Bridging the Gap – Transforming EU Biotech Policy

Challenges and opportunities in EU biotech

CREATED BY AMSTERDAM DATA COLLECTIVE AND DANISH BIO
COMMISSIONED BY THE NOVO NORDISK FOUNDATION

Table of Contents

Preface: The EU risks losing the global biotech race

Advancing EU's strategic autonomy with biotech innovation

The European biotech industry stands at a pivotal moment, with the potential to transform human health through groundbreaking innovations. As the EU seeks strategic autonomy, minimizing dependence on external sources for vital technologies becomes crucial. The biotech sector is central to this ambition, driving advancements in medical treatments and diagnostics while significantly contributing to economic stability. Unfortunately, the EU has experienced stagnation in terms of growth in the biotech industry as other regions invest heavily in the sector.

Economic impact undermined by business barriers

With over €75bn in value added and nearly one million jobs across its industry and value chains, biotech's impact on Europe's economy and healthcare is undeniable.[1] Yet, despite these strengths, the European biotech industry lags behind its American counterpart in scale and influence. The EU, equipped with a robust scientific infrastructure and a diverse research and education ecosystem, is uniquely positioned to capitalize on the growing biotech landscape. However, decisive action is needed to create favourable conditions for biotech companies within the EU, or Europe risks falling behind in the rapidly advancing global biotech arena.

Focus on addressing challenges and seizing the opportunities

This report is crucial as it delves into the current status of the EU biotech along with the challenges and opportunities that the industry faces. It offers strategic insights to enhance funding, streamline regulations, and nurture talent. By prioritizing biotech, the EU can secure its autonomy, drive innovation, and pave the way for a healthier, wealthier, and more resilient Europe.

By Morten Engsbye,
CEO Dansk Biotek

Sources: [1] Haaf and Sale (2025)

ADC Data & AI Consultancy

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Executive summary and methodology

Executive summary: EU biotech cannot keep up with the US – Structural changes need to happen for the EU to catch up

Chapter 1: The EU biotech industry is far behind the US

Biotech is a critical driver of global innovation and healthcare, yet the EU is falling behind major international competitors. While the EU **produces research volumes similar to the US, its quality lags behind** - measured by a lower share of highly cited papers. Moreover, the EU translates less research into commercial innovation, reflected in **significantly fewer patents**. Scaling of biotech companies remains limited, leaving the sector relatively underdeveloped. Finally, and perhaps most crucially, the EU faces a **substantial funding gap across all stages - from early financing to IPOs** - where the US is far ahead. This chapter unpacks the obstacles holding EU biotech back and how they interact to shape its current state.

Chapter 2: Three key policy areas are crucial for the EU gap

Our analysis highlights three policy areas where the EU consistently trails the US.

First, funding: access to capital in the EU is constrained by regulation, cultural factors, and investment guidelines that discourage risk-taking, driving capital abroad.

Second, idea translation: the EU lags in turning research into commercial products, as its start-up support ecosystem is less professionalised than in the US.

Third, regulation: long approval times for clinical trials and drug approvals slow innovation and weaken competitiveness.

Overlaying these policy issues are **cultural factors** - including lower tolerance for risk and failure in the EU, a language barrier across many countries, and stricter and less flexible labour laws - that shape entrepreneurial behaviour, workforce hiring and firing flexibility, and relocation decisions.

Chapter 3: Policy changes are needed to remove the barriers and create better conditions for EU Biotech

Closing the gap with the US requires decisive EU policy action, and we propose three recommendations.

First, establish a fund-of-funds to pool capital from large institutional investors, including pension funds, thereby mobilising growth financing for EU biotech scale-ups.

Second, create professional translation offices staffed with experts to support researchers, bridge entrepreneurial skill gaps, and facilitate commercialisation, backed by EU-level funding across member states.

Third, harmonise and streamline regulation to shorten approval times for clinical trials and drug approvals, reducing bureaucratic hurdles and increasing the EU's attractiveness for biotech investment.

While these steps will not solve every challenge, they would remove several of the most critical barriers facing EU biotech.

If the EU were to reach parity with the US, the impact on the biotech industry and society would be transformative. Aligning EU pension fund allocations with US levels could unlock more than **€15 billion in biotech funding**, enabling significantly more seed, Series A, B, and C investments. Streamlining and harmonising approval processes to reach US speed for trials and drugs would **reduce approval processes with over one-third of the time**. If the EU reaches parity for the approval speed and especially funding, more drugs will likely reach the EU market to the benefit of the patients. EU has the potential of approving **14 additional drugs to EU patients each year**, if reaching the US standard. This would improve healthcare outcomes and creating long-term economic benefits for the EU patients.

Methodology and contributions

Context of the report

Healthcare innovation is one of several pressing global challenges, and biotechnology has the potential to overcome this through developing new technologies and drugs that target a wide range of healthcare needs. However, the EU significantly lags the US in its biotechnology sector, due to a variety of interlinked factors such as funding and regulatory support. This report aims to understand these obstacles better, in order to discover how the EU can make high-impact changes that significantly improve biotech innovation.

Approach

This study uses a mixed-methods approach to assess the European biotechnology industry's current state and pinpoint key challenges limiting its growth. It investigates the question: *What is the current state of the European biotechnology industry, and what are the main challenges restricting its development compared to global leaders?* Insights are gained through a comparative framework, benchmarking the EU against the United States as the leading biotechnology nation, and, where data is available, against China as an emerging competitor.

The analysis has been conducted by Amsterdam Data Collective (ADC) with invaluable support from Dansk Bio, Galecto Inc., and Sunstone Life Science Ventures, who provided Pitchbook access. The report also benefits from industry expert contributions. Any remaining inaccuracies or errors are the responsibility of ADC.

Quantitative data

Quantitative data was systematically collected from multiple databases including OECD emerging technology indicators (R&D expenditures, intensity, and patent shares), WIPO patent statistics, Pitchbook (venture capital deals and IPOs), US Census and Bureau of Labor Statistics (employment data), Eurostat structural business statistics, SCImago journal rankings, IPEDS and Eurostat education databases (biotechnology graduates). Given the absence of unified EU-US datasets, we implemented a tailored approach for each variable, selecting sources with the most valid definitions and ensuring maximum cross-regional comparability.

Data limitations included inconsistent country coverage within EU datasets and varying definitional standards across regions. All collected data was consolidated into a comprehensive master table, supplemented by manually extracted metrics from industry reports. Key performance indicators included funding levels, innovation outputs measured through scientific publications and patents, regulatory timelines, employment figures, and market valuations.

Policy mapping

The qualitative component comprised a comprehensive policy mapping exercise, reviewing academic literature, industry reports, and regulatory frameworks to identify patterns in the factors constraining EU biotechnology development.

Through thematic analysis, we categorised findings by impact level and interconnections, focusing on regulatory barriers, funding ecosystem challenges, talent retention, and market fragmentation.

This analysis was enriched by five semi-structured interviews with experts in entrepreneurship, innovation, and venture capital, whose insights validate our findings and inform actionable recommendations throughout the report. The integration of quantitative benchmarking, policy analysis, and expert perspectives enables a triangulated understanding of systemic factors contributing to the EU's performance gap, moving beyond simple metrics to develop targeted, high-impact interventions.

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Current status of the EU biotech industry

In which area is the EU lagging behind the US?

Chapter 1 summary: EU biotech is lagging behind the US

EU has difficulties translating academia into successful companies

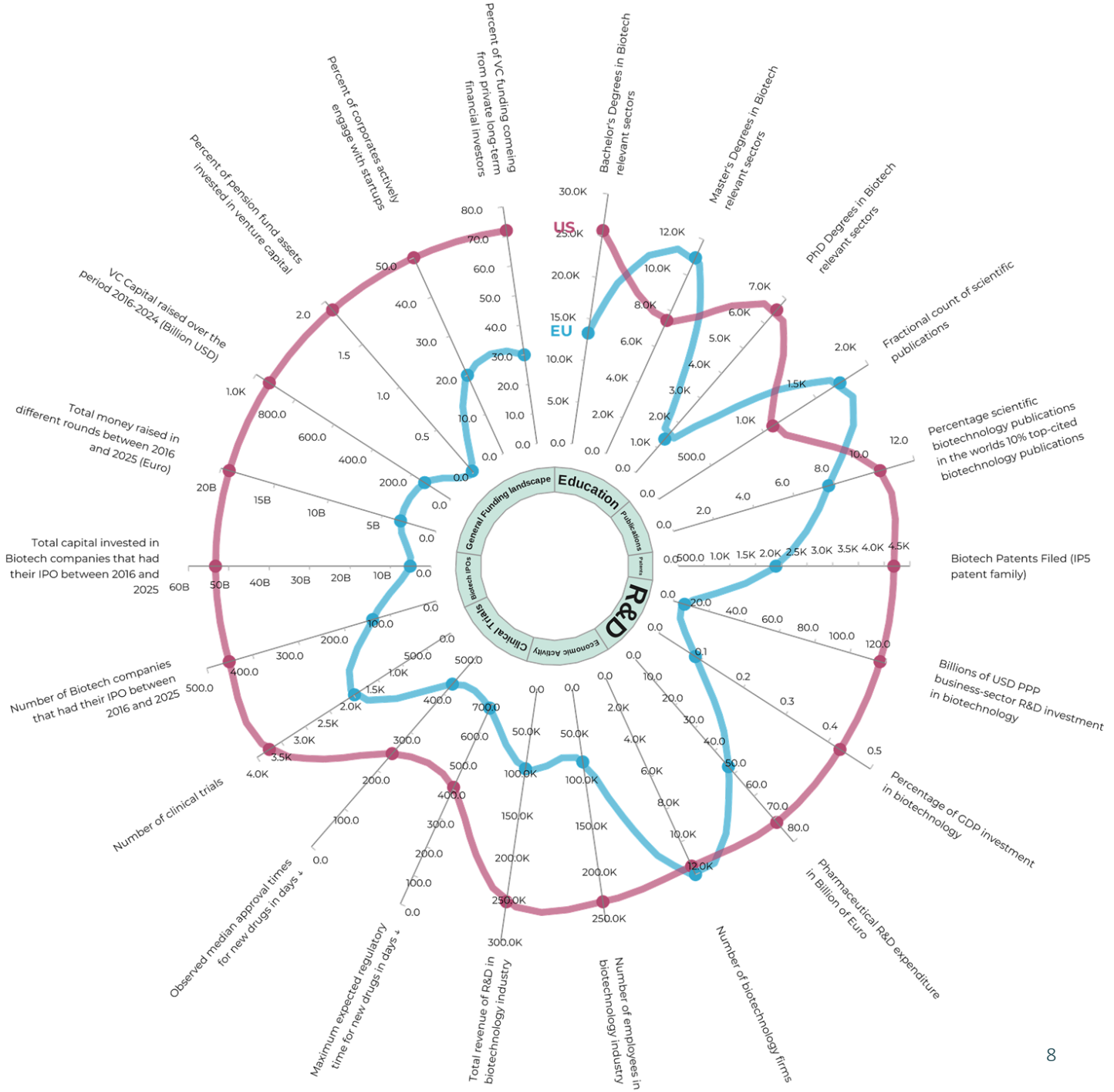
While the EU and the US are comparable in terms of biotech education and academia, the EU significantly lags behind when it comes to translating academic excellence into successful companies. This translational gap materializes across multiple dimensions - **the EU trails in patents, R&D investments, and overall economic activity** from the biotech industry. The table on the next page and the visualisation on the right provide an overview of how many areas the EU biotech industry is behind its US counterpart.

EU has a funding gap

The EU struggles particularly in the later stages of biotech company development, **with fewer clinical trials, fewer IPOs, and substantially less funding available**. US biotech companies raised significantly more capital. Access to capital through IPOs or venture funding represents the most critical structural barrier for EU biotech companies, limiting their ability to scale operations, conduct expensive late-stage trials, and bring products to market. This funding disparity creates cascading effects throughout the ecosystem. The result is a biotech ecosystem where promising research struggles to advance beyond early stages, leaving potential breakthroughs unrealised.

Outline of the chapter

This chapter aims to deliver comprehensive insights into the current state of the EU biotech industry, compared to its US counterpart. It will present a chronological analysis of the EU biotech sector's performance relative to the American industry, beginning with the academic achievements of students and researchers and concluding with the success rates of funding and IPOs for biotech companies.



The EU keeps up with the US in biotech academia but falls behind on almost all other aspects

Biotech Sector Performance: US vs EU

Comparison of some baseline figures

Category	Metric	United States	European Union	Trend & Analysis
Education	Bachelor's Degrees in Biotech relevant sectors	25,608*	13,289	US grew with 31% since 2015, while EU grew 19%
	Master's Degrees in Biotech relevant sectors	7,471	10,993	EU maintains lead
	PhD Degrees in Biotech relevant sectors	6,564	1,352	US produced 2.4 times the number of PhDs
Publications	Fractional count of scientific publications	1,089	1,730	EU consistently publishes more papers
	Percentage scientific biotechnology publications in the worlds 10% top-cited biotechnology publications	10	7.7%	US publishes higher impact papers
Patents	Biotech Patents Filed (IP5 patent family)	4,186	1,894	United states apply for more Biotechnology patents each year than the EU
R&D	Billions of USD PPP business-sector R&D investment in biotechnology	$117.1B	$6.3B	In absolute terms, the EU is falling increasingly behind the United States
	Percentage of GDP investment in biotechnology	0	0.1%	Also in relative terms, the R&D intensity gap widening in recent years
	Pharmaceutical R&D expenditure in Billion of Euro	€71.5B	€47B	By 2000, the US had overtaken Europe, and the gap has continued to widen
Clinical Trials	Maximum expected regulatory time for new drugs in days	408	685	The regulatory process take more time in EU than US, Mostly due to the post-approval process
	Observed median approval times for new drugs in days	244	426	FDA approved 95% of therapies first, with a median delay to market authorization in Europe of 241 days
	Number of clinical trials	3,747	1,987	North America - primarily led by the US - accounted for 26% of clinical trials, totaling 3,446. By 2023, the number had risen to 3,747. In contrast, the EEA experienced declines in both relative share and absolute terms. In 2013, the EEA contributed 18% of trials, or 2,424 starts, but by 2023 this fell to 9%, or 1,987 trials.

