Strengthening Europe's biotechnology ecosystem through a competitive and coherent Biotech Act

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Executive summary

Europe faces a strategic opportunity and need to strengthen its position in global life sciences. While the EU has strong scientific capabilities, it must create the right regulatory and investment environment to ensure that innovation can scale, attract investment and remain in Europe. The Biotech Act[1] is a key step towards building a more competitive and innovation-friendly biotechnology ecosystem.

To fully realise this ambition, the framework must:

- ensure a clear, workable and globally competitive Supplementary Protection Certificate (SPC) extension that effectively incentivises innovation;
- deliver a more harmonised EU clinical trials system, with improved coordination between Member States, aligned assessments and simplified procedures;
- reduce inconsistent implementation and ensure a coherent, predictable and investment-friendly EU regulatory framework;
- make Strategic Projects a driver of scale by focusing on excellence, industry involvement and global openness;
- and provide ambitious funding, including under the future MFF European Competitiveness Fund, while enabling secure, coherent AI- and data-driven innovation across the lifecycle.

The proposal introduces important measures to incentivise and accelerate innovation, improve regulatory efficiency and reinforce Europe's attractiveness for research, development and manufacturing. A central element is the **modernisation of the clinical trials ecosystem**. These reforms could significantly increase clinical research activity in Europe, enabling earlier patient access to innovative therapies and strengthening the EU's global competitiveness. **These provisions of the Biotech Act are essential. They must be retained and, where possible, strengthened throughout the legislative process**.

There is also room for further improvement. The Act introduces a **12-month SPC extension for biotechnology products and advanced therapies,** reinforcing incentives for innovation. However, **in its current form, it risks falling short of providing a meaningful and competitive incentive.** The effectiveness of the SPC extension will depend on its scope, duration and the robustness of the eligibility criteria. A more ambitious and workable SPC extension—which strengthens these elements while ensuring alignment with existing EU regulatory concepts and maintaining global openness—would send a stronger signal of Europe's commitment to remain an attractive location for innovation and investment.

[1] https://health.ec.europa.eu/document/download/ec1475b7-e3f9-409e-b927-fc7e69306a8c_en?filename=biotech_reg-com2025-1022_act_en.pdf

The proposal introduces the concept of **strategic projects and seeks to strengthen biotechnology innovation clusters and access to funding**. These positive measures can support the scale-up of companies and foster collaboration across the innovation ecosystem. There is also welcome recognition of the growing importance of **data and artificial intelligence**, proposing trusted AI testing environments and improved data governance frameworks.

Overall, the Biotech Act has the potential to transform Europe's life sciences ecosystem by reducing fragmentation, improving regulatory predictability and supporting innovation—from research to large-scale manufacturing and enhanced patient access to innovative therapies.

Introduction

Europe stands at a strategic crossroads. In a world where life sciences are redefining healthcare, economic growth and geopolitical influence, **Europe must create the right ecosystem to support innovation at scale, attract investment, and regain global competitiveness.**

The Biotech Act offers a unique opportunity to shape a system that is truly innovation-friendly: one that is faster, better funded, more coordinated and predictable. Europe needs to foster an environment that rewards risk-taking and scientific breakthroughs; enables data-driven and AI-enabled research and development; and incentivises innovation and manufacturing in the EU.

It is important to reflect on recent legislative developments, including the EU's new Pharmaceutical Legislation. While the reform of pharmaceutical legislation aimed to strike a balance between fostering innovation and improving access, in practice it has not resulted in a strengthened framework for innovators. As a result, there is a clear **need for the Biotech Act to go further**.

At the heart of this ambition lies the clinical trials ecosystem. Clinical trials provide patients with early access to new medicines under development. **By increasing the number of clinical trials by 50%, more than 150,000 additional patients could benefit from participation in clinical research.** Clinical trials connect patients with potentially life-saving therapies 10-15 years before they are widely available, while also strengthening the healthcare systems that deliver that care. By embedding research into routine clinical practice, trials support better treatment decisions, faster adoption of innovation, and improved outcomes for patients – including those not directly enrolled in studies. That is why conducting clinical trials in Europe matters[2].

An innovation-friendly ecosystem is not simply about shortening timelines or introducing new incentives. **It is also about creating a coherent regulatory system where clinical trials are efficient and harmonised, where credible intellectual property incentives are designed to drive investment decisions, and where legislation is coherent. This would allow companies to plan with legal certainty.** Creating the right environment is about ensuring not only that Europe becomes a place where medicines are discovered, but where they are also developed, produced and delivered to patients at scale, leveraging Europe's industrial and commercial strengths.

[2] https://efpia.eu/news-events/the-efpia-view/statements-press-releases/35-000-more-patients-to-get-access-to-clinical-trials-if-new-eu-targets-are-met/

Our shared ambition should not be to deliver an incremental adjustment, but rather to move from scientific excellence to industrial leadership — positioning Europe as the most competitive and innovation-friendly biotech ecosystem globally.

