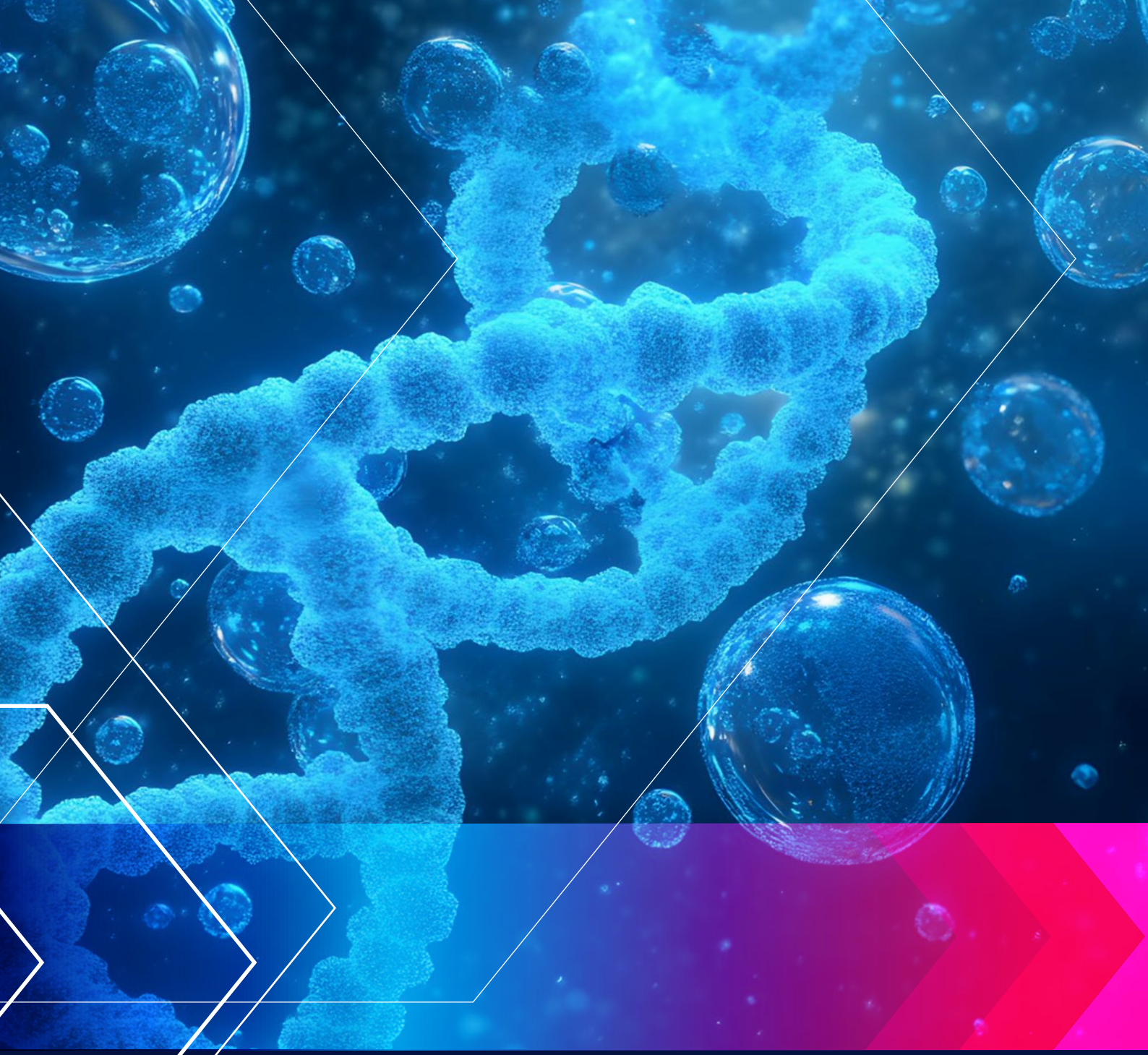

A report by EIT Health, April 2026

Skills, scale and science: Uniting European Innovation Ecosystems through the Biotech Act

THINK TANK

eit Health

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Foreward

Europe stands at a critical moment for health biotechnology. With policymakers increasingly recognising biotechnology as a strategic sector for economic competitiveness, resilience and technological sovereignty, the forthcoming European Biotech Act has the potential to be a powerful catalyst for progress, both now and in the decades ahead.

Europe's relative decline in biotechnology compared with the United States and China has been widely discussed, particularly as those ecosystems continue to expand at pace. The experts who contributed to this report agreed that significant work is required if Europe is to compete globally and fully realise the potential of its biotech sector.

Despite the recent decline, Europe still benefits from a substantial biotech base. Across European Member States there are clear examples of excellence and success. Several regions have created cycles of capital, talent and entrepreneurship, where successful biotech companies cultivate the next generation of innovators. Argenx, now Europe's most valuable biotech company, emerged from exactly such an ecosystem in Belgium. At the same time, countries such as Poland, Spain and Hungary have rapidly expanded their clinical trial infrastructure, while Europe's researchers continue to lead the world in discovery science.

The experts who contributed to this report expressed a consistent message: Europe does not need to create a new ecosystem. What it needs is stronger connections between the biotech ecosystems that are already in place. With stronger coordination, clearer pathways from discovery to scale and sustained investment in skills and leadership, Europe has the potential to become a genuine Single Market for health biotechnology and a global leader in end-to-end innovation.

Throughout our discussions, one theme came up repeatedly – the importance of the intersection between research, business and education in driving biotech innovation. At EIT Health, the power of this 'knowledge triangle', sits at the heart of our mission. By connecting innovators, policymakers, industry, healthcare providers and investors, we work to turn Europe's scientific excellence into real health and economic impact.

This report shows how EIT Health can strengthen biotech research as a cornerstone of Europe's innovation landscape.

Thelma Matuk
Interim CEO and Transition Director

www.eithealth.eu
EIT Health is a pioneering community of world-leading health innovators backed by the European Union. We collaborate across borders to connect and enable the brightest minds from business, research, education and healthcare delivery, creating a productive environment in which innovation can flourish.

Together, we address the biggest health challenges Europe faces.

Acknowledgements

We thank the 15 experts across the health biotechnology industry in Europe who participated in the working groups and whose insights shaped the key findings and analysis in this report. Their engagement reflects a shared belief in Europe's potential, and a determination to ensure that biotechnology developed in Europe delivers lasting value.

Oversight and coordination of the working group series and development of this report was ensured by the team at EIT Health, including Anna Wurm, Public Affairs and Stakeholder Relations Manager; Claire Nassiet, Head of the Innovation Adoption & Healthcare Transformation; Christina Hertel, Head of Asset Management and Montse Delgado, Head of Entrepreneurship & Venture Builder.
This report was produced for the EIT Health Think Tank by Syneos Health and funded by EIT Health.

Disclaimer: This report solely represents the views of the experts involved in the **EIT Health** working group series. The insights and solutions included in the report stem from three working group discussions organised in Brussels in early December 2025. On 16th December 2025, Part One of the Biotech Act was published by the European Commission. Therefore, certain content in this report may appear outdated in relation with the text in the Act. The **EIT Health** Think Tank report is not intended to align with the text in Part One of the Biotech Act, as it aims to reflect in an accurate and objective way the insights and information collected through the Think Tank process.

Executive summary

In December 2025, the European Commission unveiled the first part of the European Biotech Act centred on health-related measures. Its publication comes at a time when biotechnology is increasingly central to Europe's health, economic and strategic priorities. Although the sector contributes €38.1 billion to the European Union's (EU) Gross Domestic Product (GDP), it has experienced a relative decline compared to the US and China over the last decade.[1] Europe risks falling behind as global competitors take advantage of technological disruption to claim leadership in new fields of advanced therapies and AI-enabled discovery.

Europe must capitalise on its strengths, such as its world-class scientific research, trusted healthcare systems, established data registries in certain countries and strong ethical and regulatory frameworks. These features create a robust foundation for biotechnology, but Europe has specific weaknesses when it comes to translating scientific discoveries into innovative medicines and devices.

Solving this will involve addressing fragmentation across Member States. Connecting clinical trials, data governance, funding and skills development across the continent is a priority. This report explores the benefit of Europe becoming a single 'shop-front' to attract investors and retain home-grown biotech innovation.

