INVEST EUROPE

The European Biotech Act I
The venture capital and private equity perspective

Executive Summary

The current context

Europe has world-class scientific excellence in biotech and healthcare, yet it underperforms in translating this strength into globally competitive companies, industrial capacity and patient access.

Public capital is retreating from biotech and healthcare faster than from the wider PE/VC market, while institutional investors remain underrepresented in the sector, limiting long-term, stable capital.

The number of critical funds, across all PE and biotech and healthcare-focused funds is declining, and relevant biotech and healthcare developers continue to lose administrative and funding incentives due to private capital backing.

Clinical trial timelines and biomanufacturing certifications remain lengthy relative to competing jurisdictions, while fragmented rules on biobanking continue to limit the reuse of high-value biological samples and clinical data.

IP and open-science requirements lead to premature disclosure of commercially valuable research before protection and financing are secured, and governance structures risk remaining over-politicised, all while Europe is increasingly exposed to external policy and market dynamics that influence launch strategies.

At the same time, several opportunities remain untapped: the impact of early-stage investment, entrepreneurship and company creation, the potential of conventional modalities, and the benefits of geographically concentrated biotech clusters.

The result is continued relocation of companies, trials, and their value – jobs, talent, IP, manufacturing, social and security benefits – making this an issue of competitiveness, strategic autonomy, health security and economic growth.

Our key recommendations

The Biotech Act introduces different tools to strengthen financing, accelerate clinical research, expand biomanufacturing and improve coordination. **However, despite these advances, Europe will continue to underperform unless it is implemented as an end-to-end ecosystem strategy. Otherwise, many of the Act's objectives risk being only partially realised.**

Public funding must act as a catalyst, not a substitute for private capital, by reinforcing the PE/VC fund management ecosystem and fund-of-funds structures, complemented by clear structural incentives and enabling regulatory conditions for institutional investors, while allowing companies sufficient time to protect and commercialise innovations – in line with a possible patent protection extension up to 24 months.

Clinical trial authorization timelines, especially for multinational trials, need further reductions and alignment with GMP certification processes to unlock biomanufacturing capacity and retain clinical research within the EU, **while addressing fragmented national rules on biobanking and data reuse**.

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The HSP and HISP status should encompass the full biotech and healthcare value chain, including early-stage capital, entrepreneurship, all biotech modalities, neglected diseases, and biotech clusters, **while being complemented by incentives like transferable priority review vouchers** to improve investor risk-reward profiles.

Company definitions should be updated to avoid penalizing private capital-backed firms, and **governance must balance Member State involvement with transparent, science-based decision-making**, integrating **investor expertise** without politicizing regulatory processes, while **enhancing resilience to external policy and market dynamics by enabling light-touch EU-level monitoring and coordination** to mitigate launch delays and access divergence, without hindering Member State pricing competences.

In more detail

The European Biotech Act I ("Biotech Act") is a timely and important step in acknowledging the structural challenges facing the European biotech and healthcare ecosystem and introducing tools aimed at strengthening the conditions for innovation, investment and industrial development – marking a welcome and meaningful shift in how Europe approaches biotech and healthcare policy.

By establishing dedicated financing instruments, such as the EU Health Biotechnology Investment Pilot, accelerating clinical trials, introducing strategic project statuses with accelerated permitting procedures and support, strengthening biomanufacturing capacity, and creating more coordinated governance mechanisms, the Act reflects a growing recognition that biotech and healthcare policy must address the full innovation ecosystem – from research and development to industrial deployment – and how it is financed.

As the Act sets the tone for its upcoming implementation, the base framework needs to be sufficiently ambitious, comprehensive and future-proof to address the bottlenecks that arise across the full biotech and healthcare lifecycle. The biotech and healthcare sector sits at the intersection of scientific discovery, industrial policy, global competition and resilience, and the ability to translate scientific discovery into investable companies increasingly determines which regions capture the associated economic, technological and societal benefits.

From the perspective of Invest Europe – representing pan-European private equity and venture capital (PE/VC) fund managers and their investors – the Biotech Act provides a strong foundation, to prevent barriers and unlock untapped opportunities in the sector. However, its potential will depend on whether remaining structural constraints are adequately addressed.

This paper identifies any remaining challenges and opportunities and puts forward recommendations to:

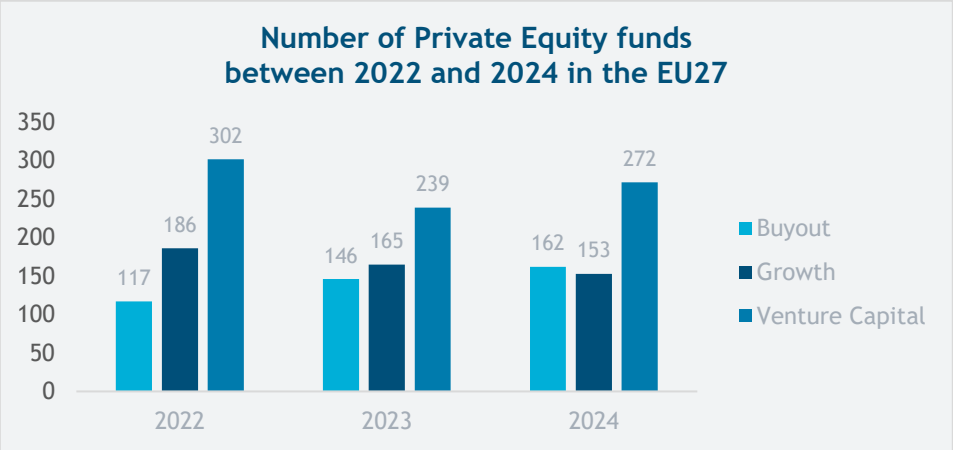
- crowd in private capital by using public funding as a catalyst and reinforcing Europe's fund ecosystem, while aligning public research funding with commercialisation and investment,
- make speed a competitive advantage, by accelerating clinical trials, biomanufacturing certification and data reuse,
- establish a complete and resilient biotech ecosystem, spanning early innovation, company creation, all modalities, and cluster-based development, while creating further incentives for companies and investors alike,
- safeguard innovation incentives, including through strengthened patent confidentiality,
- deliver predictable and efficient governance, and
- ensure fair access to support measures for SMEs, startups and scaleups.

- ***Reframing public funding as a catalyst for private investment in biotech and healthcare***

1. Strengthening Europe's fund management ecosystem

The focus introduced on mobilising private investment alongside public funding is, indeed, a welcome signal for the industry. The EU Health Biotechnology Investment Pilot and the BioTechEU initiative, developed together with the European Investment Bank (EIB), point in the right direction, including in their formulation: unlocking private capital, sharing risk, and supporting companies through their full growth journey. This is particularly important where market failures persist – as previously mentioned in our Biotech and Healthcare position paper from November 2025. Channelling the capital and expertise of the many biotech and healthcare investors in Europe will ensure that promising companies do not need to relocate.

However, both initiatives remain ambiguous regarding the role and share of capital that should be deployed through PE/VC fund managers, despite recognising their importance. This is particularly concerning given the recent contraction of Europe's fund management ecosystem, which signals a weakening of Europe's domestic scaling infrastructure. Fewer European fund managers mean fewer vehicles capable of supporting companies through successive financing rounds, building sectoral expertise and anchoring value creation within European markets. This matters because different types of funds play complementary roles in the financing ecosystem. Over time, this reduces depth, resilience and strategic capacity across the ecosystem.

