Whitepaper

European Biotech Act

Regulatory impact and practical implications for sponsors

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Whitepaper contents

1 About the European Biotech Act

On 16 December 2025 the European Commission published a proposal for a framework of measures to strengthen the Union's biotechnology and biomanufacturing sectors particularly in the area of health; the so-called Biotech Act.

Background and Intent

The European Union (EU) has a strong scientific research base in biotechnology but is facing issues with taking the early-stage research of these products into further development, manufacturing and commercialization within the EU. The Biotech Act's overarching ambition is to reverse Europe's declining competitiveness relative to leading biotech hubs particularly the major regional ecosystems found in the United States of America (USA) and China.

The Act introduces frameworks for recognizing "high-impact health biotechnology strategic projects", which would gain priority access to funding, administrative support, and network collaboration opportunities. Alongside these funding measures and guidance initiatives, several changes to the regulatory legislation are proposed.

Key regulatory legislation affected

The present proposal will amend, among others, the Clinical Trial Regulation No 536/2014 (CTR) and the Regulation No 1394/2007 on Advanced Therapy Medicinal Products (ATMPs). It also considers other legislation that is being revised, like the Medical Devices Regulation 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR).

Clinical Trials

The proposal has a strong focus on clinical trials. The assumption is that strengthening EU's role in clinical trials will increase investment, production and patient access in the region. The proposal aims at reducing costs and administrative burden for biotech companies by simplifying regulatory frameworks and shortening procedural timelines. Amendments include:

- FAST EU - a voluntary initiative with national Medical Agencies and Ethics Committees, to coordinate a fast-track approach for multinational clinical trial evaluations.

- Introducing regulatory sandboxes to facilitate atypical clinical trials. These controlled environments will support innovative trial designs and facilitate the use of AI tools.

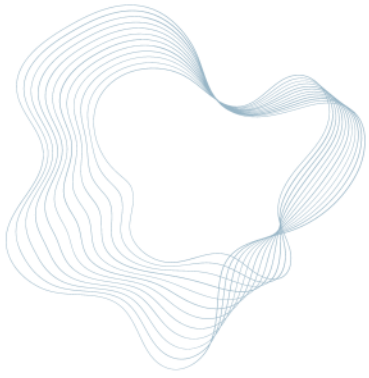
- Introducing a single authorization process for combined studies (biopharmaceutics plus medical devices).

- Strengthening reliance on the reporting Member State's assessment to reduce duplication of work and allow Member States and sponsors to allocate resources more effectively.

- Shortening the assessment timelines from 75 to 47 days when there is no need for complementary information, and from 106 to 76 days if there is such a need. The additional 50 days for assessment of an ATMP will be removed. Assessment of substantial amendments will be shortened from 96 to 47 days, or from 64 to 33 days if there is no request for information. More than one substantial amendment will be allowed in parallel as long as the changes concern distinct and independent aspects of the dossier.

- Introduction of a single core dossier for investigational medicinal products that can be referenced across several studies with one member state being responsible for the assessment of its completeness and suitability.

- A new "minimal-intervention" category of clinical trials will be introduced for products already authorized. These studies would only need an ethical review before starting.



Supplementary Protection Certificate (SPC) Extensions

The Biotech Act proposes a 12-month extension to the existing Supplementary Protection Certificate (SPC) for biotech medicinal products and ATMPs that contains a new active substance distinctly different from that of any authorised medicinal product in the EU, and has a mechanism of action distinctly different to that of any authorised medicinal product in the Union for the same disease.

The clinical trials need to be conducted in more than two Member States, and at least one manufacturing step, excluding packaging, quality testing and certification shall be performed in the EU to achieve this SPC extension.

Key expected improvements for Biotech

- Faster and more streamlined approval of clinical trials authorizations
- An extra year of patent protection for eligible biotech innovations
- Improved access to funding and targeted administrative support to SMEs
- Enhanced digital-enabled oversight and AI-friendly regulatory environments

2 Practical Implications: Regulatory Affairs, Quality Assurance, Supply Chain, and Operational Readiness

While the proposed Biotech Act primarily targets innovation, clinical development, and competitiveness, we can foresee material downstream impacts on regulatory, quality systems, supply chains, and commercialization strategies. These impacts will require early anticipation and structured operational responses from biotech sponsors, particularly SMEs and virtual companies relying heavily on outsourcing models.