EIT Health developed this report to support the implementation of the Biotech Act. It reflects insights from a series of working groups attended by cross-sector experts on the themes of innovation, competitiveness and futureproofing. In summary, the participants identified the following key findings Europe can implement to improve the biotech ecosystem:

- **Use new coordination bodies to amplify existing strengths**, and tackle challenges in funding and skills
- **Enable faster and more predictable multi-country clinical trial set-up** by harmonising processes and reducing unnecessary administrative burden across Member States
- **Improve alignment across regulatory, market access and reimbursement pathways** to create clearer and more predictable routes to market for biotechnology products
- **Offer tools, incentives and implementation support to translate the principles of the European Health Data Space** into practice. High standards of data protection are compatible with competitiveness
- **Build on Europe's existing research strengths by better connecting biotechnology clusters** into a coordinated network of excellence
- **Adopt longer-term, clear, milestone-based EU funding approaches** aligned with biotechnology development timelines and designed to catalyse private investment
- **Strengthen Europe's biotechnology workforce** by linking existing skills and leadership programmes and enabling greater cross-border talent mobility

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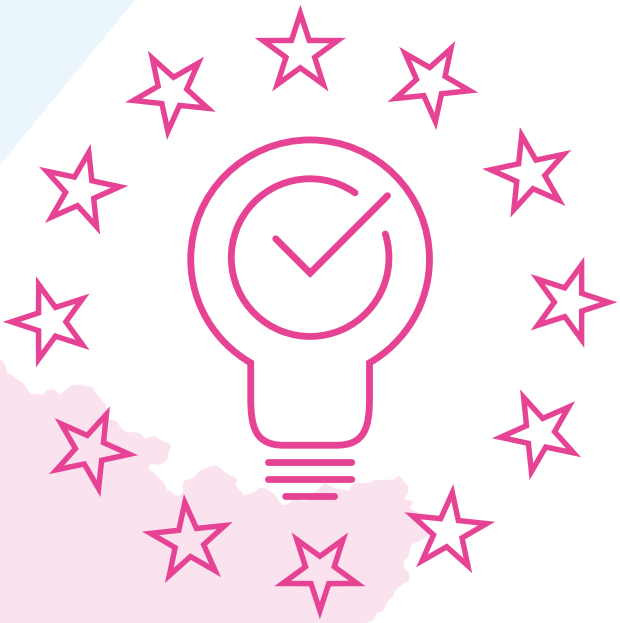
1. Introduction

1.1 Europe's moment of strategic risk and opportunity



Biotechnology, referred to as 'biotech' throughout this report, is central to Europe's economy, security and societal wellbeing. Across health, agriculture, industry, food and the environment, biotech affects us all daily. The biotech industry is a major driver of economic growth and prosperity, contributing €38.1 billion to the European Union's (EU) Gross Domestic Product (GDP) and growing almost twice as fast as the overall economy in 2022.[1] This contributed 913,160 direct, indirect and induced jobs to the EU labour market, 75% of which were attributable to the healthcare sector.[1]

However, what these figures do not show is the relative weakening of Europe's biotech sector compared to other regions around the world. Over the last decade, the EU's share of global commercial clinical trials has significantly declined, from 22% in 2013 to 12% in 2023, despite remaining a leader in medical research.[2] Even more directly, the flow of venture capital investment in European health biotech remains significantly below global competitors, with approximately €25 billion invested in the EU compared to €219 billion in the US between 2015 and June 2025.[3] These trends signal a weakening of Europe's position in biotechnology, limiting future economic growth and its strategic autonomy in producing medical products.

European policymakers are acutely aware of the situation. Key policy analysis has underlined this risk with seminal publications like the Draghi and Letta reports.[4,5] They warn that Europe risks 'falling behind' global competitors in key technologies, including biotechnology, due to fragmented markets, slow regulatory adaptation and limited access to private capital. The Draghi report specifically highlights Europe's relative decline in biologics and advanced therapy medicinal products (ATMPs) as concerning for the future health of European pharmaceuticals.

The Biotech Act is a key piece of legislation to address these concerns and improve the conditions for Europe to retain and grow its biotech industries within a Single Market.[3]

> ***In five years, Europe's ambition should be to have a healthy growing biotech industry where funding capital is much more available than today... where companies aren't just early-stage biotechs, but have products on the market... where Europe has a practical, safe, regulatory framework, access to data that supports discovery and development, manufacturing capacity in Europe, and clinical trials prosecuted with speed.***
>
> ***Dr Martin Hornshaw***
> *Senior Director,*
> *Scientific Collaborations, Thermo Fisher Scientific*

1.2 The EU Biotech Act – an opportunity to unite an ecosystem

The EU Biotech Act is a flagship measure under the European Commission's Strategy for European Life Sciences (July 2025), aimed at strengthening Europe's biotech industry.[6] The Biotech Act is separated into two legislative proposals. The first, focused on health-related biotech, was published on 16th December 2025.[3] The second part of the Act, expected in Q3 2026, will include the wider biotech ecosystem, such as industrial and agricultural biotech, and environmental applications.

The Biotech Act forms part of a coordinated effort to make Europe more competitive and bring investment, businesses, manufacturing and jobs to the region. Other initiatives relevant to health biotech include the European Health Data Space,[7] the European Skills Agenda,[8] the EU Start-up and Scale-up Strategy,[9] the General Pharmaceutical Legislation[10] and the Critical Medicines Act.[11] The Biotech Act will need to complement and strengthen existing and future policies across related sectors to achieve its overarching ambition.

The objectives set out in the Biotech Act proposal[3]

The Biotech Act intends to create 'an enabling environment to make it easier to bring biotech products from the laboratory to the factory and then onto the market'.

The Biotech Act proposal sets out seven objectives:

1. **Strengthen the EU biotech sector, and R&D and production capacity**
2. **Improve access to funding and capital** for biotech companies
3. **Expand EU manufacturing capability and expertise in biosimilars**
4. **Accelerate the adoption of AI in biotech and health technology manufacturing**
5. **Create an innovation-enabling legislative framework**
6. **Strengthen safeguards against misuse of biotech** and reinforce EU biodefence capabilities
7. **Ensure effective implementation across all pillars** by aligning EU legislation

2 Methodology

Objectives

This EIT Health Think Tank report convenes experts across Europe's biotech ecosystem and explores their view of the Biotech Act. To support the Act to reach its full potential, this report identifies current challenges and opportunities as seen by working group participants and examines whether the Act provides adequate solutions and where it can go further.

The key objectives of this report are to:

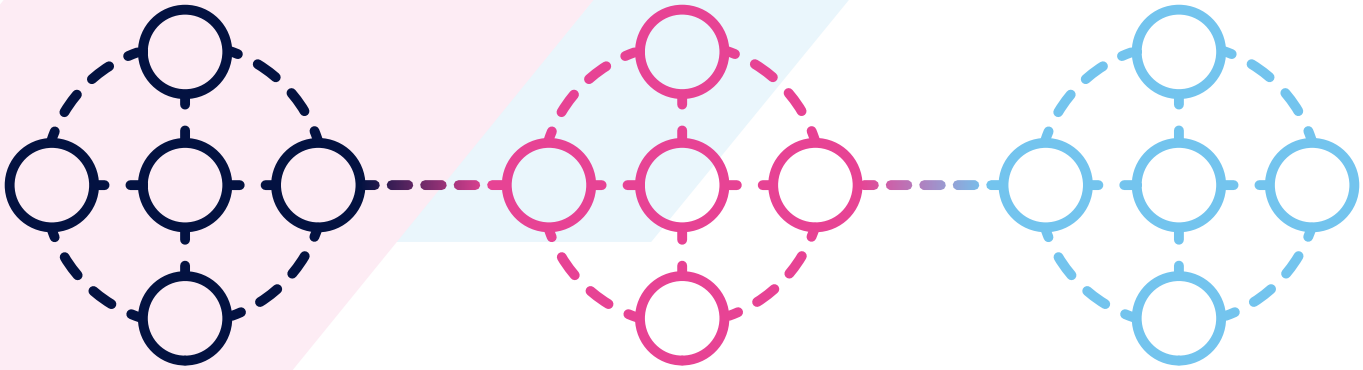
- **Map the biotech innovation pathway,** by identifying key policy, funding and ecosystem challenges across the full innovation lifecycle
- **Identify key opportunities to strengthen Europe's biotech sector,** aligned with the Biotech Act and related EU policy
- **Synthesise insights and best practices** from across Europe's biotech ecosystem to inform the Biotech Act and broader decision-making

The EIT Health Think Tank working groups

In December 2025, EIT Health brought together expert stakeholders in Brussels to explore how Europe can strengthen the biotech innovation pathway from ideation to market launch, generating actionable insights across the following three policy pillars:

1. **Innovation:** To understand how to accelerate research translation and market uptake through collaboration, digitalisation and data-driven discovery
2. **Competitiveness:** To delve into how Europe can remain the most attractive region for biotech innovation and investment, and the impact of go-to-market regulations and market fragmentation on this goal
3. **Futureproofing/Sustainability:** To explore how to embed responsible, ethical and long-term value creation in the biotech ecosystem, and reskilling and retaining talent in Europe

Participants represented a range of stakeholder groups (e.g. start-ups, small and medium-sized enterprises (SMEs) or researchers) to ensure that those most affected by the topic were included. They were joined by complementary actors (investors, policymakers, regulators, academia) to co-create policy-relevant findings presented in this report.



