-market reform is long standing and well accepted,[54] with Draghi arguing for mobilisation of private savings into long-term, high-risk/high-reward investment that can sustain the creation of large European companies. A closer look into Europe's shortcomings in the biopharma sector shows more difficulties in late-stage and scaleup capital. While the VC market has grown, it still suffers from fragmentation and under-allocation by big institutional funders. Importantly, relevant policy levers would need to be better coordinated at EU level to address the kind of structural barriers that Draghi highlighted in his report[55] and enable better scaling of VC.

Europe still loses many high-potential companies to US listings or acquisitions. The EU strategy explicitly cites this leakage in its assessments of the biopharma ecosystem in Europe. Notably, the Commission's Life Sciences Strategy issued in July 2025[56] and the EU Startup and Scaleup Strategy (May 2025) recognise this gap in the life-science sector, and propose a range of actions, including: the mobilisation of public and private finance (for example, co-investment, ramp up InvestEU); creation of incentives to channel institutional capital to VC funding; reducing fragmentation; and strengthening the translational infrastructure, for example through regulatory workstreams to reduce time to market for strategic therapies, and pan-EU clinical networks to increase the commercial potential of science. The Life Sciences Strategy reiterates the link between competitiveness gaps and fragmented R&I/finance and proposes public co-investment (through InvestEU, EIC and the EIB's venture-debt role) to crowd in private capital.

Europe has improved overall with a larger VC ecosystem than 10 years ago; a larger number of scaleups and later-stage deals and overall exit conditions have improved vs 2022-2023 (though overall IPOs still lag the US).[57] While the number of biotechs has decreased over the past two years, Europe's relative importance as a hub for new biotechs remains strong. However, the structural differences with major competitors such as the US in terms of late-stage capital markets and pipeline of IPOs are unchanged. Europe will need to double-down on efforts in this space, with the rise of other contenders. For the biopharma sector, the gap matters due to the capital-intensive and high-risk nature of clinical development.

Country	Funding into biotech/life sciences (focus on VC, unless otherwise indicated)[58]
China	Approximately $20.61 billion funding raised by Chinese biotech firms in 2023, encompassing VC, public listings, follow-on rounds and other disclosed investment sources. China accounted for around 12.7% of global biotech funding in that period (Crunchbase data, Drug Discovery and Development, 5 Jan 2024).
Denmark	€770 million raised by healthtech startups (biotech, pharma and health platforms) across 56 rounds – a record year with 11% growth over 2021 and representing 58% of Denmark's total VC[59]
France	France Biotech/EY's 'Panorama France HealthTech 2023' study states around €1.8 billion raised in 2023 across healthtech (figure includes public funding, and stretches across biotech, medtech, digital health). France Biotech's new release shows €2.6 billion raised in 2024, but €1.7 billion of that was public refinancings.

54 Read, for example, the extensive analysis by the EIB on the scaleup gap: EIB, 'The Scaleup Gap', June 2024

55 For example, the IMF argues that: "giving public financial institutions like the European Investment Fund a more active and expanded role in kickstarting VC markets where needed and in familiarizing investors with the VC asset class can be a helpful interim step". In: IMF Working Paper, WP/24/146

56 European Commission, 'Choose Europe for life sciences', COM/2025/525 final, 2 July 2025

57 Various trackers show life-sciences VC activity recovered in 2023-2024. Examples: FCF reported around €9.1 billion for healthcare and life sciences in 2024 (up vs 2023); Sifted and Labiotech report biotech funding in the €2–3 billion range for particular years and record rounds in select deals. These figures show meaningful activity but concentrated in a subset of hubs (UK, France, Germany, Nordics).

58 With data from Crunchbase, reported in: Buntz B, 'The global biotech funding landscape in 2023', Drug Discovery & Development, 5 January 2024

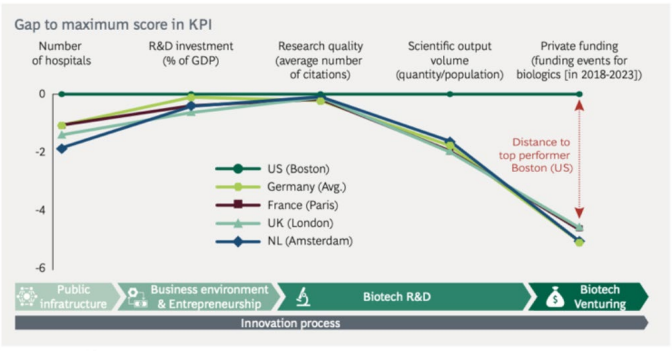
59 Hamilton, Alex. (2024). 'Denmark: the European outlier for VC growth in 2023', Dealroom Blog, January 2024

Japan	Historically conservative investors but growing ecosystem; 2023 biotech VC and corporate VC raised amounted to approximately $913 million[60]
Singapore	Singapore is attracting more international VC firms, with several global VC firms and according to some estimates, has raised more than US$250 million so far, with VCs attracted both to Singapore's science and as a connection to the broader Asian market[61].
UK	Biotech and pharma companies had a record year of investment in 2024 with £3.5 billion of equity raised. First half of 2025 has underscored the enduring appeal of UK biotech innovation, with total VC investment reaching £1.23 billion (figure from the BioIndustry Association [BIA], April-June 2025). The BIA reports that in 2024, the UK attracted 37% of total VC investment in European BIA biotechnology.
US	US biotech firms attracted a total $56.79 billion in funding in 2023, more than 35% of global investment in the sector (Crunchbase data, Drug Discovery and Development, 5 Jan 2024); FierceBiotech reports US biopharma VC at around $23 billion across 613 deals in 2023.
South Korea	KoreaBIO's annual brief shows around KRW752.4 billion private bio-medical investment for full-year 2023.
Saudi Arabia (KSA)	No consolidated 'biotech/life-sciences-only' figure published for 2023. As a proxy, total VC funding across all sectors reached $1.38 billion.

Stand-out performers: US and China

United States: the US has a world-leading mature and dynamic financing ecosystem for biotech and biopharma. In 2023, US biotech companies raised approximately $56.8 billion from all funding sources. Deep VC availability exists across all stages, with specialist funds driving early-stage innovation, and abundant later-stage capital and public markets that enable exits. In the current economic and geopolitical climate, and given recent developments in the US, while investors still back high-risk science, current cycles prefer later-stage, derisked assets.[62] The NIH's $47 billion annual research budget underwrites a large discovery pipeline, while agencies like BARDA and ARPA-H derisk translational projects. Regulatory frameworks (for example, the FDA's Breakthrough Therapy Designation) accelerate time to market without lowering standards. The US consistently produces commercial spinouts and remains the global hub for biotech IPOs, with NASDAQ listings attracting companies worldwide and remaining the main venue for global biotech listings (22 biopharma IPOs raising around $3.27 billion in 2024). This combination of capital depth, public-private R&D investment and large domestic market makes the US the benchmark for biotech growth and scaleup.

Exhibit 2 | **Gap along the translation process per country.**



Source: BCG analysis

China: China is the second-largest biotech funding market globally, raising $20.6 billion in 2023 from VC, public listings and other sources. The sector benefits from strong state direction under the Made in China 2025 (MIC25) and Healthy China 2030 strategies, which consider biotech as a strategic industry. The government offers direct subsidies, low-interest loans and significant tax incentives for R&D. The HKEX Chapter 18A rule enables pre-revenue biotech IPOs, unlocking earlier public capital. Provincial governments such as those in Shanghai and Guangzhou provide incubators, free or subsidised laboratory space and co-investment funds. China excels in scaling domestic innovation rapidly and building manufacturing capacity, though its ecosystem remains currently more domestically oriented than globally integrated.

60 Citeline data, quoted in Labiotech: 'After decades of stagnation, is Japan's biopharma industry set for an upswing'?, 19 December 2024

61 "Singapore draws international biotech VCs as Asia-Pacific life sciences sector takes off" (Economic Development Board, 5 October 2025).

62 See for example: Senior M, 'Biotech financing: divide and reset', Nature Biotechnology 43,1028–34, 2025; and Gormley B, 'Biotech venture investors optimistic, but uncertainties persist', WSJ, 23 January 2025

Honourable mentions: Denmark and France

Denmark – a model of openness: Denmark outperformed the broader European market in investment volume and number of deals. In 2023, Denmark saw particularly strong VC growth while most of Europe declined. In 2024, life sciences (biotech, medtech and healthtech) while decreasing, still made up a significant share of VC volumes with about 33% of total venture capital, with €375 million invested (around 45% below 2023 levels)[63]. The overall trend shows a continued dynamic market in Denmark. This is contributing to positioning Denmark as a rising life-sciences hub in Europe. Early commercialisation is helped via the BioInnovation Institute, which offers funding (up to €1.3 million per start up) and support for science-to-market startups and drives EU-scale pharma innovation. Alumni have raised around €559 million in VC funding following participation, since inception. Other features of the Danish ecosystem, such as a national digital health strategy ("A coherent and Trustworthy Health Network for All – Digital Health Strategy 2018-2022, extended to 2024), a streamlined regulatory process and clinical trial access, are supporting Denmark's translational strength. It can be argued that Denmark's model is difficult to replicate as it is based on a tightly integrated ecosystem at a relatively small scale. However, its highly efficient capacity of moving research into biotech startups and its openness to PP collaboration should inspire other countries.

France – early stage derisking: PP investment model with a growing VC base in biotech. Paris and Lyon have emerged as leading hubs, which have received Bpifrance grant aid. France attracted €1.8 billion in healthtech all-sources investments in 2023, and €2.6 billion in 2024 (as reported by France Biotech). France relies on risk-sharing models (grants and co-investment) – notably via Bpifrance, which supports the sector with €682 million in 2024 (source: France Biotech) through risk-capital funds such as the Fonds Accélération Biotechnologies Santé and Innobio 2, focused on early- and mid-stage biotechs and medtechs – and public funds reduce downside risk for private limited partners (LPs), enabling earlier-stage investments. The state plays an active role through direct VC support, France's R&D tax credit (crédit impôt recherche), public co-investment programmes and support to a network of incubators, such as in Paris and Lyon, with Lyonbiopôle. This approach is aiming at more university spinouts, greater cluster specialisation in oncology and bioprocessing in several parts of the country, and a more supportive exit environment (although major exits remain rare, as the ecosystem is still maturing). Venture financing and M&A activity in 2024 were robust, with major private equity rounds supporting biotech firms. However, no new life-science IPOs were recorded for French companies in 2023 or 2024, highlighting a possible challenge in public market exits.[64] A survey published in 2024 by France Biotech[65] of biotech/healthtech leaders highlights the impact of economic (rising inflation and tighter financing context) and political challenges on the overall uncertainty dominating the sector.

