

Building Europe's biotechnology future: from discovery to delivery

A close-up, high-angle photograph of laboratory glassware, including a test tube and several beakers, all containing a clear liquid. The image is overlaid with a semi-transparent red filter. The glassware is arranged in a way that creates a sense of depth and scientific precision.

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Executive summary

Biotechnology is one of Europe's most dynamic sectors, employing nearly a million people and contributing €40bn annually to Europe's economy. At the same time, the continent's share of global clinical trials has halved in the past 15 years, venture capital investment remains well below levels in the United States and promising companies routinely scale up outside Europe.

The European Biotech Act aims to address these challenges by cutting clinical trial timelines, incentivising manufacturing in Europe and mobilising investment across the biotech lifecycle. With negotiations intensifying in the European Parliament and the Council, Friends of Europe convened senior decision-makers from EU institutions, member states, industry, investors and patient organisations to debate what it will take to turn Europe's scientific strengths into a lasting competitive advantage. The discussion centred on a broader strategic question: can Europe build a distinctive biotech model that converts excellence in science, data and healthcare into investment, scale and patient access – and is the proposed Biotech Act ambitious enough to support it?

The discussion showed broad support for the Biotech Act alongside a clear message that its ambition must be maintained through the legislative process. Europe should not simply seek to mirror the US or China; it needs a European model capable of connecting scientific excellence, capital, clinical development, manufacturing and health systems. The Act's impact will therefore depend on bold implementation, adequate administrative and financial capacity, and its ability to deliver tangible benefits across member states and for patients.

Key recommendations

- Preserve and strengthen the ambition of the Biotech Act through the legislative process, backed by sufficient EU and national capacity to ensure its effective implementation.
- Set a European objective for faster clinical trial start-up times and strengthen the role of the reporting member state to reduce duplication and inconsistency across national systems.
- Unlock more long-term European capital for biotech, including pension and institutional investment, and align public funding commitments with the sector's actual development timelines.
- Design strategic project designations and investment facilities to build capability where they are weakest, rather than simply reinforcing established life sciences clusters.
- Link additional intellectual-property incentives to measurable European public value, including manufacturing commitments, clinical trial activity and improved patient access.

- Strengthen European cooperation on health technology assessment and reimbursement pathways so that authorisation translates more quickly into access for patients across member states.
- Connect the Biotech Act to the broader European Health Union agenda, ensuring biotechnology investment supports health systems, patient access and cross-border care

A strong foundation, but growing competitive pressure

Europe's biotechnology sector has genuine strengths to build on: world-class research, strong universities and hospitals, high-quality health data and a large Single Market. Participants stressed that these give Europe a solid foundation for a more competitive life sciences sector. The central challenge is to turn that scientific strength into investment, clinical development, manufacturing and commercial growth in Europe.

Participants broadly agreed that Europe should not try to copy its competitors. Instead, the more useful question is what capabilities Europe needs across manufacturing, infrastructure, data, talent and regulatory capacity, and whether it is building them at sufficient speed and scale.

Three priorities emerged most clearly: making clinical trials faster and more predictable; creating the conditions to attract and retain long-term investment; and ensuring the benefits of a stronger biotech sector are spread more widely across Europe.

Clinical trials as the critical bottleneck

The strongest consensus concerned clinical trials. Industry analysis presented during the discussion, drawing on more than 300 trials conducted in Europe since the EU Clinical Trials Regulation came into force showed that Europe takes roughly twice as long as the US to move from protocol approval to first patient enrolled. The gap is not only regulatory: it spans the entire operational pathway, from contracting and ethics assessment to site activation.

For shorter studies, participants warned that trials may already be well underway or even concluding elsewhere by the time European approvals are granted, leaving Europe out of the process altogether. For many oncology and rare disease patients, for whom a clinical trial is often the only remaining treatment option, Europe's shrinking share of global research has direct consequences.