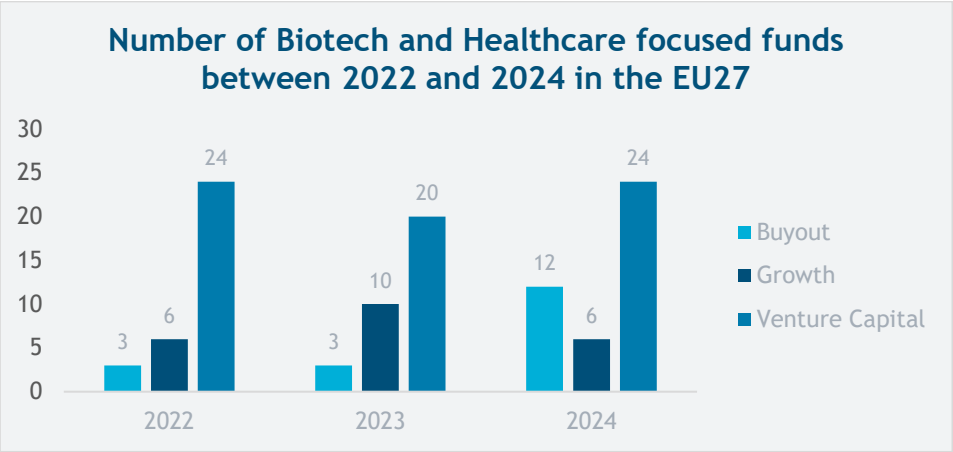


Source: Invest Europe / European Data Cooperative (EDC)[1]

Over the past three years, between 2022 and 2024, in the EU27, the number of growth equity funds has decreased by 16%, and the number of generalist funds by 13.8%. Access to capital for scaleups is particularly affected by the latter, as generalist funds bring scale across sectors, while specialist funds bring the knowledge, thus having a detrimental effect for the whole European investment landscape. Within VC, the total number of funds declined by 10%, although it is recuperating, with late-stage VC funds decreasing by more than 36%. At the same time, while the number of buyout funds increased, the contraction in growth and late-stage venture funds creates a structural bottleneck in the scaling pipeline, contributing to the well-evidenced scaleup gap.

[1] Invest Europe (2025), *Investing in Europe: Private Equity activity 2024*, Invest Europe, published 8 May 2025.

In particular, within biotech and healthcare-focused funds, VC consistently accounts for half (or more) of all of these specialised funds, underscoring a strong dependence on a relatively small pool of venture managers, compared to growth or buyout.



Source: Invest Europe / European Data Cooperative (EDC)[2]

Nonetheless, while VC continues to play a central role in financing biotech and healthcare innovation, this should not be interpreted as a sign of overall robustness. In fact, the number of early-stage VC funds declined by around 11% over the same period, indicating that, despite its role, even the venture segment is not insulated from market pressures. A contraction at early-stage places additional strain on venture managers and directly affects the future pipeline of companies progressing toward later stages of development and scale. In addition, VC's central role in financing in the sector should not be mistaken for overall ecosystem depth. Even at its peak, fewer than 25 VC funds were raised across Europe between 2022 and 2024, within a much broader VC market, as highlighted above.

The total number of biotech and healthcare-focused funds also remained small in absolute terms, representing around 6-7% of the total PE universe between 2022 and 2024. Even in 2024, fewer than 50 specialised biotech and healthcare funds were raised across all stages combined, highlighting the limited scale of Europe's specialist fund management base in a strategically critical sector.

The contraction in the number of funds across the European ecosystem, in addition to the reliance on VC funds in the biotech and healthcare sector, points to a structural vulnerability in Europe's capital ecosystem. The local fund management ecosystem capable of consistently recycling capital, building expertise and supporting companies across their full growth trajectory cannot be an afterthought.

The European fund management ecosystem should be recognised as a strategic asset. The EU Health Biotechnology Investment Pilot and BioTechEU should ensure that European PE/VC fund managers serve as the primary transmission channel for public capital to innovative and growing biotech and healthcare companies, reinforcing Europe's domestic investment capacity and ensuring that innovative companies remain anchored in Europe. The most effective way to mobilise private investment is not through the reallocation of existing private capital, but through the creation of additional investment capacity that crowds in private investors, and the avoidance of formulations that inadvertently increase competition for the same pools of private capital without expanding overall supply.

[2] Invest Europe (2025), *Investing in Europe: Private Equity activity 2024*, Invest Europe, published 8 May 2025.

In practice, **this means prioritising mechanisms such as:**

- **commitments to European PE/VC funds, and**
- **fund-of-fund structures investing in specialised biotech and healthcare funds.**

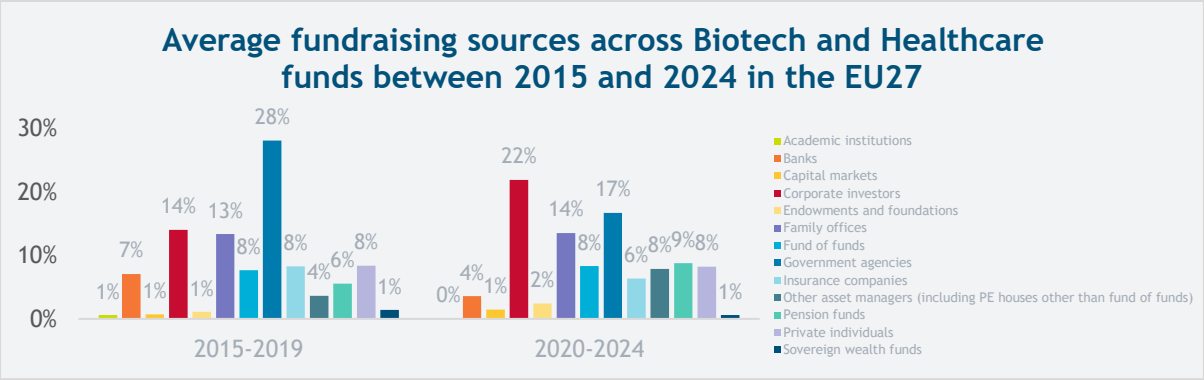
Specifically, the EU Health Biotechnology Investment Pilot could be amended as follows:

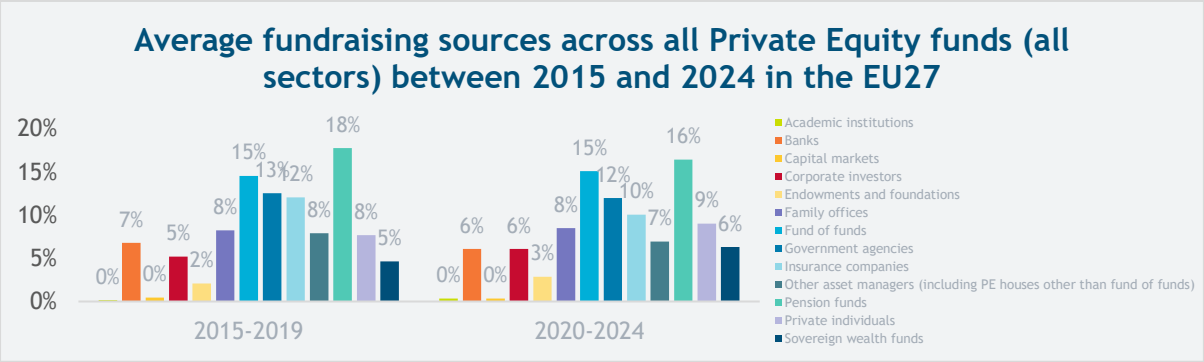
- **Article 22(4)(e):** *mobilise private investments, including from institutional investors such as pension funds, and strengthen the availability of long-term risk finance for biotechnology companies established in the Union. Financial actors, including private institutional investors, shall be targeted by leveraging expertise in catalysing private capital and use appropriate risk-sharing mechanisms to achieve this objective,* ***notably through investments in European venture capital and private equity funds, fund-of-funds structures that crowd in private capital.***
- **Article 22(4)(f):** *assist early- and growth-stage companies through blended and concessional finance, encompassing equity or debt operations,* ***including through indirect financing mechanisms such as investments in venture capital and private equity funds****, complementing the direct equity support provided by the European Innovation Council Fund and the Scale-Up Europe Fund under Horizon Europe, including via the development of new products;*

2. Ensuring feasibility, credibility and scale to attract private capital

A significant share of the announced BioTechEU funding envelope relies on the mobilisation of private capital – an aspect that might be replicated within the EU Health Biotechnology Investment Pilot. While this reflects an appropriate recognition of the role of private investment in supporting biotech and healthcare innovation, greater clarity is needed regarding the structure of these instruments and the mechanisms through which private capital is expected to participate.

This is particularly important considering the fundraising trends observed between 2015 and 2024.





Source: Invest Europe / European Data Cooperative (EDC)[3]

Historically, biotech and healthcare funds have relied heavily on public sector participation. Between 2015 and 2019, government agencies accounted for an average of 28% of total sources of funds for biotech and healthcare-focused funds, compared with 13% across all PE funds (investing in any sector). In the period 2020-2024, public fundraising for biotech and healthcare-focused funds declined to 17%, representing an 11-percentage-point reduction. By contrast, public participation in the broader PE market decreased only marginally (by 1 percentage point) over the same period. This divergence indicates that biotech and healthcare funds have experienced a materially faster withdrawal of public capital than the rest of the market, increasing their reliance on institutional capital.

While private capital has partially filled this gap, Invest Europe's data shows that this substitution has been uneven and conditional. Corporate investors increased their share of funding for biotech and healthcare funds from 14% to 22% between the two periods, a much stronger shift than observed across PE as a whole. This reflects growing strategic and industrial interest in the sector, but also suggests a greater dependence on capital that is often selectively deployed, driven by corporate priorities.

At the same time, long-term institutional investors remain structurally under-represented in biotech and healthcare fundraising. Pension funds increased their share from 6% to 9% between 2015-2019 and 2020-2024, but this remains significantly below their participation in PE overall, where pensions account for around 16% of fundraising – although a lot of this capital is actually coming from United States managers. In addition, in the first half of 2025, pension funds represent only 1% of fundraising activity for biotech and healthcare-focused funds. Insurance companies and banks, meanwhile, both reduced their exposure in biotech and healthcare funds – with banks doing so more sharply than in the wider PE market – reflecting regulatory constraints and risk-weighting considerations that affect capital-intensive and high-risk sectors. As a result, the investor base supporting biotech and healthcare funds remains narrower and less diversified than that of PE overall.

Taken together, these patterns show that initiatives that rely heavily on the mobilisation of private capital in biotech and healthcare must be designed with particular care. From an investor perspective, there is understandable caution regarding initiatives where a substantial portion of the headline investment volume depends on uncertain private co-investment, particularly when the incentives and risk-sharing structures remain undefined. In such cases, announced funding volumes may overstate the effective capital available to companies if the expected private participation does not materialise. This is particularly the case for institutional investors, whose participation is shaped by regulatory frameworks, policy incentives and risk-return considerations as much as by market opportunity.

If Europe aims to mobilise institutional capital at scale in strategic sectors, such as biotech and healthcare, this will require clear structural incentives and enabling conditions. Institutional investor participation requires instruments that are credible, investable and aligned with the constraints faced.

This includes, as highlighted in our position paper on the Savings and Investments Union from March 2025, or our Taxation White Paper from February 2026:

- **appropriate prudential treatment, capital requirement adjustments and fund management rules** for long-term equity investments in innovation, and
- **tax incentives** that encourage long-term institutional investment in high-growth sectors.

[3] Invest Europe (2025), *Investing in Europe: Private Equity activity 2024*, Invest Europe, published 8 May 2025.

3. Aligning public research funding with commercialisation and investment to protect innovation

As public research funding programmes continue to play a very important role in supporting early-stage biotech and healthcare discoveries across Europe, their design should also ensure that the research they fund can be effectively translated into protected innovations, investable companies and scalable technologies.

Currently, although grants do not force early publication, they do create pressure through the "open science" principle under Horizon Europe – including the rapid dissemination of research output. In highly competitive fields such as biotech and healthcare, the immediate publication of research results, particularly when supported through public grants, may expose strategically valuable innovations before intellectual property (IP) protection or commercial development pathways have been secured. This can reduce the ability of European innovators to capture value from their discoveries.

For PE/VC investors, the ability to protect innovation is a critical condition. If publicly funded research outputs are disclosed before appropriate protection mechanisms are in place, this may inadvertently undermine the commercial potential of the underlying technology and discourage private investment in early-stage translation, company creation, and subsequent development stages.

To prevent the premature disclosure of strategically valuable biotech and healthcare innovations, **the EU Health Biotechnology Investment Pilot, as well as other public funding sources, should introduce confidentiality mechanisms linked to grant funding. Publication of research outputs should be temporarily deferred where necessary** to allow appropriate IP protection, financing and industrial partnerships to be secured. **This could include confidentiality periods of up to 24 months**, ensuring that European startups and research teams have sufficient time to protect their discoveries and attract investment before sensitive technical information becomes publicly available.

Accordingly, the following point should be added to Article 22:

- ***(h) support the translation of biotechnology research into commercially viable innovations by allowing temporary confidentiality periods of up to 24 months for research results generated under projects supported by the pilot, where necessary to secure intellectual property protection before publication and facilitate private investment.***

- ***Enhancing speed and unlocking untapped value as a driver for investment and innovation***

1. Accelerating clinical trials to retain innovation breakthroughs in Europe

The clinical research ecosystem is, globally, a hyper-competitive race to reduce the "white space" in drug development – the time between the conceptualization of a clinical protocol and the enrolment of the first patient. In this regard, the Biotech Act's push to simplify and accelerate clinical trials and regulatory procedures, without lowering Europe's high safety and quality standards, is one of the key levers to render the European market attractive to investors. For investors, this kind of certainty matters.

The EU Clinical Trials Regulation (CTR) has delivered meaningful structural improvements, including harmonised documentation requirements, a single submission portal (CTIS), and legally binding review timelines across Member States. In several countries, this has translated into tangible progress. For example, Germany and Belgium now demonstrate significantly faster review timelines for

mono-national trials, and some authorities have developed strong expertise in complex and innovative trial designs.