*latest available data is shown

Biotech Sector Performance: US vs EU

continued

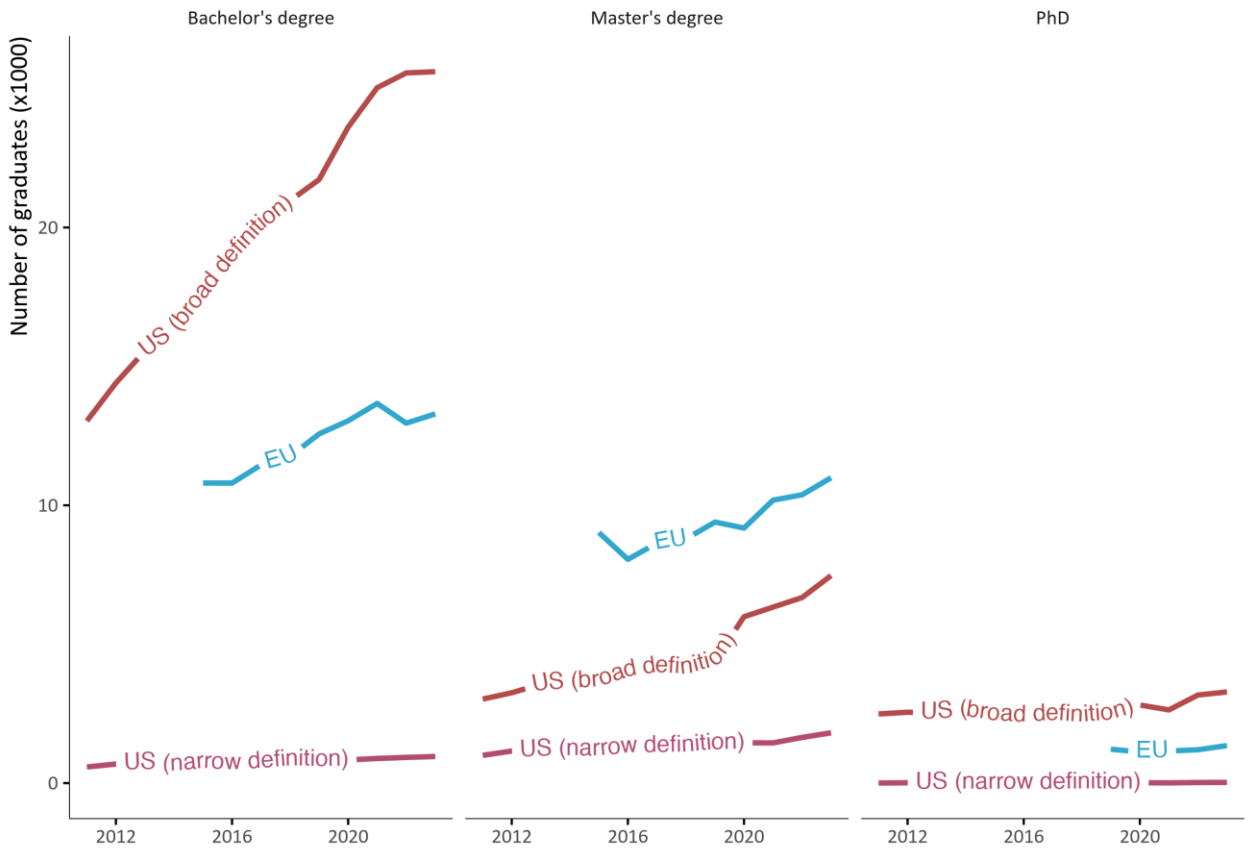
Category	Metric	United States	European Union	Trend & Analysis
	Number of biotechnology firms	11,482*	12,000	Number of notechnology R&D firms between the US and the EU was very similar in 2020
Economic Activity	Number of employees in biotechnology industry	228,329	78,500	More employees are working in US biotechnology research than EU employees
	Total revenue of R&D in biotechnology industry	254,385	95,613	The total market size of R&D biotech sector is about 2.7 times bigger in the US as compated to the EU
Biotech IPOs	Number of Biotech companies that had their IPO between 2016 and 2025	451	138	Only 138 biotech healthcare companies in the EU completed an IPO, compared to 451 in the United States
	Total capital invested in Biotech companies that had their IPO between 2016 and 2025 (Billion Euro)	€53.3B	€5.1B	This gap also explains why the total capital raised through IPOs is significantly higher in the US than in the EU
General Funding landscape	Total money raised in different rounds between 2016 and 2025 (Euro)	19,233,150,000	3,284,810,000	The total amount of money raised in diffent rounds (seed to series C) is consistently higher in the US. Relatively speaking, even more funding is available in the US at later stages. 19.7% (30.7B EUR) of funding is raised in the series C round in the US as compared to 14.9% in the EU (3.2B EUR).
	VC Capital raised over the period 2016-2024 (Billion USD)	$932B	$133B	US-based companies raised substantially higher levels of VC capital than the EU over the period 2016-2024
	Percent of pension fund assets invested in venture capital	1.9%	0.018%	US pension funds invest more than 100 times the share of their assets into venture capital than their European counterparts
	Percent of corporates actively engage with startups	50	20%	20% of European corporates actively engage with startups in contrast to 50% in the US
	Percent of VC funding comeing from private long-term financial investors	72	30%	Between 2013 and 2023, private long-term financial investors in the EU accounted for only 30% of the VC funding, compared to 72% in the US

*latest available data is shown

Note: This table illustrates the comparison between the EU and the US, like what is on the previous page, but includes trends and descriptions.

1) The biotech students: EU and the US are comparable in number of biotech students

Figure 1.1: The US leads in bachelor's and PhD graduates in biotech and life sciences, while the EU has more graduates at the master's level.



Sources: ISCED (2015), CIP system (2025), Eurostat (2024a), IPEDS (2024)

The US produces more university graduates at the bachelor's and PhD levels in biotechnology and life sciences, whereas the EU leads at the master's level. These differences reflect both structural variations in education systems and how degrees are classified and reported.

In 2023, the EU awarded about 13,300 bachelor's degrees in biotechnology and related fields, up from 10,800 in 2015. In contrast, the US awarded only 958 degrees under the narrow biotechnology category, a figure that has remained below 1,000 for over a decade. However, using a broader set of life science fields, the US total rises to 25,600 in 2023 nearly double the EU numbers. At the master's level, the EU awarded nearly 11,000 degrees in 2023, compared to 7,500 in the US under the broader definition. The gap reflects structural differences, as terminal master's degrees are less common in the US, where many students proceed directly to PhDs. For doctorates, the EU awarded about 1,350 PhDs in 2023, while the US produced only 26 under the narrow definition, but 3,280 when using the broader classification.

Different classification system

The EU classifies education programs using the ISCED system, while the US relies on the CIP system. The figures present both a narrow US definition, covering only biotechnology, and a broader one that was applied to better align with the EU's scope. Although some codes overlap between the two systems, exact equivalence is not possible, making direct comparison challenging.

Note: The following codes were selected in the categories. ISCED 0512, the EU category for biochemistry, explicitly includes biotechnology. In contrast, the US CIP 26.12 refers solely to biotechnology and is thus narrower in scope. The broader definition includes CIP codes 26.02 (Biochemistry, Biophysics and Molecular Biology), 26.10 (Pharmacology and Toxicology), 26.11 (Biomathematics, Bioinformatics, and Computational Biology), 26.12 (Biotechnology), 26.14 (Molecular), 26.15 (Neurobiology and Neurosciences), and 26.99 (Other Biological and Biomedical Sciences).

2) EU Biotech research: Matches US in volume, lags in quality — China takes the lead

China surpasses both the EU and the US in the number of scientific publications, as well as the number of publications in the top 10 percent most cited publications. This highlights the need for the EU to strengthen its competitiveness in this field.

China surpasses both EU and US in publications

The EU produces more biotechnology publications than the US, but recently China is surpassing both regions. While the number of publications, based on a fractional count, has fallen slightly in the EU, US numbers – that where already on a lower amount – also dropped. In the meantime, the number of publications from China has increased sharply, surpassing the US in 2013 and the EU four years later in 2017.

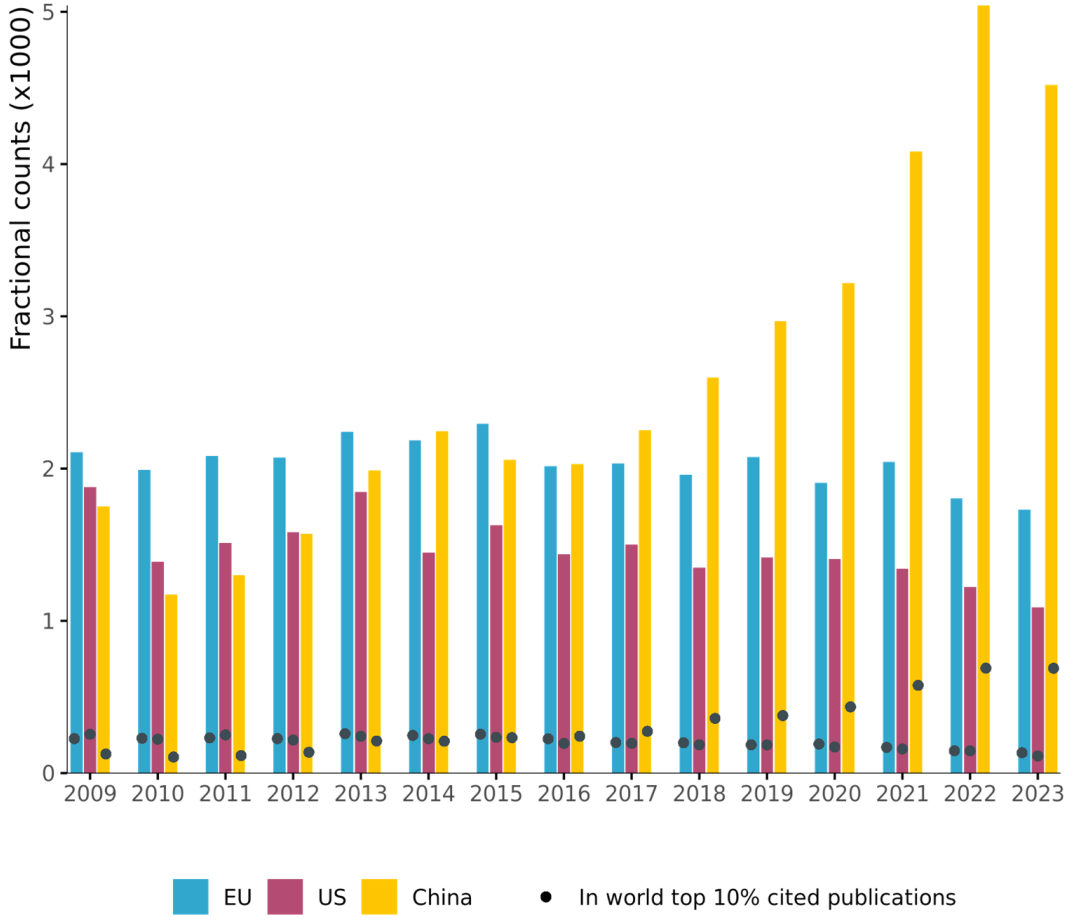
Articles from the EU have a lower citation impact

While the EU produces more biotechnology publications than the US, their citation impact is lower. The share of EU publications among the top 10% most cited has dropped below the global average, whereas the US has declined to the global average. This is evident in the fact that, despite publishing more overall, the EU has a similar number of highly-cited papers as the US. While China has by far the highest share of top 10% cited publications, China's rise in top-cited publications is partly driven by researchers excessively citing researchers from their own country, which leads to an overstated citation impact.[1]

China highly focused on biotechnology

Also, in terms of the specialisation of publications both the EU and the US are seeing a decline in their specialisation in biotechnology research, as indicated by falling specialisation index scores (not shown in figure). The index measures how strongly each region focuses on biotechnology relative to the world average. Over time, these scores have dropped below the global average for both regions. In contrast, China maintains a high and rising level of specialisation, highlighting biotechnology as a clear strategic research priority.

Figure 1.2: Despite a higher publication output, the EU's share of the world's top 10% most-cited scientific papers is no greater than the United States.



Sources: OECD (2024a). OECD bibliometric indicators are calculated on Elsevier's Scopus Custom Data. Journal classification 'Biotechnology' selected.

[1] *Qui et al. (2025)*

3) From lab to market: EU falls behind in patenting biotech research

Biotechnology patent trends reveal that the US continues to outperform the EU in patent filings from IP5

Since the mid-1980s, the US has consistently filed more biotechnology patents than the EU. While both regions experienced strong growth in filings up to 2000, US patent activity resumed growth after a brief dip, whereas EU filings have largely plateaued. Both regions were affected by a decline in filings during the COVID-19 pandemic.

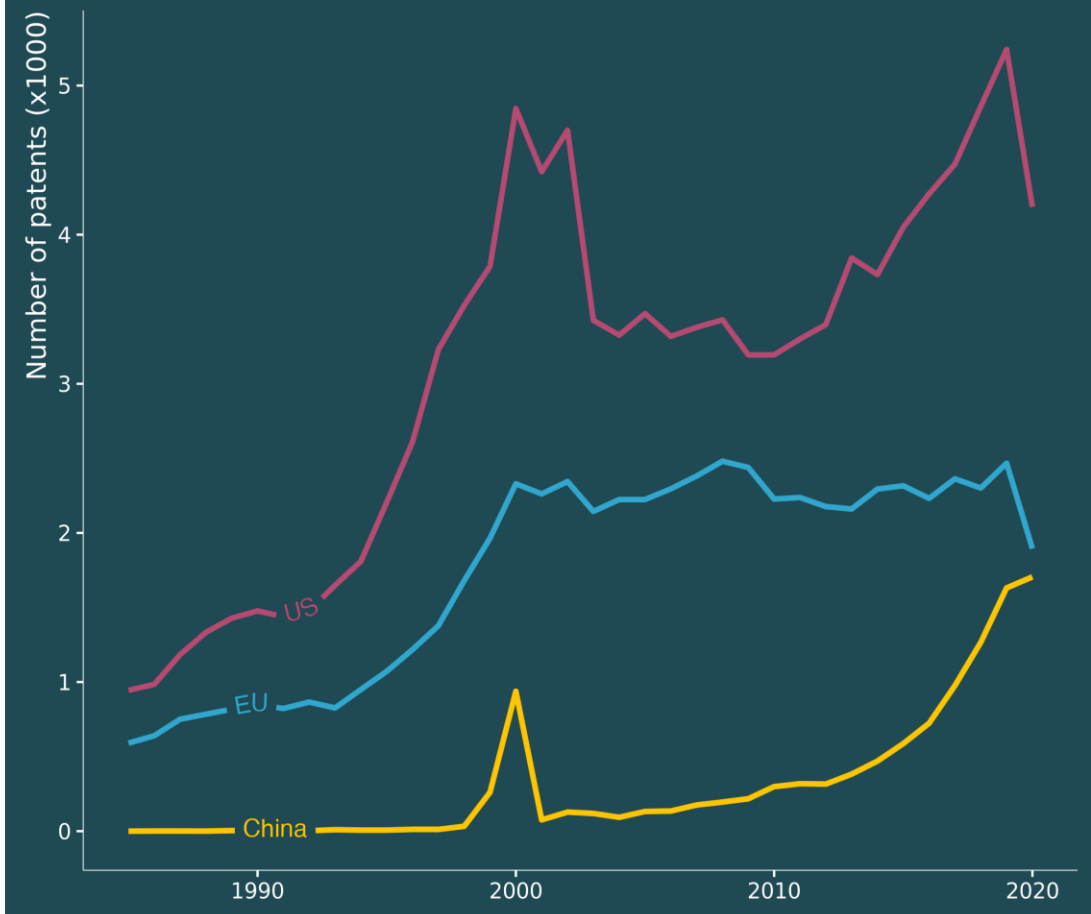
In the meantime, China is rapidly catching up

Meanwhile, China has shown steady growth in biotech patenting and had nearly reached parity with the EU by 2020. This trend suggests that China is on track to overtake the EU in biotechnology innovation output. These developments highlight the need for both the EU and the US to enhance their capacity to convert biotech research into commercially viable innovation to stay globally competitive.