Detailed recommendations:

In the legislative proposal for the Biotech Act, EFPIA identified the following five core pillars on which an innovation-friendly system must rest:

1. SPC Extension – Ensuring an effective and legally certain incentive

EFPIA welcomes the **introduction of a 12-month SPC extension for biotechnology-derived products and Advanced Therapy Medicinal Products (ATMPs) as a positive signal to reinforce Europe's attractiveness for innovation and investment.** However, in its current form, this measure risks falling short of providing a meaningful and competitive incentive. Its effectiveness will depend on the duration, scope and award criteria of SPC extensions. At the same time, the new Pharmaceutical Legislation is eroding existing incentives that have historically underpinned Europe's attractiveness for R&D, making it vital that any instrument introduced under the Biotech Act is strong, credible, and capable of offsetting this decline.

Against this backdrop, **we urge EU legislators to pursue a more ambitious and effective SPC extension under the Biotech Act, by ensuring a duration that constitutes a meaningful and attractive incentive for innovation broadening its scope** to encompass all innovative medicines without regard to their particular classification**, and establishing clear and predictable award criterias**. This would send a strong and credible signal, illustrating Europe's determination to remain competitive and attractive location for biopharmaceutical innovation and investment.

The **effectiveness of this incentive will depend on the way in which the eligibility criteria are set and applied in practice. For the reward to meet its goal, the eligibility criteria should be clear, predictable attainable and non-cumulative to avoid that the extension becomes largely theoretical.** EFPIA supports refining the conditions to enhance legal clarity, ensure predictability based on established regulatory principles, and provide flexibility to recognise additional investments, patient benefits, and EU research and manufacturing contributions across the product lifecycle. Concretely, EFPIA recommends **broadening the scope to encompass all innovative medicines**. Such an approach is important to ensure that the Regulation supports innovation based on scientific advances rather than arbitrary classification, thereby remaining technology-neutral and future-proof.

At the same time, while acknowledging the objective of strengthening Europe's industrial base, EFPIA stresses that elements of geographical preference linked to manufacturing or operational presence in the EU must be carefully calibrated. Such conditionalities should consider the global nature of biopharmaceutical R&D and supply chains and the economic value of the various steps in the manufacturing process

The requirements should not risk creating unintended consequences for globally integrated R&D and supply chains, raising trade complications and legal uncertainties, and potentially affecting investment decisions. The SPC incentive should therefore reinforce Europe's competitiveness, , preserve legal certainty, and recognise the global and collaborative nature of pharmaceutical innovation.

2. Clinical Trials – Reducing fragmentation and strengthening coordination

The Biotech Act represents an opportunity to reinforce the EU's attractiveness as a global hub for clinical research. EFPIA strongly welcomes the Commission's focus on improving the clinical trials ecosystem, notably through measures aimed at reducing timelines, enhancing coordination, and increasing predictability of assessments across Member States. **These provisions are essential, must be retained and further strengthened throughout the legislative process, and should be consistently enforced.**

2.1 Faster review and approval timelines

One of the most important improvements proposed in the Biotech Act is the shortening of clinical trial authorisation timelines across the EU. In practice, this would enable faster approval of multinational trials (reduced from 106 days to 75 days), quicker decisions where no additional questions are raised (as short as 47 days), parallel validation and assessment, removal of additional delays for ATMPs, shorter timelines for substantial modifications, and the possibility to assess certain document changes in parallel rather than sequentially.

These improvements will allow innovative medicines to enter clinical testing more quickly, provide patients with earlier access to new therapies, improve predictability for sponsors, enhance flexibility and simplify implementation during trials. Robust, internationally accepted quality and safety standards are maintained in the proposals, while reducing administrative burdens and strengthening the EU's global competitiveness.

The introduction of a core dossier for investigational medicines is particularly impactful. It avoids repeatedly submitting the same information to different Member States, reducing duplication and saving time for both Member States and sponsors. EU-harmonised templates will further streamline applications and improve consistency across countries.

The proposal to introduce coordinated assessment for combined studies (e.g., a medicine in combination with a medical device or in vitro diagnostic test) better reflects scientific progress and innovation. Modern treatments increasingly combine different technologies, and fragmented reviews across separate regulatory systems slow down innovation. A single coordinated assessment better reflects scientific reality and improves efficiency.

The Biotech Act furthermore seeks to better align the respective assessment timelines so that Part I and Part II of the Clinical Trial Application can proceed in a more synchronised way, enabling a smoother, faster overall authorisation process. In addition, the proposal limits the ability to conclude the review of one of the two parts of the application if the review of the other is still pending. This is to enable submission of any necessary updated documents triggered by either part of the review.