While proposed improvements to clinical trial authorisation timelines are also welcome, Europe remains structurally less competitive on trial timelines compared with jurisdictions such as Australia – where regulatory review can take only a few days – and the United States, which relies on a 30-day regulatory review clock. In Europe, EU regulatory reviews often exceed 100 days, driven by high volumes of requests for information, Q&A windows, and administrative rather than scientific considerations. In practice, administrative complexity, duplicative requests, CTIS limitations, and fragmented national implementation continue to extend the time to first patient enrolment, particularly for multinational and innovative trials.

As a result, biotech and healthcare companies often choose to initiate early-stage clinical trials in the aforementioned jurisdictions, where the regulatory framework is faster, more predictable and often less costly, particularly for Phase I and Phase II studies. This trend has tangible consequences: when clinical trials move abroad, R&D expenditure, know-how and downstream value creation tend to follow, alongside losses in workforce productivity and broader innovation spillover impacts that are difficult to repatriate at later development stages.[4]

Multinational trial timelines, indeed, remain particularly important in this context. In practice, very few clinical trials are conducted in a single Member State, as most studies require multiple clinical centres across Europe to recruit sufficient patient populations. Multinational trials, therefore, represent the standard model for clinical research in Europe. A 75-day authorisation timeline risks continuing to act as a bottleneck, particularly for innovative therapies where rapid trial initiation is critical, thereby limiting the attractiveness of Europe as a location for clinical research.

The authorisation process for multinational trials should be treated as the primary benchmark for EU competitiveness. The Biotech Act should encourage **further reductions in authorisation timelines for multinational trials**, ensuring that the EU regulatory framework remains competitive with leading clinical research jurisdictions.

In addition, there appears to be a disconnect between the timelines for initial clinical trial authorisations without requests for information and those for substantial modifications. Under the Biotech Act:

- an initial clinical trial authorisation without requests for information would take 47 days, and
- the assessment of substantial modifications (standard procedure) would also take 47 days.

As currently drafted, the timelines appear to suggest equivalent review durations for procedures of different complexity.

To better reflect procedural proportionality and the objective of accelerating clinical trial approvals, **the timeline for initial clinical trial authorisations without requests for information could be further reduced**, ensuring that straightforward applications are processed more rapidly than substantial modifications requiring additional review.

[4] Frontier Economics and European Federation of Pharmaceutical Industries and Associations (2026), *The economic impact of industry clinical trials across Europe*, published February 2026.

2. Accelerating certification of facilities to unlock Europe's biomanufacturing capacity

The Biotech Act rightly places a strong emphasis on strengthening Europe's biomanufacturing capacity and accelerating the development of biotech production facilities. The recognition of high biotechnology strategic and high-impact strategic projects (HSP/HISP), combined with accelerated permitting procedures, represents an important step toward reducing administrative delays associated with the construction and expansion of biotech manufacturing plants.

However, while the Biotech Act introduces faster procedures for permitting and project recognition, the certification of manufacturing facilities under Good Manufacturing Practice (GMP) requirements may still operate on significantly longer timelines. In practice, companies may wait several months for a National Competent Authority to conduct the inspection required for GMP certification of a manufacturing site, even after other regulatory approvals have been obtained.

The effective deployment of new manufacturing capacity depends not only on the speed of permitting procedures, but also on the timely certification and regulatory inspection of manufacturing facilities. Certification and inspection timelines can therefore represent a significant bottleneck – particularly for biologics and other complex therapies. As a result, newly built or upgraded facilities may remain temporarily unable to operate while awaiting certification, effectively leaving manufacturing capacity locked up despite significant investments.

To ensure that the accelerated procedures introduced by the Biotech Act translate into operational production capacity, **GMP certification processes should be better aligned with the timelines foreseen for HSPs/HISPs**. **In particular, the final building permit and the initial GMP manufacturing authorisation should be processed in parallel wherever possible**, allowing regulatory inspections to take place during the final stages of construction and validation of the facility.

3. Unlocking the value of biological materials and datasets

Beyond speed, the attractiveness of clinical trial locations is also shaped by the ability to generate and reuse high-value clinical samples and associated data. Clinical trials produce biological materials and (omics) datasets that are critical for subsequent research by both industry and academia, enabling the identification of novel applications and the redirection of clinical development pathways.

The Biotech Act makes significant progress in harmonising the processing and secondary use of personal data in clinical trials (Article 93). However, this is not matched by a corresponding harmonisation of rules governing the collection, storage, access and reuse of biological samples and associated data. The current requirement of compliance with applicable rules on these – which are often national and fragmented – misses an opportunity to establish a single standard for biobanking procedures.

The current fragmentation creates legal uncertainty and hidden disincentives for researchers and sponsors, limiting the effective use of data. In contrast, competing jurisdictions offer more integrated clinical research ecosystems, which has been a contributing factor in location decisions by companies, such as BioNTech.

The Biotech Act should introduce a more harmonised approach to biobanking, through common minimum standards aligned with CTR, the Substances of Human Origin (SoHO) Regulation, and the European Health Data Space (EHDS). This would strengthen the Union's clinical research ecosystem, enhance the reuse of high-value clinical data, and improve the EU's attractiveness as a location for innovative clinical research.

- ***Ensuring the optimal identification and prioritization of strategic and impactful biotech and healthcare projects***

The introduction of the concept of high biotechnology strategic and high-impact strategic projects (HSP/HISP) – and the associated prioritisation concerning permits, approvals and access to support – clearly reflects investors' needs. When status is transparent, predictable and clearly linked to tangible benefits, it reduces risk and directly influences investment decisions.

However, the current criteria risk being too narrowly framed. To maximise impact, the framework should ensure that all relevant opportunities across the biotech and healthcare value chain can qualify.

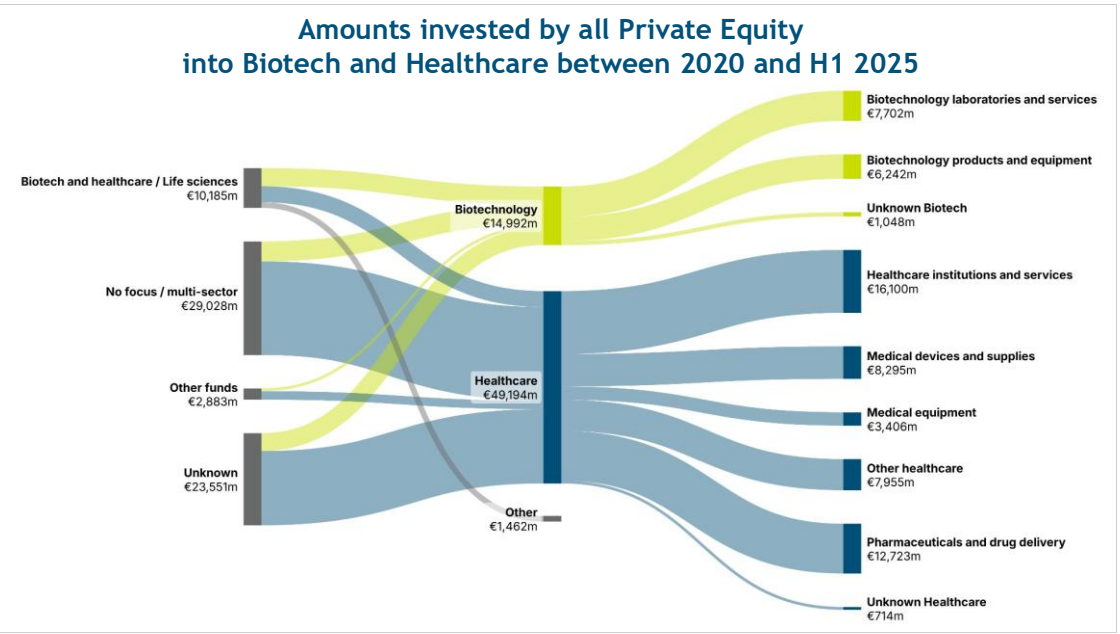
At the same time, prioritisation in administrative processes alone may not be sufficient to fully address the investment challenges associated with high-risk biotech and healthcare innovation. The designation of HSP and HISP projects should also be accompanied by additional incentives that strengthen the overall risk-reward profile for investors and developers working in areas of high unmet medical need.