Patenting indicates the ability to translate research to commercial leverage

Patent applications serve as a key indicator of the ability to translate scientific research into commercial impact, reflecting both innovation and strategic efforts in commercialisation. Since patents can be filed in multiple jurisdictions, it's best to use patent families which represents groups of related filings for the same invention. IP5 patent family data covers filings submitted to at least one of the world's five largest patent offices, together handling about 90% of the world's patent applications. This ensures a robust basis for comparison.

Figure 1.3: The US leads in biotech patenting, China is rising fast, and the EU is holding steady but not keeping pace with global shifts.



Sources: OECD (2024c). Patents in Biotechnology. Number of IP5 patent family applicant. Note: The reference data is the priority date. The unit measure is on sets of parents/families. In this graph applicants are plotted, as the difference between inventors and applicants is minimal.

4) Commercialisation: The EU has more companies, but fewer employees than the US

The European Union has been successful in creating small biotechnology firms

Based on three different scopes, over time in both the EU and the US an upward trend in the number of companies is signalised. At the broadest definition of 'biotech firms', the EU has more scientific R&D firms than the US. However, as the scope narrows to a more specific biotechnology definition, the number of firms in both regions becomes roughly equal (although limited observations available).

The US firms employ more people

Despite this parity in firm count, the US science and biotechnology sector clearly employs more people than the EU, regardless of whether a broad or narrow definition is applied. This suggests that EU firms tend to be smaller in size, both in general R&D and in the biotechnology sector specifically, indicating a higher proportion of small and medium-sized enterprises in the EU biotech landscape relative to the US.

The indication that EU's firms are smaller and less likely to scale, points to structural barriers that may be limiting the growth of biotech firms in the EU and underline the need for stronger measures to support the expansion and maturation of these companies. This is also reflected in revenue. In 2022, the US had a revenue of approximately €250 billion in experimental R&D in natural sciences and engineering, compared to a turnover of around €100 billion in the EU.

Comparable statistics despite different classification systems

We compare the number of companies and employees across three levels: a broad definition covering all scientific R&D companies, a mid-level definition focused on life science R&D, and a narrow definition limited to biotechnology R&D. While the EU and US use different classification systems, the categories are broadly comparable.

Figure 1.4: EU has more (life) science R&D companies than US

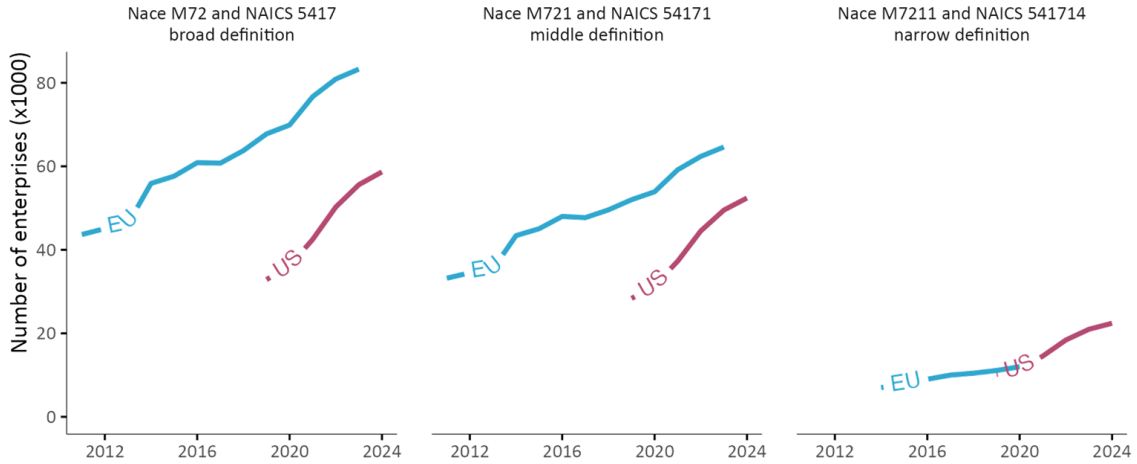
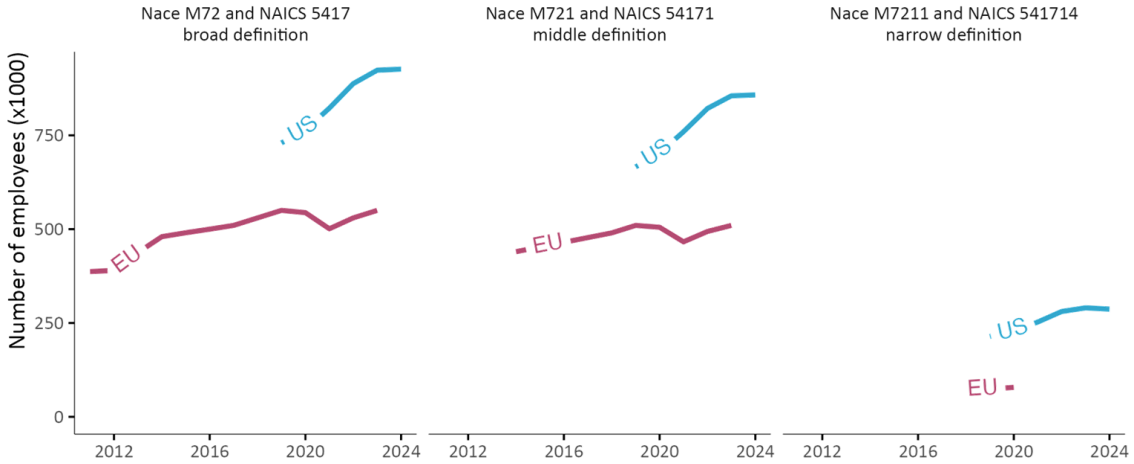


Figure 1.5: In the US more employees work in (life) science and biotechnology R&D than EU



Sources: Eurostat (2024b), US Bureau of Labor Statistics (2024). Note: The definition for the EU is based on the NACE codes: the broad definition consists M72: Scientific research and development, the middle definition of M721: Research and experimental development on natural sciences and engineering, and the narrow definition of M7211: Research and experimental development on biotechnology. For the US the categories are based on the NAICS. The categories range from 5417: Scientific R&D Services (broad), to 54171: R&D in Physical, Engineering, and Life Sciences (middle) to 541714: R&D in Biotechnology (exc. Nanobiotech) (narrow). US Revenue numbers were taken from Latest Annual Services Report (Re-released on 2017 NAICS-basis) and EU Revenue numbers from Enterprise statistics by size class and NACE Rev. 2 activity.

5) The funding for scaling: Companies cannot get the needed capital in the EU – especially in the late-stage funding

In the US there is consistently more funding available

Across all funding rounds the US has more funding available compared to the EU, as shown in figure below. For all of the last ten years, the EU has been far behind the US in terms of funding across all the stages, from Seed to Series C. Limited access to funding in the EU drives companies to seek capital abroad, which in turn reduces job creation within the EU.

The later the stage, the larger the gap

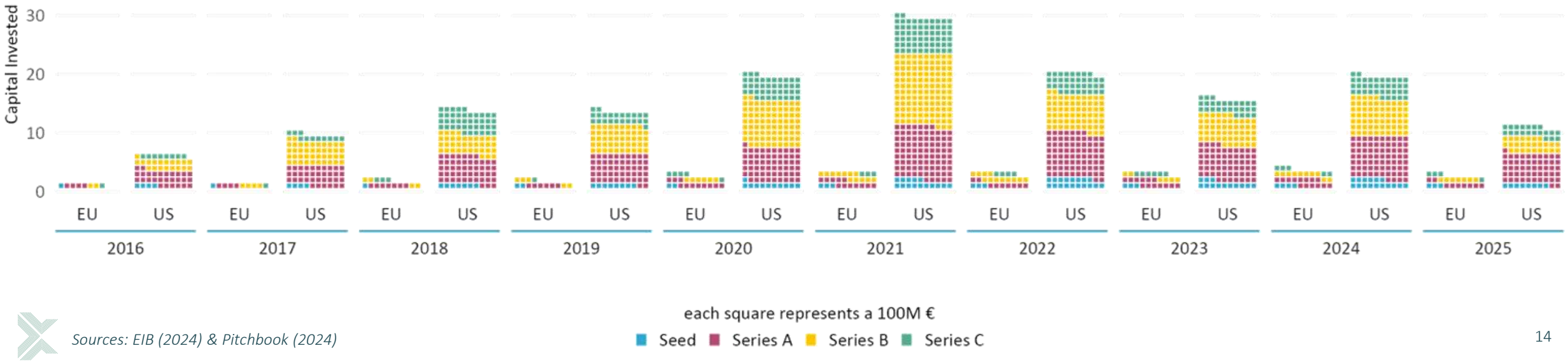
There is a tendency for the funding gap to be larger, the later stage it is. The largest gap is at the later-stage funding, where the US has had 870% higher amount of capital raised in Series C funding in the last 10 years compared to the EU. In the opposite end, the amount of capital raised for US Seed funding is "only" 370% higher than in the EU.

The gap widens in the long-term trend

Looking at the historical trend, the Seed funding is where the EU has had the largest relative increase in capital raised in the last ten years compared to the decade before. However, the increase has been much higher in the US Seed funding in the same period, so the funding gap has widened between the EU and US for the Seed funding.

For Series A funding the EU has actually managed to reduce the gap in relative terms in the last decade, whereas it has increased for Seed, Series B, and Series C. However, when looking in absolute terms, or the actual money raised, the gap widens by a large margin, across all funding stages, and the EU is falling further and further behind.

Figure 1.6: Through all investment rounds there is more funding available for biotech companies in the US as compared to the EU.



Sources: EIB (2024) & Pitchbook (2024)

6) Biotech IPOs: IPOs happen in the US – not in the EU

945% more capital raised in US IPOs

Since 2016, US biotech IPOs have raised over €53bn, compared to just €5bn in the EU. This means that capital raised in US IPOs is about 945% higher than the amount raised in the EU. This is a massive difference between two regions, which is quite comparable in terms of population, economy, and the focus on human health. The difference is driven by both more IPOs in the US and larger IPOs in the US.

Far more and far larger US IPOs

In the last 10 years, there has been 227% more IPOs in the US than in the EU. The US has had 451 IPOs since 2016, while the EU has had 138. Not only do we see more biotech IPOs in the US, the average amount of capital raised at the biotech IPOs is also much higher. The average IPO in the US was about €118m, while the average for the EU was about €37m in the period from 2016 to 2025.

EU biotech go to the US for IPO

Part of the explanation for these numbers is that many European biotech companies IPO in the US. From 2012 to 2018 about 1/3 of European biotech companies choose to IPO in the US.[1] While it for US companies is almost unthinkable to IPO in the EU, it is often the only logical outcome for European companies to IPO in the US.

This pattern is partly explained by the greater access to capital in the US in terms of stock exchange and venture capital. The lack of capital in the European capital markets often leads EU biotech to premature IPOs in the EU, as well as a tendency for the European biotech companies to exit through an M&A, when they need later-stage funding.[1]

Figure 1.7: Number of biotech IPOs from 2016 to 2025

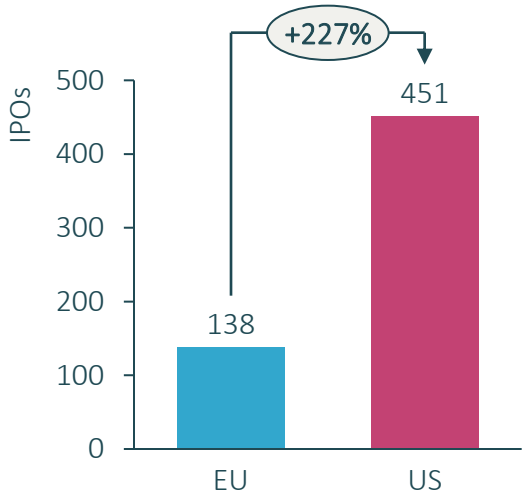


Figure 1.8: Average amount raised for biotech IPOs

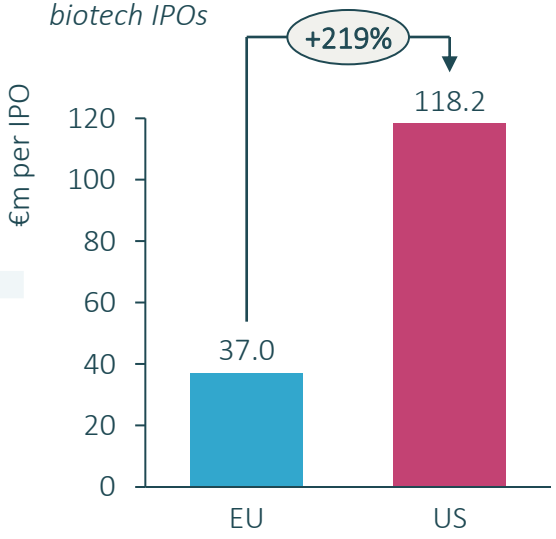
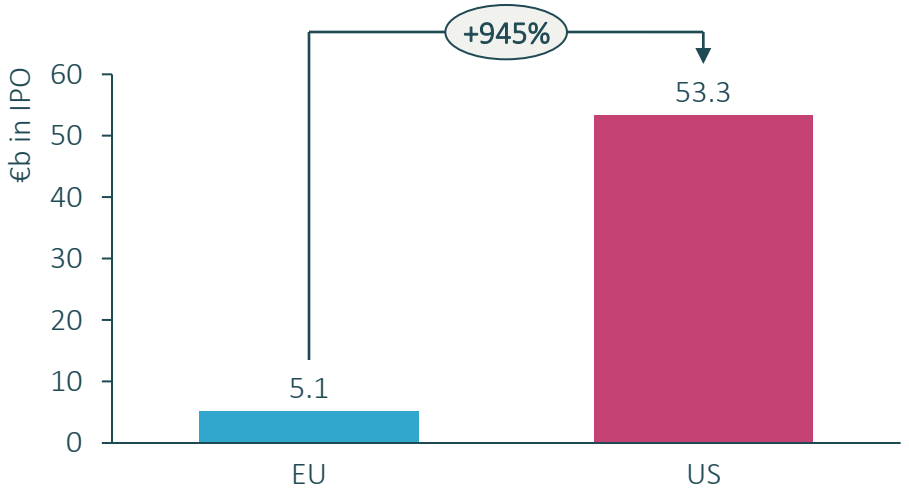


Figure 1.9: Amount of money collected in biotech IPOs from 2016 to 2025



Sources: Pitchbook (2024); [1]McKinsey (2019)
Note: The Pitchbook data was extracted in August of 2025, so IPOs happening after this are not a part of the data.