6. Infrastructure support for translational ecosystems and startup generation

Relevance for Europe:

Science-to-product efficiency is the rate at which scientific research (for example, publications, patents, academic discoveries) is turned into startups, commercial IP, licenced products and approved drugs (especially NASs). Countries that invest in facilitating this, coupled with clustered/partnered capacity, are more likely to see economic and health impacts from their research. The Draghi report on competitiveness has emphasised Europe's relative weakness in translating ideas into commercial success and that a non-trivial share of Europe's unicorns relocates to deeper capital markets, reflecting Europe's scaling constraints. The report urges the EU to focus more resources and efforts on funding and better coordination between research and industry, an area in which there are many different country-specific factors holding back progress. This is echoed in the Competitiveness Compass, which calls for a more innovation-friendly environment, where innovative products can be taken to market faster through simplified rules and seamless single-market access. The EU's recent Startup and Scaleup Strategy highlights not only the framework conditions that must be addressed but also the financing part, arguing that Europe captures only 5% of global VC, compared to 52% in the US and 40% in China, with 60% of scaleups based in North America. The strategy aims to reverse this and retain startups within the EU. The lesson here for Europe is to couple its research excellence and the strength of its single market with a strong translational focus, especially for late-stage acceleration.

This section looks specifically at a country's investment into incubators/accelerators, such as providing shared services and support to startups, but also at the strength of translational infrastructure such as wet-lab capacity, shared GMP pilot space and regulatory expertise. Commercialisation of university research is an essential part of enabling industrial competitiveness and innovation, and the ready availability of tech transfer offices/facilities (for example, existence of clear Bayh-Dole-type rules, standardised model agreements, proof-of-concept funds) is therefore essential. Finally, the number of biotech startups that are generated (where available, data on number of domestic clinical-stage biotechs and recent EMA/FDA approvals by domestic biotechs) is also a good indicator of performance.

63 Data from EIFO, 'Danish venture capital market analysis 2024', March 2024
64 Biotech Gate, 'France life science trend analysis 2025', 19 March 2025
65 France Biotech. (2024), Enquête auprès des adherents sur la situation financière des entreprises HealthTech

Country	Existence of Incubators/accelerators	Tech transfer infrastructure	Biotech startup strength
 **China**	**Government-planned biotech parks and state-backed incubators:** Zhongguancun Life Science Park (Beijing) provides incubation space, funding access, pilot GMP plants; Zhangjiang Hi-Tech Park (Shanghai), local government-backed biotech incubators (typically, these provide talent grants, tax incentives and access to shared facilities)	**Improving:** institutes under the Chinese Academy of Sciences, tech transfer supported by government but still bureaucratic	Strong growth of biotech numbers. As of August 2025, 14 Chinese biopharma and medical device companies had listed in Hong Kong, raising HK$18.2 billion ($2.33 billion), roughly quadruple 2024's total. Strong government backing, success in volume with a large pipeline and rising out-licencing, EMA/FDA wins still remaining low relative to volume.
 **Denmark**	**Strong foundation-backed incubator/ accelerator:** BioInnovation Institute – foundation-backed, functions as both incubator and accelerator with programmes for early-stage startups, academic spinouts and later-stage acceleration. Provides lab space and mentorship as well as direct funding (grants and convertible loans); Copenhagen Bio Science Park (COBIS), Technical University of Denmark (DTU) Science Park; startups have clear, supported paths from discovery to clinical proof of concept	**Lean and effective system:** university TTOs, coordinated nationally by the Technology Transfer Office Association (Danish Tech Transfer Office); public research well linked to industry; clear IP pathways (IP from publicly funded research is owned by institutions; researchers share revenue)	Strong on academic spin-outs – the BioInnovation Institute has supported more than 100 spinouts since 2018, portfolio is mainly early stage, global approvals are rare among them. Ecosystem is high quality and seeing momentum, but still maturing towards more frequent approvals
 **France**	**Has been growing steadily:** Paris Biotech Santé with academic incubator linked to university medical faculty offering lab space, mentoring, IP support; Génopole, which hosts more than 60 biotech firms and academic labs, shared platforms providing wet lab space, core facilities, startup incubation and scaleup support; major new investments have been made under the France 2030 biocluster programme	**Historically fragmented but with clear progress:** Inserm Transfert (specialist TTO dedicated to INSERM); creation of 13 SATTs (each SATT manages their region's university IP portfolio, jointly funded by state and university) to simplify and unify university IP licencing and proof-of-concept funding and make practices more homogeneous. Processes remain bureaucratic	Around 820 biotechs in 2023.[66] 10% of the solutions produced by French biotech companies are commercialised (Panorama France Healthtech 2023). With 59% of French biotech products in earliest stages of development (research/ POC/preclinical), the share of solutions in advanced phases is almost not progressing. Panorama report: the number one concern of French biotech companies is finding funding sources and actually raising funds, with 67% of the surveyed entities placing it as their top challenge[67]
 **Japan**	**Few biotech-specific accelerators:** Japan has more than 100 accelerators/ incubators, but very few are tailored to biotech or derisk translational paths with wet-lab access or shared GMP/ translational infrastructure	**Fragmented:** universities can own and licence IP, however the tech-transfer ecosystem is still hampered by insufficient connection between academia and industry and remains weak and fragmented/of variable effectiveness.[68] This is one of the focus areas for Japan's strategies to support the sector	Pipeline strength is concentrated in several larger incumbents, whereas the venture-backed biotech sector is smaller in comparison with countries such as the UK. Startup out-licencing and approvals from domestic biotechs remain more infrequent

66 Adam J. 'Biotech in France: what's holding back progress and how to move forward?', Labiotech, 21 March 2024

67 ibid

68 Sakai T and others, 'Technology transfer performance: a comparative analysis of two universities in Japan', International Journal of Technology Management 90, 78, 2022

Saudi Arabia (KSA)	**Nascent:** King Abdullah University of Science and Technology (KAUST) Entrepreneurship Center, KAUST's Venture Studio, KAUST Innovation Ventures fund, and TAQADAM accelerator form Saudi Arabia's primary startup engines (structured ideation support, non-dilutive funding, and mentorship for deep-tech ventures). Ministry of Health-KAUST biotech accelerator for biotech-specific innovation. Shared translational infrastructure (for example, wet-lab incubation) still lacking, as Saudi Arabia is still building foundations for a future biotech hub (Vision 2030)	**Emerging:** very early-stage IP and tech-transfer frameworks	Early efforts with an emergent ecosystem, there are very few clinical-stage biotechs and no known recent EMA/FDA approvals
Singapore	**Targeted, government-funded accelerators:** Biopolis R&D hub is an infrastructure platform created by the government to accelerate translational spillovers – this brings together public research institutes (A*STAR – public institute/agency), multinational pharma R&D centres and incubator space for startups, and provides co-location with hospitals and research institutes; Singapore Biodesign (acts as a talent pipeline)	**Efficient and centralised:** A*STAR handles much of national-level tech transfer through it's A*ccelerate programme, which is the commercialisation arm of A*STAR; it manages IP portfolios for A*STAR's researchers, spins out startups, runs licencing, standardises model licencing agreements and provides services (IP management, venture building)	High translational efficiency, despite small pipeline; global partnerships amplify reach. More than 70 biotech companies, forecast to increase to more than 80 by 2032 by some estimates.[69] First globally approved drug originating from Singapore received EMA and FDA approval in 2024 (Crovalimab)
South Korea	**Solid network:** hosts around 155 accelerators and incubators; key biotech/ translation platforms include Seoul BioHub offering lab space, tech resources, industry connections; KHIDI, which runs biotech-focused incubator programmes to support early-stage projects	**Strengthening:** KHIDI supports tech transfer, startup help and industry links across the bio-health sector, IP still more often retained in academia	Strong state backing, active spinouts scene but startups still face scaleup financing gaps and rely on licencing out to US/EU pharma. More than 1,000 biotechs (reported by KoreaBIO), with more than 1,300 new drug candidates in the past three years.[70] Recent FDA approval of first-line treatment in non-small cell lung cancer, developed in South Korea (licenced to J&J)
Switzerland	Switzerland Innovation: joint public-private initiative (with academia), network of innovation parks across Switzerland (16 sites, various sectors, including life sciences), offering labs, specialised research facilities, workstations. Accompanied by international outreach activities. BaseLaunch, launched in 2018, is a healthcare acceleration programme for startups, located in Basel; provides access to labs and related infrastructure and supports ventures; its portfolio has raised over US $800 million in financing with an average first VC round of more than $28 million per company[71]	Federated and professionalised system of university tech transfer organisations. This is complemented by service providers and innovation hubs, like Switzerland Innovation, which offer expertise in tech transfer, as well as by Innosuisse's approach to co-funding innovation projects	Dynamic and export-oriented ecosystem, with 324 R&D biotech companies in 2024 (data from www.scienceindustries.ch); CHF2.5 billion capital invested in 2024 (CHF833 million private); robust spin-out pipeline (the ETH (Eidgenössische Technische Hochschule) in Zürich: 37 spin-offs in 2024; CHF425 million raised). Recent examples of substantial funding rounds for GlycoEra (CHF107.5 million) and Windward Bio (CHF183.1 million) illustrative of academia to investor-grade company shift. Basel area anchors late-stage productivity and partnering

69 US Department of Commerce, 'Market intelligence – Singapore biotechnology', 25 April 2024
70 Siddiqui A, 'The rise of K-Biotech', BioSpectrum Asia, 1 May 2025
71 Base Launch. 'Building the next generation of Biotech ventures'

UK	**Robust and publicly anchored, with several centres:** catapults are partly funded through Innovate UK (part of UK Research & Innovation), public R&D programmes and industry. One of these is the Cell and Gene Therapy Catapult at Stevenage, focused on late-translation acceleration and scaling in ATMPs, providing specialist GMP manufacturing, process development and regulatory support to scale CGTs; Stevenage Bioscience Catalyst focused on early incubation, Babraham Research Campus, Cancer Research UK incubator	**Mature ecosystem:** university-based TTOs such as Oxford University Innovation, Cambridge Enterprise, UCLB embedded in ecosystem, IP owned by institution with rapid licencing and standard agreements for academia-industry deals	UK still accounts for more than 30% of biotechs in Europe (in 2021[72]) and leads in biotech startups (for Europe) as well as ability to raise VC. However, scaleup ecosystem is more influenced by broader operational/ commercial environment, than only the institutional/academic drivers
US	**Extensive and deep:** the US hosts hundreds of startup accelerators and incubators. Among these, biotech-specialised accelerators such as SOSV's Indie Bio, Alchemist Accelerator, StartX (Stanford-based), plus corporate and local life-sciences accelerators and hundreds of university- and VC-run programmes	**Strong:** well-funded, highly professionalised technology transfer offices (TTOs) at most research universities (MIT, Stanford, UC system)	Highest globally; multiple university-origin biotechs that reach valuations of more than $1 billion

Stand-out countries:

South Korea – prime example of the power of integration: South Korea is growing in importance as an innovation hub. It combines strong public investment and an increasingly active VC environment; strong government-backed clusters such as the OSONG BioValley, and the Innopolis Daedeok push to fully integrate incubators, GMP facilities, translational research institutes and regulatory offices in one location/ecosystem. The KDDF and Korea Institute for Advancement of Technology co-invest alongside domestic and global VCs, reducing early-stage risk. Its universities (KAIST, Seoul National University, POSTECH) have strengthened IP commercialisation, with spinouts in cell therapy, gene editing and AI-enabled drug discovery gaining international attention. As is the case in other APAC countries, South Korea's biotech startups attract licencing and strategic partnerships with US and European pharma companies.