3 What Europe does well: Strategic strengths to build on

The strengths in this section highlight where working group participants believe Europe already has much to offer and provide a strong foundation upon which to build a globally competitive health biotech sector.

3.1 Europe's scientific excellence and world-leading institutions

Across working groups, there was agreement that Europe's greatest scientific strength lies in its preclinical research base. Universities, like the Karolinska Institute, major research hospitals and European centres of excellence continue to draw global talent and produce world-leading discoveries. These institutions produce an impressive volume of breakthrough research and highly skilled researchers, highlighted by Europe's share of the top 10% of publications across biology, biomedical and clinical medicine in 2022 compared to the US and China. Of the top 10% of publications, 21% were from Europe, and 22% and 24% from the US and China respectively.[3]

This research is supported by long-standing public investment at both EU and national levels. Working group participants agreed basic research has been strengthened by EU policy, specifically successive Framework Programmes for Research and Technological Development over the last few decades, which have driven excellence through cross-border collaboration.[12] This scientific strength provides a strong foundation for building a robust European biotech sector.

In Europe, universities, translational institutes, specialised training centres and teaching hospitals play a critical role in upskilling the workforce to help meet the demand of new technologies and innovation – which they are often at the forefront of deploying. They also enable clinical trials by embedding research and generating real-world data.

3.2 Trusted public health systems as a foundation for clinical research and real-world evidence

Participants stated Europe's publicly funded healthcare systems are not just a social good, but a competitive asset. For clinical research, universal health coverage and strong research ethics support the recruitment of diverse and representative patient populations and long-term follow-up. These features, when coupled with effective national clinical trial agencies, have led to progress in boosting clinical trial initiations in several Member States (e.g., Spain, France and Poland).[13,14] The challenge is that this relative success at the national level has not been sufficient to prevent Europe from falling behind China and the US overall.[2]

Member States have also demonstrated Europe's ability to generate real-world evidence at the national level. Public health systems collect extensive health data, including electronic health records and disease registries.[15] In some cases, these assets already support outcomes research, post-market monitoring and real-world evidence generation, particularly in oncology and rare diseases. The European Health Data Space should further enhance this, enabling researchers to pool anonymised health data across borders, building larger representative datasets.

> ***There is strength and trust in European public healthcare systems, and we need to harness this to support innovation through public–private partnerships.***
>
> ***Dr Silvia Lopez Vidal***
> *Technical Director, Commissioner's Office for the Strategic Project on Cutting-edge Health, Spanish Ministry of Science, Innovation and Universities*

3.3 Ethical and regulatory leadership

Working group participants repeatedly noted that ethical and regulatory leadership is a desirable strength for Europe, even if there is a need to ensure it is proportionate, risk-based and streamlined across all Member States. Europe's approach to ethics, safety and governance provides a stable and trusted framework for innovation.[16] Regulations in areas such as data protection, AI oversight and product safety shape international standards and reinforce public confidence in new technologies.

Ethical and regulatory leadership also has benefits for innovation adoption. Some participants did point out regulatory hurdles are hard to overcome, but this difficulty was also a reflection of Europe's high ethical and moral standards which engenders trust. When patients, clinicians and payers trust the systems governing innovation, adoption becomes more predictable and durable. This trust is particularly important as biotech increasingly intersects with digital automation and advanced data analytics.

4 Challenges and opportunities to build a world-leading biotech ecosystem in Europe

The challenges and opportunities set out in this section highlight where working group participants believe targeted action can most effectively improve system performance and translate scientific strength into health and economic impact.

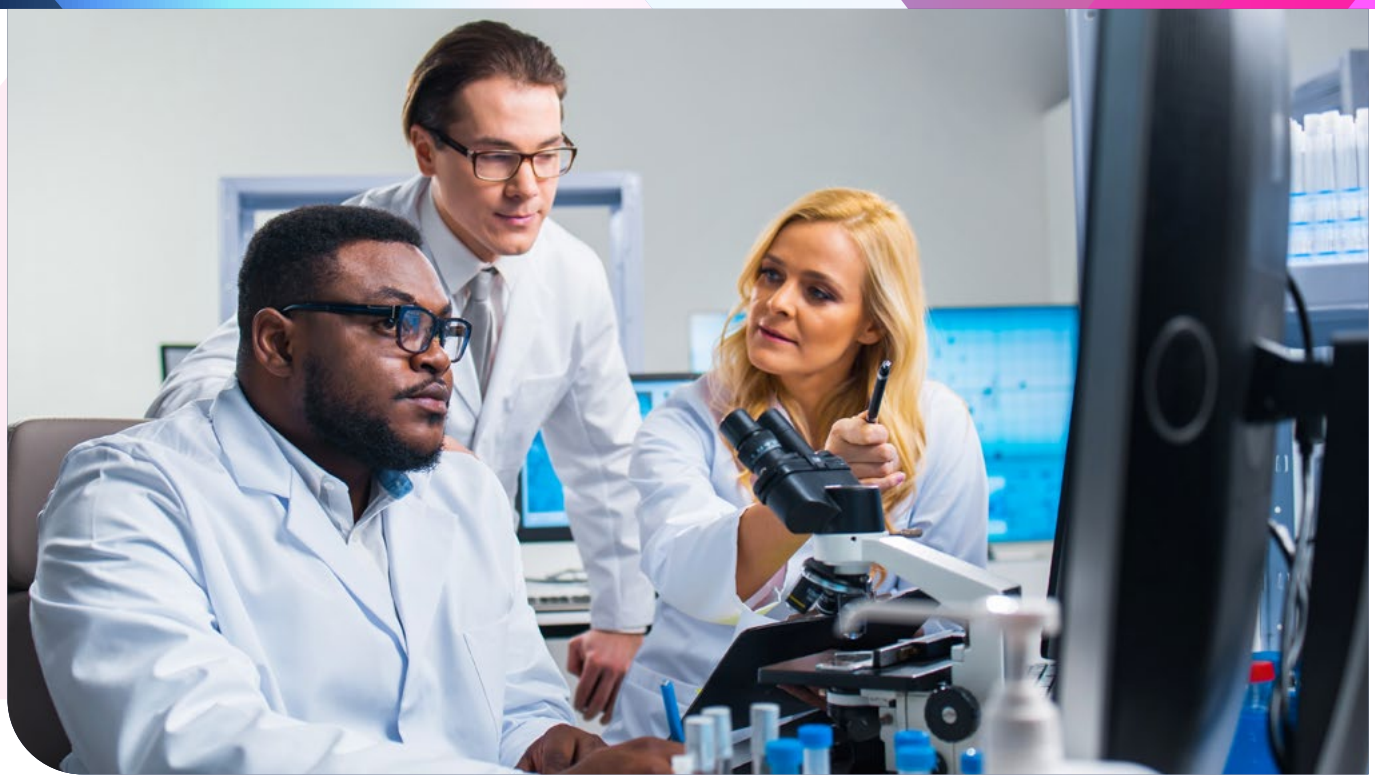
4.1 Strategic alignment and reducing fragmentation across Europe

Challenge

Fragmentation across Europe was identified by working group participants as the key issue underpinning the range of individual challenges across regulation, funding, skills and innovation.

Many Member States have their own biotech strategies and initiatives[17] and a range of organisations operate at EU, national and regional levels. This breadth reflects the strategic importance of biotech, but it also creates a complex landscape of organisations with distinct mandates and processes.

For example, the diversity of research and innovation funding streams across Member States and EU programmes was viewed as broadly positive, but insufficient to constitute a coherent, pan-European offer tailored to the specific needs of the biotech sector. Participants highlighted the complexity and fragmentation of funding mechanisms at both EU and national levels often make it difficult to identify and access the most appropriate sources of support. There is no single point of contact within the European biotech ecosystem and participants felt companies are frequently passed between multiple government departments, agencies and initiatives.