7) R&D intensity: EU's economy is less focused on R&D in biotechnology

EU growth has been stagnant, and the US leads the EU by a wide and growing margin in biotechnology business-sector R&D investment, reflecting stronger innovation efforts

The EU lags both in terms of R&D intensity in the business sector and in absolute R&D expenditure in biotechnology.[1] The US consistently demonstrates a significantly higher level of R&D intensity, increasing from approximately 0.2% of GDP in 2009 to over 0.4% in 2021, before a slight decline in 2022. This reflects a strong and sustained growth in biotechnology investment within the US business sector. In contrast, the EU shows much lower R&D intensity levels, ranging from 0.04% to 0.12% of GDP, without a clear upward trend. Among EU countries, France recorded the highest intensity in 2022 at 0.16% of GDP.

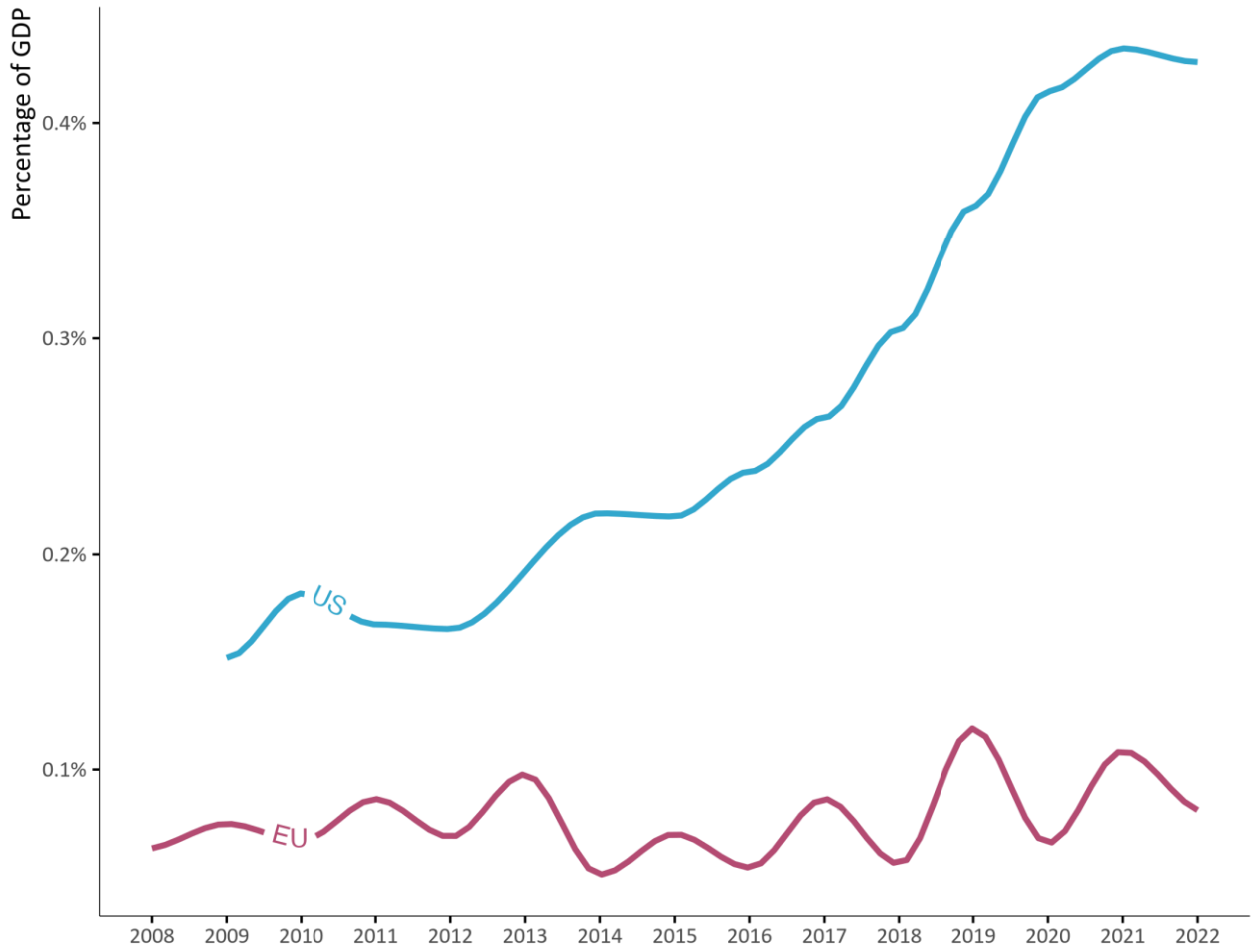
Higher absolute growth in the US

In absolute terms, U.S. biotechnology R&D investment rose from an estimated $25–30 billion USD PPP in 2009 to approximately $115 billion in 2022. The EU countries (for which we have data), by comparison, showed more modest growth, with expenditures ranging from $5 billion to $25 billion over the same period. This growing disparity highlights a widening gap in biotech innovation investment between the two regions.

R&D intensity can be difficult to measure

The R&D intensity in the business sector refers to the ratio of R&D expenditures to value added in the private industry investment in biotechnology R&D, excluding public and academic spending. Different definitions are used between countries and not all EU countries are available all the years data, causing small spikes in the R&D intensity line.

Figure 1.10: The biotech R&D intensity gap between the EU and US is widening further in recent years



Sources: OECD (2024b).

Note: [1] *Only the following EU countries are included Italy, Czechia, Estonia, Belgium, Latvia, France, Austria, Portugal, Spain, Slovak Republic, Sweden, Denmark, Germany, Slovenia, Finland, Ireland, Poland, and Lithuania. For R&D intensity, the data represent the weighted average of these countries; for absolute expenditure, the figures reflect their combined total. Differences in national definitions and incomplete country coverage may lead to underestimation of the EU's overall biotechnology R&D investment.*

8) The clinical trials: the EEA has fewer clinical trials compared to North America and the gap widens

Fewer clinical trials are conducted in European Economic Area (EEA) compared to North America, and the gap is continuing to widen. Europe's declining share in clinical trials threatens its global competitiveness, patient access to innovation, and long-term investment in life sciences.

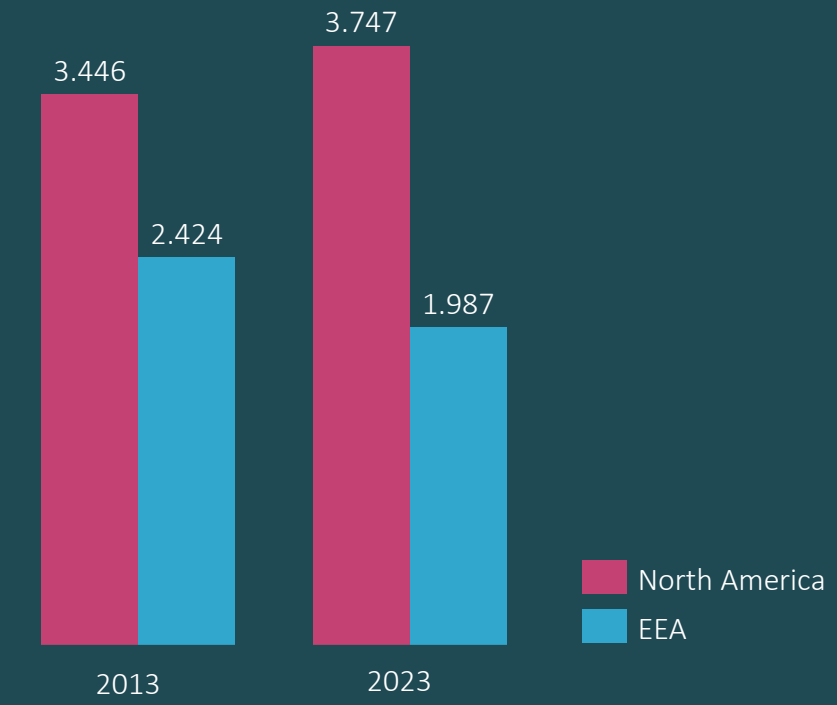
Number of North American trials increase, while European decreases

In 2024, North America conducted 3,747 clinical trials, while the EEA conducted 1,987 - slightly more than half. Over the past decade, North America has seen a 9% increase in clinical trials, whereas the EEA experienced an 18% decline. The clinical trials consist of phase 1 – 4. These figures cover all phases and provide an overview of the entire clinical trial ecosystem, not just biotechnology-related trials.

Slower European processes

This regulatory structure plays a role when comparing the EU to the US. In the US, clinical trial approvals are centralised, with a 30-day review period and parallel ethics evaluation. In contrast, the EU's process, although governed by the Clinical Trials Regulation (CTR), remains decentralised, with each member state conducting its own review. This leads to longer timelines of 60 to 105 days, including ethics review, and contributes to the EEA's slower trial start-up. EFPIA (2024) mentions possible additional reasons for the loss of market share in commercial multi-country clinical trials. These are slow patient recruitment, with limited data access, further hindering recruitment speed, and China's more favourable regulatory framework and funding environment.

Figure 1.11: Number of clinical trials (entire ecosystem, phase 1-4) started in North America and EEA



Sources: EIFPIA (2024), FDA (2023), EMA (2022).
Note: Although the available data refers to the EEA and North America rather than the EU and US specifically, these regions serve as close proxies. EEA contains of the EU countries in addition to Norway, Iceland and Liechtenstein. North America consists of Canada, Mexico and the US.

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Policy gaps for EU biotech

What are the barriers to the EU biotech success?

Chapter 2 summary: The key obstacles faced by the EU biotech companies are funding, idea translation, regulation, and culture

The EU's regulatory environment does not promote biotech innovation successfully when viewed in direct contrast with the US innovation-led system. To understand the distinct challenges in the data outlined in the previous chapter, this section dives into the obstacles that the EU is facing in its regulatory and policy landscape surrounding its biotech innovation sector.

In our expert interviews, three issues repeatedly surfaced: 1) the EU is **lacking available funding**, 2) the process of **idea translation and spinning-off a company is less clear** than it is in the US, 3) the **EU regulatory process provided obstacles** rather than shortcuts for the companies.

The following section explores these issues through tackling four key obstacles: funding, translation of research into commercial products, regulatory hurdles, and cultural divergences.

Funding

There is a significant gap in available funding to biotech ventures across the development stages, which grows especially wide in the later (and larger) funding rounds. This is slowing down the EU scale-up industry and resulting in lower returns to VCs that consequently stay smaller and less capable of making larger investments. Perhaps due to the under-serviced venture capital market in the EU, US VCs have recently targeted EU startups more, providing some capital and benefitting of the returns that could be strengthening the EU venture market. To understand why the VC scene is lacking behind so significantly, we dive into the regulatory requirements that inhibit large, institutional investors from committing to funding VCs.

Idea translation

The EU's focus on commercialisation of research is relatively weak when contrasted with the US. Instead of innovation-related university offices such as the tech transfer offices being regarded collaborators in the spin-off process, they are seen as obstacles. Changes in regulation around IP ownership have given the US a decades-long head start in their innovation focus, an effect still felt today. The underdevelopment of targeted translation offices is preventing many research innovations from maturing into commercial products. We compare the general European innovation process with some examples from US institutions to indicate where impactful changes can be made, particularly to support researchers with gaining entrepreneurial skills.

Regulation and culture

EU regulation is frequently critiqued for its long approval timelines that significantly inhibit competitiveness, particularly in biotech. This bureaucratic disadvantage is considered alongside several interlinked cultural factors that prevent the EU's biotech innovation sector from working in the same pace and efficiency as the US. Understanding the environment around the regulations and institutions that are supposed to facilitate innovation indicates how these gaps have worsened and emphasises the importance of talent being able to move across the EU to where it is needed most. Without this, many institutions act in isolation and projects struggle to reach their full competitive potential.

Funding across different start-up development stages is underdeveloped, resulting in major losses of European IPOs to the US

EU is lacking funding across all stages

One of the major obstacles that European biotech start-ups encounter in their development is the access to funding across all stages. US startups receive significantly more funding in all funding rounds, yet the gap widens, especially in the later stages.

The diagram to the right depicts a simplified illustration of the development and funding stages and how these may align in the fundraising process. There is significant room for variation from this model, yet on average the funding requirements increase significantly during the later-stage clinical trials (Phase II and III), which are essential for achieving the Proof of Concept and commercialising the technology. It is precisely at these high-cost stages that European funding is least developed.[1]

Especially at the exit or IPO stage many founders seek out the most profitable opportunities. Whereas Euronext, the largest European stock exchange (excluding the London Stock Exchange), holds a market cap of around $4.36 trillion, the New York Stock Exchange's market cap is roughly $28.33 trillion.

Figure 2.1: Development and funding stages for many biotech startups

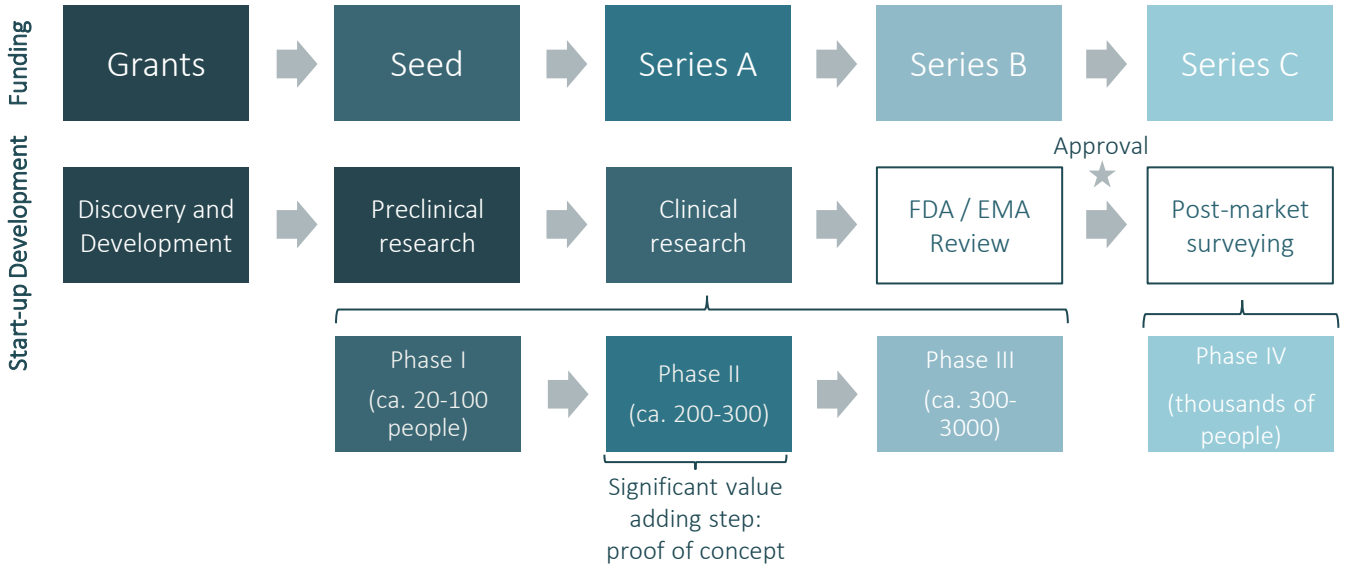
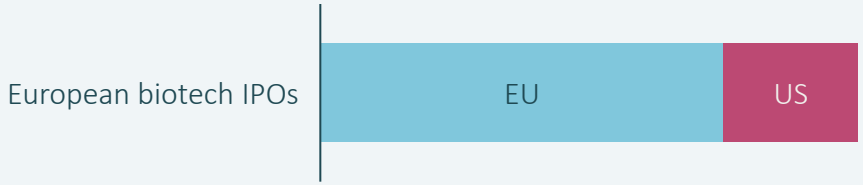


Figure 2.2: Distribution of IPOs for European biotech (2012-2019)



Notes: [1]See chapter 1 for distribution of funding.
Sources: [2]McKinsey (2019). These numbers are relatively outdated now, and the percentage of IPOs made by European firms in the US is expected to be significantly higher.