A special case – China, for its scale: China is a rapidly scaling biopharma leader with clear global ambitions. China's biopharma funding is booming, with $3 billion in H1 2025 alone. It surpasses many established innovation systems with a scientific-to-product ratio that is rapidly rising. Its state-backed VC funds and government incubators in early-stage biotech funding (for example, China Life, Sinopharm Capital) play an important role. China's rise in terms of innovative assets that are attractive candidates for licencing agreements has been amply documented. In 2024, China approved 48 first-in-class drugs, with more than 70% of these developed by Chinese companies (according to the NMPA's '2024 Drug Review Report'[73]). However, despite the impressive increase in novel drug candidates, there is still room for improvement in the conversion rate into globally competitive assets, with many preclinical and early-phase assets licenced from China still requiring further development and derisking by Western partners.

Honourable mentions – Singapore plays to its strengths through connectivity: scale, connectivity, regulatory credibility and strong IP protection, while pragmatically adapting to its limitations. The biotech/biopharma sector is small in absolute terms but strategically positioned as a hub with strong state steering, where innovation can be incubated, piloted and plugged into global commercial networks. In 2023, companies raised about $947 million from all sources. State-led agencies like A*STAR and the Economic Development Board co-invest in ventures, run sector-specific incubators, and offer generous R&D tax deductions, grants, and subsidised lab space. Initiatives such as the Biomedical Sciences Initiative focus on translating research into pilots, IP licencing and industry partnerships. By attracting multinational R&D hubs, Singapore has strengthened its translational research base and clinical trial capacity. While far smaller in scale than the US or China, its regulatory credibility, strategic location, and integration into global pipelines make it a key APAC node for biotech cooperation and GMP/clinical trial uptake.

72 McKinsey: 'The UK biotech sector: the path to global leadership'
73 Simin W, 'China greenlit record number of innovative drugs last year', YiCai Global, 19 March 2025

Part 2: Country descriptions

Stand-out features at a glance

China: China's integration of AI, substantial health-data resources, and clinical research capacity into a vertically coordinated biotech innovation chain, which is designed to deliver drugs to global markets faster, cheaper and at scale, is an important differentiator.

Denmark: Deeply integrated public-private research model, exemplified by the Medicon Valley cluster and flagship initiatives like the BioInnovation Institute and by building on a tightly knit infrastructure and open-collaboration model.

France: Full-value chain angle of its strategy, supported by coordinated public investment and anchored in Innovation Santé 2030, from discovery to industrial manufacturing, from target-enabling technologies to AI adoption in biopharma, and coupled with a national plan to double bioproduction capacity and repatriate essential drug manufacturing.

Japan: Long-standing and consistent focus on regenerative medicine through academic leadership, liberalised early approval, heavy R&D funding, and academic excellence in stem-cell science is a clear example of a country using regulation as a competitive tool to build a global leadership niche. Japan now ranks among the top three countries in regenerative medicine (according to multiple market analyses, for example, Fuji Keizai, GlobalData).

Saudi Arabia: High-velocity ecosystem building: Saudi Arabia is compressing strategy into a single cycle, combining sovereign-backed funding, regulatory acceleration and infrastructure scaleup, and could position itself as a model for rapid biotech ecosystem emergence in resource-rich economies.

Singapore: Focus on building a solid 'niche' of expertise (for example, cell therapy manufacturing, biologics, precision medicine, diagnostics), playing to its strengths as a small country, while offering a competitive environment for global biopharmaceutical companies – both western multinationals that are seeking an APAC base and Chinese companies seeking to expand their leadership in the region.

South Korea: Strategic approach and long-term vision for its biomanufacturing strength, which it plans to turn into a global innovation strength by integrating R&D, AI-enabled drug discovery and clinical trials infrastructure within its bioclusters.

Switzerland: Hosts both the headquarters of global pharmaceutical leaders and one of the world's most advanced CDMOs, which gives Switzerland an important influence on global biopharma innovation and manufacturing relative to its size.

United Kingdom: The UK is leveraging the NHS's unified health-data infrastructure from genomics to real-world patient records as an AI-ready, globally distinctive platform to accelerate trials, attract investment and differentiate the UK's life-sciences sector from competitors. No other major market has the same combination of a single-payer health system, longitudinal patient records, genomics leadership (UK Biobank, Genomics England), and now a £600 million investment to establish a dedicated Health Data Research Service (HDRS).

United States: The US retains unmatched scale, capital depth and scientific leadership in biotech, but recent policy developments are raising uncertainties in the overall ecosystem.

China

China's biopharmaceutical sector has moved from fast follower to a significant competitor in the innovative biopharma sector in less than two decades, reshaping global R&D dynamics. Backed by long-term industrial policies such as Made in China 2025 plan (MIC25) and the 14th Five-Year Plan, China has shifted from dominance in generics and active pharmaceutical ingredients (APIs) to a much stronger position in innovative biologics, cell and gene therapies and AI-enabled drug discovery. This acceleration rests on a cost-competitive clinical trials ecosystem, a strong base of contract research and manufacturing organisations, and deliberate integration of biotechnology with AI, big data and genomics. Coupled with targeted incentives, licencing deals with multinational companies, and the 'new-co' model for global market entry, China's approach is setting new benchmarks for speed, scale and price competitiveness in drug development.[74] At the same time, China is in many ways not a transferable model for Europe given the state-capital scale of investment and the state-security dimension. The Chinese ecosystem also still has regulatory unpredictability, geopolitical risk and data localisation laws that deter full global integration. Despite China's strengths, its share of the pharmaceutical market remains relatively modest. In 2023, North America accounted for 53.3% of world pharmaceutical sales, compared with 22.7% for Europe and around 11.5% for China.[75] China's evolution in the innovative drug sector will depend on its ability to sustain global delivery of first-in-class launches and competitiveness while addressing key challenges, such as geopolitical tensions, regulatory alignment, domestic price pressures, investment in R&D and enhancing multi-country clinical trial efficiency.[76]

Standout feature: China's integration of AI, substantial health-data resources, and clinical research capacity into a vertically coordinated biotech innovation chain, which is designed to deliver drugs to global markets faster, cheaper and at scale, is an important differentiator.

Quick facts	• Share of global pharmaceutical pipeline assets: 15% (2022), up from 4% in 2012. • More than 1,600 biotech firms (according to BCG data: Biopharma Trends 2025) established between 2010-2020 (notable: BeiGene, Zai Lab). • 29% of newly launched global clinical trials involved a Chinese site (2023). • Licencing deals worth $44.1 billion in 2023;[77] large pharma in-licencing 28% of innovator drugs from Chinese biopharma in 2024,[78] 18% of global licencing deals in H1 2025.
Key strategies	Several industrial policy frameworks: MIC25, the 14th Five-Year Plan (2021-2025), the sector-specific Five-Year Plan for the Bioeconomy (2022), and the Healthy China 2030 Strategy. • Biopharma, medical devices, biotech named as strategic priorities, with an objective to reduce reliance on foreign technology and expand domestic IP, combined with openness to foreign drugs (through the Healthy China 2030 Strategy), alignment with global regulatory standards and foreign direct investment. • Recent policy shifts address the entire innovation value chain, from basic research and financing to reforms to the regulatory approval system, pricing and reimbursement, providing a 'full-chain' policy environment in key hubs (for example, Beijing, Shanghai, Suzhou, Guangzhou). • Strategic priority is given to synthetic biology, CGTs, AI-biotech integration, and brain-computer technologies, alongside measures to secure technological sovereignty and reduce foreign dependency.
Financial and early commercial support	• Extensive public sector investment with estimates suggesting between 2015-2020 more than $100 billion channelled into the life sciences through central, provincial and municipal funds, including the National Fund for Technology Transfer (NFTTC) and local venture funds.[79] • The National Natural Science Foundation (NSFC) allocates 34% of its budget to life sciences and healthcare. • Incentives include tax breaks, talent recruitment schemes and accelerated approval pathways. • International expansion is encouraged through the new-co model, enabling Chinese biotechs to raise foreign capital, run overseas trials and secure FDA/EMA approvals while retaining domestic control. • Licencing-out activity is at record levels, with US firms increasingly sourcing investigational drugs from Chinese partners, with around 30% of big pharma deals involving China in 2023/2024 (based on Financial Times [FT], Wall Street Journal [WSJ] reports).

74 Groenewegen-Lau J, Brown A, 'Lab leader, market ascender: China's rise in biotechnology', MERICS, 24 April 2025

75 EFPIA figures, IQVIA

76 Tan R and others, 'Current landscape of innovative drug development and regulatory support in China', Signal Transduction and Targeted Therapy 10, 220, 2025

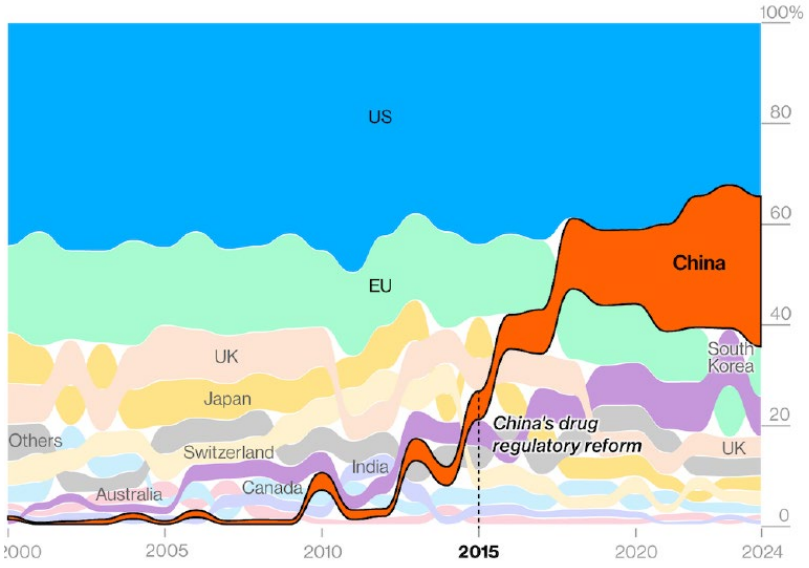
77 Figure quoted in FT, referencing UBS research: Olcott E, 'Western companies drive Chinese biotech licensing deal blitz', 26 May 2024

78 Global Data, 'Large pharma drug licensing from China reaches record high at 28% in 2024, reveals GlobalData', 9 April 2025

79 Figure quoted in CSIS: 'China adopts biotechnology regulation, amid authoritarianism concerns', 31 August 2020

Biomanufacturing	• Transitioned from a leading position on APIs and generics (though this is segment-specific), to a greater share in the high-value biologics and advanced therapies segment. • Maintains a large network of contract research and manufacturing organisations (contract research organisations CROs/CDMOs, such as WuXi and Tigermed), offering speed and cost advantages over US and EU facilities. Infrastructure supports both large-scale production and highly specialised manufacturing for CGTs. Since 2015, with MIC25, the government has greatly increased its investment and support for biotech to stimulate innovation in the sector.[80] • Manufacturing expertise is underpinned by decades of process optimisation in generics, now adapted to cutting-edge modalities.
Highlights – strengths and challenges	**Strengths**: • Highly coordinated state-led strategy integrating industrial, health and national security goals. • Large-scale, cost-efficient clinical and manufacturing capacity. • Strong domestic talent pool, increasingly experienced in global-standard trials. • Advanced AI-enabled drug discovery capabilities. • Ability to disrupt global pricing models for innovative drugs. **Weaknesses:** • Dependence on overseas markets and investors for top-tier revenue streams. • Geopolitical tensions may limit partnerships, data flows and overseas market penetration. • Concerns over data transparency, especially genomic data.
Health resilience and geopolitical aspects	• Biotechnology is central to China's broader economic security and geopolitical strategy. The sector features prominently in the state's military-civil fusion doctrine, which frames biotech as a "strategic emerging industry" with both civilian and defence applications. National security documents explicitly call for transforming China from a "biotech power" into a "biotech superpower", with heavy investment in gene editing, synthetic biology and neurotechnology.
Main structures	• **National strategies:** MIC25, 14th Five-Year Plan, Five-Year Plan for the Bioeconomy, Healthy China 2030. • **Funding bodies:** NFTTC, NSFC, local/provincial VC funds. • **Industrial clusters:** Beijing, Shanghai, Suzhou, Guangzhou. • **Key companies:** BeiGene, Zai Lab, WuXi AppTec, Innovent, BioMap. • **Notable facilities:** large-scale CRO/CMO networks, AI-biotech labs, genomic sequencing centres. • **Policy mechanisms:** talent-recruitment programmes, preferential tax regimes, regulatory acceleration, new-co globalisation model.