Finally, EFPIA welcomes the simplified procedures for public health emergencies, which would enable Europe to respond more rapidly and effectively in crisis situations.

2.2 Stronger coordination between Member States

Experience operating under the Clinical Trials Regulation shows duplicative Requests for Information cause delays. The Biotech Act strengthens the role of the Reporting Member State (RMS) — the country

leading the joint scientific and core ethical review — to ensure a more coordinated, predictable and consistent EU process. It will result in fewer duplicate assessments across countries, more predictable outcomes for trial sponsors and a genuinely harmonised EU system instead of parallel national reviews. The RMS Ethics Committee will manage the assessment of ethical aspects of Part I, reducing the burden of full ethics assessment and alleviating ethics committees' workload. This will accelerate assessment timelines.

Importantly, this does not remove national responsibilities. It ensures that the original goal of the Clinical Trials Regulation — a coordinated and efficient EU-wide assessment — is properly implemented.

2.3 Regulatory simplification and data governance

The proposal introduces important structural improvements, including:

- a harmonised GDPR legal basis for clinical trial data processing,
- clearer and harmonised responsibilities regarding controllership of data under GDPR,
- the possibility for the further use of clinical trial data for research purposes, subject to limitations (e.g. restricted to the same controller and to certain types of research),
- reduced fragmentation of national data processing rules.

These improvements are essential to enable data-driven and AI-enabled research. We also welcome the introduction of clinical trial sandboxes which will allow innovative trial designs and digital research methodologies to be tested within a controlled regulatory environment.

In addition, the proposed risk-proportionate exemption for certain ATMP clinical trials involving Genetically Modified Organisms (GMOs) — by removing environmental risk assessment and GMO-related obligations where products present no or negligible risk — is a crucial simplification. This measure represents an important step towards addressing long-standing bottlenecks and reducing unnecessary administrative barriers for innovative therapies, while maintaining appropriate safeguards. However, the implementation process should be further streamlined to avoid unnecessary duplication. EFPIA supports the introduction of parallel substantial modifications, which address a key challenge where sponsors previously had to bundle and prioritise changes. This improvement will increase flexibility and responsiveness in the regulatory system, enable faster updates to trial documents, and enhance operational efficiency. It will also support timely safety updates, allow quicker responses to new scientific insights, and facilitate operational adjustments to improve patient access and trial efficiency.

The proposals in the Biotech Act's regulatory chapter have the potential to strengthen Europe's innovation ecosystem if they optimise existing EU frameworks rather than introducing additional layers of governance. Their implementation should prioritise streamlined processes and better coordination of regulatory governance, infrastructures and systems across the EU.

3. Strategic Projects and prioritisation – From concept to delivery

Strategic and high-impact projects located in the EU should serve as true catalysts for scale, competitiveness and the translation of research into market-ready innovation. EFPIA supports a Strategic Projects framework that **accelerates innovation while strengthening the entire ecosystem through**

structured cooperation between large industrial players, SMEs, start-ups and scale-ups. To maximise impact, the framework should actively reduce fragmentation and promote critical mass.

- ***Avoiding fragmentation:*** **Europe's competitiveness challenge is not a lack of scientific excellence, but the dispersion of capabilities across regions**. Strategic Projects should build on existing concentrations of expertise, infrastructure and investment in a way that replicates the success of globally leading life science innovation hubs.

- ***Involvement of industry in the recognition process:*** EFPIA supports enhancing the governance and recognition criteria for Strategic Projects. However, **engagement with industry stakeholders from the early stages to project assessment and implementation is critical to ensure commercial viability**, prevent duplication of existing capabilities, promote smart concentration and ensure investment predictability. In addition, more precise and ambitious timelines for implementing decisions are necessary to match Member State approval timelines and provide predictability.

- ***Biotechnology accelerators:*** Building structured, long-term industry-SME collaboration is essential to ensure effective scale-up and uptake of biotechnology innovation in Europe. Biotechnology development accelerators should **include testing and demonstration facilities that replicate industrial environments and real-world biomanufacturing processes, including GMP-compliant environments**.

- ***Centres of Excellence for advanced therapies****:* EFPIA supports a **model that is inclusive of industry-led initiatives** and designed to build high-density innovation clusters. It will be important to allow centres to qualify by meeting core conditions (including quality and safety testing) to avoid favouring exclusively hospital- or academic-based infrastructures. Crucially, Centres of Excellence should embed structured and continuous regulatory science engagement, involving EMA and national authorities, to enable early dialogue and convergence between scientific, clinical and regulatory requirements.

- ***Appropriate definition of new approach methodologies (NAMs):*** **Strategic projects should not be negatively impacted by a restrictive definition of NAMs.** Extending the definition to cover all 3Rs (Replacement, Reduction, Refinement) leads to regulatory alignment with the EMA and global regions. It also provides opportunities for further system-wide impact and to deliver on the upcoming EU roadmap to phase out animal testing.