Opportunity

Some participants suggested a new authority, initiative or organisation responsible for EU biotech should be established given its strategic importance, but their roles and responsibilities should be clearly identifiable. To this end, one option could be an online platform to provide biotech innovators with a clear and user-friendly overview of each body in the ecosystem. Other participants were concerned with duplication or overlap already and were reluctant to see a brand-new EU executive agency or similar organisation. All participants did agree there was a critical need for forums or coordination mechanisms where existing strengths, expertise and capabilities can be connected and amplified.

> ***What Europe needs is a shop front for the rest of the world... The US has one, Asia has one... Europe does not yet have a comparable, visible proposition because activity remains fragmented across Member States.***
>
> ***Dr Fiona Killard***
> *CSO & Director of Research & Innovation, National Institute for Bioprocessing Research & Training (NIBRT)*

Alignment with the Biotech Act proposal

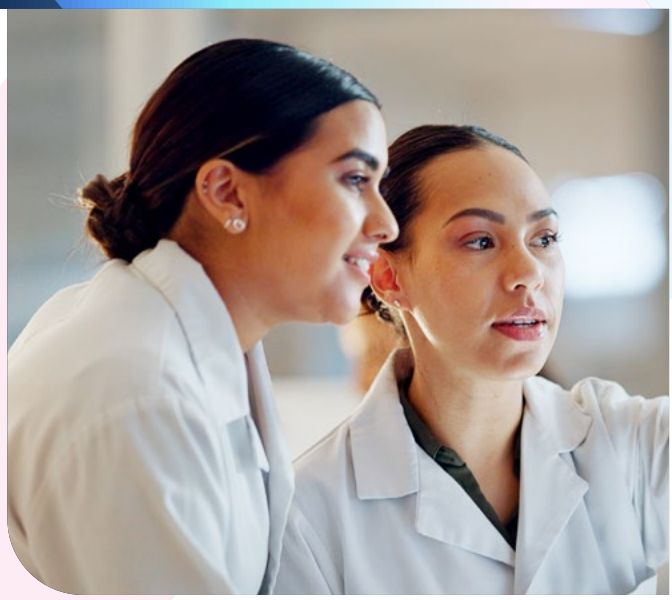
The Biotech Act proposal explicitly recognises the coordination challenges highlighted in the working groups and introduces new governance structures intended to improve alignment, visibility and navigation across Europe's biotech ecosystem. In particular, the proposal establishes:

- **The EU Health Biotechnology Support Network:** A network of national and regional contact points known as antennas intended to help companies navigate regulatory procedures, identify funding opportunities, support scale-up and connect with relevant partners.
- **The European Health Biotechnology Steering Group:** A forum for strategic coordination between the Commission and Member States. Its role is to facilitate information exchange, support consistent implementation of regulation and oversee strategic mapping.

Based on participants' comments, these bodies could be a good first step to support efforts to tackle challenges with funding and skills gaps raised later in this report.

Key findings

- **Use new coordination bodies to amplify existing strengths and tackle challenges in funding and skills**



4.2 Streamlining policy and processes in Europe to increase competitiveness

Participants highlighted that disjointed regulatory processes and pathways create delays and duplication, which in turn lead to higher costs and longer timelines for biotech companies. This influences companies' decisions about where to locate clinical trials, invest resources and scale up activity. Real coordination across these policies would reduce friction and promote investor confidence within the region.

> ***If you invest, you want your money back as quickly as possible. In Europe, we need to speed up our regulatory processes to attract investment.***
>
> ***Dr Knut Steffensen***
> *Director, Karolinska ATMP Centre*

4.2.1 Reducing delays and uncertainty in clinical trials

Challenge

Europe's clinical trial approval processes remain slow, complex and resource-intensive, creating a significant barrier to efficient biotech development. Despite efforts to improve the system through the Clinical Trials Regulation and the Clinical Trials Information System, trial activation still requires layered European and national approvals, ethics and administrative processes.[18,19] This results in long and unpredictable timelines, even with multiple strong individual trial ecosystems in Member States. For biotechnology, uncertainty and delays increase costs and weaken the overall value proposition of conducting trials in Europe.

These challenges are felt most acutely by smaller biotech companies and can be decisive in determining whether products go into trials in Europe, or shift to other regions with faster, larger-scale and less friction. Participants contrasted the complex picture in Europe with the comparative advantages of the US and China. In the US, there is a single regulator which is more open to discussing trial design with companies before formal submission. The US Food and Drug Administration (FDA) also provide tailored support to companies through multiple discussions and feedback. In China, the size of the patient population available at each trial site streamlines set-up.

Opportunity

Participants, from outside and inside the biotech industry, noted that harmonisation of clinical trial regulation is feasible and would have positive impact on Europe's biotech standing. Greater alignment of standards and reduced duplication in authorisation procedures between different Member States would allow Europe to operate more effectively as a single clinical research area, matching China and the US without compromising on Europe's own unique strengths.

Experience from high-performing Member States shows that faster trial initiation is achievable without compromising patient safety or ethical oversight, provided processes are streamlined and consistently applied.

Adequate regulatory resourcing and expertise are essential to sustain these improvements. Emerging technologies, including Advanced Therapy Medicinal Products (ATMPs), increasingly challenge traditional regulatory approaches and require specialised scientific and operational expertise. This could involve strengthening the capacity of the European Medicines Agency (EMA) and national authorities, but also supporting EU-level expert pools and structured scientific dialogue with developers.

> ***A Single Market for clinical trials, both academic and sponsor-led, is within reach.***
> ***If we harmonise ethics and authorisation processes, Europe can unlock real, tangible growth in its innovation ecosystem.***
>
> ***Loredana Simulescu***
> *Executive Director, Biomedical Alliance*

Alignment with the Biotech Act proposal

Part One of the Biotech Act proposal responds directly to several priorities raised across the working groups, particularly the need to reduce time-to-market, lower administrative friction in clinical trials, streamline regulatory pathways and accelerate trial approval through the following measures:

- **Shorter clinical trial authorisation timelines,** reducing approvals to 47 days where no additional information is required and to 76 days where further information is requested, with substantial modifications cut to 33 or 47 days respectively
- **Removal of the additional 50-day assessment period for ATMP trials,** addressing a long-standing bottleneck for advanced therapies
- **Introduction of regulatory sandboxes** for innovative or atypical trials where existing regulatory pathways are not fit for purpose
- **Development of a single authorisation pathway for combined medicinal product and medical device or in Vitro Diagnostic device trials,** easing a major barrier for complex and innovative products, subject to alignment with forthcoming reforms to medical device legislation

Working group participants suggested the Act's impact will depend on whether measures are implemented consistently across Member States and supported by sufficient regulatory coordination and capacity. Positively, progress has started with the launch of the FAST-EU (Facilitating and Accelerating Strategic Clinical Trials) pilot initiative in January 2026, implemented within the framework of the Clinical Trials Regulation.[22]

Key findings

- Enable faster and more predictable multi-country clinical trial set-up by harmonising processes and reducing unnecessary administrative burden across Member States

Case study 1: Integrated clinical research networks (Spain)[20]

Spain operates a nationally coordinated model for clinical research that integrates hospitals, universities and accredited research institutes within a public healthcare system. The ISCIII Clinical Research Support Platform, SCReN (Spanish Clinical Research Network) is currently distributed across 14 Autonomous Communities in charge of providing support to hospitals throughout the Spanish National Health System and coordinated from the Hospital Universitario la Paz. The platform provides scientific-technical support in the management of national and international projects.

Hospitals within the network routinely collaborate rather than compete for studies, allowing sponsors to activate multiple sites simultaneously and recruit patients more predictably. This structure also supports consistency in data quality and trial execution, which is particularly important for complex and multi-site studies.

The Spanish Agency for Medicines and Health Products has become Europe's leading authority for trial authorisations, supported by a hospital network of almost 1,000 centres involved in research over the past five years. This model has helped Spain be the most active country for clinical research in the EU, with 962 clinical trials authorised in 2025 alone, following more than a decade of sustained growth. Oncology accounts for nearly 40% of the national total, placing Spanish hospitals at the forefront of cancer research in Europe.[21]

4.2.2 Creating accessible and predictable routes to market

Challenge

While regulatory evaluation is undertaken at EU level, health technology assessment (HTA) and reimbursement decisions are a national level competency. Therefore, some variation in reimbursement is inevitable, and occasionally desirable, given the different views and preferences of Member States. However, participants noted unpredictable market access processes can be as detrimental as delays in product development. They highlighted that divergent HTA methodologies and variable approaches to reimbursement mean that strong clinical outcomes do not reliably translate into predictable market access. This limits Europe's capacity to function as a primary launch market rather than a secondary destination for new biotech products. For medical devices using biotechnology, the situation is even more complicated, with additional bottlenecks across regulatory and HTA processes.[23]

Opportunity

Participants frequently raised the importance of regulatory, market access and reimbursement processes which determine whether Europe is a good place to commercialise biotech products. While strategies at the Member State level (see case study 2) can address issues at the local level, wider EU-level action could have a greater impact through influencing the whole European market.