Regulatory Affairs (RA)

While the proposed Biotech Act primarily targets innovation, clinical development, and competitiveness, we can foresee material downstream impacts on regulatory, quality systems, supply chains, and commercialization strategies. These impacts will require early anticipation and structured operational responses from biotech sponsors, particularly SMEs and virtual companies relying heavily on outsourcing models.The Biotech Act increases both the strategic importance and the executional complexity of RA functions in the early development of a biotech product.

Key implications include:

- Facilitated multinational coordination: while accelerated clinical pathways and reliance mechanisms like FAST EU procedures, reliance on reporting Member States, and core IMP dossiers streamline multinational CTA management for biotech RA teams, residual national requirements may still arise and must be addressed within compressed timelines.

- Navigation of innovative regulatory tools: regulatory sandboxes, atypical trial designs, and AI-enabled processes will require RA functions for Biotech products to engage proactively with authorities. Training of the RA functions on these novel development concepts will be needed.

- Closer integration of regulatory activities during clinical trial application: shortened CTA and amendments assessment timelines, particularly for ATMPs, will compress the window for resolving regulatory questions related to manufacturing, comparability, and release strategies, reinforcing the need for tightly coordinated RA–QA–TechOps interfaces.

- Strategic use of SPC and EU-based incentives: The RA function can play an important role in ensuring early cross-functional alignment for project strategies considering the eligibility for SPC extensions and other incentives.

Quality Assurance (QA)

The acceleration and simplification of clinical trial authorization processes will place increased pressure on the robustness and maturity of sponsors' Quality Management Systems (QMS).

Key implications include:

- Earlier QA involvement in development: Faster clinical timelines and the introduction of regulatory sandboxes will require QA to be embedded earlier in protocol design, IMP strategy, and vendor selection to ensure GxP compliance is immediately addressed.

- Greater reliance on core dossiers: The introduction of a single core IMP dossier assessed by one Member State increases the importance of dossier consistency, lifecycle management, and change control across multiple trials and jurisdictions.

- Enhanced oversight of innovative trial designs: Atypical trials (e.g. decentralized, adaptive, AI-supported) will require QA frameworks capable of assessing novel risks related to data integrity, patient safety, and technology validation.

- ATMP-specific quality challenges: Removal of extended ATMP assessment timelines will require sponsors to demonstrate a high level of oversight on manufacturing, testing, comparability, and release strategies earlier in development.

Supply Chain & Technical Operations

The Biotech Act creates clear incentives to anchor manufacturing activities within the EU, particularly through the proposed SPC extension requirements.

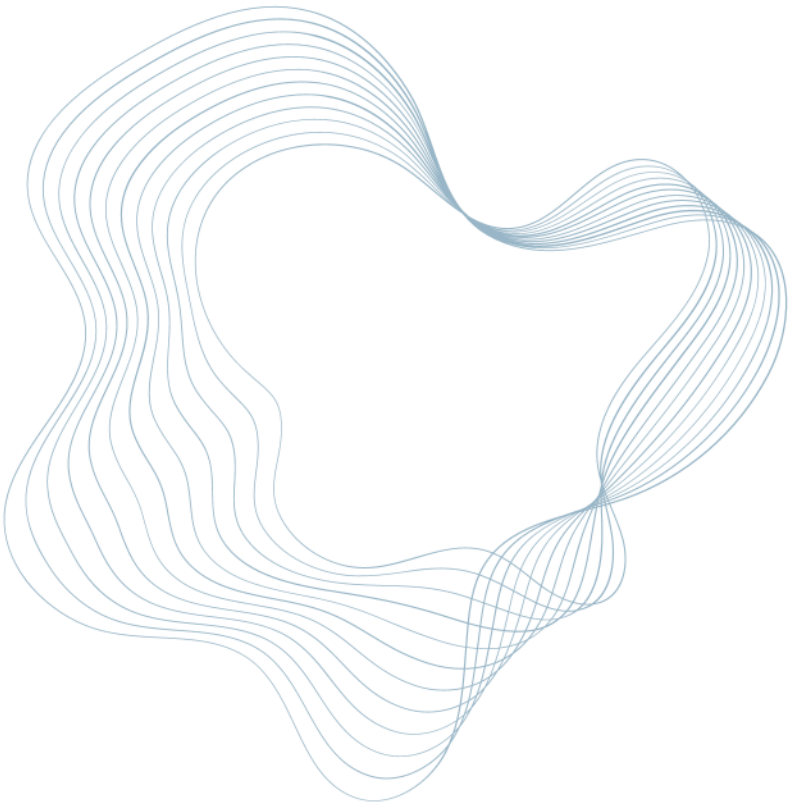
Expected impacts include:

- Strategic EU manufacturing footprint: The requirement that at least one manufacturing step (excluding packaging and QC testing) be performed in the EU will influence CDMO selection, make-or-buy decisions, and technology transfer strategies.