- ***Openness to third-country partners:*** EFPIA further supports opening Strategic Projects to aligned third-country partners where appropriate, to reinforce excellence and global competitiveness. This has the potential to further attract investment to Europe and reflects the importance of open global manufacturing and supply chains. At the same time, the designation of geographically concentrated EU Biotech Flagship Zones could provide a strong global signal to investors and talent, combining cross-border networks with visible, high-density centres of excellence capable of competing globally.

- ***Strengthening disease prevention and preparedness:*** EFPIA supports the explicit recognition of measures that enhance Europe's preparedness, resilience and capacity to respond to future health security challenges. In addition, voluntary dedication of development and manufacturing capacities to Strategic Projects should qualify as a strategic contribution, as it enhances preparedness, flexibility and timely availability of medicines in times of crisis while reinforcing Europe's industrial resilience.

- ***Strategic Mapping:*** EFPIA welcomes the objective of establishing a strategic mapping of the Union's biotechnology and biomanufacturing landscape. In line with Better Regulation principles, this exercise should build on existing EU regulatory data sources and repositories including the European Medicines Verification System, marketing authorisation and regulatory submission data, pharmacovigilance information, and manufacturing and inspection datasets. Any mapping of industrial capacities and infrastructure should also ensure appropriate aggregation and confidentiality safeguards, while protecting trade secrets and the legitimate commercial interests of companies.

- ***Clarify and secure funding opportunities***: High Impact Strategic Projects should be prioritised and supported by targeted calls for proposals rather than being given "particular consideration" for funding under EU programmes. This should be secured in the Biotech Act and in the future Multiannual Financial Framework (MFF), in particular the European Competitiveness Fund.

4. Access to funding

EFPIA welcomes the Biotech Act's timely initiative to improve access to funding for all biotech companies throughout their lifecycle. The creation of a new financing instrument together with the possibility to access mixed financial tools could improve access to capital, support scale-up, and reduce the risk of European biotech innovation relocating outside the EU.

Pharmaceutical innovations often originate in smaller biotech companies that rely heavily on external funding to develop their clinical pipelines. Strengthening the European biotech base will benefit the entire innovation ecosystem, including large companies that collaborate or partner with smaller biopharmaceutical companies to bring new therapies to patients.

However, extending the investment pilot to 4 years instead of 2 would better reflect biotech timelines, attract investment and generate meaningful evidence to optimise its efficiency. Furthermore, the overall impact of these funding instruments will **depend on their implementation, and how ambitious and accessible the funding instruments will be.** If the Biotech Act repackages existing instruments without significantly increasing funding capacity or simplifying access, the effect may remain limited.

5. AI governance and access to data – Avoiding duplication and ensuring coherence

EFPIA supports the Biotech Act's strong emphasis on digitalisation. The recognition of trusted AI testing environments and data quality accelerators as High Impact Strategic Projects is also welcome. EFPIA emphasises the need to ensure a **coherent, secure and innovation-friendly framework that enables responsible AI integration across the medicines lifecycle while avoiding duplication and regulatory fragmentation**.

Guidance on the use of AI models and systems should be developed by the EMA and European Medicines Regulatory Network (EMRN) following stakeholder consultation, aligned with existing EMA/HMA AI workplans, and coordinated with the Commission and the AI Office. To safeguard regulatory predictability and trust, new guidance must be risk-based and proportionate, focusing on AI applications that pose high regulatory impact or patient risk, while avoiding unnecessary reporting obligations for lower-risk uses.

In parallel, data integration into EU infrastructures should comply with robust technical, interoperability and security safeguards, including **alignment with the European Health Data Space framework, and ensure appropriate protection of confidential and commercially sensitive information**. Together, these elements are essential to create a predictable, interoperable and secure ecosystem that supports AI-driven innovation without undermining legal certainty, data protection or the integrity of regulatory decision-making.

Conclusion

The Biotech Act is a defining moment for Europe's life sciences future. It has the potential to transform Europe from a continent of scientific excellence into a globally competitive lifescience leader. To achieve this, the framework must reduce fragmentation, reinforce coordination, ensure workable and credible incentives, enable AI- and data-driven innovation, and build concentrated ecosystems capable of scaling breakthroughs into industrial successes.

The objective should not be incremental optimisation of existing structures, but the creation of a coherent, predictable and investment-attractive system that supports the full lifecycle of innovation – from research and clinical development to manufacturing and global deployment.

With the right political ambition and harmonised implementation, the Biotech Act can anchor research, development and manufacturing capacity in Europe, strengthen patient access to innovation, and secure Europe's position at the forefront of global lifescience competition.

Europe has a strong scientific foundation on which to build. The Biotech Act must provide the architecture for a globally competitive future.