With more investment opportunities, the decision for many founders to list abroad comes naturally. This has significant consequences, as one third of all European biotech IPOs between 2012 and 2019 took place on US exchanges rather than within the EU.[2] A weak funding and exit environment mean that capital generation from European research is frequently escaping the Eurozone area, causing the ecosystem to remain relatively underdeveloped compared to its US counterpart.

Yet the IPO opportunities are certainly not the only cause of this, and rather the symptom of a series of issues European biotech founders are facing in their development journey. The analysis targets the availability of public grants for research and development and the size of venture capital.

US government funding programs invest more into research and development than the EU

The US has historically made more public grant money available to research than the EU

The United States has consistently outperformed the European Union in terms of annual investment in research and development (R&D), a trend sustained over several decades. Throughout the 20th and 21st centuries, innovation and R&D have been central to U.S. economic growth, driven by highly productive research and commercialisation ecosystems such as Silicon Valley and the Boston biotech cluster.

Both EU member states and US state-specific institutions give out public grants, yet Horizon Europe (EU) and the NIH Funding (US) present the largest public funding bodies and are thereby most comparable. The size of the programs differs substantially. Horizon Europe (2021-2027) is the latest program in a series of EU Foundational Programs for Research and Developed, initiated in 1984 and with budgets including from €3.8b for 4 years in 1984, €16.3b over 4 years in 2002 and €50.5b over 7 years in 2007.[1]

The NIH funding has likewise increased over the years, yet both the base amount and the total increase of annual funding is substantially larger. In 1998, NIH annual funding was around $13.675b and grew to $27.167b in 2003. By 2007, annual funding was just under $30b and by 2019 just under $40b.[2]

Despite presenting only one element of the many interconnected factors that support research, innovation, and commercialisation in the biotech industry, the wider availability of public funding in the USA supports and contributes to its advanced biotech maturity. In recent years, this gap has been narrowing, yet it remains substantial.

Recent US policy changes raises questions of public US funding

The future of this advantage has become uncertain in recent months. In President Trump's 2025 budget proposal, significant cuts have been directed at NIH funding, which is already raising concerns across the biotech sector. Given that many early-stage biotech ventures rely heavily on NIH grants, the effects of these reductions are expected to materialise in the coming years.

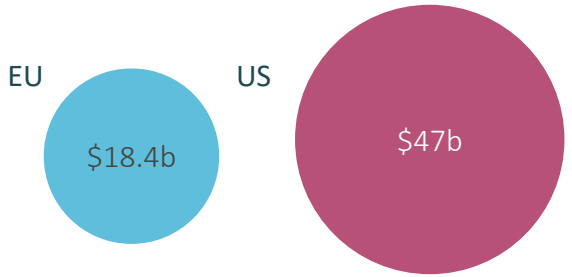


Figure 2.3: 2024 annual grant money available by largest public funders: Horizon Europe and NIH (in $)

Public Funding EU

European Innovation Council

A capital allocation by Horizon Europe with a budget of around €10.1b, this focuses on giving grants to startups at different stages.

European Research Council

Offers core grant schemes for Starting, Proof of Concept, Consolidation and more, targeting commercialisation. Recent €16b injection through Horizon Europe.

Public Funding US

National Institutes of Health (NIH)

This is the largest funder of biomedical research which offers an annual $48b to medical research in roughly 500,000 grants. Includes research and career development grants.

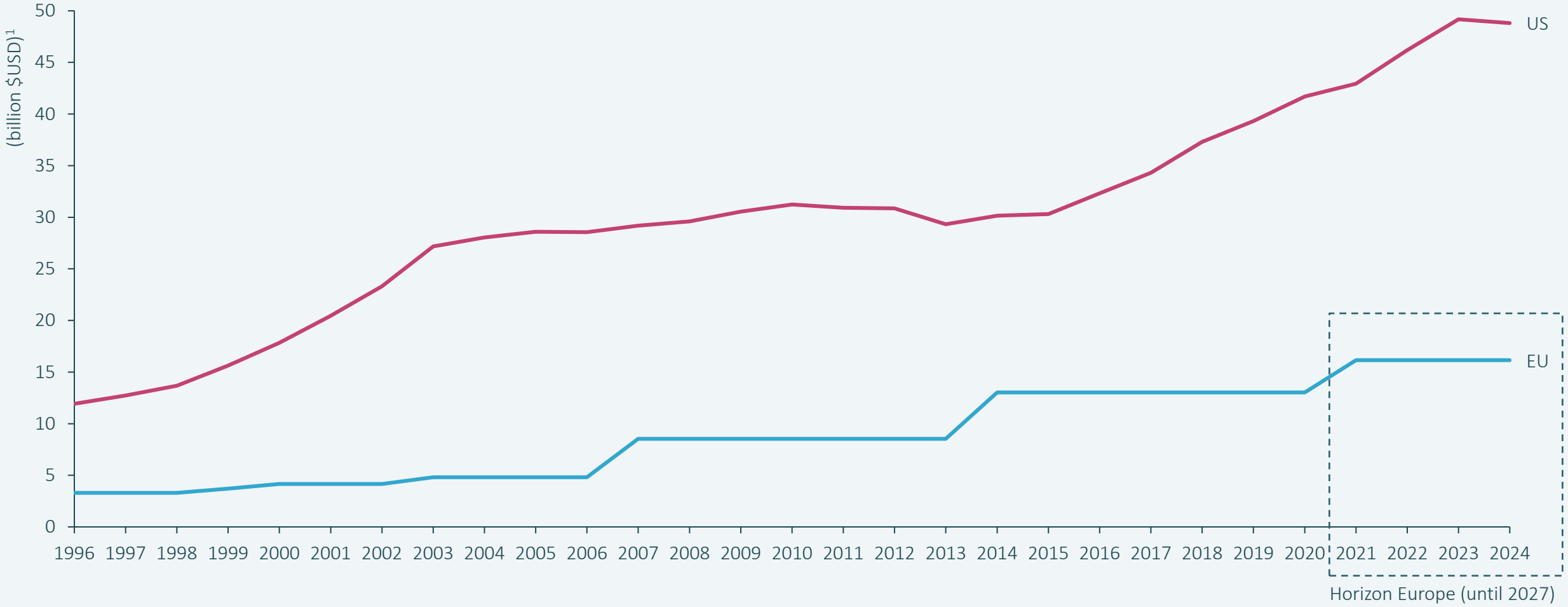
US's Seed Fund

Supports research-based startups in early-stage R&D with non-dilutive grants from Proof of Concept to Commercialisation. Gives out around $200m annually.

Sources: [1]EUR-Lex (1994), EUR-Lex (1998), EUR-Lex (2002), EUR-Lex (2007), European Commission (2025a); [2]European Commission (2025b), US Congress (2024).

US annual funding budget of NIH is higher than the European Framework Program for Research and Technology Development

Figure 2.4: US funding budget of NIH compared to European Framework Program for Research and Technology Development



Sources: EUR-Lex (1994), EUR-Lex (1998), EUR-Lex (2002), EUR-Lex (2007), European Commission (Horizon 2020); European Commission (2025b), US Congress (2024).
Notes: [1]EU to US conversion based on the 1999 to 2024 spot exchange rate average. EU annual budget based total budget divided by the number of years it spans. Budgets that overlapped in years with previous budgets did not include the first year. Spend may differ from budget.

EU VCs have lower fund sizes, giving US VCs the space to enter the funding market

European VCs continue to concentrate on early-stage investments

The focus on early-stage ventures leaves promising startups with limited access to the capital required to scale in later funding rounds. What was once a necessary foundation has now contributed to a structural imbalance. In fact, reports from the early 2000s specifically emphasised the need to boost Europe's seed-stage capital to spur the region's venture capital ecosystem.[1] While that focus was justified at the time, its long-term effects are still shaping today's investment landscape.

The fund sizes of US VCs are larger, due to a series of interconnected factors including taxation of VCs

Of the most prominent biotech VC funds, nearly all are US based.[2] Part of the reason behind this are taxation differences. Fund managers earn carried interest, which is a share of profits above a predetermined rate with limited partners. In many EU countries, this is taxed as a capital gain rather than regular income, but only if assets under management (AUM) remain below a certain threshold. With average EU capital gains tax at 18.6% and income tax significantly higher, many managers prefer to stay under the threshold.

Due to the tax thresholds European VC managers tend to prefer stability over scale

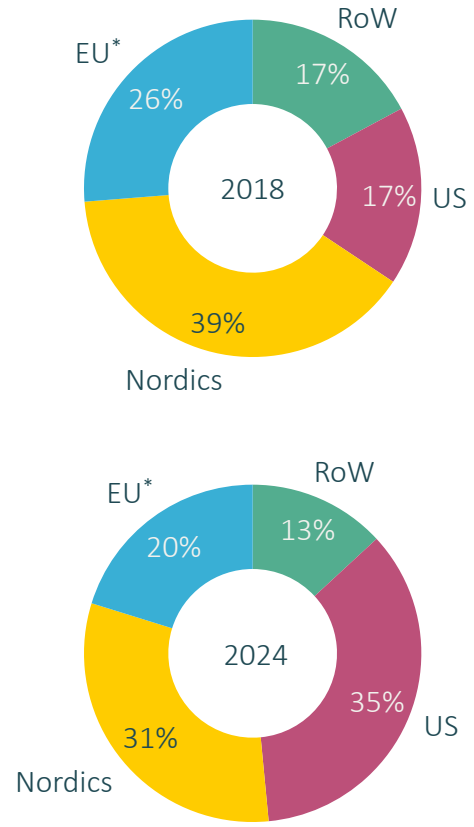
In the US, no such threshold exists, and carried interest is taxed as capital gains if assets are held over three years, encouraging managers to scale funds and benefit from larger carried interest. This is part of the reason why US funds tend to grow very large, while EU funds generally remain small to mid-sized. US tax rules thus create a more growth-friendly environment, whereas EU conditions limit fund expansion.

However, size of funds is only one aspect: activation of their capital is another. US VCs act quicker and more efficiently, offering a term sheet before many EU start-ups have scheduled a meeting. Even within Europe, many founders prefer getting VC capital from the US, with one founder remarking that in their future startups, they would look exclusively towards US VCs.[3]

International investors are entering the European investor base, particularly in the later-stage rounds.

Across the life sciences (which includes biotech alongside Healthtech and Medtech) in Denmark, US investors now make up 35% of total investors (+18pp from 2018), whilst Danish investors make up only 22% from previously 39%.[4] Where US investors are slowly filling the gaps and reaping the rewards, pan-European VC flow across the fragmented ecosystem is still significantly lacking. This can be attributed to one of the frequently cited EU obstacles: a lack of standardised regulations across borders.

Figure 2.5: Percentage of investors in Danish life science ecosystem[3]



*EU excluding the Nordics

Sources: [1]Europe Innova (2007) [3]From our interviews; [4]EIFO (2025).
Notes: [2]Data on following slide.

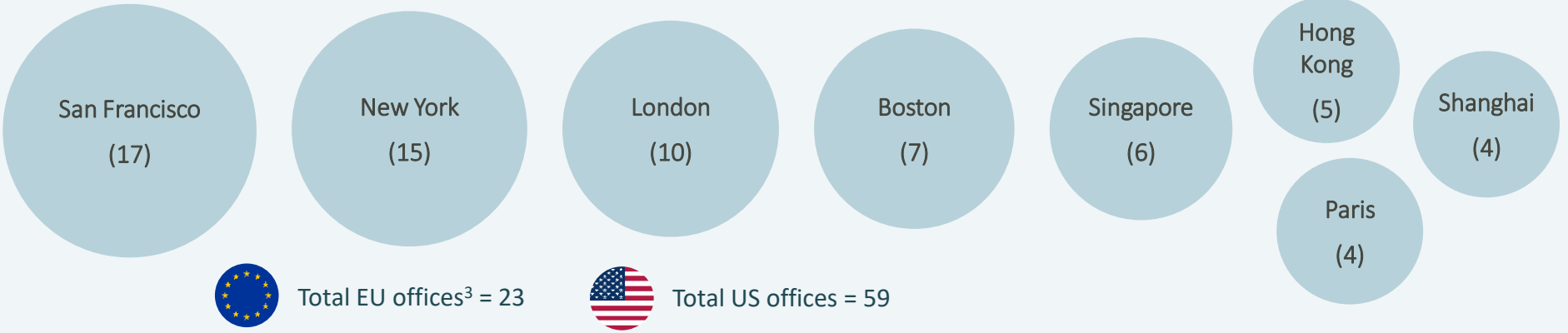
Understanding the VC landscape: out of the top 10 biotech VCs, 8 are US based

Top 10 Biotech VCs	AUM	HQ
Novo Holdings[1]	142,000	Copenhagen, Denmark
OrbiMed	14,554	New York, US
Deerfield Management	13,745	New York, US
Qiming Venture Partners USA	8,563	Cambridge, US
RA Capital Management	8,563	Boston, US
Avoro Capital	8,469	New York, US
ARCH Venture Partners	7,707	Chicago, US
Perceptive Advisors	7,244	New York, US
Forbion	5,000	Narden, the Netherlands
Versant Ventures	4,709	San Francisco, US

Assets under management (AUM) in millions €

Of the top 100 VCs (measured by assets under management), 39 invest in biotech to some extent.

Out of these biotech investing firms, 29 (74%) have their HQ in the US. Yet, many of these VCs have multiple offices globally. The following cities have the most top biotech-investing VC offices (number of offices in parenthesis).



Sources: Pitchbook (2024); OrbiMed (2023).
Note: [1]Novo Holdings ranks highest with AUM of around $142b, yet as this includes the shares of Novo Group, and only a fraction of the assets are invested in VC. [2]1 USD = 1.168 EUR used as exchange rate.
[3]Dutch VC EQT Life Sciences has offices in 10 EU cities.

EU VCs are underfunded by institutional investors

In Denmark, the average Series C and D biotech funding round measures up to roughly €47m and €50m respectively, evidently requiring VCs to hold significant capital. Many funds are not large enough to make multiple investments of this magnitude due to limited capital investments from institutional investors.

US pension funds invest 100 times more in VC than EU

Time and maturity are two reasons for the ticket and fund size difference between the US and the EU, yet the role that institutional investors play is equally important. VCs raise their own funds and require capital from external investors to do so. Whilst in the US around 1.9% of pension funds' assets under management are invested into venture capital, in the EU this number is only around 0.018%.[1] Even a small increase in the share of pension fund assets under management towards VC funding would yield impactful results. Yet, long-standing regulation and attitudes towards risk remain an obstacle.