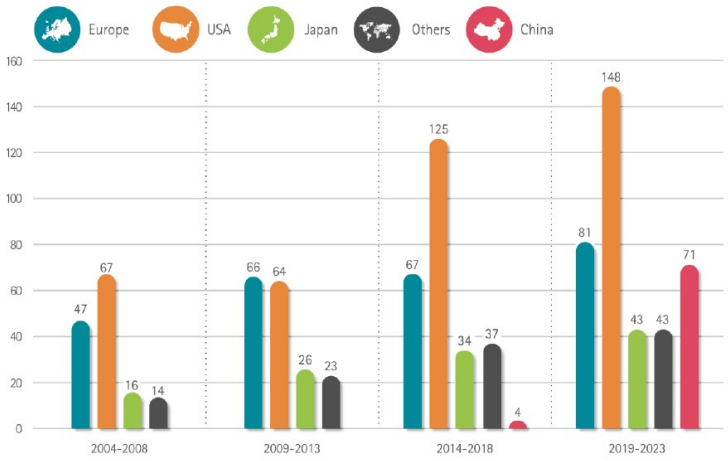
Annual share of innovative drugs entering development, by country:



Source: Bloomberg, 'China biotech's stunning advance is changing the world's drug pipeline', 13 July 2025

80 See NRI Digital/Global Data: 'Chinese manufacturers' transition to innovative pharma needs more investment', December 2022

Number of new chemical and biological entities (2004-2023):



Source: CITELINE April 2024 & SCRIP – EFPIA calculations (according to nationality of mother company)
Note: Up to 2017 China is included under 'Others'

Denmark

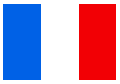
Denmark's life-sciences sector is a key driver for its national economy, accounting for around 20% of Denmark's total exports in 2023,[81] and ranking among Europe's most innovative countries in the 2025 European Innovation Scoreboard.[82] Denmark's collaborative and tight-knit approach, to which is added a strong clinical trial infrastructure, an open and proactive mindset on data usage and targeted investment in sustainable biomanufacturing, gives it the capacity to drive translation of research into globally competitive biopharma products, despite its small domestic market.

Standout feature of Denmark is its deeply integrated public-private research model, exemplified by the Medicon Valley cluster, shared with Sweden, and by flagship initiatives like the BioInnovation Institute, backed by a €470 million Novo Nordisk Foundation grant.

Quick facts	• Life sciences are a cornerstone of the Danish economy, accounting for more than 22% of total exports in 2020 and employing more than 49,000 people. • According to the 2025 European Innovation Scoreboard, Denmark ranked second among EU member states, having held the top position from 2020 to 2024. • High per-capita biotech patenting, driven by public-private research and top ranking in public-private co-publications (across all sectors, as indicated in the 2025 EU Innovation Scoreboard). • Top Europe ranking in terms of clinical trials per 100,000 people (46.31 per 100,000 people).[83]
Key strategies	**Strategy For Life Science Towards 2030** (revised on 1 November 2024) anchors political commitment in several concrete actions: • Research and translational infrastructure: public investment via Danish National Research Foundation and the Innovation Fund Denmark; science-to-market support through the BioInnovation Institute stablished in 2017, backed by a €470 million Novo Nordisk Foundation grant to accelerate life-science startups. • Clinical trial infrastructure: supported by Trial Nation, a centralised body to streamline trial recruitment and approvals. Danish hospitals are among Europe's most active clinical trial sites (per capita). • Support for health-data use and AI: data access through strengthened infrastructure, national AI supercomputer centre (Gefion) launched with funding from the Novo Nordisk Foundation to support health and biotech innovation. • Investment in STEM education, PhDs, and public research centres (for example, DTU, the University of Copenhagen, Aarhus University). • Biomanufacturing: large investments in sustainable biomanufacturing (for example, Kalundborg Eco-Industrial Park) and domestic API/biologics production.
Financial and early commercial support	• Government has set aside DKK400 million (2024-2027) for the new life-science strategy.[84] • R&D tax credit – up to 130% of eligible R&D expenses from their taxable income 2020-2022, for 2023-2025 the rate is 108%, rising to 110% in 2026.[85] • Innovation grants through the Danish Innovation Fund for more targeted, high-risk projects, including in healthcare. • Support to early commercialisation via the BioInnovation Institute, which offers funding (up to €1.3 million) and support for science-to-market startups. In 2023, €779 million in total was raised by healthtech startups, accounting for 58% of all Danish VC activity (according to Dealroom data) and 34% in 2024. • Export promotion and support schemes for innovative SMEs and scaleups.
Biomanufacturing	• Biomanufacturing is one of the pillars of the Strategy for Life Science Towards 2030, with support for facilitating permitting, infrastructure expansion and public investment, as well as sustainable biomanufacturing and green energy integration, and investment in the relevant skills base - bioprocess engineers, technicians, and data specialists. • One of Europe's largest hubs for biologics, advanced therapies and APIs, with a global insulin manufacturing hub. • Kalundborg BioIndustrial cluster is Europe's largest biomanufacturing hub, spearheading the process of industrial symbiosis (circular economy-based model).

81 Saionz A, 'Small country, big ambitions: Denmark's bold life science bet', Pharma Boardroom, 30 April 2025
82 European Commission, 'European Innovation Scoreboard 2025: country profile Denmark', Independent Expert Report, July 2025
83 Quoted in: Wells A, 'Which countries produce the most clinical trials?', Arkivum, 5 June 2025
84 Ministry of Industry, Business and Financial Affairs, 'Economic footprint of the life science industry in Denmark', December 2023
85 PWC, 'Denmark, corporate-tax credits and incentives', 5 September 2025

Highlights – strengths and challenges	**Strengths**: • Strong PP coordination, Medicon Valley cluster (with Sweden), prioritisation and forward-looking approach that is key to delivering a strong startup pipeline. Denmark ranks high among EU member states on PP co-publications and international scientific publications (EU 2025 Scoreboard). • Innovation-driven and joined-up approach: strong capacities in AI, cloud computing and quantum technology. **Challenges:** • Denmark is challenged by difficulties in recruiting sufficient skilled R&I employees and for attracting foreign researchers.
Health resilience and geopolitical aspects	• Strengthening resilience in drug and vaccine development. Strong push to enhance domestic API and biologics production, reduce overdependence on global supply chains. Healthcare Denmark facilitates global partnerships.
Main structures	• Strategy coordinated by Ministry of Industry, Business and Financial Affairs, implemented via regional hubs and overseen by the National Life Science Council (government, academia, industry). • **Key hubs:** Medicon Valley, DTU Science Park, and COBIS incubator.



France

France is one of Europe's largest biopharmaceutical markets[86] and a leading research hub. It combines a strong talent pool, world-class research centres (INSERM, CNRS), and attractive R&D tax incentives (crédit impôt recherche) with an increasingly dynamic healthtech ecosystem and a national strategy for AI for health, linking INSERM, Institut National de Recherche en Informatique et en Automatique (INRIA), Assistance Publique-Hôpitaux de Paris (AP-HP), and major tech firms to accelerate translation of algorithms into clinical workflows. Through France 2030 and its Innovation Santé 2030 programmes, the country has set out a highly integrated national strategy. Progress is tangible: bioproduction capacity has grown by 60% in six years, and France has built recognised biomedical clusters (Genopole, Paris-Saclay, Lyonbiopôle) and advanced research centres. It has a strong position in rare diseases (21% of the solutions French biotechs are developing are in rare diseases[87]) and healthtech/AI-biotech. Yet, challenges remain. Only eight of 76 biomedicines approved in Europe in 2022 were produced domestically, with 95% still imported.[88] Scaleup to globally competitive mid-caps and unicorns is limited, and regulatory execution lags political ambition. High sector-specific taxes and a tightening pricing and access environment further dampen attractiveness. Public debt and cost-containment pressures (Social Security Financing Act 2025) risk constraining the impact of France's objectives defined within the framework of the France 2030/Innovation Santé 2030 strategies, making EU-level collaboration an increasingly critical lever for success.

Standout feature: the full-value chain angle of its strategy, supported by coordinated public investment and anchored in Innovation Santé 2030, from discovery to industrial manufacturing, from target-enabling technologies to AI adoption in biopharma, and coupled with a national plan to double bioproduction capacity and repatriate essential drug manufacturing.

Quick facts	• One of Europe's largest biopharmaceutical markets at €73.3 billion in sales in 2023 (LEEM/ Comité Économique des Produits de Santé). • More than 3,100 life-science businesses, including 820 biotechs, 1,393 medtechs, and 450 digital health firms, generating €90 billion in healthcare revenues and supporting 455,000 jobs (data from Business France (www.businessfrance.fr). • Ranks second in Europe for preclinical biomed pipeline and fourth for clinical-stage products, with 20% of Europe's total biomedicines under development (data from Franch Healthcare www.frenchhealthcare.com). • Among Europe's top three by trial volume (2023-2024, LEEM), especially in oncology and rare diseases.
Key strategies	• Launched **France 2030** (€54 billion over 10 years) and Innovation **Santé 2030** (€7.5 billion for health), which aim to position France as a leading European hub for innovation and sovereignty in health. • Major allocations within Innovation Santé: €1 billion for biomedical research; €2.4 billion for biotherapies/ digital health; €1.5 billion for industrial scaleup; €2.1 billion via Bpifrance for startup growth; €800 million for bioproduction of innovative therapies; €1.5 billion for industrial investment and IPCEI (Important Projects of Common European Interest) projects. • Includes a focus on accelerating market access, supporting ATMPs and integrating enabling technologies like AI into biopharma. • **Choose France:** annual flagship investment summit, launched in 2018, to attract foreign direct investment, including for biopharma.
Financial and early commercial support	• 2023 biotech funding reached almost €1.8 billion, with Bpifrance investing €1.2 billion. However, venture flows into French life sciences fell in 2023 vs 2022.
Biomanufacturing	• 52 bioproduction sites (up 60% in six years) under a national relocation plan for essential medicines. • Niche focus on green manufacturing and bioprocessing. • Industrial anchoring still weak despite strong R&D investment (€5.9 billion in 2023).