The Biotech Act's proposals to reduce approval timelines, standardise templates and strengthen the role of a reporting member state were broadly welcomed. Several participants argued, however, that the proposed targets remain insufficiently ambitious. As one participant put it: "We believe Europe will remain approximately two months slower than the US. It would be really good if Europe can consider that we should not think in terms of being less slow. Europe needs to increase the speed, be faster."

Ethics committees emerged as a contested area. Some participants supported greater harmonisation to reduce duplication and inconsistency across member states. Others noted that ethical oversight is rooted in national legal traditions and patient trust, and that regulation alone cannot resolve these differences. There was, however, broad agreement that the two goals are not incompatible and that harmonisation should be pursued where it reduces unnecessary duplication.

Voices from the patient community argued that what patients want, above all, is access to treatment options, and that a European-level ethics framework need not undermine trust if it is designed with patients at the centre.

The economics of innovation: who pays, and what do they receive in return?

Regulatory reform will have limited effect if European companies cannot find the capital they need to grow. Participants argued that the challenge is not simply the availability of money, but where and how European savings are invested. Pension funds tend to avoid life sciences investment due to political risk aversion, and retail investors tend to save rather than invest in capital markets. The result is that early-stage public funding runs out before private capital steps in, and that gap is where European companies can be pushed to seek scale elsewhere.

Supplementary protection certificates (SPCs) prompted the sharpest divisions of the evening. Industry and investors argued for broader, impact-based extensions that reward therapeutic value and include small molecules, which account for 60% of European drug approvals but are entirely excluded from the current proposal. For member state representatives, however, SPC extensions are a direct cost to public payers. As one participant put it: "As a buyer, you are not paying for the health of a patient with money. You are paying for the health of a patient with the health of another patient. That is called opportunity cost." The question, therefore, is not whether industry or patients matter more, but whether incentives can be structured to generate a visible public return through manufacturing commitments, clinical trial activity and improved patient access.

Making it European: access, geography and the politics of ambition

Europe's life sciences sector is economically and strategically important for Europe, yet participants noted that its benefits remain concentrated in a relatively small number of countries and are insufficiently visible in many others. Clinical trials, manufacturing and centres of excellence are heavily skewed geographically. For member states without sizeable biotech clusters, some of the economic gains targeted by the Biotech Act may therefore seem relatively distant. Strategic project designations and investment facilities should be used not only to reinforce existing strengths but also to build credible capabilities in parts of Europe where they remain weak.

Participants stressed that biotechnology cannot be separated from the health systems it serves. Europe needs to think in terms of a European Health Union, connecting biobanks, registries, hospitals, research centres and manufacturing capacity across all 27 member states, with patients at the centre. Competitiveness and innovation are not ends in themselves: their value lies in their ability to improve health outcomes, widen access and strengthen health system resilience.

Delivery will depend as much on implementation capacity as on the final legislative text. Participants highlighted the need for clearer coordination between the European Commission, regulators, member states, research institutions, health systems, investors and industry. Faster procedures will only make a difference if the organisations responsible for applying them have the resources, skills and incentives to deliver consistently across Europe.

Participants also pointed to capabilities that Europe is not yet fully exploiting. The European Health Data Space could become a significant advantage for research if health data can be accessed safely and used effectively across borders. Artificial intelligence is already reshaping drug discovery and clinical trial design, and participants cautioned against risk aversion that could prevent European researchers and health systems from using tools that are transforming practice elsewhere.

Biotechnology's growing relevance to defence and biosecurity also broadens the case for strategic investment beyond health policy. NATO's Innovation Fund and DIANA accelerators are already investing in the sector, with a focus on battlefield medicine, novel therapeutics and biosecurity preparedness. Defence demand could serve as a stable anchor for early-stage biotech investment, generating capabilities that benefit civilian health as much as military preparedness.

From ambition to delivery

Europe's biotechnology challenge is therefore not simply regulatory. The real challenge is whether the EU can connect science, capital, clinical development, manufacturing, data and patient access into a functioning European ecosystem. The Biotech Act can provide an important catalyst, but its success will ultimately be measured by whether more discoveries made in Europe can also be developed, financed and manufactured here, and reach patients across the EU more quickly.

Friends of Europe

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