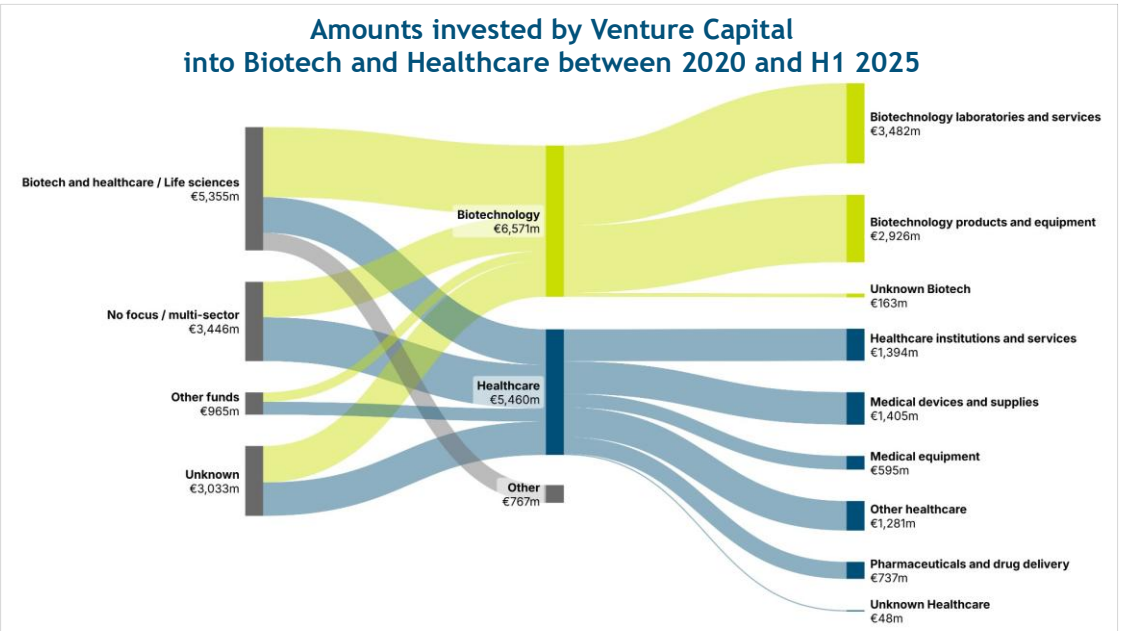
1. <u>Strengthening the full financing pipeline</u>

The EU Biotechnology Late-Stage Capital Booster Pilot is widely seen as critical. Limited access to growth capital is one of the most acute weaknesses of the European ecosystem and a key driver of company relocation to the United States.

However, late-stage capital cannot be treated in isolation. Without a robust pipeline of early-stage companies, there will be insufficient opportunities for later-stage deployment. If biotech and healthcare-focused VC funds in Europe struggle to raise capital, this would directly undermine the future supply of scaleups. In the VC segment, in particular, risk aversion remains substantial, especially in the context of specialist funds, for which concentration is high in strategically important and innovative industries.

The capital allocation patterns across venture, growth and buyout strategies underline why late-stage interventions cannot stand alone.





Source: Invest Europe / European Data Cooperative (EDC) – created with SankeyArt.com [5]

In fact, VC plays a disproportionately central role in biotech financing, and remains particularly reliant on specialist funds, while diversified investors tend to gravitate towards lower-risk healthcare segments.

Across growth and buyout, capital is overwhelmingly concentrated in more mature healthcare segments – particularly services, pharmaceuticals and medical devices – while biotech remains materially smaller in scale. This means that R&D-intensive biotech continues to depend primarily on earlier risk capital. Focusing exclusively on late-stage capacity – although rightfully so, given the current scaleup gap – does not compensate for potential gaps in the earlier stages. If VC is constrained, biotech is the first to be affected, and late-stage instruments are unlikely to repair that deficit ex post.

This structural sequencing means that without sustained support across the whole value chain, the pipeline of companies eligible for late-stage instruments will remain insufficient.

The Biotech Act should focus on addressing the financing continuum holistically, rather than treating early- and late-stage capital needs as isolated issues, especially if the aim is to address all of Europe's financing gaps in the biotech and healthcare industry**. Capital needs to be channelled to areas where market failures are most pronounced, notably both VC and growth equity. Therefore, we suggest renaming the booster as "EU biotechnology early- and late-stage capital booster"**

The Biotech Act should, therefore, be amended in the following way:

- **EU biotechnology late-stage capital booster criteria, Article 23 (2)(b):** ***or*** *mobilising long-term capital and attracting private investment, including institutional investors, and through private* ***and public*** *markets, with credible commitments or structures that support liquidity* ~~***and***~~ *, follow-on financing****; and the development of specialised public market investors capable of supporting biotechnology companies through IPOs and subsequent capital raises;***

[5] Invest Europe (2025), *H1 2025 European Private Equity Activity,* Invest Europe, published 6 November 2025; Invest Europe (2025), *Investing in Europe: Private Equity activity 2024*, Invest Europe, published 8 May 2025.

- **EU biotechnology late-stage capital booster criteria, Article 23 (2)(e):** ***or*** *mobilising private capital through* ***venture capital and private equity funds, as well as through*** *biotechnology accelerators and venture builders* ***that support company creation and early-stage development across all stages of company development, including early-stage and scale-up financing****,* ~~***including***~~ ***and through*** *the potential use of risk-sharing mechanisms.*

As the delegated acts for the HSP and HISP frameworks are developed, we look forward to contributing our expertise to ensure that all relevant strategic opportunities across the European biotech and healthcare ecosystem are fully captured.

2. Translating European science into biotech companies

Although Europe has a strong scientific base in biotech and healthcare, it often struggles to translate academic discoveries into successful companies and investable opportunities. While the Biotech Act rightly emphasises infrastructure such as pilot facilities, testing environments and development accelerators, one of the main bottlenecks in Europe frequently occurs earlier in the innovation pipeline. Infrastructure should therefore not be understood only as physical facilities, but also as the capabilities that turn scientific discoveries into biotechnology ventures.