The introduction of Joint Clinical Assessments provides a near-term mechanism to increase consistency in clinical evaluation across the EU, while preserving national competence over pricing and reimbursement.[24]

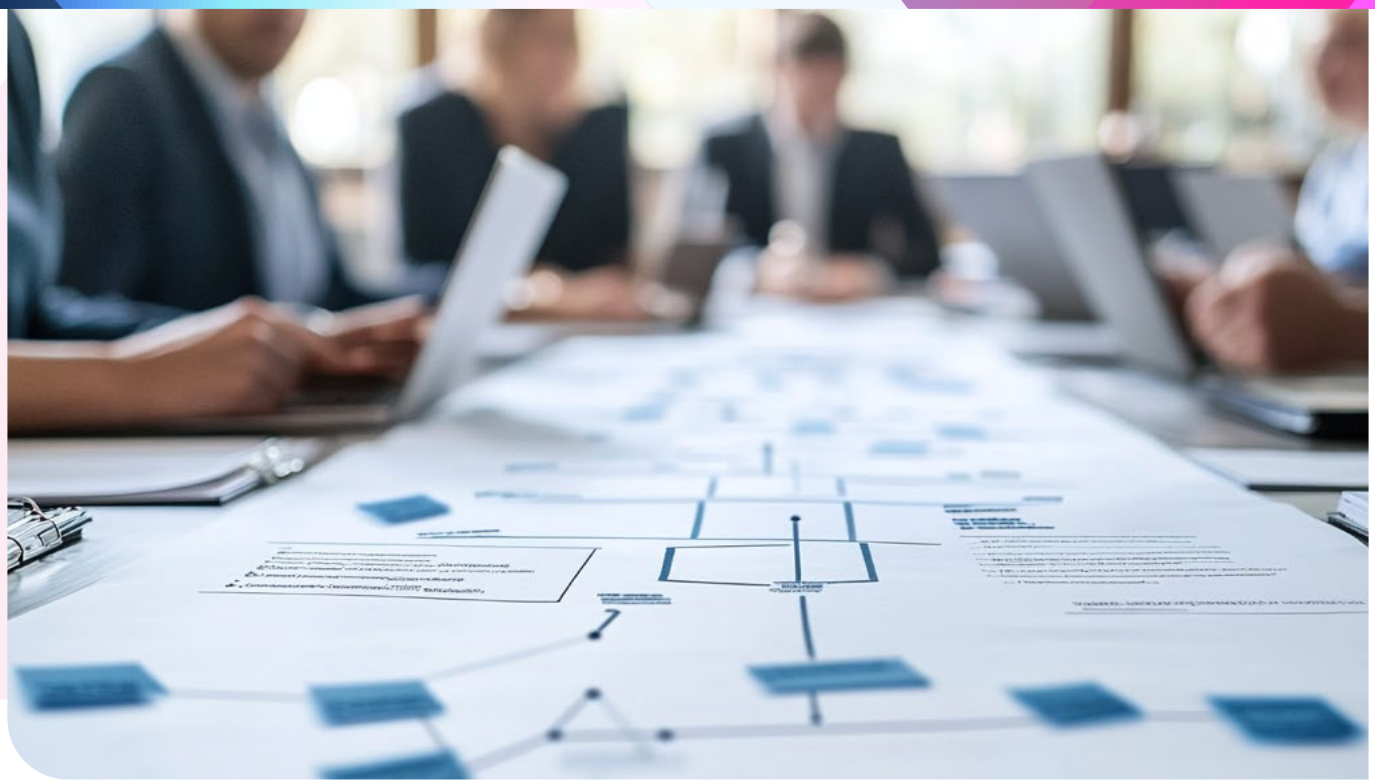
Participants believed that clearer and more predictable routes to market would improve investor confidence and have upstream effects on research and development. Over time, this would ensure that more of the economic and health benefits of biotech innovation are realised within the Union.

Case study 2: Coordinated approach to gene- and cell-based therapies (Germany)[25]

Germany has developed a nationally coordinated strategy for gene- and cell-based therapies that aligns translational research centres, clinical sites, regulators and industrial partners. This approach recognises that advanced therapies cross traditional boundaries between research, clinical care, manufacturing and regulation.

By concentrating regulatory expertise and coordinating development pathways, the German model reduces uncertainty for developers working on complex modalities. Clearer expectations around regulatory assessment, clinical development and manufacturing requirements support more predictable progression through the development lifecycle.

This coordination also supports skills development and leadership capacity by creating centres of excellence where clinical, regulatory and manufacturing expertise co-locate. For investors and developers, the model provides a clearer signal that the system can support the full lifecycle of advanced therapies within a single national framework.



Alignment with the Biotech Act proposal

While the Biotech Act does not directly address routes to market or reimbursement decision-making, it does seek to strengthen Europe's attractiveness for biotech innovation through targeted financial incentives. For example, the Act proposes a 12-month extension to the patent protection provided by supplementary protection certificates (SPCs) for biotechnology-derived medicinal products and advanced therapy medicinal products, subject to meeting four criteria:

- **Novelty,** requiring a new active substance that is distinct from any medicinal product previously authorised in the EU
- **Differentiated clinical value,** demonstrated through a distinct mechanism of action with safety and efficacy at least equivalent to existing treatments for the same condition
- **Cross-border clinical development,** with supporting clinical trials conducted in more than two Member States
- **EU-based manufacturing,** with at least one substantive manufacturing step carried out within the EU, excluding packaging, testing and certification

The working group discussions did not identify SPC extensions specifically, but they consistently highlighted challenges around reimbursement, predictability of returns and the need to strengthen Europe's overall value proposition for investment in health biotechnology.

Key findings

- **Improve alignment across regulatory, market access and reimbursement pathways to create clearer and more predictable routes to market for biotechnology products**

4.2.3 Harnessing data and digital infrastructure

Challenge

Europe holds some of the world's richest health datasets due to population and disease registries, with ethnicity and additional characteristics captured within these. However, participants underscored data availability varies considerably across Member States and access to this data remains inconsistent and difficult to operationalise in practice. Divergent consent models and governance arrangements limit access to anonymised data for secondary use in research. For example, patients may have given consent for their data to be used for certain research uses, but if follow-on research uses for that data are envisaged later, it can be difficult to re-consent this data for the new use. As well as the legal risk, participants note institutions which hold large amounts of data lack a positive incentive to share or pool with others. These barriers are particularly constraining for AI-enabled research and registry-based studies, which depend on large datasets.

Opportunity

Clear and consistent pathways for responsible data use would unlock significant value across the biotech innovation lifecycle. For example, aligning data governance practices across Member States would support effective implementation of the European Health Data Space and reduce duplication in evidence generation, allowing Europe's rich data assets to be used more efficiently at scale (see case study 3).[26]

Participants emphasised Europe's strong principles on data privacy and patient protection can be upheld while still enabling more seamless and flexible research. This could be achieved through greater harmonisation of General Data Protection Regulation (GDPR) implementation, alongside clearer guidance for data holders, which would provide the confidence needed to enable responsible secondary use of data without compromising privacy.

Beyond access, wider acceptance of real-world data, registries and innovative study designs is critical. Participants stressed the importance of improving patient communication and consent processes, ensuring individuals understand how contributing data to registries or secondary research supports public health and innovation.