86 2023 global sales estimated at €73.3 billion (LEEM figures)

87 Data from France Biotech, quoted in: Adam J, 'Biotech in France: what's holding back progress and now to move forward?', Labiotech, 21 March 2024. Additional resources: Shah-Neville W, 'Illuminating biotech in the City of Light: inside Paris's thriving ecosystem', Labiotech, 24 June 2025; OECD, 'Benchmarking government support for venture capital', 27 June 27 2025; France Biotech, 'Panorama France healthtech 2024', 2024

88 Chaffin Z, 'La France tente de combler son retard dans les biomédicaments', Le Monde, 27 June 2024

Highlights – strengths and challenges	**Strengths**: • Generous R&D tax credit (crédit impôt recherche), targeted biopharma funds, strong public research base (INSERM, CNRS). • Commitment to drawing in foreign direct investment with Choose France (cross-sectorial). • Strategic bioclusters (Paris-Saclay, Lyon, Toulouse) with robust tech-transfer mechanisms. • Strategic intent to make AI a competitive differentiator; seeks to become a frontrunner on digital health; leading EU health-data infrastructure with the Health Data Hub, with PariSanté Campus as the flagship AI/health hub alongside AP-HP/INSERM/INRIA. • Strong preclinical asset base offering scope for partnerships/licencing and excellence in rare diseases. **Challenges:** • Limited domestic production (only 9.4% of EMA-authorised drugs since 2017 manufactured in France; 95% of biomedicines consumed are imported). • Fragmented tech transfer, slower regulatory processes and weaker late-stage commercialisation. Public funding without coordinated private follow-through could create stranded assets, ie, facilities or clusters without sustained operational pipelines. • High effective sector tax, with LEEM 2024 Barometer indicating a 60% effective tax burden, worsening pricing/access climate. • Venture funding gaps, public debt and continued company outflow to US/UK markets for IPOs or HQ relocation. • Slower regulatory timelines than leading APAC hubs; EU clinical trials regulation has improved this, but the perception of slower approvals persists. • France's overall political ambition not always matched by actual execution and mindset at administrative/ministerial level (for example, long time to reimbursement, clawbacks).
Health resilience and geopolitical aspects	• Health innovation framed as part of strategic autonomy, with supply-chain security, domestic manufacturing and EU-level cooperation central to policy. Geopolitical positioning integrates industrial policy, research and innovation infrastructure in a manner that is rare among EU peers. • National agencies are coordinating with the EU's Health Emergency Preparedness and Response Authority to secure stockpiles, diversify supply sources, and accelerate domestic vaccine and biologics manufacturing. AI-enabled modelling and health-data integration through the Health Data Hub are being mobilised to strengthen epidemiological surveillance, speed up clinical trials and anticipate emerging health threats. • Geopolitically, France positions its life-sciences sector as both a driver of strategic autonomy and an instrument of global health diplomacy, and has consistently pushed for EU-wide industrial sovereignty measures in health, aligning its domestic efforts with European Commission initiatives to safeguard supply chains, reduce import dependency, and set pan-European standards for data governance and AI in healthcare. • Health data are viewed as a strategic asset, and France advocates a European alternative to US- and China-dominated health AI ecosystems. The French state also closely scrutinises foreign investment in critical health technologies under its strategic sectors regime, aiming to keep key R&D and production capabilities under national or EU ownership.
Main structures	• **Bpifrance:** public investment bank driving funding and scaleup. • **Agence Innovation Santé:** coordinates national health innovation strategy. • **Health Data Hub:** centralised platform for health data access and AI research. • **Medicen Paris Region and Lyonbiopôle:** leading competitiveness clusters for healthtech and biopharma. • **PariSanté Campus:** flagship hub for AI and digital health startups.

Japan

Once a frontrunner in biopharmaceutical R&D and early drug launches, Japan's relative global position has eroded. Its pharma market share fell from 12% in 2003 to 4.4% in 2023.[89] Japan remains the world's fourth-largest pharma market (by sales, 2024, IQVIA) but still suffers from 'drug lag' (approval delays) and 'drug loss' (non-launches in Japan), particularly in paediatrics, rare diseases and gene therapy.[90] It's a cautionary tale of how a combination of factors – ranging from strict price controls to reduced government investment and effort in improving its regulatory system, slow commercialisation pathways for startups, and weak collaboration between public and private sector have impacted Japan's pull for global launches and pushed local firms toward overseas R&D. Recognising these challenges, the government's 2024-2028 roadmap names drug innovation a growth pillar, with FY2024 reforms to pricing, access and global investment rules. A new multi-stakeholder dialogue framework aims to restore trust and transparency. Intensified competition from China makes EU-Japan cooperation, Horizon Europe access, and expanded science and technology ties even more critical for staying competitive.

Key stand-out feature: long-standing and consistent focus on regenerative medicine through academic leadership, liberalised early approval, heavy R&D funding, and academic excellence in stem cell science is a clear example of a country using regulation as a competitive tool to build a global leadership niche. Japan holds a strong regional and global leadership position on regenerative medicine (for example, iPSC and stem cell technologies).[91]

Quick facts	• Total R&D spending is about 3.4% of GDP, among the highest in the OECD economies. • Japan's pharma market share shrunk from 12% (2003) to 5% (2022).[92] • Attracted around $913 million in biotech VC (around 3% of the US total – figure from Citeline).
Key strategies	• Launch of the **2024-2028 biopharma roadmap:** positions drug innovation as a national growth pillar, targeting pricing reform, accelerated approvals and alignment with global trials through improvement of clinical trial structure; aims to attract foreign pharmaceutical companies and VC firms and provide support from the early stage. In addition to accelerate drug discovery and delivery of novel drugs, and become "one of the world's leading drug discovery sites", the following targets were set to "cyclically develop investment and innovation": • Increase the number of initial clinical trial plan notifications for global clinical trials in Japan from 100 to 150 (from 2021 to 2028). • Ensure private investment in drug discovery startups (two-fold increase; 2023-2028). • Develop 10 or more new drug discovery startups with a corporate value of JPY10 billion or more (2028); develop drug discovery unicorns by 2033. • Ensure recognition of Japan's cities as among the world leaders in drug discovery (within the top 10; 2028). • Creation of a **public-private council:**[93] will play an important role in eliminating drug lag and drug loss and strengthening the international competitiveness of the pharmaceutical industry. • Bring together government officials and stakeholders to consider on-site issues, organise system improvement proposals and incorporate them into policy; 'open-system formation' in drug discovery will be achieved. • A working group will be established under the council to enable the public and private sectors to share ideas across boundaries.
Financial and early commercial support	• Grant programmes by Japan's AMED support high-priority segments including regenerative medicine, clinical data R&D, advanced biologics and translational drug discovery. • VC remains limited: in 2023, Japan's biotech VC investment was just $913 million, only 3% of US levels. • Government includes tax incentives, Japan Science and Technology Agency (JST) translational grants, and the Innovation Network Corporation of Japan's (INCJ's) early-stage support, plus expanded collaboration via D-Global and startup acceleration programmes.

89 IQVIA, 'The global use of medicines 2024: outlook to 2028', 16 January 2024

90 While Japan falls behind both the US and EU in terms of total approved NASs (potentially due to drug developers not submitting their products), once approved they are almost always available within a few months (IQVIA). Japan closely follows the US in terms of available NASs at 55% (299); however, another 37% (202) out of all 545 NASs that were approved by the US, EU, and/or Japan from 2014-2022 have never been approved in Japan. Among drugs approved by all three major regulators - FDA (US), EMA (Europe) and PMDA (Japan) - only 6-8% reach approval in Japan more than 1.5 years earlier than the others.

91 Market Data Forecast, 'Asia Pacific regenerative medicine market report', July 2025; Healthcare Business Review, 'Japan's role in global regenerative healthcare', April 2025

92 Ezell S, 'How Japan squandered its biopharmaceutical competitiveness: a cautionary tale', ITIF, 25 July 2022; Siddiqui A, 'Rebooting Japan's biotech growth engine', BioSpectrum Asia Edition, 1 September 2024

93 See: 'Joint statement on the public-private council for enhancing drug discovery capability', PhRMA/EFPIA, 26 June 2025

Biomanufacturing	• Strong biologics and pharma manufacturing zones (Osaka, Kobe, Tokyo), but lacks global-scale. CDMO infrastructure; reliance on automation and modernisation remains nascent.
Highlights – strengths and challenges	**Strengths**: • Established capabilities in biomanufacturing, regenerative medicine with a conditional and time-limited approval system for regenerative products – allowing marketing after limited phase II trials if safety is confirmed, while efficacy data are still collected; strong manufacturing ecosystem. • Digital health market projected to grow at 5.5% CAGR through 2032; national medical data infrastructure reforms enable AI-led R&D. **Challenges:** • Japan's biopharma ecosystem underperforms on collaboration metrics despite strong individual players in both academia and industry. Its mid-tier standing reflects missed opportunities in translation, commercialisation and startup formation. Open innovation has not yet become widely adopted practice. While academia actively conducts basic research, the number of drugs with such origin remains much lower than in the US or Europe, indicating a gap in startups that link scientific discoveries and technologies in academia to drug discovery.[94]
Health resilience and geopolitical aspects	• Post-COVID-19, Japan is partly restoring domestic supply resilience, including expanded vaccine and API infrastructure. Engagement with Horizon Europe and regulatory alignment with the EU/APAC feature proactively in the new roadmap. Strong policy framework for economic security.
Main structures	• **Government-level:** Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, AMED, JST, INCJ. • **Clusters and hubs:** Kobe Biomedical Innovation Cluster, Tsukuba Science City, Shonan Health Innovation Park (Shonan iPark). • **Additional bodies:** PMDA (regulator), Japan Pharmaceutical Manufacturers Association and Japan Biotech Association (industry associations).

94 Okuyama R, 'Strengthening the competitiveness of Japan's pharmaceutical industry: analysis of country differences in the origin of new drugs and Japan's highly productive firm', Biological and Pharmaceutical Bulletin 46, 718–24, 2023; Noji F and others, 'Bridging the gap in open innovation between academia and pharmaceutical companies in Japan', DIA Globalforum, April 2024

Saudi Arabia

Saudi Arabia is pursuing ambitious, state-led biotech growth strategies, aiming to become the Middle East and North Africa (MENA) hub by 2030 and a global leader by 2040. Guided by the 2024 National Biotechnology Strategy, it is focusing on vaccines, local biomanufacturing, genomics and agricultural biotech to strengthen health resilience, food security and sustainability. Flagship initiatives include the Saudi Genome Programme (63,000 samples collected), accelerated clinical trial approvals and major infrastructure investments at KAUST, King Abdullah International Medical Research Center (KAIMRC), and new biotech clusters like Riyadh BioCity. Public investment is the main engine in this strategy, and since 2021, more than $3.9 billion has been committed to biotech and genomics, backed by capital-rich sovereign vehicles (PIF, NEOM Investment Fund, Sanabil) to underwrite early-stage risks. Private venture activity is at its beginning but growing, complementing accelerator partnerships and investor-friendly incentives like tax breaks and special economic zones. Saudi Arabia's biomanufacturing push aims for vaccine self-sufficiency and MENA export capacity.