The EU Prudent Person Principle limits risk-allowance and capital

In the EU, the Prudent Person Principle impacts what institutional investors such as pension funds should and should not invest in. It has been determined that risks need to be identifiable and manageable, which evidently makes investments into VC near impossible.[2] Meanwhile, in the US the Labour Department adjusted the Employee Retirement Income Security Act (ERISA) in 1978, effectively allowing managers of pension funds to invest up to 10% of their assets in VCs as long as the whole portfolio is diversified and risk is reasonably minimised.[3] This change brought about significant injections of capital into VC.[4] With this change occurring alongside the establishment of Bayh-Dole Act, the US VC and startup ecosystem has had significantly more time to grow its funds, invest, and see returns. Furthermore, the separation of European VCs across the different member states leads to a fragmentation that keeps much of the capital locked up within borders and the funds smaller.

The EU VC landscape is constrained by limited capital, driven by regulatory and structural barriers that discourage institutional investment. Overcoming these obstacles will be crucial to ensuring that the next wave of biotech innovation can stay in Europe rather than relying on funding from abroad.

Sources: [1]Jacques Delors Centre (2024); [2]EIOPA; [3]ECMI (2024).
Note: [4]Data on the next slide. [5]Legal Information Institute, EUR-Lex (2009)

Differences in US and EU Prudent Person Principle[5]

Section 404(a)(1)(B) of ERISA, codified at 29 U.S.C. § 1104(a)(1)(B)

It requires fiduciaries of employee benefit plans to act:

(b) with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.

(c) by diversifying the investments of the plan so as to minimise the risk of large losses, unless under the circumstances it is clearly prudent not to do so.

DIRECTIVE 138/2009/EC (SOLVENCY II DIRECTIVE)

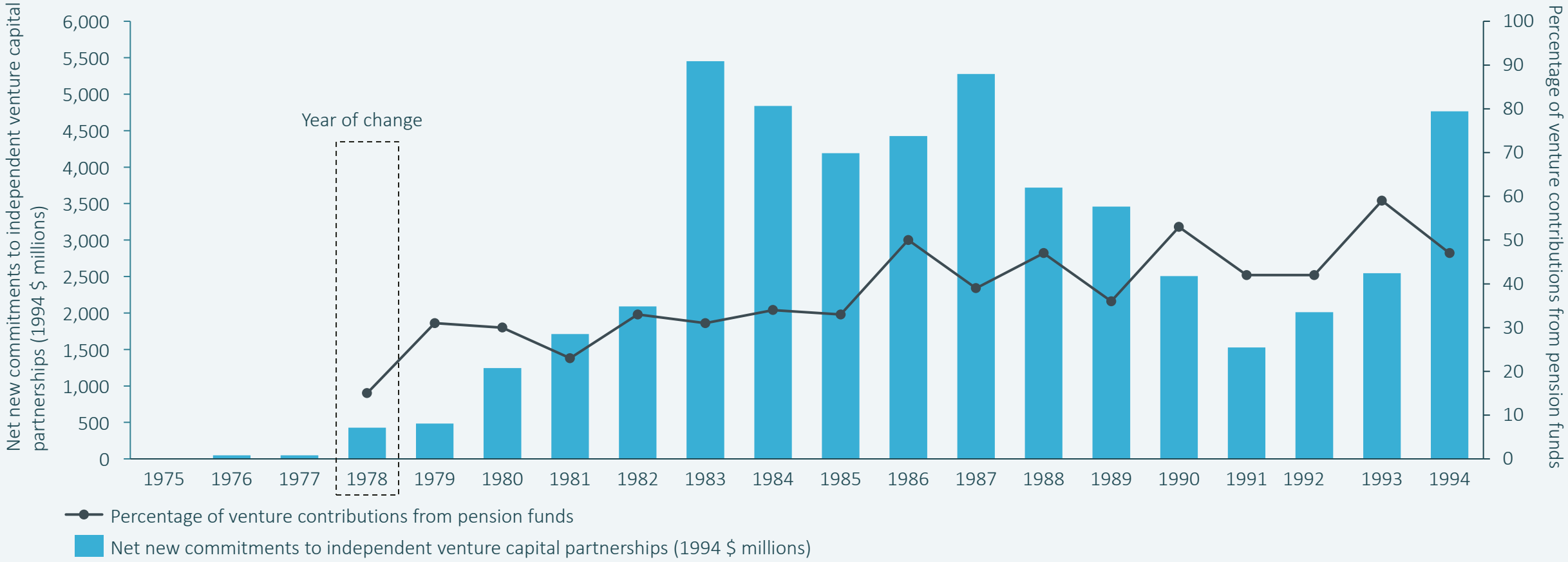
With respect to the whole portfolio of assets, insurance and reinsurance undertakings shall only invest in assets and instruments whose risks the undertaking concerned can properly identify, measure, monitor, manage, control and report, and appropriately take into account in the assessment of its overall solvency needs in accordance with point (a) of the second subparagraph of Article 45(1).

The EU principle is clearly more limiting, whilst the US code remains vague and enables some freedom to invest in alternative assets as long as this is done responsibly

Impact of change in interpretation of Prudent Man Rule in 1978 on net new investments committed to venture capital in the US

Figure 2.6: Development of US venture capital contribution before and after the change to the prudent man principle

The graph shows how, following the reinterpretation of Prudent Man Rule in 1978, investment into VC by institutional investors significantly increased, allowing VC firms to grow their funds. The Y axis on the right measures the percentage of contributions from venture funds, which have grown significantly between 1978 and 1994.



Sources: Data from Table 1 in Gompers and Lerner (1999). Note that table only offers data from 1978-1994, the previous numbers are approximations from the graph in the text. No data available for pension fund contributions to VC pre-1978.

The US leads in research translation due to earlier regulatory reforms and collaborative support offered to researchers that overcomes the entrepreneurial skill gap

US laws on IP transfer have supported commercialisation since the 1980s

Whilst European patent generation has significantly increased over the last two decades, the historical trend of the US outperforming the EU nonetheless persists. One of the factors contributing to the EU's slow growth in commercialisation is the early focus that the US placed on Intellectual Property (IP) ownership. The Bayh Dole Act of 1980 assigned universities the default right to IP from research conducted on federal funding. Prior to the Act, there was a smaller focus on commercialisation as the government-ownership made IP transfer for spin-offs more difficult.[1] Through the transition to centralised university IP ownership, the Bayh Dole Act developed a uniform framework to promote innovation and focus on spin-off generation.

EU following the US – but with 20 years delay

Around 20 years after the US, EU member states began adopting similar laws. The Netherlands were the first in 1993 to adopt the Higher Education and Research Act, followed in 1999 by the Danish Act of Inventions. Throughout the 2000s almost all member states enforced similar rules, with only Croatia, Greece, Romania, Spain and Sweden still holding mixed or decentralized IP ownership structures.[2] Whilst the Bayh Dole Act initiated a sustained focus on commercialisation of innovations in the 1980s for the USA, EU members adapted their own laws slowly and differently across countries, stunting its own growth journey and reinforcing European fragmentation.

The introduction of the act, gave rise to the Tech Transfer Offices

The introduction of the Bayh Dole Act gave rise to a surge in focus on innovation and patenting. This was followed by the establishment of Tech Transfer Offices (TTO), which transfer IP from the institutions to spin out companies.

Expert-led Technology Transfer Offices can support researchers in their research commercialisation

Following their own reforms, European institutions also implemented TTOs, yet in many cases they are still perceived primarily as bureaucratic hurdles, rather than a support system, which many founders need in the early stages.[3] Yet, for many researchers the process to commercialisation remains difficult due to an entrepreneurial skill gap. Large US research institutions have therefore worked towards overcoming this obstacle through establishing professionally staffed translation offices that do not just include the TTO but that collaborate with researchers on the translation process.

US has specialised institutions with industry experts

The Broad Institute in Boston established a translation office that collaborates with researchers to accelerate the translation of their research. What differentiates this translation office is its focus on employing industry experts from various stages of the spin-out process.[4] This structure enables researchers to concentrate on their scientific work, while experienced professionals with entrepreneurial expertise guide the commercialisation process. By working with researchers beyond Technology Transfer, universities can provide the skills and support needed to bring innovations to market.

Funding is missing for the EU's tech transfer offices

Whilst the establishment of such highly supportive TTOs is an invaluable resource for commercialisation and effective translation, European institutions lack the necessary funding to establish these. An increase in funding to translation without cutting funding to research is necessary to overcome this obstacle and to make EU institutions more competitive in their commercialisation strategies.

Sources: [1] European Parliament (2012); [2] StepUp Startups (2025); [3,4] From our interviews.

University-based accelerators promote an entrepreneurial focus and commercialisation

Anchor ecosystems and accelerators at universities encourage and support commercialisation

Part of the supportive translation offices is the focus on fostering strategic partnerships with the industry, which are crucial in commercialisation. Many biotech research institutions have fostered biotech-focused ecosystems that bring the incentive to commercialise much closer to academic researchers. Besides the professionalised translation offices, this includes university-based accelerators and incubators designed specifically to support the spin-out of biotech ventures.

Accelerators has helped the transition from academia to commercial in the US

At Harvard, the Blavatnik Biomedical Accelerator supports researchers in creating translational impact through advice, funding, and industry partnerships. Similarly, the Columbia Translational Therapeutics Accelerator focuses on the transition from academic research to commercial therapeutics, and UCSF's Rosenman Institute presents itself as an ecosystem for patients, entrepreneurs and investors.

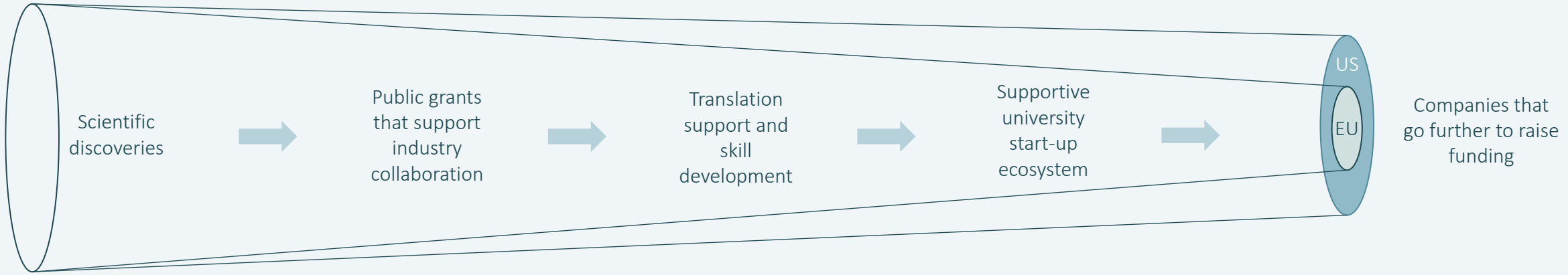
Through acting as anchors that facilitate strategic partnerships with the industry, these institutions have laid a crucial foundation to support translation from the first IP transfer to the development and growth phases.

Danish BioInnovation Institute is a step in the right direction

Institutions with a specific focus on commercial translations are still underdeveloped in the EU and access to biotech accelerators is generally less common. However, the Danish BioInnovation Institute presents an important step in the right direction, through showcasing a commitment to the industry collaboration and start-up support.

Overall, the translation process in the US supports researchers in the commercialisation process through supplementing skillsets and offering guidance along the way. For the EU to compete, it must treat translation as a critical component of the system.

Figure 2.7: Illustration of how the EU is narrowing its funnel by underproviding at decisive stages, leaving many ideas behind



Longer regulatory approval times in the EU can be a barrier creating a gap between EU and the US

Slower process gives longer timeline in the EU

The European regulatory approval process for clinical trials and for biotech and pharmaceutical products is generally longer and more complex than in the US, leading to a slower time-to-market for new drugs. Since speed is critical for innovation, the extended timelines in the EU create three main challenges:

1. **Higher costs and delayed revenue** – Companies must sustain operations and funding for longer before generating income, increasing cash burn.
2. **Reduced trial attractiveness** – Slower and fragmented approvals make the EU less appealing for running clinical trials, leading companies to prioritise faster markets.
3. **Weakened innovation incentives** – Extended timelines and administrative complexity reduce the expected return on investment, discouraging EU projects from starting.

Complex approval processes make clinical trials in the EU less attractive

The longer regulatory timelines in the EU put financial pressure on companies, as they must sustain operations longer before generating revenue. Even when they successfully navigate the EU approval process, the commercial rewards are typically lower than in the US, where prices for innovative medicines are considerably higher. As a result, the incentive to develop and launch new drugs in the EU is often weaker than in the US.

Slower and more complex processes also make Europe less attractive for clinical trials, pushing some companies to regions with faster and more predictable approvals. Over time, these delays and uncertainties reduce the perceived return on investment and discourage innovation. As a result, the EU's share of global clinical trials has fallen from 22% in 2013 to 12% in 2023, while China has grown its share.

As shown in the comparative timelines in Figure 2.8, the median time from the submission of a clinical trial application to a regulatory authority to the first patient receiving a dose in a subset of commercial trials in 2022 was longer in the EU than in the US. Figure 2.9 shows that also the drug approval process takes longer in the EU than US.

Often a post-approval process in the EU countries

Most EU countries require a post-approval market access process, which can vary significantly between member states. These national-level procedures add complexity and can further delay patient access, as they are influenced by local legislation, pricing, and reimbursement negotiations.

Figure 2.8: Median number of days required to set up clinical trial are longer in EU

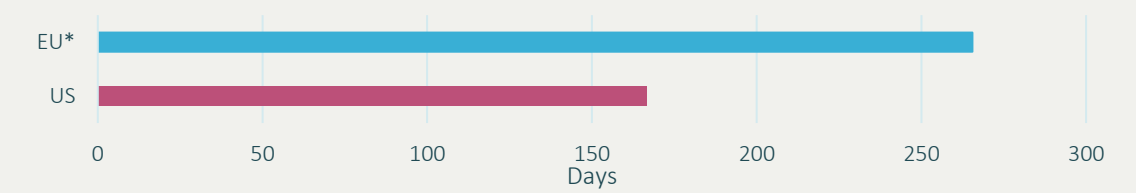
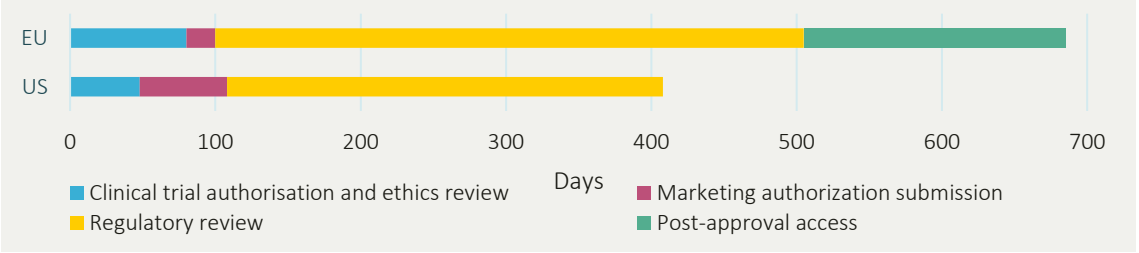


Figure 2.9: Regulatory approval drug processes take longer time in EU than US



Sources: Assistant Secretary for Planning and Evaluation (ASPE) U.S. Department of Health & Human Services (2024), *FDA (2023a), FDA (2023b), Financial Times (2024), Financial Times (2024) Human Research Protection Program (2025), EMA (2022a), EMA (2022b), EMA (2024), EFPIA (2025b), Gov.uk (2024). Note: These are point estimations based on input from different sources and serve to get a global insight in the regulatory process length. Individual cases my widely differ. *EU is the average of France, Germany, Italy, Netherlands, Spain.*

Faster decision-making in the US is enabled through formal and informal cultural factors

There is a larger flexibility of decision-making in the US that enables entrepreneurs to work at a faster pace, which is central to their competitiveness. This flexibility comes about through a series of interconnected regulatory and cultural factors.