- Increased complexity of multi-country clinical supply chains: Faster multinational trial approvals and parallel substantial amendments will increase the need for agile supply planning, labelling strategies, and depot models.

- Supply chain risk management: Shortened regulatory timelines reduce buffers for resolving quality deviations, batch failures, or logistics disruptions, increasing reliance on robust risk assessments and contingency planning on IMP management.

- Earlier definition of supply chain control strategies: Sponsors will need to define manufacturing and testing requirements, comparability strategies, and release models earlier to support both clinical development and future commercial scalability.



Launch Readiness and Commercialization

By incentivizing EU-based development, manufacturing, and clinical activity, the Biotech Act indirectly accelerates the transition from late-stage development to commercialization.

Key considerations include:

- Earlier commercial mindset: Biotechs leveraging accelerated clinical pathways and SPC extensions will need to advance launch readiness activities earlier, including Target Operating Model (TOM) design, enhancement of the Quality Management System for Commercialization and proactive regulatory alignment. Regulatory requirements are Dossier related but considerations on Distribution Licenses must be explored.

- Alignment between clinical and commercial quality systems: The transition from clinical to commercial phases will require careful management of QMS scalability, data continuity, and product lifecycle documentation.

- Serialization, packaging, and market-specific requirements: While excluded from SPC manufacturing criteria, downstream activities such as packaging, labeling, serialization and distribution will remain critical for EU market access and must be integrated into launch planning.

Territory Expansion and EU Market Strategy

The Biotech Act strengthens the attractiveness of the EU as a unified development and launch territory but also raises expectations regarding regulatory and operational readiness.

Implications include:

- Increased use of multinational clinical strategies as a foundation for market access: Early engagement with multiple Member States during development may facilitate smoother future pricing, reimbursement, and market entry discussions.

- Greater regulatory convergence, but persistent local complexity: While reliance mechanisms reduce duplication, national requirements for clinical operations, importation, distribution and quality oversight will remain and should be anticipated.

- Need for scalable operating models: Virtual and emerging biotech companies will need operating models that can transition from early clinical trials to multi-country commercial operations without rework.

3 Reactions & Conclusions

Reactions on the Act

Industry reactions are mostly positive about the proposed Act. The European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomes the Biotech Act's measures to improve clinical research efficiency thereby making innovation in Europe easier. However, EFPIA criticises the absence of centralisation in the MDR revision and warns that limiting the SPC-extension incentive to only certain products could unintentionally exclude key biotech innovations and distort investment priorities. They also argue that tying IP protection to "manufactured in the EU" criteria does not reflect real-world innovation and risks undermining Europe's attractiveness for R&D. (https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-and-vaccines-europe-see-biotech-act-and-revision-of-the-mdrivdr-as-a-positive-signal-for-european-innovation/)

Conclusions for biotech sponsors

Overall, the Biotech Act shifts the industry beyond a purely research-driven model toward an integrated development, manufacturing, and commercialization strategy anchored in the EU.

For biotech sponsors and service providers, this means:

- Disciplined investment in regulatory, quality and supply chain capabilities early in development,
- Structured vendor oversight and strategic partnerships,
- Regulatory foresight and operational agility

In this context, regulatory, quality and supply chain excellence become not only compliance enablers but strategic and competitive differentiators for biotech companies seeking to fully leverage the opportunities created by the European Biotech Act.

Authors

Josefin Jönsson MSc.
Expert RA & CMC
Arex Advisor

Tim Foetisch BSc.
Managing Partner
Supply Chain Operations

Contact

Arex Advisor
contact@arexadvisor
arexadvisor.com

Supply Chain Operations
info@supplychainoperations.ch
supplychainoperations.ch