Stand-out feature: high-velocity ecosystem building – Saudi Arabia is compressing strategy into a single cycle, combining sovereign-backed funding, regulatory acceleration and infrastructure scaleup, and could position itself as a model for rapid biotech ecosystem emergence in resource-rich economies.

Quick facts	• Biotech VC nascent but growing, through sovereign-backed accelerators. • More than $3.9 billion committed since 2021 to biotech, and genomics, underwritten by sovereign funds. • Strong focus on genomics, with the Saudi Genome Programme (more than 63,000 genetic samples collected). • Objective to build biomanufacturing capacity, including in vaccines.
Key strategies	• **National Biotechnology Strategy** (2024)[95], aiming to become MENA's biotech hub by 2030 and a global leader by 2040, focuses on four pillars: vaccines (self-sufficiency), local biomanufacturing, expansion of genomics and focus on genomics and cell and gene therapy (CGT) in medical research, and plant optimisation to boost health, food security and sustainability; emphasises global partnerships and incentives, including streamlined business setup, fast-track approvals, tax privileges, and special economic zones to attract private and international biotech investment[96]. • Regulatory reforms via the SFDA aim to significantly accelerate clinical trial approvals, with statutory review timelines now between 10 and 60 working days, depending on trial phase.
Financial and early commercial support	• **Emerging but capital-rich**: private VC is limited domestically, but large state funds (PIF, NEOM Investment Fund, Sanabil, others) are actively deploying capital into life sciences and creating VC vehicles/accelerators. • Public/sovereign vehicles are willing to underwrite early risks to build domestic capability (biomanufacturing, genomics). Private local LPs are still nascent. • Public investment has ramped up significantly: around $3.9 billion has been dedicated to biotech and genomics since 2021, with goals to dedicate 2.5% of GDP to R&D by 2040. • A $200 million KAUST fund supports early-stage high-tech enterprise development within priority sectors including health and biotech. • The PIF actively seeds large-scale ventures, including partnerships with global asset managers, to channel private investment.
Biomanufacturing	• Commits to building a national biomanufacturing platform for biologics and vaccines, aiming for localisation and MENA export capability. Saudi biotech institutions have begun vaccine and MERS trial development, including a phase I vaccine trial for MERS at King Abdullah International Medical Research Centre. High investments into infrastructure at King Abdullah University of Science and Technology (KAUST), King Faisal Specialist Hospital and biotech clusters support scaleup goals.

95 Saudi Vision 2030: National Biotech Strategy, January 2024 (https://www.vision2030.gov.sa/media/5hqj4m1t/national-biotech-strategy-en.pdf)
96 Shah-Neville, W. (2025). Saudi Arabia: is the country set to become a global biotech hub?, LABIOTECH, January 9, 2025

Highlights – strengths and challenges	National Biotechnology Strategy + Vision 2030, accelerator partnerships (for example, Biolabs), NEOM biotech, and PIF-backed initiatives target rapid ecosystem building. **Strengths**: • Ambitious, state-led vision backed by Vision 2030 delivers clear targets, strong funding and integrated policy support. • Major investment in **biomanufacturing, genomics**, and **vaccines.** • Growing **talent and innovation ecosystem**, anchored by institutions like KAUST, King Abdulaziz City for Science and Technology (KACST) and KAIMRC. • **Investor-friendly environment,** with fast approvals and incentives attracting global biotech players. **Challenges:** • The biotech sector is still nascent, with limited private seed and early-stage financing infrastructure. • Dependence on global talent and know-how; belated development of internal commercialisation and scaleup mechanisms. • Global biotech brand recognition is still forming, and the strategy's success hinges on execution over the long term.
Health resilience and geopolitical aspects	
Main structures	• Ministry of Health and National Biotechnology Strategy Committee steering biotech policy and execution. • **Regulatory and R&D infrastructure:** SFDA (regulation), Saudi R&D & Innovation Authority, KAUST, KACST, KAIMRC, King Saud University's Riyadh Techno Valley. • **Public investment engines:** PIF for co-investment; KAUST's $200 million early-stage venture fund. • **Global biotech engagement:** international partnerships highlighted at BIO 2025; Riyadh Biotech City and global outreach accelerating Saudi's biotech diplomacy.

Singapore

Singapore's ambition is to establish the country as a leading global APAC hub for biotech and biopharma R&D, biomanufacturing, medtech and advanced life sciences. Starting around 2000, Singapore actively sought to attract global biopharma companies through a favorable business climate with a mix of generous tax incentives, strong IP rights and R&D grants, as well as investments into infrastructure, pro-active policies to advance public-private collaboration and partnerships with academia. In parallel, it also sought to build a startup ecosystem. It is a leading country in APAC for startups in advanced CGT development. With more than 350 startups/life-science/medtech companies, there is an established product-development-trained workforce, in addition to extensive trade relations in the region. However, Singapore is struggling to grow a critical mass of globally strong homegrown biopharma startups, with limited VC depth and risk appetite and a small local market continuing to be persistent constraints.[97]

A stand-out feature is Singapore's focus on building a solid 'niche' of expertise (for example, cell therapy manufacturing, biologics, precision medicine, diagnostics), playing to its strengths as a small country, while offering a competitive environment for global biopharmaceutical companies – both western multinationals that are seeking an APAC base and Chinese companies seeking to expand their leadership in the region.

Quick facts	• Several top-selling global drugs including biologics and vaccines are manufactured in Singapore. • The National University of Singapore (NUS) and Nanyang Technological University (NTU) are ranked among the global top science universities and host several R&D institutes (including in bioinformatics, bioprocessing, bioengineering and nanotech). • Biotech startups are currently around 52, projected to rise to 84 by 2032. Examples include many early-stage firms such as Lion TCR, Mojia Biotech, Allozymes, Cellivate Technologies.
Key strategies	Five-year plans on priorities and funding, with current strategic framework: research, innovation and enterprise strategy (RIE), which includes the pharmaceutical and biomedical sectors, including: • **therapeutics and precision medicine** – drug discovery and development, pharmacogenomics, biomarker research, personalised treatment pathways • **infectious disease preparedness** – vaccine platforms, antiviral development, diagnostic tools, and pandemic readiness • **healthy longevity and translational infrastructure** – ageing research, clinical trial networks, biobanks, and the National Clinical Translational Research Programme • **advanced manufacturing and digital innovation** – biopharma manufacturing platforms, AI for drug discovery, and technology translation platforms to accelerate market entry. • Funds Singapore's A*STAR institutes (for example, Institute of Molecular and Cell Biology, Bioinformatics Institute, Experimental Drug Development Centre [EDDC]), universities, hospitals and startup incubators involved in pharmaceutical R&D.

Financial and early commercial support	• The Research, Innovation and Enterprise 2025 (RIE2025) scheme allocates SGD25 billion ($19 billion) for 2021-2025, making human health one of its four pillars. Support combines tax incentives, R&D grants, funding from A*STAR, and major public investment in infrastructure, talent development and academic excellence. PP institutes such as EDDC, DxD Hub, and Biologics Pharma Innovation Programme Singapore serve as key collaboration vehicles.
	• In 2023, Singapore launched the Enhanced Innovation Scheme, expanding existing tax measures:
	  • Up to 400% tax deductions/allowances on SGD400,000 of qualifying R&D expenditure per year (100% for overseas R&D).
	  • Reduced tax rates under the IP Development Incentive for companies commercialising locally developed IP.
	  • 400% deductions on up to SGD50,000 for innovation projects with qualified partners.
	  • Deductions for SkillsFuture-eligible training courses.

Biomanufacturing	• Singapore has committed more than SGD1 billion to biomedical R&D under the RIE2025 plan, including a dedicated SGD80 million initiative for CGT manufacturing. The Research and Innovation Scheme for Companies targets investments into new products and processes within Singapore, covering activities and investments into upgrading, innovating and growing operations.

97 Shah-Neville W, 'Singapore's biotech scene: 7 companies leading the way in 2025', Labiotech, 14 January 2025; NRF Singapore, 'RIE 2025 handbook', (nd); Ministry of Foreign Affairs, 'Healthcare and R&D landscape in Singapore', January 2022

Highlights – strengths and challenges	**Strengths**: • Openness to multinational investment; strong tax incentives and IP protection, plug-and-play science and technology infrastructure. **Challenges:** • Early-stage funding is available for startups, but funding gaps still exist at later stages, compounded by a still maturing risk-taking entrepreneurial culture. • Often viewed as a strongly MNC-led model, but with high R&D costs and with a relatively small base of domestic anchor companies and slow translation of local science into global scale, which has created a 'satellite hub' dynamic: strong in manufacturing and regional headquarters functions, less organic ecosystem density. • Talent shortage and lack of managerial expertise might become a future risk.
Health resilience and geopolitical aspects	• Strong pandemic preparedness infrastructure and vaccine manufacturing capabilities. Role as neutral regional connector between Western and Chinese biopharma networks. Heavy reliance on open trade and foreign inputs, so supply-chain diversification is a policy focus.
Main structures	**Government-level:** • RIE agenda is coordinated by the National Research Foundation (NRF), which sets the national direction for R&D, policies, plans and strategies for research, innovation and enterprise under the Prime Minister's Office. • A*STAR and its biomedical research council. • Several A*STAR institutes lead drug target research (for example, Bioinformatics Institute, EDDC, Institute of Molecular and Cell Biology). • Synapxe: national healthtech agency. • Health Sciences Authority: in charge of the regulatory system. **Clusters and hubs:** Biopolis: around 500 companies in collaborative R&D; Tuas Biomedical Park: major MNC manufacturing presence; Geneo/Science Park upcoming expansions.

South Korea

South Korea is emerging as a dynamic biopharma market (R&D intensity of 4.85-4.9% of GDP) and valued at $25 billion in 2022 with projected growth to $35.1 billion by 2030. Historically a leader in biosimilars, large-scale biologics manufacturing, and CDMO (with companies like Samsung Biologics), it is expanding AI-driven drug discovery (28% annual growth since 2016) and advanced clinical trial capabilities, ranking fourth globally and with a 9% rise in trial activity in 2023. It is setting its ambitions high, aiming to become a top-six pharmaceutical global leader, nearly quintuple biotech output by 2035, and rank third in clinical trials by 2027, supported by multi-billion-dollar public and private investment, expansion of integrated bioclusters such as Songdo and Osong, and targeted initiatives in synthetic biology and precision medicine. Strengths include high R&D intensity, advanced infrastructure, and strong public research institutions, though challenges remain in scaling a globally competitive startup ecosystem and translating innovation into novel drug breakthroughs. While out of scope for this report, it is worth noting the government's objective to address a 'virtuous circle' in drug pricing to reward innovation and halt the steady price erosion. It should invest in new drug development and establish a drug price system for companies that create social value, such as supplying essential drugs.