> ***Europe has exceptional university hospitals and research institutions, robust ethical and governance frameworks, and diverse patient populations that provide ideal conditions for high-quality data generation. With strong public funding supporting early research, addressing inflexibilities, delays, and scale-up challenges would allow Europe to fully unlock this potential.***
>
> ***Dr Agnès Arbat***
> *CEO & Co-Founder, Oxolife*

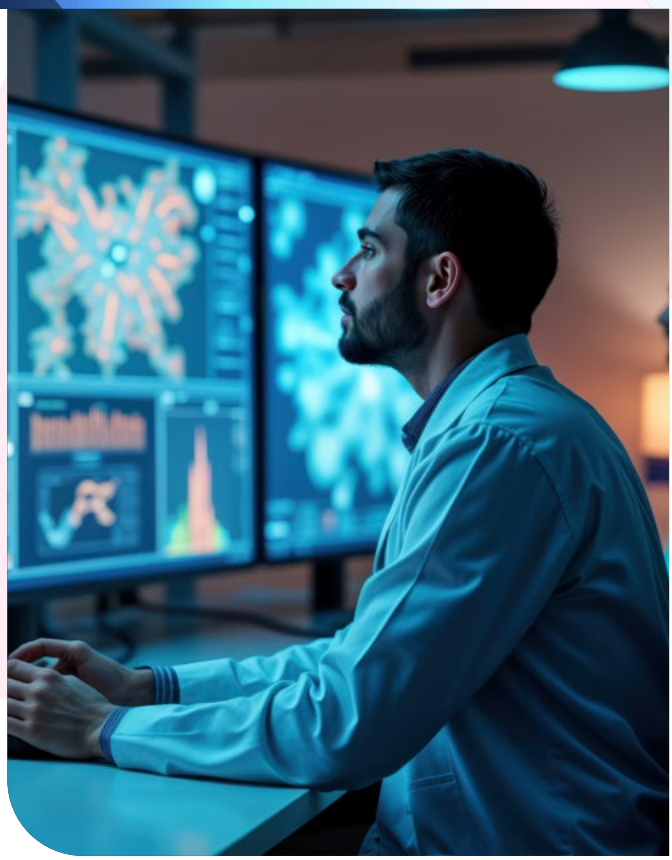
Case study 3: Nordic population registries as a foundation for real-world evidence[27,28]

Several Nordic countries operate population-wide health registries that link clinical data, prescription records, outcomes and socioeconomic information through national identifiers. These registries support longitudinal follow-up across entire populations and enable robust real-world evidence generation.

The Nordic model demonstrates the feasibility of using routinely collected health data for decision-grade evidence, including post-authorisation safety studies, outcomes tracking and health economic analysis. The representativeness of these datasets supports evaluation across diverse patient groups to reduce bias and improve the ability to generalise.

While academic access to these registries is well established, industry access remains more constrained and subject to national rules. Nonetheless, the technical and organisational foundations already exist to support broader use for regulatory and HTA-relevant evidence.

This example reinforces the argument that Europe's advantage lies in its data volume, quality and population coverage. It provides a concrete reference point for how the European Health Data Space could enable consistent, cross-border use of real-world data to support regulation and value assessment.



Key findings

- **Offer tools, incentives and implementation support to translate the principles of the European Health Data Space into practice. High standards of data protection are compatible with competitiveness**

4.3 Strengthening Europe's pathway from discovery to scale

Despite strong research performance, many European biotech innovations stall at the transition from discovery to development. Working group participants consistently highlighted gaps in Europe's ability to translate scientific discovery into feasible biotech products that can move into clinical trials, commercialise and scale, particularly those developed by start-ups or spin-outs.

> ***Europe's real strength seems to be early discovery... but the translational focus isn't as strong.***
>
> ***Jack O'Meara***
> *Chief Executive Officer, Aerska*

4.3.1 The importance of innovation ecosystems

Challenge

The Draghi report argues a key reason Europe struggles to convert science into innovation is that researchers are less well integrated into innovation clusters, dense networks of universities, start-ups, large companies and venture capitalists that drive successful commercialisation in high-tech sectors.[4] Similarly, the Heitor report highlights that successful innovation ecosystems depend on "concentrated pools of highly skilled talent" created through proximity between research, industry and education.[29]

The importance of clusters and networks was a recurring theme across the working groups. Participants emphasised that Europe does not lack clusters; on the contrary, it has many geographically concentrated ecosystems where research institutions, companies and investors co-exist. However, participants noted many projects still stall because early research is not sufficiently shaped by translational, regulatory, manufacturing and commercial considerations.

Alignment with the Biotech Act proposal

The Biotech Act proposal aligns with working group priorities on data and digital infrastructure by recognising data and AI as essential enablers of future health biotechnology. The proposal focuses on improving data quality, regulatory clarity and safe experimentation, while maintaining Europe's high standards for data protection and patient trust.

Rather than changing core data protection rules, the Act introduces enabling tools to address fragmentation and uncertainty in data access and use. Key measures include:

- **Trusted testing environments** for AI-enabled biotechnology, supporting experimentation and validation under controlled conditions
- **Biotechnology data quality accelerators** to improve access to high-quality, well-curated datasets for research and AI development
- **EMA guidance on the use of AI** across the medicinal product lifecycle, to promote consistency and reduce regulatory uncertainty
- **EU-level regulatory sandboxes and a cross-framework regulatory status repository,** to support novel technologies and improve transparency across authorities
- **A foresight panel for emerging health innovation,** to enable anticipatory and adaptive regulation

Opportunity

Working group participants identified a clear opportunity to strengthen Europe's biotech ecosystem by focusing EU-level action on connecting and enabling collaboration across existing clusters. Stronger connections between these clusters would allow Europe to operate as a network of excellence, further amplifying its potential.

While research universities are only one part of a successful cluster, participants emphasised they are foundational institutions to build upon. Several examples were cited where universities partnered with specialised training centres, venture-builders, co-creation models, incubators or translational institutes that provided capabilities beyond traditional academic strengths (see case study 4). They stressed the value of early-stage and consistent integration of different types of expertise, as scientific and research skills alone are not sufficient for innovation success. However, this cross-sector collaboration is not necessarily straightforward, or easy to do across borders. For example, intellectual property claims can be difficult to resolve particularly if large complex organisations like universities are involved.

Case study 4: Accelerating Research Commercialisation (ARC) programme (Ireland)[30]

Ireland's ARC programme supports the progression of academic research towards commercial development by bringing researchers together to critique projects, assess commercial readiness and identify translational pathways. The programme operates across institutions, encouraging shared evaluation.

ARC focuses on improving the quality of translational projects before company formation or significant investment. By subjecting research to structured peer challenge and early commercial scrutiny, the programme helps teams identify weaknesses in development strategy, regulatory planning or market positioning at an early stage.

ARC does not require all researchers to become entrepreneurs, but it creates clearer pathways for those projects with genuine translational potential.

Alignment with the Biotech Act proposal

The Biotech Act proposal acknowledges the need to strengthen translation from research to development, primarily through the recognition of health biotech strategic projects and high-impact strategic projects. These provisions aim to concentrate support on initiatives that connect research, development, manufacturing and scale, aligning with working group calls to integrate successful projects with European neighbours.

Key findings

- **Build on Europe's existing research strengths by better connecting biotechnology clusters into a coordinated network of excellence**

> ***Europe does not lack science, talent, or ambition in life sciences; what we probably need is a coherent translational system that moves discoveries to patients at speed, aligns public and private capital, and allows European companies to scale without leaving Europe.***
>
> ***Dr Montserrat Daban***
> *President, Council of European BioRegions*

4.3.2 Funding and capital mobilisation: Matching finance to biotechnology development cycles

Challenge

In European innovation policy, there is an established consensus that acute funding gaps in the innovation pipeline (or 'valleys of death') when a start-up is getting a product ready for commercial launch, or immediately after commercialisation while a start-up is scaling-up. Participants noted the pathway to scale-up for a medicine-focused biotech, and therefore the funding needs, differ considerably from other forms of innovation, even in healthcare.

Some participants identified that the funding 'gap' was most acute when preparing an asset for first-in-human trials. According to them, there is a relatively small number of specialised investors ready to invest at this point, and large pharmaceutical companies are generally reluctant to engage this early. Additionally, this preclinical stage is when public funding starts to fall away (see figure 1). A policy focus on supporting biotech companies working towards first-in-human trials would help attract clinical trials, particularly as the location of Phase 1 trials is correlated with the location of Phase 2 and 3 trials and initial commercial launches.

While participants highlighted the need for a large, unified capital market or late-stage buyers who could facilitate an 'exit' for initial investors, the reality is that the lack of funding manifests itself far earlier in a biotech's lifecycle. Too few European investors have the capital depth or specialist expertise to support biotech companies through clinical development. This is exacerbated by the fact institutional investors in Europe are less likely to allocate funds to venture funds that invest in higher-risk sectors like biotech. As a result, biotech companies often depend on US investment. This dynamic can lead to early relocation closer to investors and prevents Europe from building serial entrepreneurs, reinvested capital and experience loops that underpin mature biotech ecosystems.