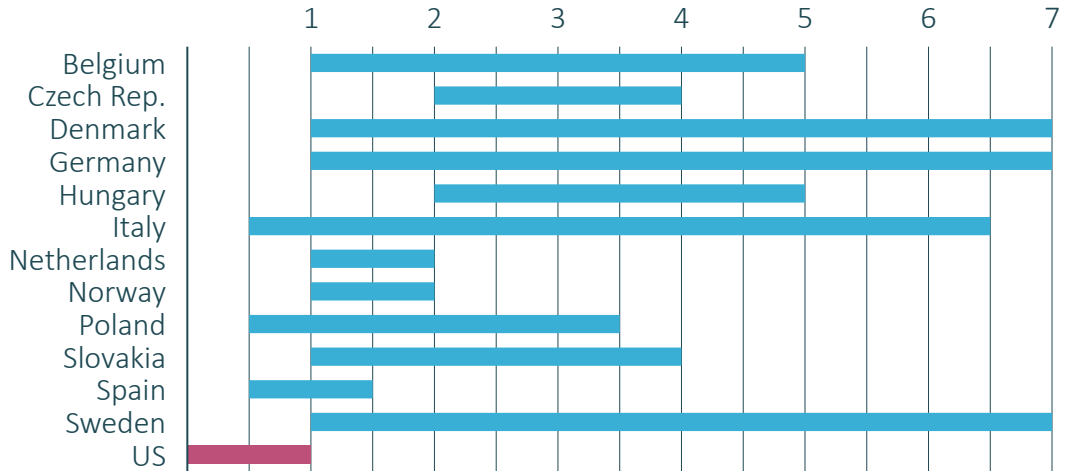
Greater openness to risk-taking in the US

The US is known for a culture of entrepreneurship, which has historically grown in clusters such as Silicon Valley or Boston, with their proximity to world-class education and research institutions. Within these clusters, and increasingly beyond them, there is a lower aversion to failure. Studies on risk-attitudes have shown the way that US respondents are generally more tolerant of business failures than in the EU.[1] Therefore, at US research institutions with a large focus on entrepreneurship, a trial-and-error attitude of patenting and spinning-off is actively encouraged, especially by the TTOs. This environment is the result of a long-standing commitment to innovation, which the EU must fully embrace to cultivate a similar experimental mindset towards entrepreneurship. Adding to this challenge, EU companies often face greater liabilities for employee compensation in the event of business failures, which can further hinder risk-taking and innovation in the sector.[3]

Labour laws can be a barrier to EU firms

Talent attraction is key to a biotech startup developing its competitive advantage through novel technology. Yet, whilst strong labour laws create a good work environment for the European labour force, it makes it difficult for start-ups to hire and fire casually, which is necessary for the volatile startup growth journey. Furthermore, the strong employee protection makes working for larger companies attractive, especially with data showing that Danish employees hired by startups earned 17% less over a decade than those working for larger firms.[2]

Figure 2.10: Range of notice periods required by law (in months)[4]



Formal cultural differences across EU states

Beyond risk aversion and labour laws, formal cultural differences further complicate the development of an agile talent pool with free movement across the EU. Talent attraction remains crucial, yet the perceived distance when relocating within the EU is greater than within the US, due to crossing national borders rather than moving between states. Language differences also contribute, making integration and willingness to relocate more challenging within the EU. In contrast, the US, with its host of top-tier educational and research institutions, already possesses a diverse international talent pool, readily accessible to startups. Consequently, US start-ups often find it easier to source relevant talent, as workers tend to relocate more willingly.

Overall, these different factors lead to an environment in which pace and flexibility is enabled for entrepreneurs. This, coupled with the US's quicker regulatory processes and time-to-market, significantly accelerates the journey from research to commercialisation.

Sources: [1]Burchell and Hughes (2006); [2]Sorensen et al. (2019); [3]Coatanlem and Coste (2024); [4]Madison Bridge (2022)

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Policy recommendations and potential by reaching US parity

How can we remove the barriers and unlock the opportunities for the EU?

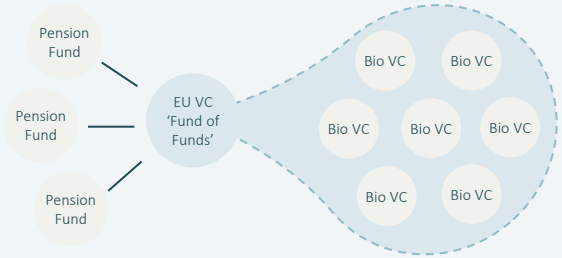
Chapter 3 summary: Fund of funds, professional translation offices and harmonised approval processes can remove some of the major obstacles for EU Biotech

Chapter 3 presents strategic recommendations aimed at overcoming the barriers that currently limit the competitiveness of the EU biotech sector. By tackling **challenges related to funding, translation, and regulatory processes**, the EU has the opportunity to cultivate a more dynamic and innovative biotech ecosystem.

This chapter provides actionable recommendations for how to overcome these barriers. The recommendations include **establishing a fund-of-funds** to address funding gaps, creating **professional translation offices** to facilitate the transition of university research into successful private enterprises, and **harmonizing approval processes** to eliminate redundancies and accelerate timelines. Implementing these strategies will significantly enhance the EU's biotech competitiveness, allowing it to reach its full potential.

Establish a fund-of-funds

Establish a fund-of-funds pooled from large investors, particularly pension funds, to unlock significant capital for Series B and C investments. This approach aims to mobilise institutional funding and enable critical mass for biotech scale-ups, as illustrated.



Develop professional translation offices

Develop expert-staffed translation offices to support researchers in the commercialisation process. This requires dedicated funding and a commitment from the EU to implement these offices across member states, bridging the entrepreneurial skill gap. These offices will serve as vital hubs for innovation, providing researchers with access to business development resources and mentorship opportunities. By fostering collaboration between academia and industry, translation offices can accelerate the transformation of scientific discoveries into viable products and services. Additionally, they will play a crucial role in navigating regulatory landscapes, ensuring that new biotech solutions meet compliance standards and reach the market efficiently.

Harmonise and accelerate approval processes

Implement a unified regulatory framework across EU member states to eliminate redundant country-by-country approvals, reducing duplication and administrative overhead. Foster collaboration between national regulatory agencies and the European Medicines Agency (EMA) to ensure seamless communication and faster decision-making. Strengthen the capacity of regulatory bodies with resources and training to efficiently handle increased application volumes.

Some of these initiatives are a part of the EU Biotech Act, however ensuring implementation is key for the success.

A fund of funds based on pension fund assets can unlock €15b new capital for EU biotech

The private funding gap is especially prevalent at the later funding stages, which is where the EU needs to focus. A fund of funds can help overcome this gap.

Later stage funding requires greater ticket sizes. At an average of €50m for a Life Sciences Series C round, funding even 200 startups requires around €10b.[1] For many VCs, who focus on the €1m to €5m seed rounds, having to fulfil this target would mean replacing an entire portfolio of early-stage startups with one later stage one.

This is where a 'Biotech Fund of Funds' would provide an impactful solution. This fund would be a pan-European investment vehicle, that pools funds from institutional investors, to either invest in other venture capital funds or directly into biotech start-ups. Focusing on late-stage funding allows for diversification and reduced risk.

The EU evidently needs access funding sources that can inject large amounts of capital. Pension funds are currently under-utilised and have the potential of unlocking €15b amount of new funding. Currently, pension funds limit their investment into alternative assets due to the limitations set through the prudent man principle. Yet, the diversified and late-stage focus aligns the proposed fund of funds more closely with investment profiles that pension funds are already comfortable with, such as private equity.

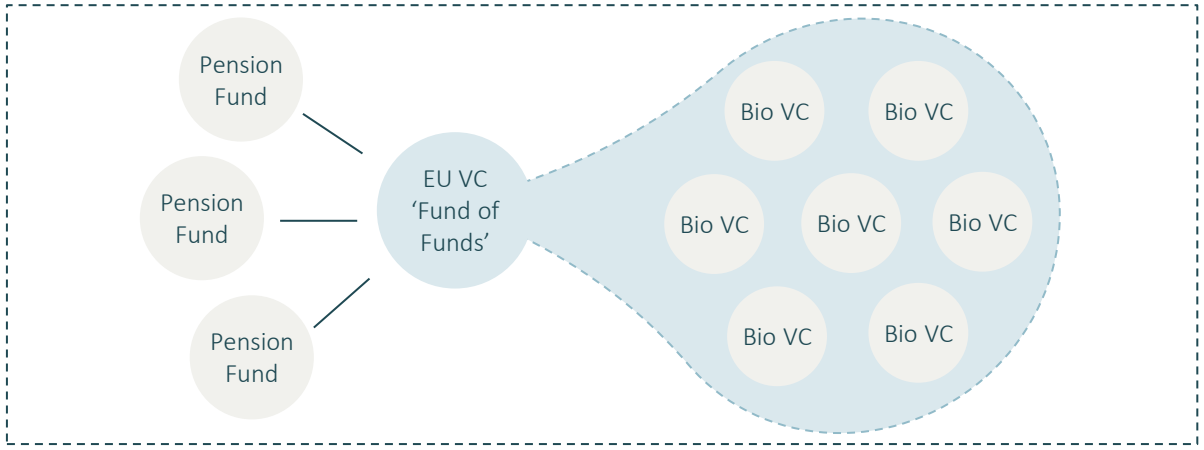
The fund of funds will help overcome some of the key cultural barriers

To further de-risk this fund and attract the relevant institutional investments, a guarantee scheme could be established to secure a portion of the institutional investors' initial investments. This would require backing by the European Investment Bank to be successful.

Culturally and structurally, a fund of funds offers a way to navigate the fragmented nature of Europe's biotech venture capital landscape. The EU's mixture of different cultures and regulatory systems has been complicating the ability for VCs to fund across borders.

With essential governmental and European Union support, this highly impactful investment vehicle can transform the European biotech start-up environment.

Figure 3.1: The fund pools pension fund assets and distributes these among European biotech VCs



Existing initiatives that mobilise institutional investors in the EU[4]

Switzerland: Implemented additional asset clause for institutional investors to invest an additional 5% in alternative private funds (PE and VC).

Germany: Fund of Funds by 20 institutional investors investing €1b into German VCs.

France: Tibi Initiative involved €6b in institutional backing and a 'stamp-of-approval' process which gave LPs more trust in the VCs to fund.

Where do current fund-of-fund initiatives fall short?

1. Many government backed funds are geographically restricted, such that county of origin remains more important than the quality of the company.
2. This fragmentation does not reach the critical mass to enable late-stage investments.
3. Pension funds are not yet incentivised enough to invest in these assets.

Sources: [1]Pitchbook (2024).

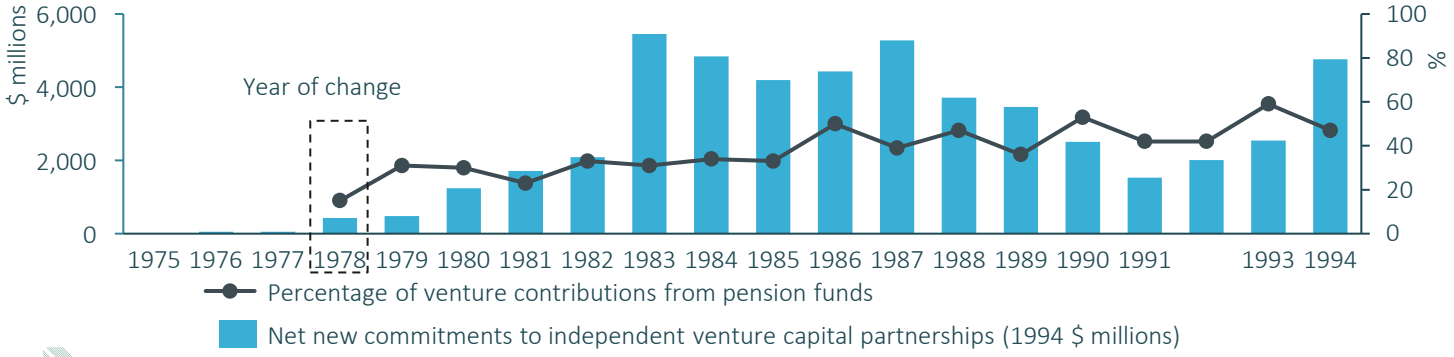
Reinterpret the Prudent Man principle in the EU

Changing the principles of the Prudent Man Principle could unlock institutional investment in venture capital
A reinterpretation of the EU's Prudent Man Principle, inspired by the US approach, could substantially increase institutional investment in venture capital. Under the current European interpretation, the principle often leads pension funds and other institutional investors to avoid high-risk assets, even when they represent a small share of a diversified portfolio. This conservative approach limits the flow of capital into innovative sectors such as biotechnology.

The US experience provides a powerful precedent. Following the 1978 reinterpretation of the Prudent Man Rule, which allowed fiduciaries to assess risk at the portfolio level rather than the individual asset level, institutional allocations to venture capital rose sharply. This shift unlocked significant funding for high-growth industries and contributed to the rapid expansion of the U.S. innovation ecosystem.

Proposal: Reinterpret the EU's Prudent Man Principle to align with the U.S. framework, placing emphasis on the overall portfolio's risk–return balance rather than the perceived risk of individual assets. Such an adjustment would enable institutional investors to channel more capital into venture capital, without materially increasing portfolio risk. This could improve diversification, support innovation, and potentially enhancing long-term, risk-adjusted returns.

Figure 3.2: US investments in venture capital before and after changes to the prudent man principle



Sources: Data from Table 1 in Gompers and Lerner (1999), [1]Legal Information Institute, EUR-Lex (2009)

The US and the EU has significant differences in the interpretation of the Prudent Person Principle, which likely leads to difference in risk taking[1]

Attitudes towards risk

"by diversifying the investments of the plan so as to minimise the risk of large losses"

"shall only invest in assets and instruments whose risks the undertaking concerned can properly identify, measure, monitor, manage, control and report"

Whilst the US principle is vague about the process of minimising risk, the EU principle is limiting through requiring the identification and management of risk

Manner of investment

"…with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use"

"All assets…shall be invested in such a manner as to ensure the security, quality, liquidity and profitability of the portfolio as a whole"

For the US, prudence requires care, skill and diligence. In the EU, a focus is on ensuring profitability.