Key stand-out feature: South Korea's biomanufacturing strength, which it plans to turn into a global innovation strength by integrating R&D, AI-enabled drug discovery and clinical trials infrastructure within its bioclusters.

Quick facts	• Second highest R&D spender as a share of GDP (5-5.2%) for OECD region. • Key emerging global markets (13th globally, according to Intralink Korea) for biopharma valued at $27.9 billion in 2020; is expected to grow at a CAGR of 4.4% and reach $35.1 billion by 2030. • Rapid expansion of its AI-driven drug development sector, with an average annual growth rate of 28% since 2016.[98] • In 2023, South Korea ranked fourth globally for clinical trial hubs, and despite a 5.5% fall in global clinical trials in 2023, it saw a 9% increase in the same year, according to Korean National Enterprise for Clinical Trials.

Key strategies	• **Bio-Health Vision 2040** and **Third Five-Year Plan** for the biopharma industry aim to transform South Korea into a top six global pharmaceutical leader:
	  • Aims to increase the country's biotechnology output nearly fivefold, from $43 billion in 2020 to $149 billion by 2035, rank third globally in clinical trials by 2027,[99] expand the number of biotech venture firms significantly, from around 400 annually to more than 1,000 by 2035. It aims to double biopharma exports by 2030[100].
	  • National Synthetic Biology Initiative launched in November 2022 to foster innovation in biomanufacturing and strengthen capabilities and skills in synthetic biology, one of the 12 key technologies identified under the National Strategic Technology Nurture Plan.
	  • Focus on bioclusters, with an expansion of Songdo Bio Cluster, Osong Life Science Complex and others, to integrate R&D, manufacturing, academia and regulatory support in one ecosystem.
	  • Support development of AI-based drug discovery, AI-and robotics-driven laboratories, cell and gene therapies.
	• The government also plans to revise its certification system for innovative pharma companies as part of its national health and welfare strategy to strengthen its biopharma sector. An innovative pharma company designation provides tax credits, R&D support and preferential drug pricing, but only four out of 49 certified companies were foreign owned. The Special Act on Fostering and Support of the Pharmaceutical Industry will be amended by year-end, and the government is also considering a separate certification system for global manufacturers.

Financial and early commercial support	• Multi-sectoral funding initiatives (R&D, infrastructure, bioeconomy) are being scaled. Government-led translational initiatives (for example, KHIDI funding, Bio-Health Vision) channel both public and private capital to therapeutics, precision medicine and biomanufacturing. Recent licencing and financing deals between South Korean startups and major multinationals.

98 Chmielewska I, 'Spotlight on South Korea: innovation, clinical trials and market trends shaping 2025', Norstella, 4 March 2025
99 Siddiqui A, 'The rise of K-Biotech', BioSpectrum Asia, 1 May 2025
100 Korea aims to double biopharma exports by 2030, BioSpectrum Asia, 12 September 2025

Biomanufacturing	• Builds on its tradition as a hub for biosimilars and biomanufacturing and a rapidly expanding CDMO market. Home to Samsung Biologics, a leading global CDMO, Celltrion (biosimilars), and the world's largest biomanufacturing capacity (with more than 1 million litres of biologics production). Strong government support for biomanufacturing skills, CDMOs by easing licencing rules and codifying GMP standards.
Highlights – strengths and challenges	**Strengths**: • World-class CDMO capacity, leadership in biosimilars and biomanufacturing, clinical trial volume and high R&D intensity. • Renowned public research institutions (including in mRNA and gene therapy). **Challenges:** • Startup ecosystem is nascent and still very much focused on strengthening clusters; capacity for translating innovation into groundbreaking new drugs remains limited.
Health resilience and geopolitical aspects	• Korea is leveraging its biomanufacturing and clinical trial strength as trusted partner for third countries seeking supply-chain stability. It is building biotech partnerships (for example with the UAE). In response to US tariffs in 2025, the government pledged KRW28.6 trillion (around $20.6 billion) to support liquidity, reshoring and export expansion in biopharma (and cars).[101]
Main structures	• **Government-level:** National Bio Committee, a presidential advisory body tasked with overseeing national strategies for biotechnology and the life-sciences industry. • **Clusters and hubs:** Songdo Bio Cluster, Osong Life Science Complex, Daejeon's Daedeok Innopolis.

101 Lee J, 'South Korea vows more policy support, including for drugmakers, as US tariffs weigh', Reuters, 21 May 2025

Switzerland

Switzerland is a key hub for biopharmaceuticals in the EEA. It maintains a strong standing for high-quality pre-clinical research and development, strong IP protection, a skilled workforce and a supportive tax and regulatory environment. It regularly scores top marks in WIPO's GII index (across all sectors) for its strong R&D, patenting performance and education system, transparent regulatory environment and governance, predictable policy environment and stable macroeconomic conditions. However, global competition, high export dependence and shifting market dynamics will require a pro-active and clear strategy that seeks to maintain Switzerland's global attractiveness as a pharma hub and that can anticipate and manage geopolitical risks.

Stand-out feature: hosts both the headquarters of global pharmaceutical leaders and one of the world's most advanced CDMOs, which gives Switzerland an important influence on global biopharma innovation and manufacturing relative to its size.

Quick facts	• Life sciences are Switzerland's largest export industry and a major driver of the Swiss economy (according to the 2023 report by the Swiss Federal Office for Customs, the share of total exports for the pharma and chemical sector increased from 48% in the previous year to 49%, with pharma representing 77.8% of that total); the pharma sector has a workforce of around 47,000 (5.4% of total employment in 2022). • It has some of the highest R&D spending per capita, and attracts substantial private pharma R&D investment, with Interpharma members contributing CHF8.9 billion in R&D in Switzerland in 2023.
Key strategies	• No unifying nationwide pharma-related industrial strategy, but several initiatives to strengthen clusters, regulatory harmonisation and R&D incentives. Relies on its overall attractiveness via its stable regulatory environment, competitive corporate tax and R&D deductions, skills and clusters. Cantons compete to attract and retain life-science investment through tax policies, permitting and clusters (Basel, for example, has a strong 'cluster strategy' supported by cantonal authorities; Zürich hubs are strong in translational medicine and biotech spin-offs). • Strong infrastructure for R&I, with a combination of leading universities, research hospitals, a well-funded basic-science environment and accessibility to several biotech hubs across the country (Basel, Zurich, Geneva). • Establishment in 2017 of the Swiss Personalized Health Network (SPHN), a national programme to build a national infrastructure for clinical and omics data, to enable countrywide exchange of health data and multidisciplinary research. It provides common standards for data formats, semantics, governance and exchange.
Financial and early commercial support	• Regulatory, tax and IP environment is generally favourable for the sector: • Patent box since 2020, to exempt a portion of patent-derived income from taxation, allows a maximum tax base reduction of 90% on income from qualifying IP. Depending on canton, this can reduce the effective tax rate on qualifying income to between 8.5% and 12%. • R&D tax deductions, allowing for enhanced deductions of qualifying R&D expenses. Level of additional R&D tax deduction varies from canton to canton but can provide up to 50% deduction against a company's taxable income at cantonal and municipal level; contract R&D is eligible as well. • Multiple funding schemes for precision medicine, digital health, novel biologics, with Innosuisse providing grants for innovation projects including in life sciences; Swiss National Science Foundation funding translational/biotech research. • Continued strength of Swiss life-science sector. 'Swiss Biotech Report 2025' highlights a record CHF833 million raised by privately funded companies, driving 22% overall rise in capital investment to CHF2.5 billion (CHF2 billion in 2023) and overall sector R&D investment growth reaching CHF2.6 billion (CHF2.4 billion in 2023).
Biomanufacturing	• Globally competitive hub for high-value/complex biologics, vaccines and CGT manufacturing; HQ to Lonza, a global CDMO leader; and hosting a large range of multinational pharma companies' biotech manufacturing sites. Innovation/tax incentives benefiting biomanufacturing at cantonal level.

Highlights – strengths and challenges	**Strengths**: • High R&D per capita, strong innovation environment, global leadership in biotech pipelines. • Strong PP collaboration, with leading research institutions, innovative products often developed in close collaboration with international partners, based on an active trade strategy with more than 30 free trade agreements. **Challenges:** • Less competitive on domestic clinical trial capacity/speed of trial startup.
Health resilience and geopolitical aspects	• Policy interest in immunologicals, vaccines, antibodies is rising (as seen in growth of immunological exports). Switzerland's export orientation in biopharma makes supply-chain resilience important; dependency on imported raw materials, APIs can be a vulnerability.
Main structures	• Swiss Federal Institutes of Technology (Eidgenössische Technische Hochschule Zürich, École Polytechnique Fédérale de Lausanne), and national research funding bodies/networks. • Federal offices involved include the State Secretariat for Education, Research and Innovation and regulatory authority Swissmedic. • **Research infrastructure projects:** SPHN, Biotech clusters (for example, BioValley), incubators, translational research centres.

UK

The UK's 2025 Life Sciences Sector Plan seeks to turn world-class science into global commercial leaders, aiming to be Europe's number one life-sciences economy by 2030 and top three worldwide by 2035. It couples £600 million for the HDRS, £520 million for the Innovative Manufacturing Fund, clinical trial startup time targets of less than 150 days by 2026, and MHRA-National Institute for Healthcare and Excellence (NICE) reforms to shorten approval-to-market windows. The plan touches upon a broad range of factors from NHS reform to industrial policy, recognising health data, trials capacity and digital enrolment as competitive levers. However, structural barriers remain and have been at the centre of industry-government discussions: substantial drug clawbacks, slow follow-through on regulatory reforms, late-stage capital shortages and persistent leakage of promising biotechs to US listings. Significant public investment in health R&D, the British Business Bank, and a strong VC base (£2.24 billion in 2024) underpin early growth, but retaining and scaling homegrown firms will require more predictable pricing, deeper domestic finance and faster uptake of innovation within the NHS. While there are many potentially attractive R&D incentives in the UK, without matching commercial incentives (the Association for the British Pharmaceutical Industry [ABPI] argues that medicines currently account for only 9% of total UK spending, against 15% in France and 17% in Germany and Italy), the risk is that investors and high-potential companies will continue to scale elsewhere.

Stand out feature: the UK is leveraging access to longitudinal NHS whole-population health data as a key differentiator that sets the UK's life-sciences sector apart from competitors. No other major market has the same combination of a single-payer health system, longitudinal patient records, genomics leadership (UK Biobank, Genomics England), and now a dedicated £600 million HDRS.

Quick facts	• Globally renowned science base, infrastructure and academic institutions. • Wealth of biotech companies; life sciences contribute more than £94 billion to the UK economy and employs around 250,000 people. • Leading in health-data resources: UK Biobank (500,000 participants), Genomics England (100,000 Genomes Project), NHS datasets. • VC in life sciences reached £2.24 billion in 2024, but late-stage capital gaps persist. • UK clinical trials performance remains in the top 10 globally but has fallen to eighth place in 2024 (it is fourth for phase II trials and fifth for phase I[102]).