Universities remain the primary source of biotech innovation, yet academic systems still largely prioritise publications and teaching, while entrepreneurship and company creation receive limited recognition. Europe's performance in spinning out investable biotech and healthcare companies remains heterogeneous and often lags behind global competitors. A key challenge lies in the lack of sufficiently professionalised, specialised technology transfer, incubation capacities, as well as limited very early-stage funding to generate the data required for investment readiness.

At the same time, Europe faces a broader talent and perception challenge. A relatively small share of early-career researchers and biopharma professionals consider Europe as the preferred location to start their careers, reflecting both structural barriers and limited exposure to entrepreneurial pathways.

Without stronger translation and talent pathways, Europe risks building infrastructure that supports existing companies while failing to generate the next generation of biotech and healthcare firms.

We suggest strengthening the translation stage between research and companies, as well as entrepreneurial training, while embedding translational skills in academic careers, and creating clearer incentives for researchers to engage in company creation. This includes funding for applied drug discovery research, stronger training in translational science, closer collaboration between universities, contract research organisations and industry, and academic career pathways that reward innovation and spin-out creation.

In order to strengthen translational research infrastructure, technology transfer and ecosystem collaboration, talent and translational skills, academic spin-out pathways and early-stage research, **the Biotech Act should be amended in the following way:**

- **Health biotechnology strategic projects criteria, Article 3 (1)(b):** ***or*** *scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing and validation of health biotechnology products, including but not limited to* ***drug discovery and preclinical stage development, early-stage translational research activities,*** *pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities…*

- **Health biotechnology strategic projects criteria, Article 3 (1)(c)(iii):** ***or*** *promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law****, including the development of incubation capacities within universities and research organisations, as well as training and the dissemination of best practices across Member States****.*
- **Health biotechnology strategic projects criteria, Article 3 (1)(d)(i):** *attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills,* ***drug discovery, drug development translational skills,*** *data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners,* ***as well as company creation and spin-out activities****;*
- **Health biotechnology strategic projects criteria, Article 3 (1)(d)(ii):** ***or*** *establishing public-private partnerships between universities, vocational education and training providers, businesses, in particular SMEs, startups and scale-ups,* ***contract research organisations,*** *social partners and applied research institutes****, including partnerships aimed at supporting pre-incubation, or proof-of-concept development****;*
- **Health biotechnology strategic projects criteria, Article 3 (1)(d)(iii):** ***or*** *establishing university alliances, also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent****, including strengthening capabilities in drug discovery and translational research and fostering collaboration with industry partners.***
- **Centres of Excellence for Advanced Therapies criteria, Article 6 (2)(e)(i):** *provide acceleration programmes****, including programmes targeted at academic researchers in translational biology and related life sciences,*** *to transform innovative ideas****;*** *into viable business* ***propositions and support the transition from academic research into biotechnology ventures and spin-out companies;***

The Biotech Act should also add the following:

- **Health biotechnology strategic projects criteria, Article 3 (1)(b)(v):** ***or establishing or strengthening academic or hybrid translational drug discovery institutes across the Union, including through the recruitment of industry-experienced scientific and technical staff;***
- **Health biotechnology strategic projects criteria, Article 3 (1)(b)(vi):** ***or supporting the development and expansion of biotechnology incubators and dedicated wet-lab infrastructures accessible to SMEs, startups and spin-outs within the Union.***
- **EU biothreat radar high impact health biotechnology strategic projects, Article 41 (1)(b):** ***or targeted (early-stage) funding for AMR and novel viruses research and development of novel antibiotics and anti-virals and vaccines.***

3. Ensuring support for all biotech modalities

The Act places a strong emphasis on advanced therapies, where Europe indeed has strong scientific capabilities. However, biotech and healthcare innovation spans a much broader set of technologies.

Importantly, conventional modalities such as small molecules and biologics (including next-generation variants) continue to represent a substantially larger share of scientific research, investment activity and drug development in the global therapeutic pipeline than advanced therapy medicinal products (ATMPs), and, therefore, carry a significantly greater economic and strategic impact for Europe. They have also evolved significantly in recent years and increasingly rely on innovation across the value chain – including in areas such as biomanufacturing.

At the same time, ATMPs remain highly specialised and complex, with significant scientific, regulatory and manufacturing challenges that continue to limit their scalability and attractiveness, especially for VC. To date, ATMPs have not yet demonstrated their ability to consistently translate into large-scale, sustainable value creation in terms of companies and widely accessible therapies. While we recognise their long-term potential, they cannot be considered the most immediate or scalable pathway for strengthening Europe's biotech and healthcare competitiveness.

Moreover, several emerging therapeutic approaches that fall outside the strict regulatory definition of ATMPs – such as bispecific antibodies, antibody-drug conjugates, molecular glues, and targeted protein degraders (TACs) – present scientific and development challenges comparable to those faced by ATMPs.

A policy framework that focuses too narrowly on ATMPs risks overlooking a large portion of ongoing innovation and investment in the biotech and healthcare sector. While the focus on ATMPs may serve as a useful "stress test" for the regulatory framework, an overly narrow prioritisation risks concentrating policy attention and resources on a highly complex and still maturing field, potentially at the expense of more established and scalable modalities where Europe is well positioned to deliver faster and broader impact.

In order to ensure that support mechanisms cover all major biotechnology modalities, including small molecules and biologics, so that policy measures reflect the full diversity of innovation and investment activity across the European biotech ecosystem, the Biotech Act should be amended in the following way:

- **Health biotechnology strategic projects criteria, Article 3 (1)(a)(ii):** ***or*** *creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars~~;~~* ***vaccines, complex biologicals (i.e., gene therapy, bispecific antibodies, antibody-drug conjugates), radiopharmaceuticals;***
- **Centres of Excellence for Advanced Therapies criteria, Article 6 (2)(a):** *specialise in at least one advanced therapy, such as* ***(advanced) biologics*** *cell and gene therapies~~;~~* ***or radiopharmaceuticals;***
- **Centres of Excellence for Advanced Therapies criteria, Article 6 (2)(d):** ***and*** *establish structured cooperation among clinical centres, research organisations,* ***academic centres with specialisation in specific advanced therapies,*** *industrial developers of biotechnology products, investors and regulators;*

Additionally, the Biotech Act does not seem to cover neglected diseases.

In the United States, created by the Food and Drug Administration (FDA), there is a Priority Review Vouchers (PRV) program, a "pull" incentive granted on top of approval to encourage companies to develop drugs for diseases that are often not profitable (i.e., a neglected tropical disease or rare pediatric disease), entitling the bearer to a priority review for a future drug application. The most unique feature of this initiative, however, is that vouchers are transferable. The key mechanism is that these are two separate drugs: the drug that earns the voucher (by treating a neglected condition) and the drug that uses the voucher (which may be a commercially lucrative product entirely unrelated to the original neglected disease). A small biotech company can sell its voucher to a large pharmaceutical company for hundreds of millions of dollars. This creates an invaluable financial secondary market that does not exist within Europe. For these companies, hitting the market four months early can be worth significantly more than the cost of the voucher.

Unlike the PRV, HSP and HISP status is non-transferable and realized during the research and development phase, not after approval. However, by taking advantage of existing market forces, patients could have faster access to lifesaving products that may not otherwise be developed, and sponsors of neglected disease drugs can be rewarded for their innovations, while attracting investors.