Participants indicated that current EU funding instruments were ill-suited to the biotech sector. Biotech innovation requires continuity, longer time horizons and milestone-based progression. Instead, funding is often perceived as short-term, fragmented and process-driven, with limited ability to automatically unlock additional support when projects succeed. Given that it takes years to go from proof-of-concept, preclinical and completing first-in-human clinical trials, funding that only lasts for one year does not allow innovators to reach a value inflection point that can enable them to raise enough capital required to fund the next stage of their development.

> ***Europe's funding systems are highly fragmented it is difficult to know where to start when accessing funding, limiting Europe's ability to innovate.***
>
> ***Judith Kalina***
> *Director, Government Affairs (Europe), Cytiva*

Biotechs need private sector funding to advance to pre-clinical development and Phase 1 trials

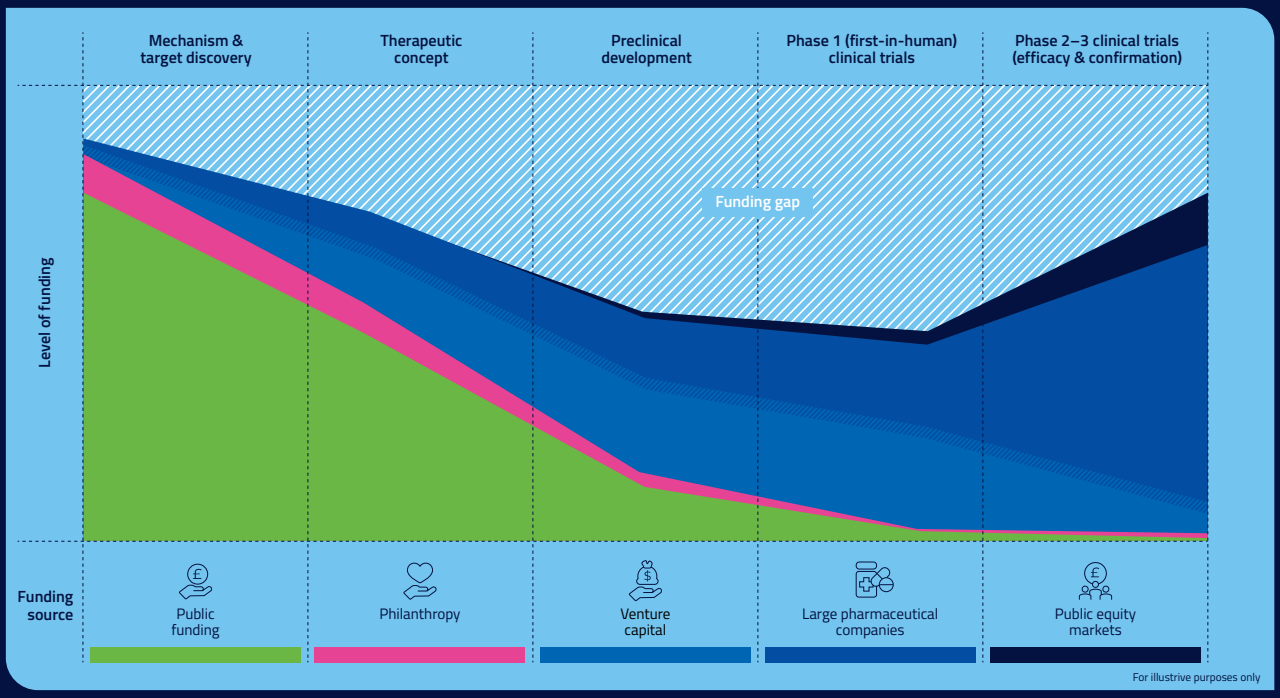


Figure 1: This diagram, which should be used for illustrative purposes only, helps visualise how public funding dominates early biotech research, but a critical private-sector funding gap emerges during preclinical development and early clinical trials stages where venture capital is particularly important.

> ***Biotech assets can have multiple funders before reaching the market. Because of this, investor confidence is a must at every stage of the innovation journey.***
>
> ***Sarah Parkinson***
> *Research Leader, RAND Europe*

Opportunity

To overcome the challenges of public funding models that do not reflect the realities of biotech product development, participants suggested creating a biotech-specific funding mechanism. This would operate over longer time horizons and release funding against clearly defined scientific and regulatory milestones. Participants raised that this mechanism could be overseen or supported by a form of biotech council.

At the same time, participants emphasised that public funding alone will not solve this challenge. Several noted that public funding does not carry the same value signal as private investment; the decision of a specialised private investor to engage often shapes wider market confidence. From this perspective, participants suggested the most effective role for public funding is to reduce early risk and catalyse private capital, rather than substitute for it. This also means that wider European reforms which might lead to more private funds going into venture capital are particularly important. Reforms under the Capital Markets Union, the Savings and Investment Union and changes to prudential rules around pensions could all serve to do this.

> ***We need to shift our mindset to see health-related biotech and innovation as a strategic investment and not as a cost or drain on resources.***
>
> ***Cara Rogers***
> *Policy Advisor, BPI German Pharmaceutical Industry Association*

Alignment with the Biotech Act proposal

The Biotech Act proposal includes several funding-related measures that align with parts of the opportunities identified in the working groups, particularly around scale-up and investment coordination:

- **EU health biotech investment pilot,** delivered with the European Investment Bank Group, combining equity and venture-style debt to mobilise private capital for later-stage development and scale-up
- **EU biotech late-stage capital booster pilot,** aimed at crowding in private investment for high-impact strategic projects approaching commercialisation or manufacturing scale
- **Recognition of health biotech strategic projects** and high-impact strategic projects, prioritising selected initiatives for access to existing EU and Member State funding and regulatory facilitation
- **EU-level regulatory sandboxes and a cross-framework regulatory status repository,** to support novel technologies and improve transparency across authorities
- **Improved coordination and visibility of existing funding instruments,** including links to future EU budget tools, such as the European Competitiveness Fund, rather than creating new standalone grant programmes

Taken together, these measures align with stakeholder calls to strengthen scale-up financing specific to biotech and complement other new schemes, such as the late-stage Scaleup Europe. Given participants' comments about the role of a biotech council in overseeing this funding but concern about duplication, the proposed Steering Committee and Network in the Act could ensure these funding reforms have the desired impact

Key findings

- **Adopt longer-term, clear, milestone-based EU funding approaches aligned with biotechnology development timelines and designed to catalyse private investment**

4.3.3 Skills and leadership: Building depth across the value chain

Challenge

Europe has strong scientific training, but biotech increasingly requires a much broader skillset well before commercial launch. The working groups highlighted that as technologies become more complex, companies need translational, manufacturing, regulatory and commercial expertise earlier in development, not as late-stage add-ons. Translational research demands a different mindset and skillset from basic research, while complex products such as biologics and advanced therapies require early consideration of bioprocessing, quality systems and scale-up feasibility during clinical development. For a few participants, such skills issues were seen as the most critical and important issues in the sector.

Participants emphasised that many scientists and clinicians are not equipped or do not wish to take on senior business leadership roles in biotech companies. Simultaneously, Europe lacks a sufficient amount of experienced biotech leaders able to support founders through translational development, fundraising and scale-up. This creates a persistent gap in operational leadership, particularly when projects need to articulate credible development, manufacturing and market strategies to attract investment. Similarly, the technical and operational skills needed for manufacturing are distinct from research skills and are also needed in the research phases of development.

Universities play a central role in Europe's biotech ecosystem but struggle to support the full breadth of skills required for translation and scale. At the same time, the current volume of training programmes is simply not sufficient to generate the talent pipeline required. In parallel, many universities find it challenging to continuously adapt their curricula and delivery models to keep pace with fast moving technological, regulatory and industrial developments. Traditional academic training does not always align with industrial or business needs, and universities face challenges competing with industry on salaries for highly skilled technical staff. Many graduates enter the workforce with strong theoretical foundations but limited exposure to applied, on-the-job learning, making the transition to industrial and translational roles more challenging. New models of training and education are emerging, including industry-linked programmes and hybrid academic–industrial pathways.

> ***Most CEOs in biotech start-ups come from academia – they're confident with the science but often do not have as much experience with the entrepreneurial aspects. Here, we need additional early educational formats and dedicated proactive support structures for scientists to help them realise their full potential.***
>
> ***Dr Christian Gallus***
> *Project Lead, Germany's National Strategy for Gene and Cell-Based Therapies, Berlin Institute of Health at Charité*

Opportunity

Participants suggested that an integrated and modular approach to skills and leadership development would strengthen capability across the entire biotech value chain. Aligning training initiatives more closely with industrial needs, particularly in manufacturing-intensive areas such as advanced therapies, would improve readiness for scale. This would ensure process design, quality systems and supply chain considerations are addressed early and in parallel with clinical development.