EU pension funds investing in venture capital at US levels would support 857 additional biotech investments

Current pension fund AUM invested into VC

0.018% 1.9%

US pension funds invest more than 100 times the share of their assets into venture capital than their European counterparts

If the EU pension funds invested the same as US pension funds

1.9% = €15.34b invested into biotech VC

€15.2b new biotech VC capital unlocked

Figure 3.3: Average distribution of funding into rounds in the US

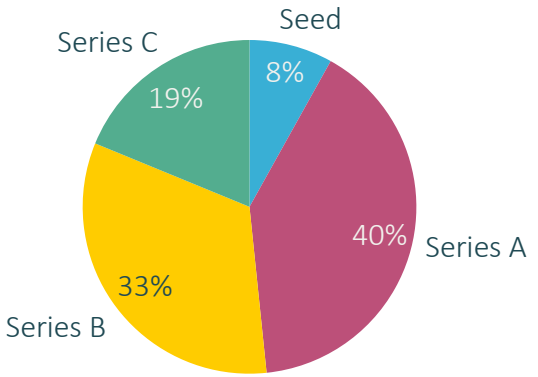


Figure 3.4: Average EU funding round size (€ million)

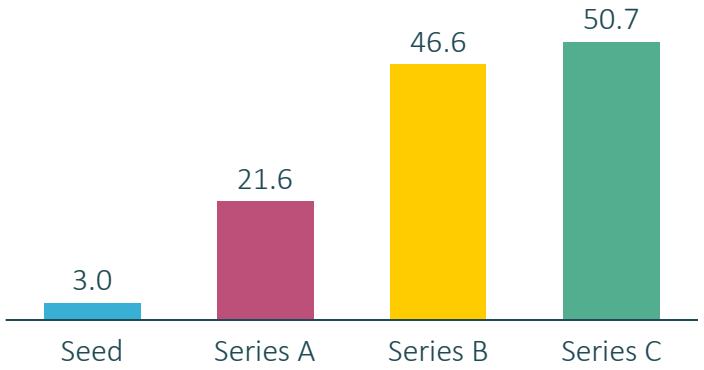


Figure 4.4: Additional funding into biotech if the EU reaches parity with the US

- 411 Seed investments
- 283 Series A investments
- 107 Series B investments
- 56 Series C investments

We depict an ideal scenario in which EU pension funds invest the same relative share of their assets in VC as US pension funds do currently. This can unlock €15.2b in new VC capital, to be invested into companies across different funding stages. With the current EU funding round sizes, the EU VCs would be able to make significant investments into companies of all sizes.

Sources: Pitchbook (2024); ECB (2023); Jacques Delors Centre (2024)
Note: We have conservatively assumed that 25% of total VC funding is allocated to biotech funding, this is lower than e.g. in Denmark (Mazanti, 2025). Distributions and funding round sizes based on 2024 data.

The EU needs to develop a supportive translation infrastructure

In addition to significantly improving its funding availability, the EU needs to focus on supporting research translation through developing the necessary infrastructure for knowledge transfer. The current difference between the US and EU research translation processes can be largely attributed to the capacity to assist researchers in bridging the entrepreneurial skills gap. Equalising this requires additional funding, that should not be diverted from research funding.

Proposal: European research institutions receive the necessary financial backing to develop competitive translation offices staffed with experts that support the translation process. The aim is to create well-resourced infrastructure that supports researchers and allows them to concentrate on their areas of expertise.

The experts in the translation offices would be selected for their relevant experience in the entrepreneurial sphere, including backgrounds as entrepreneurs, within venture capital, or at major corporations. They would be actively involved in the translation process, helping researchers with those tasks that are beyond their general skill set. This approach fosters complementary skill transfer, grounded in understanding and a commitment to promoting entrepreneurship.

Such a commitment to improving the translation process would transform university TTOs and associated offices from bureaucratic hurdles into collaborators. However, such an improvement naturally requires substantial funding, which should not detract from the EU's current scientific output.

Furthermore, it risks keeping European institutions from working collaboratively with each other, as it maintains the existing insular structure. This proposal can therefore not be treated in isolation, but alongside the necessary improvements in funding. Nonetheless, a comprehensive improvement in the EU biotech sector will require the EU to recognise the importance of skill and knowledge transfer.

Figure 3.5: Illustration of how the EU can ensure the funnel is narrowing less, so more ideas commercialise

The EU plans to take on measures to speed up approval times and removing regulatory burdens but the success depend on the implementation

EU has proposed initiatives to speed up approval times

To enhance the competitiveness of the EU biotech industry, EU could streamline regulatory processes to reduce approval times and facilitate innovation. However, streamlining regulation is often a political policy, but it is the specific legislation, which determines the effect.

The Biotech Act aims to tackle some of the issues

The EU Commission has with the EU Biotech Act taken a step towards faster approval times for the biotech industry. While the act is not yet final, the current draft includes 1) harmonised & faster clinical trial approvals, 2) regulatory sandboxes for novel therapies, and 3) clarification & streamlining across overlapping regulatory regimes. These three topics all aim at simplifying and streamlining the process to speed up the approval times.

The EU's longer approval timelines partly stem from robust safeguards designed to protect patients and ensure high product quality. While these checks are essential, they also add layers of review and coordination that slow market entry. The policy challenge is to shorten timelines without compromising safety or public trust.

The success depends on the implement

While the EU Biotech Act represents a significant step towards improving the regulatory environment for biotech in Europe, its success will depend on overcoming implementation challenges, including harmonisation of trials, regulatory sandboxes, and regulatory pathways. By addressing these shortcomings, the EU Biotech Act could play a pivotal role in positioning Europe as a leader in biotech innovation, aligning with its broader economic and environmental goals.

The EU Biotech Act aims to simplify and streamline approval processes through three different ways

1. Harmonised & faster clinical trial approvals

Change: A single coordinated application for clinical trials through a central EU system, with aligned ethics reviews and standardised documents across countries.

Intended impact: Removes country-by-country duplication, reduces rework, and speeds the start of trials in multiple member states.

2. Regulatory sandboxes for novel therapies

Change: Controlled environments where regulators and developers agree in advance on tailored evidence and trial designs.

Intended impact: Resolves complex regulatory issues early and allows flexible evidence, avoiding long delays during assessment.

3. Clearer, simpler regulatory pathways

Change: Clear rules for products that fall under multiple legal frameworks, such as medicines, medical devices, genetically modified organisms, and advanced therapies.

Intended impact: Reduces legal uncertainty and prevents lengthy delays when products cross regulatory boundaries.

Sources: Charles River Associates (2024), EU Commission (2024)

Reaching parity for approval processes could save significant time for the EU biotech

Significant effects of reaching parity in approval times

Achieving parity with the US in approval processes offers significant benefits for the EU biotech sector. The EU Biotech Act aims to harmonise and expedite these processes, eliminating redundant approvals across member states and streamlining clinical trial and drug approval timelines.

More than a third of the approval time could be reduced

Currently, the EU faces longer approval times compared to the US, delaying the market introduction of innovative biotech solutions. By aligning with US standards, the EU could reduce clinical trial approval times by 99 days, a 37% decrease, bringing the average down to 167 days. This acceleration would enhance competitiveness and foster a dynamic environment for biotech innovation.

Similarly, achieving parity in drug approval processes could save the EU 277 days, a 40% reduction. This time saving would allow faster access to new treatments, benefiting patients and healthcare systems across Europe.

EU Biotech Act aims to remove approval duplication

The EU Biotech Act's ambition to remove country-by-country approval duplication is crucial. While the act's exact impact is uncertain, its goal is clear: to create a more efficient and unified approval framework that supports EU biotech growth.

By addressing these approval challenges, the EU can drive economic growth and establish itself as a global biotech leader. The path to parity is about fostering innovation, improving healthcare outcomes, and enhancing the EU's competitive edge in the global biotech landscape.

Figure 3.6: Reaching US parity for approval of clinical trials can save 99 days

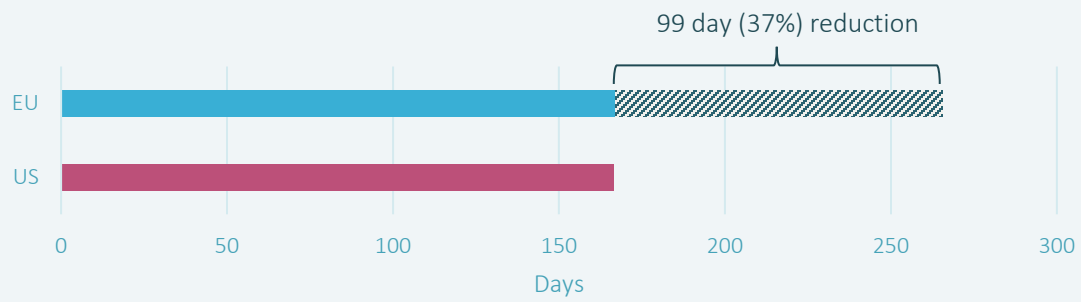
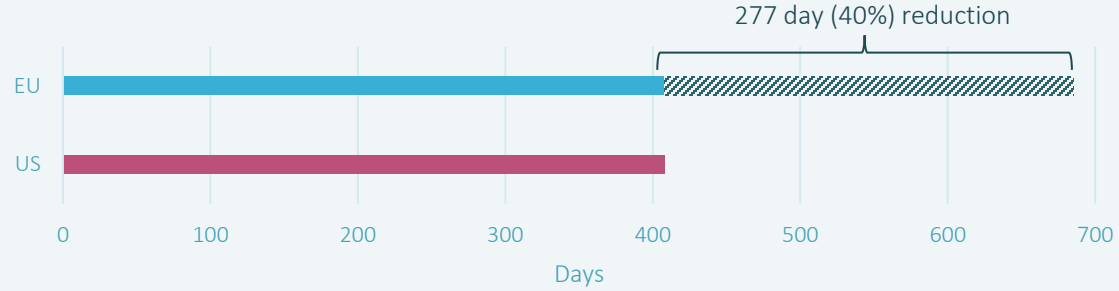


Figure 3.7: Reaching US parity for drug approval process can save 277 days



*Sources: FDA (2023a), FDA (2023b), Financial Times (2024), Financial Times (2024) Human Research Protection Program (2025), EMA (2022a), EMA (2022b), EMA (2024), EFPIA (2025b), Gov.uk (2024). Note: These are point estimations based on input from different sources and serves as a way to get a global insight in the regulatory process length. Individual cases my widely differ. *EU is the average of France, Germany, Italy, Netherlands, Spain.*

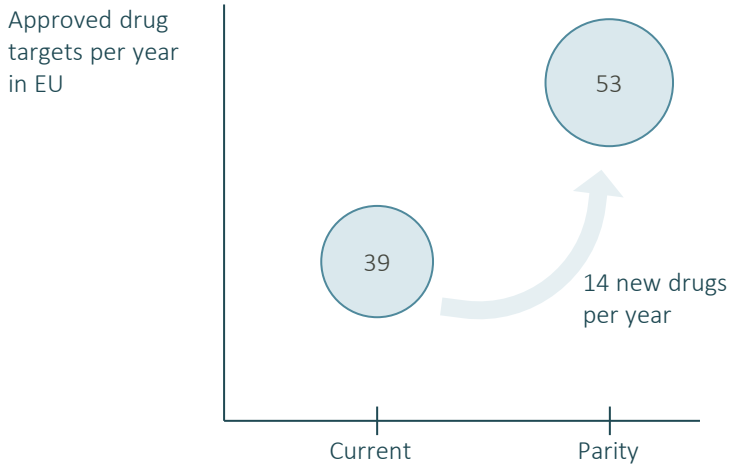
Improving biotech conditions could lead to more drug approvals, which in turn could unlock major health and economic benefits

The EU approves fewer drugs than the US , which is delaying life-saving treatments

The European Union currently approves around 14 fewer drugs per year than the United States and typically takes longer to do so, delaying patient access to critical new medicines. [1] This gap has tangible consequences: patients face longer waits for innovative treatments, reducing both quality of life and survival outcomes. At the same time, biotech companies carry higher costs and uncertainty while awaiting approval, making Europe a less attractive environment for innovation and investment.

To reverse this pattern, both funding and regulatory bottlenecks need to be solved to actually get more drugs on the EU market and to improve the conditions for EU biotech.

Figure 3.8: Illustration of the potential for increase in EU drug approvals

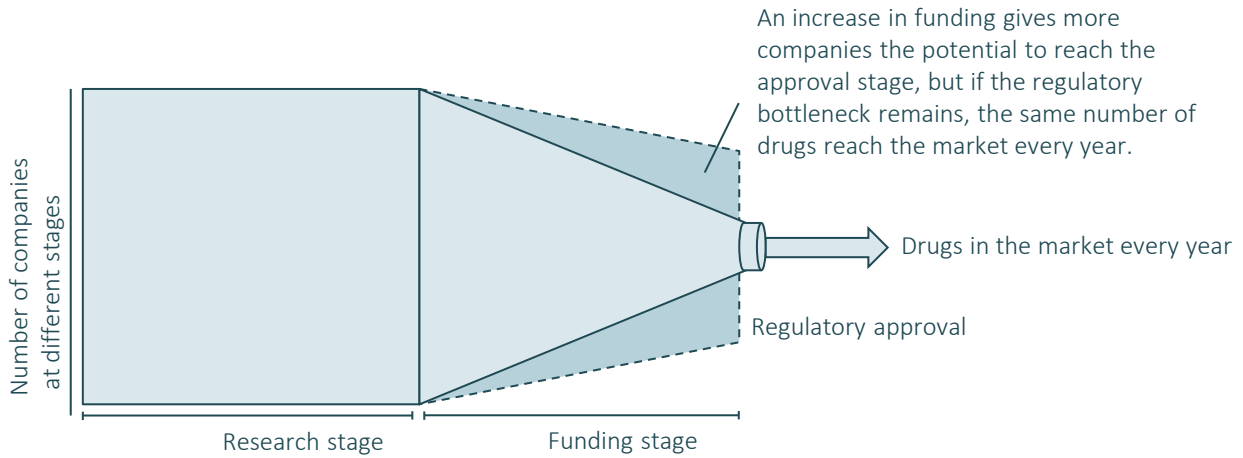


Funding alone is not enough - the regulatory bottleneck comes next

Even if substantial new funding is created, the regulatory process remains the key barrier. Without reform, additional investment will not lead to more medicines reaching the market. The entire system must improve to ensure that innovation translates into patient benefit. This is all the way from early-stage support to streamlined approval processes.

Currently, nearly all new drugs are launched first in the United States, where 84% of medicines introduced since 2012 are available, compared with only 40% in the European Union.[2] Europe is falling behind, and catching up will require addressing both funding and regulatory challenges in parallel. Solving only one will simply shift the bottleneck elsewhere in the system.

Figure 3.9: Illustration the bottlenecks in the biotech industry



Sources: [1]Lau and Seifert (2025), [2]Phrma (2023).
Note: Drug approvals in EU and US are not always comparable, as the EMA and FDA have different focus areas, and some drugs, which needs EMA approvals do not necessarily need FDA and vice versa.

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