The Biotech Act should introduce a mechanism inspired by the PRV system to create a market-based incentive for both companies and investors for the development of medicines addressing areas of high unmet medical need, especially in areas where market failures pose societal threats (i.e., pediatric, AMR, infectious diseases, etc.).

Where a company successfully develops and obtains EU marketing authorisation for a medicine originating from a qualifying HSP or HISP project, it should receive a transferable voucher entitling the holder to priority regulatory review for another medicine in its pipeline. Such vouchers could be tradable, enabling smaller biotech companies to monetise the incentive while strengthening investment in strategically important biotechnology projects.

4. Creating globally competitive biotech clusters

One of the defining characteristics of the most successful biotech and healthcare ecosystems, such as the one in Boston, is the high geographic and functional concentration of the full innovation value chain. These ecosystems combine, within a relatively small geographic area: leading academic research institutions, sophisticated hospitals and clinical trial infrastructure, startups and scaleups, specialised investors, contract research organisations and contract development and manufacturing organisations (CROs and CDMOs), large pharmaceutical companies. This density enables vertically integrated translational pipelines, covering discovery, non-clinical research, clinical development and industrial scaleup. It also provides access to local clinical trial capacity and sophisticated capital markets, allowing companies to grow without relocating to other ecosystems.

The Biotech Act recognises most of these components individually. However, it largely treats clustering as optional and project recognition as geographically neutral. This risks reproducing a long-standing structural challenge in Europe: many high-quality projects distributed across regions, but insufficient critical mass to create globally competitive ecosystems. As a result, promising companies, capital and talent often migrate to more integrated environments, such as Boston.

The Biotech Act should move beyond a distributed excellence model towards a cluster-based model that creates dense, integrated biotechnology ecosystems in Europe. We suggest adding definitions for "Integrated health biotechnology cluster" and "Integrated health biotechnology cluster projects" within Article 2:

- ***'Integrated health biotechnology cluster' means a geographically concentrated ecosystem that brings together research organisations, clinical centres, biotechnology companies, investors and enabling service providers within a defined innovation area, supporting the full biotechnology value chain from discovery and translational research to clinical development and industrial scaleup;***
- ***'Integrated health biotechnology cluster projects' means a project that establishes or develops an integrated health biotechnology cluster;***

Accordingly, **the Biotech Act should add the following**:

- **Health biotechnology strategic projects criteria, Article 3 (1)(a)(vi): *or establishing or strengthening integrated health biotechnology cluster projects.***
- **Biotechnology development accelerators, Article 5 (f): *or be physically co-located within an integrated biotechnology cluster environment bringing together early-stage biotechnology***

companies, GMP-compliant pilot or small-batch manufacturing facilities, and clinical trial units, in order to enable continuous translational development from discovery to early clinical stages.

- **Centres of Excellence for Advanced Therapies criteria, Article 6 (2)(e)(vii): *and be geographically embedded within a recognised integrated health biotechnology cluster and provide access within that cluster to shared GMP-compliant pilot manufacturing facilities and clinical trial infrastructure, ensuring continuous translational development from research and early-stage innovation to clinical testing and scaleup.***

5. Ensuring clarity and consistency in the status criteria

Clarity and internal consistency will be important elements for the effective implementation of the status criteria under the Biotech Act. The language used in the description of the different project categories should therefore be precise and coherent, in order to avoid ambiguity during the implementation stage.

Definitions should also clearly reflect the substantive focus of the category they describe, so that project developers and authorities can easily understand the scope of eligible activities. For instance, in the case of Biotechnology Development Accelerators, although the provision is drafted broadly, the category appears in practice to focus primarily on biomanufacturing-related testing, validation and scaleup infrastructure. The current wording may therefore create uncertainty regarding the types of projects that fall within its scope.

We suggest to improve the language on Biotechnology Development Accelerators to better reflect the intended function of these infrastructures. **In Article 5, the heading could be refined to: *Biotechnology Development for Biomanufacturing.***

In addition, **where a category is based on alternative eligibility conditions**, the drafting should clearly indicate that these conditions are independent. **This can be achieved by placing "or" before each condition following the first one**, ensuring that it is clear that meeting any single condition is sufficient for eligibility. Conversely, **where a category is based on cumulative conditions**, the drafting should clearly reflect that all conditions must be fulfilled. In such cases, **the conditions should be preceded by "and".**

- ***Protecting biotech and healthcare innovation through patent confidentiality***

The Biotech Act's introduction of a 12-month extension of the supplementary protection certificate (SPC) for certain innovative biotech medicines represents a welcome step toward strengthening incentives for research and development in the EU, recognising the importance of rewarding high-risk innovation while reinforcing Europe's industrial base.

In fact, IP protection plays a fundamental role in enabling biotech and healthcare innovation. The development of new therapies requires long research cycles, high upfront investment and the disclosure of highly detailed technical information. Ensuring that innovators can adequately protect their discoveries during the early stages of development is necessary to maintain Europe's competitiveness in the industry.

Under the current patent framework, patent applications are typically published 18 months after filing – as mandated by the European Patent Convention (EPC), and governed by the European Patent Organisation, and the European Patent Office (EPO). While early publication promotes transparency and knowledge dissemination, in highly competitive technological fields such as biotech and

healthcare, it can also expose sensitive technical information before innovators have been able to fully secure commercial development pathways or establish technological leadership. This is because early publication may facilitate rapid replication or reverse engineering of disclosed innovations, particularly in jurisdictions where competitors may benefit from significant cost or speed advantages. These concerns are becoming even more relevant in an environment where AI-enabled tools can accelerate the analysis and replication of publicly available technical information.

Member States, as contracting parties to the EPC, should engage with the EPO to explore a modest extension – from 18 months to 24 months – of the confidentiality period between patent filing and publication, to help ensure that European innovators retain sufficient time to consolidate IP protection, establish development partnerships and secure financing before sensitive technical information becomes publicly available. **Consideration could also be given to longer confidentiality periods for strategically sensitive fields**, where early disclosure may create particular competitiveness risks.

- ***Implementing efficient governance structures***

1. Preserving decision-making integrity

The governance framework established under the Biotech Act represents an important step toward improving coordination across Member States and ensuring more effective implementation of biotech and healthcare policy in the EU. The creation of dedicated coordination bodies and support networks reflects a welcome recognition that regulatory fragmentation can act as a barrier to both innovation and investment.

At the same time, the framework foresees significant involvement of Member States across several governance bodies. In the biotech and healthcare sectors, regulatory credibility is a key determinant of investment decisions. Companies and investors rely on approval systems that are predictable and based on clear and consistent criteria. If decision-making processes become influenced by broader national political considerations, this can undermine confidence in the regulatory framework and introduce uncertainty for innovative projects.

Maintaining a stable and predictable regulatory framework is increasingly important for Europe's global competitiveness, particularly in light of growing concerns around the politicisation of regulatory decision-making in other jurisdictions.

The implementation of the governance framework should ensure that Member State participation supports coordination and information exchange without creating procedural bottlenecks or delays in the development and recognition of strategic biotech and healthcare projects. As these structures are implemented, it will be important to ensure that decision-making processes remain efficient, fast, transparent and grounded in fair evaluation.