The working groups highlighted the value of adaptive training models that already exist across Europe, including industry-aligned technical training centres, translational commercialisation programmes and digital modular courses (see case study 5). Training programmes can be embedded within university courses and accessed by industry directly. Building on and linking these programmes at the European level would support the development of a more coherent and mobile biotech workforce. The examples discussed included public-private partnerships – such as France's Immerscio.bio and Ireland's National Institute for Bioprocessing Research & Training (NIBRT) – reinforcing the strategy behind the EU's Pact for Skills and the need to bring different types of organisations together to tackle skills gaps.

Working groups pointed out the need for a deeper pool of experienced executives – or even 'serial chief executives' – who can support researchers and guide companies through growth, because scientific knowledge alone does not drive innovation to be taken-up in practice. Taking a dual approach, such as providing biotech companies access to the most senior and experienced individuals possible while also enabling scientists to develop their own understanding of commercialisation, would be the most effective way to build depth of expertise in the European ecosystem.

Finally, participants felt that true talent mobility across Europe had not been established. While participants noted this is a challenge from a skills perspective, it also limits the interchange and connection between Europe's biotech innovation clusters. Greater mobility could support all aspects of skills, from more mobile technical and scientific talent to providing access to a larger, shared pool of serial biotech entrepreneurs and executives. Integrating existing national skills initiatives may support this, but participants felt it was worth exploring how talent mobility could be made a reality in Europe through pilots.

One idea raised by participants was to create platforms that connect multidisciplinary groups – including clinicians, biotech companies, investors and regulators – within a single therapy area to support talent mobility, the exchange of ideas and collaboration.

> ***Universities provide strong academic foundations, but the training we need today must be jointly designed by academia and industry. Rather than redeveloping existing initiatives, the key is to build combined educational programmes that align academic excellence with real industrial needs.***
>
> ***Dr Sandrine Lemoine***
> *CEO, Immerscio.bio*

Case study 5: National Institute for Bioprocessing Research & Training Facility (NIBRT) (Ireland)[31]

NIBRT provides industry-aligned training in bioprocessing and GMP-compliant manufacturing using industrial-scale equipment configured to reflect real production environments. The institute operates in close collaboration with industry and higher education, supporting workforce readiness across the biopharmaceutical sector.

NIBRT's model addresses a critical bottleneck in biotech scale-up: the availability of technically skilled staff who understand manufacturing processes, quality systems and regulatory requirements from an early stage. By exposing trainees to real-world manufacturing conditions, the programme shortens the transition from academic training to industrial deployment.

Alignment with the Biotech Act proposal

The Biotech Act proposal recognises skills, talent and workforce development as critical enablers of Europe's biotech competitiveness, particularly in light of increasing technological complexity and scale-up demands. The proposal includes measures intended to strengthen skills pipelines and align education, training and industrial needs across the biotech value chain.

Key relevant measures include:

- **Support for skills and talent development within health biotech strategic projects,** including training, upskilling and reskilling activities linked to biomanufacturing, digital technologies, AI and translational research
- **Promotion of public–private partnerships** between universities, vocational training providers, research institutes and industry, with a focus on aligning training provision more closely with real-world biotech needs
- **Recognition of centres of excellence and development accelerators** that integrate research, development, manufacturing, regulatory expertise and workforce training, particularly in areas such as advanced therapies
- **Measures to attract and retain talent in the EU,** including support for hands-on, work-based training and cross-sector collaboration to address skills shortages across the biotech value chain

These provisions align with working group calls to build on existing national and regional programmes. However, given the importance the participants placed on skills and experience, there may be value in going further.

Key findings

- **Strengthen Europe's biotechnology workforce by linking existing skills and leadership programmes and enabling greater cross-border talent mobility**

> ***We need more experienced entrepreneurs who bring their experience, track-record, knowledge, and mentorship in the development of new startups.***
>
> ***Dr Angelika Vlachou***
> *Partner, High-Tech Gründerfonds (HTGF)*

5 Key findings

Working group participants were asked to envisage what the future of the European biotech ecosystem should aim to emulate. This is the culmination of their ideas, expertise and experiences.

A future where European science can be translated into products developed and trialled in the region, supported by adequate funding and investment, and ultimately approved and launched in Europe.

A European biotech ecosystem open to international collaboration, investment and partnerships, while ensuring value creation, capability building and long-term growth positively impact Europe.

The key findings from the working group discussions, summarised below, are concrete steps that can be taken to achieve this vision.

- Use new coordination bodies to amplify existing strengths, and tackle challenges in funding and skills
- Enable faster and more predictable multi-country clinical trial set-up by harmonising processes and reducing unnecessary administrative burden across Member States
- Improved alignment across regulatory, market access and reimbursement pathways to create clearer and more predictable routes to market for biotech products
- Offer tools, incentives and implementation support to translate the principles of the European Health Data Space into practice; high standards of data protection are compatible with competitiveness
- Build on Europe's existing research strengths by better connecting biotechnology clusters into a coordinated network of excellence
- Adopt longer-term, clear, milestone-based EU funding approaches aligned with biotech development timelines and designed to catalyse private investment
- Strengthen Europe's biotechnology workforce by linking existing skills and leadership programmes and enabling greater cross-border talent mobility

6 Conclusion

Europe has the scientific strength, institutional excellence and regulatory foundations needed to support a competitive biotech sector. What continues to limit performance is not capability, but fragmentation across policy, funding, regulation, skills and markets. The working groups consistently agreed that without stronger coordination and practical support, Europe will struggle to translate excellence in research into scalable products, sustainable companies and long-term impact.

The EU Biotech Act provides an important opportunity to address these challenges. Its value will lie not only in the tools it introduces, but in how effectively they are implemented and aligned across Member States. Clearer direction, stronger ownership and a focus on execution will determine whether the Act delivers structural change or incremental improvement. If implemented with a system-level perspective, the Biotech Act could help connect Europe's strengths into a coherent ecosystem: one that supports innovation from discovery through to scale, retains talent and investment and positions Europe as a credible global leader in health biotech.

How can EIT Health help?

EIT Health's unique contribution to help address Europe's systemic challenges in innovation and competitiveness is clear in four areas: **collaboration, funding, scale** and **skills**.

Collaboration: Health innovation relies on many different actors, including researchers, healthcare providers, large corporates and start-ups. EIT Health builds multi-sector networks across Europe that are essential for healthcare innovation.

Funding: Private funding is essential for innovation at scale. By preparing innovators for private investment as early as possible, we set up Europe's innovators to compete on a global stage.

Scale: Start-ups that succeed in multiple countries from the outset are well–placed to scale across Europe and globally. EIT Health unites a truly European network, giving innovators access to partners and expertise across the continent.

Skills: There is no single profile of an innovator, or single skill which will unlock innovation. EIT Health helps to provide flexible, bespoke and co-designed training to equip innovators, clinicians and entrepreneurs with the range of skills they need for success.

Annex

Participants	Role	Roundtable
Cara Rogers	Policy Advisor, BPI German Pharmaceutical Industry Association	Competitiveness
Ferenc Marofka	Policy Officer, DG GROW	Competitiveness
Dr Knut Steffensen	Director, Karolinska ATMP Centre	Competitiveness
Sarah Parkinson	Research Leader, RAND Europe	Competitiveness
Judith Kalina	Director, Government Affairs (Europe), Cytiva	Competitiveness
Dr Silvia Lopez Vidal	Technical Director, Commissioner's Office for the Strategic Project on Cutting-edge Health, Spanish Ministry of Science, Innovation and Universities	Competitiveness
Dr Angelika Vlachou	Partner, High-Tech Gründerfonds (HTGF)	Innovation
Jack O'Meara	Chief Executive Officer, Aerska	Innovation
Loredana Simulescu	Executive Director, Biomedical Alliance	Innovation
Dr Martin Hornshaw	Senior Director, Scientific Collaborations, Thermo Fisher Scientific	Innovation
Dr Montserrat Daban	President, Council of European BioRegions	Innovation
Dr Agnès Arbat	CEO & Co-Founder, Oxolife	Future-proofing
Dr Christian Gallus	Project Lead, Germany's National Strategy for Gene and Cell-Based Therapies, Berlin Institute of Health at Charité	Future-proofing
Dr Fiona Killard	CSO & Director of Research & Innovation, National Institute for Bioprocessing Research & Training (NIBRT)	Future-proofing
Dr Sandrine Lemoine	CEO, Immerscio.bio	Future-proofing

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