Key strategies	• Vision: become Europe's number one life-sciences economy by 2030 and top three globally by 2035 (behind US and China).
	• UK 2025 Life Sciences Sector Plan[103] (meant as an integrated industrial and health system strategy), which includes:
	  • **AI & NHS data integration** – £600 million for the HDRS with the goal of enabling access to genomic, clinical and real-world datasets into a secure platform to facilitate data-enabled research, clinical trial recruitment and attract investment
	  • **clinical trials reform** – cut trial startup times to less than 150 days by March 2026, improve recruitment diversity, and expand NHS app-based enrolment
	  • **regulatory acceleration** – MHRA reform and closer coordination with NICE to reduce time to market
	  • **maintaining regulatory** influence through the MHRA's aspiration to act as a 'global reference regulator'.

Financial and early commercial support	• **R&D tax reliefs** – R&D expenditure credit of 20% for larger companies, with enhanced incentive available to loss-making R&D-intensive SMEs.[104] • **Public-backed growth capital:** sustained public commitment to early growth capital, this is provided via British Patient Capital (largest domestic investor in UK venture growth funds), which invests both in life-sciences funds and directly into growth stage life-sciences companies (more than 300 life-sciences firms have received around £1 billion of investment[105]). • **Early-growth capital availability:** UK life-sciences sector continues to attract private investment – more than £2 billion in VC funding in 2024 and £1.23 billion raised in H1 2025.

102 ABPI, 'UK clinical trials performance improves but remains in intensive care', 10 December 2024
103 UK Government, 'Life Sciences Sector Plan', 16 July 2025
104 UK Government, 'Research and development tax relief: the merged scheme and enhanced intensive support', 18 March 2024
105 British Business Bank, 'Backing innovation in life sciences – factsheet', April 2024

Highlights – strengths and challenges	**Strengths**: • Unified health-data ecosystem linked to a single-payer healthcare system. • Established academic-industry clusters (Cambridge, Oxford, London 'golden triangle'; Edinburgh; Manchester). • Competitive R&D tax-credit scheme, early-growth capital available. **Challenges:** • Punitive clawbacks discourage investment (for example, the Voluntary Scheme for Branded Medicines Pricing and Access, as highlighted by the ABPI: "a scheme that now requires companies to make record payments up to a quarter to a third (23.5%-35.6%) of a company's revenue from sales of branded medicines to the NHS"[106]). • A stagnant NICE baseline cost-effectiveness threshold has reduced the value placed on health improvements in real terms by 47%[107] and grossly under values the benefits offered by new medicines. • Late-stage capital gap persists:[108] many UK biotechs list abroad or remain sub-scale. • Slow and uneven uptake of innovation within NHS despite policy ambitions. • Fragmented follow-through between industrial policy and NHS operational priorities.
Biomanufacturing	• Manufacturing scale-up – the UK government's Life Science Sector Plan (July 2025) seeks to provide up to £520 million in a Life Science Innovative Manufacturing Fund to support domestic production capacity, plus £38 million for biomanufacturing and advanced therapy centres.[109] This represents a substantial increase in capital grants (£374 million was invested in the prior five-year funding period in medicines and vaccines manufacturing innovation[110]). The focus is on scaleup and resilience, with a time duration of 2025-2030.
Health resilience and geopolitical aspects	• Building on lessons from the COVID-19 pandemic, embeds preparedness into the NHS's 10-Year Health Plan. Investments target domestic vaccine and biomanufacturing capacity and advanced therapy production facilities to reduce dependence on foreign supply chains. • The UK Health Security Agency is strengthening national capabilities in outbreak surveillance, early warning and rapid countermeasure deployment, supported by AI-driven analytics. This approach extends to securing domestic supply of critical biologics, expanding clinical trial mobilisation and integrating genomic surveillance into routine public health operations. • The UK's life-sciences strategy has a clear strategic autonomy dimension, aiming to safeguard supply chains and position the country as a global health innovation partner. Competing directly with the US and China for biotech scaleups and high-value R&D investment, while managing foreign investment risks in strategic health assets with screening approach. Life-sciences diplomacy features prominently, with the UK providing genomic sequencing and pandemic response support to low- and middle-income countries.
Main structures	• **Office for Life Sciences:** cross-departmental body aligning health and industrial policy. • **Innovate UK:** R&D funding for early-stage and collaborative innovation. • **UK Research and Innovation:** umbrella for national research councils and translational funding. • **National Institute for Health and Care Research:** major funder of health research, infrastructure and workforce, which enables clinical trial delivery within the NHS. • **British Business Bank:** growth capital and venture co-investment. • **Genomics England:** large-scale genome sequencing and integration with clinical care. • **MHRA and NICE:** regulatory and HTA bodies. • **Devolved nation governments:** responsibility for devolved policy functions in Scotland, Wales and Northern Ireland, including health policy and the NHS, skills policy and other aspects of industrial policy.

106 ABPI, 'Medicine levy makes the UK un-investable, say pharma leaders', 20 March 2025; ABPI, 'Accelerated review of VPAG concludes without agreement', 22 August 2025

107 Using GDP deflator to 2024 and OBR estimates for 2025, the depreciating value of a QALY from £30,000 in 1999 is to £15,847 in 2025. Calculated from when NICE was established in 1999.

108 Highlighted, for example, by the UK BioIndustry Association in: 'A vision for the UK life sciences sector in 2035', 11 May 2025

109 UK Government, 'Life Sciences Sector Plan to grow economy and transform NHS', 16 July 2025

110 Medicines Manufacturing Industry Partnership, June 2022

United States

The US remains the global leader in biopharma, with significant R&D investments, attractive market dynamics, AI capacities, translational speed and dynamic private-capital markets. However, recent policy developments (pricing reforms, investment screening, tariffs) and intensified competition from an assertive China are increasing the pressure on the US's leadership. Recent moves (for example, FDA pilot programmes) signal that political actors recognise the gap and are attempting corrective action, yet leading advisory reports call for a more coherent and long-term national biotech strategy. However, domestic headwinds and policy uncertainties are raising risk, including proposed cuts to basic research, uncertainties in drug-pricing policy and other policy developments, impacting the US environment. While initiatives such as the bipartisan Congressional Biotechnology Caucus and the FDA's CNPV programme signal renewed momentum, the overarching challenge remains: to mobilise the US's unmatched capital, talent and innovation infrastructure into a coherent strategy before rivals consolidate their own leadership positions.

Standout features: retains unmatched scale, capital depth, and scientific and innovation leadership in biopharmaceuticals.

Quick facts	• The US remains the world's largest biotech/biopharma market and innovation hub, home to the leading clusters (Boston/Cambridge, San Francisco/Bay Area, San Diego), world-class universities, and the deepest VC and public capital markets for life sciences (for figures, consult PhRMA fact sheets[111]). • The federal government treats biotechnology as a strategic technology with national-security and economic-security implications across multiple administrations.
Key strategies	• **Industrial policy and R&D scale:** the CHIPS & Science funding wave strengthens core R&D infrastructure (National Science Foundation [NSF], Department of Energy [DOE], National Institute of Standards and Technology [NIST]) and complements bio/AI convergence investments. • **Security and investment screening:** Committee on Foreign Investment in the United States (CFIUS) rules and recent executive direction (America First Investment Policy) aim to expand scrutiny of foreign investment in sensitive biotech assets and data, including non-controlling stakes where there is access to sensitive IP or personal data. • **Regulatory acceleration pilots:** the FDA has launched pilots to accelerate approvals for nationally important products (for example, the CNPV pilot announced in 2025), signalling agility on regulatory timetables for high-priority areas.
Financial and early commercial support	• The US benefits from the world's deepest private-investor ecosystem for life sciences (VC, crossover funds, large pharma M&A, active IPO and listing markets) and substantial public funding through the NIH, DARPA/Biological Technologies Office (BTO), BARDA and NSF, DOE and NIST programmes. DARPA and other defence-related budgets continue to fund platform technologies (mRNA, synthetic biology) that later commercialise in the civilian pharma market. • Policy tools (tax credits, Small Business Innovation Research/Small Business Technology Transfer programme, NIH grants, advanced purchase/procurement via BARDA) derisk early development; the CHIPS/Science stack and other new appropriations add capacity for translational R&D and regional hubs.
Biomanufacturing	• The US retains large-scale biologics and vaccine manufacturing capacity (and an expanding network of CDMOs), plus targeted investment to onshore key capabilities. Defence and civilian programmes (DARPA, BARDA) have underpinned platform technologies and surge-manufacturing capacity built during COVID-19; recent industrial policy seeks to make some of that resilience permanent, as well as reshore manufacturing capacity.
Highlights – strengths and challenges	• **Strengths:** deep pools of late-stage capital; fastest market access and commercialisation pathways globally; world-leading research universities and private-sector cluster density; high capacity for rapid scaleup (CDMOs, advanced manufacturing); strong public funding (NIH, DARPA) for platform tech. • **Challenges:** increasing policy uncertainty (ongoing pricing debates, May 2025 Executive Order on drug pricing, tariffs on pharmaceuticals); potential for broader outbound/inbound investment screening and data-protection rules that complicate cross-border collaboration; concerns that episodic funding cuts or politically driven shifts could dent long-term basic research pipelines. Analysts and bipartisan commissions warn that the US approach remains fragmented and needs deeper coordination to respond to China's rapid rise.

111 PhRMA, 'Strong US trade policy fuels American leadership in biopharmaceutical innovation and manufacturing', 7 May 2025

Health resilience and geopolitical aspects	• The US has long viewed biotechnology through a dual lens of national security and economic competitiveness. Since the early 2000s, reports such as the 2004 'Biotechnology Research in an Age of Terrorism' have framed biotech as a potential target for hostile misuse, catalysing the creation of post-9/11 biosecurity programmes at the NIH, BARDA, and DARPA. Subsequent administrations have reinforced this view, with the 2018 National Biodefense Strategy, the 2022 'Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy', and ongoing export control and investment review reforms explicitly identifying biotech as a 'critical technology'. • Recent geopolitical tensions, particularly with China, have elevated biotech to a front-line arena in great-power competition. The bipartisan National Security Commission on Emerging Biotechnology warns that US policy has been "piecemeal and uncoordinated", risking the erosion of leadership in biotech innovation, manufacturing and security. In this framing, biotechnology is not only an enabler of health resilience but a strategic domain akin to semiconductors, where the convergence of AI and biology is a key battleground.
Main structures	• **Federal agencies and programmes:** NIH, FDA, BARDA, DARPA/BTO, NSF, DOE (national labs) – all central to funding, regulation and platform development. • **Security and investment bodies:** CFIUS and related export-control mechanisms; recent administration directives broaden scrutiny on foreign capital and data transfers. • **Innovation and finance ecosystem:** leading VC firms, the Bay Area/Boston clusters, a dense CDMO market, and major pharma R&D and M&A activity. • **Regulatory pilots**: the FDA's new CNPV pilot and other fast-track mechanisms aimed at shortening review times for nationally important products.