In particular, **assessments relating to medicinal products and biotech innovations should remain predictable, and shielded from political interference**, allowing the regulatory system to operate efficiently and maintain investor confidence. Regulatory decisions should remain **firmly evidence-based, while ensuring an appropriate balance between the potential risks and the benefits of innovative products**. An overly precautionary, hazard-based approach may unintentionally constrain innovation and slow the development of new technologies. A more balanced, science-based approach that considers both risks and societal benefits would support a competitive and innovation-friendly environment.

2. Enhancing resilience to external policy and market dynamics

The governance framework under the Biotech Act should be designed not only to reduce internal fragmentation, but also to strengthen Europe's resilience to external policy shocks that influence company behaviour and investment decisions.

Europe's post-authorisation environment is currently characterised by heterogeneous national access pathways, including differences in pricing and reimbursement procedures, and the use of external reference pricing.

While pricing and reimbursement remain Member State competences, the effects of these incentives are increasingly felt at EU level. These effects include widening differences in access timing for patients – undermining equity objectives – reduced predictability for innovators, and growing uncertainty for investors and healthcare systems.

In the context of heightened global pricing sensitivity, such variability becomes more consequential. Recent developments in international pharmaceutical pricing policy have increased the risk that companies adjust their global launch sequencing in ways that delay or reduce the availability of new medicines in lower-priced markets. Where companies perceive that prices accepted in one jurisdiction may influence pricing outcomes in another, incentives can emerge to postpone launches, limit volumes, or avoid smaller or lower-priced markets altogether until commercial conditions become clearer. As a result, companies increasingly view multi-country European launches as commercially complex and strategically risky.

Without a structured way to detect and address these dynamics, Europe risks late detection and inconsistent responses, leading to a gradual increase in access divergence across Member States and a weakening of its attractiveness as a launch region for innovative products.

The governance framework established under the Biotech Act could **incorporate a set of light-touch, competence-respecting measures focused on transparency, coordination, and early action, such as an EU-level monitoring capability (i.e., under the European Health Biotechnology Steering Group) to track key indicators** including EU authorisation to first launch and to reimbursement decisions across Member States, uptake and utilisation of early access pathways, cross-Member State divergence in access timing, and signals of launch sequencing (i.e., repeated delays in lower-priced markets). The purpose would be early detection of emerging access gaps and bottlenecks – without steering national price levels.

This monitoring function could be complemented with **periodic, non-binding implementation insights and best practices**, to support transparency and peer learning amongst Member States.

Taken together, these measures would allow the Biotech Act's governance framework to identify emerging access risks earlier and sustain predictable routes to market, while remaining fully aligned with Member State competences and Europe's principles of affordability.

3. Strengthening governance through structured ecosystem expertise

Although the European Health Biotechnology Steering Group plays a central role in facilitating implementation, advising the Commission and supporting the recognition and development of strategic biotech and healthcare projects, its composition is limited to representatives from Member States and the Commission, who hold the voting rights within the body.

The Biotech Act recognises the importance of mobilising private investment in the biotech and healthcare ecosystem. Despite this recognition, investor expertise is currently integrated only indirectly and on an ad hoc basis. The Steering Group may facilitate liaison between project promoters and potential investors, including the European Investment Bank Group (EIBG), national promotional banks and institutions, and PE/VC sources.

While the Chair may invite external experts to attend meetings where appropriate, the Biotech Act does not foresee structured or permanent representation of investors or institutional capital providers within the Steering Group or other governance bodies established under the Biotech Act, even though private capital investors have a broad overview of emerging technologies, market dynamics and international competitiveness.

We, therefore, suggest that **the governance framework of the Biotech Act should include independent (i.e., no longer active) representatives with expertise in PE/VC, specifically focused on the biotech and healthcare sector, within relevant advisory and foresight bodies**. Such participation could take the form of observer roles or advisory participation, ensuring that policy discussions benefit from a broader ecosystem perspective, including the valuable insights into how regulatory frameworks interact with innovation and financing conditions in practice, while maintaining the independence of regulatory decision-making.

- ***Ensuring a competition level playing field for all SMEs, startups and scaleups***

SMEs, startups, and scaleups are central to the Biotech Act's objectives of bridging the EU's competitiveness gap and translating scientific excellence into industrial capacity. In fact, several advantageous measures and incentives are dedicated to them, including: the Health Biotechnology Support Network for direct assistance to developers in identifying applicable rules, navigating regulatory procedural pathways, and finding funding and networking opportunities, dedicated communication channels at national level through the single points of contact to respond to implementation queries, pre-submission scientific advice, as well as further support to access high-performance computing and AI resources necessary for research and biomanufacturing. This is a priority that the PE/VC industry shares.

However, the Biotech Act defines an SME as a micro, small, or medium-sized enterprise within the meaning of the Annex to Commission Recommendation 2003/361/E, while the continued reliance on the existing SME definition risks producing uneven outcomes.

Companies that remain SMEs in economic and operational terms, under the current definition, may lose SME status solely because they have accessed PE or growth capital, while comparable firms financed through other channels continue to benefit from SME-specific support. This creates distortions that are particularly relevant in the biotech and healthcare sector, where access to long-term risk capital is of high importance for both innovation and scaling. The result is a disincentive to the type of financing the Biotech Act seeks to mobilise.[6]

We suggest amending the relevant SME criteria, within the SME definition in Article 2, as per the European Commission's May 2025 Recommendation on Small Mid-Cap enterprises (SMCs), as well as the March 2026 Commission Recommendation on the definitions of innovative enterprises, startups and scaleups, specifically concerning the derogations related to the "linked enterprise" and the "partner enterprise" concepts – in line also with the current and ongoing revision of the SME definition. Clarifying the treatment of private capital-backed companies within the SME framework would not expand SME eligibility beyond its intended scope, but ensure that

[6] More information is available within Invest Europe's position paper on the SME definition.

companies are assessed on the basis of how they operate in practice rather than how they are financed. This would remove unintended disincentives to private capital, strengthen the effectiveness of SME-targeted measures under the Biotech Act, and ensure coherence with wider EU initiatives.

Moreover, while startups and scaleups are frequently referenced, the Biotech Act does not provide a standalone legal definition for these terms.

As a result, it remains unclear how competent authorities, implementation bodies and support networks should determine which companies qualify for the associated benefits. The absence of legal clarity risks uneven application and fragmentation across Member States. Comparable companies may be treated differently depending on national interpretation, administrative practice or funding channel, undermining predictability for both companies and investors.

We suggest clarifying the meaning of "startups" and "scaleups" within the Biotech Act's Article 2, in line with the European Commission's March 2026 Commission Recommendation on the definitions of innovative enterprises, startups and scaleups. This would strengthen legal certainty and ensure that the Act's benefits are applied consistently and effectively.

- ***Conclusion***

Taken together, these recommendations aim to ensure that the Biotech Act not only introduces new policy instruments, but creates a coherent and investment-ready framework.

Building on Europe's world-class research institutions, highly skilled scientific talent and strong base of innovative startups and scaleups, a well-implemented Biotech Act can help ensure that European scientific excellence translates into globally competitive companies, and become a cornerstone of Europe's autonomy and competitiveness.

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