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Got it 'til it's gone?

The need for a European economic security strategy in biopharma

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Milena Richter[1]

Executive summary:

Europe's future as a biopharmaceutical hub depends on how decisively it responds to intensifying global competition. On the one hand, there is China, which has transformed from fast follower to innovation driver pursuing a path of global reach. On the other, there is the US, still the leader, using broad government power and leverage of its market size to reshore industry activity.

Europe retains an important footprint, real strengths in research excellence and biomanufacturing, but the competitive position of its biotech companies is at stake. The region is losing ground in clinical trials and R&D investment due to fragmented regulation and insufficient access to finance. Companies cannot bring their products to market as fast and as easily as in other regions. This is well documented in the 2024 Draghi Report and reiterated in the context of the European Biotech Act *Call for evidence for an impact assessment*. Without action, Europe risks an EV-style scenario.

This paper focuses on biopharmaceuticals, where competition over technological leadership, data, and manufacturing is most intense. Biotech is central to geopolitical competition and must be a priority for Europe's economic security strategy. China targets self-reliance in biotech, linking into its military-civil fusion strategy. The US frames biotech as a national security imperative.

Two scenarios emerge. Under "managed rivalry," current licensing trends between multinationals and Chinese biotechs continue with selective US controls while China expands its global reach through clinical trials and strengthens control over biopharma technology stacks, i.e. the integrated platforms, inputs and capabilities across discovery, manufacturing, and data in a broadening set of modalities. A scenario of "acceleration of chokepoints" will add tougher US outbound investment controls, stricter genomic data restrictions, and heightened licensing scrutiny, while China responds by prioritizing domestic IP and tightening export controls.

Either scenario exposes Europe to vulnerabilities across four chokepoints: capital flows redirecting toward China's innovation ecosystem and US reshoring; AI-enabled drug discovery datasets shifting competitive advantage while US restrictions complicate compliance; China enabling faster trials while Europe lags in implementation; specialized biotech supply chains creating exploitable dependencies.

Today's geopolitical uncertainty creates risks and opportunities. Europe's governments must act jointly to strengthen the region's attractiveness and resilience. Industry and governments must align on a competitive model built on Europe's foundations, balancing innovation incentives with (geo)political realities and public health priorities. Europe's competitiveness and its economic security in biopharma are two sides of the same coin and should advance through four priorities:

1. **Building strong EU-level risk assessment capacity**: Launch systematic public-private risk dialogue mapping dependencies and chokepoints (capital flows, trial locations, supply vulnerabilities etc.).
2. **Promoting Europe's innovation and strengthening its value chain position**: Form strategic partnerships for resilient supply chains. Create cross-border innovation hubs, leverage dual-use R&D, focus on EU strengths and areas of 'indispensability'.
3. **Enabling the single market**: Accelerate Clinical Trials Regulation implementation. Enable innovation-friendly procurement that rewards security and reliability, accelerate market access.
4. **Using economic security instruments judiciously**: All measures must be based on risk screening and implemented efficiently. Strengthen research security frameworks while maintaining openness to beneficial cooperation. Form biotech alliances with trusted partners.

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I. Towards an acceleration of biopharma rivalry

The acceleration of China and US' biotech and biopharma rivalry: strengthening national security, seeking technological dominance

Biotechnology has a significant economic impact across a broad range of human activity. It is increasingly central to geopolitical competition. As Mario Draghi observed, the era when geopolitical stability under US hegemony allowed the EU to largely separate economic policy from security considerations has ended. Henry Farrell and Abraham Newman's concept of "weaponized interdependence" (Farrell and Newman, 2019), where countries use chokepoints in value chains as leverage, has become a reality.

Biotech is the ability to engineer the fundamental building blocks of life. Advances in this field and its convergence with AI will profoundly impact societies' ability to address their most pressing challenges and has become a core technology for national economic security and competitiveness (Shinomiya & Tanaka, 2025). A key area is synthetic biology, which enables the design and construction of new biological parts and systems, or the re-design of existing ones. Synthetic biology takes a systems-level approach to reprogram entire pathways or networks. An example is CAR T-cell therapy, where a patient's T cells are engineered with an artificial receptor (CAR) to recognize and kill tumor cells.

AI and machine learning accelerate the understanding of complex biological systems. Advances in synthetic biology and AI enable increasingly comprehensive functional genomics experiments in silico. Advanced computational algorithms are enabling early detection of genetic disorders and AI-assisted screening is bringing greater accuracy in areas such as breast cancer detection. Quantum technology offers the potential to handle the huge complexity of molecular interactions, accelerating drug discovery and optimisation beyond the limits of today's supercomputing.

Biotech is a quintessential dual-use technology (NATO, 2025), defined as "Goods, software and technology which can be used for both civil and military applications" (European Union, 2021). Synthetic biology, genomics, and advanced gene-editing techniques all hold CBRN (Chemical, Biological, Radiological, and Nuclear threats) relevance. Military applications range from optimisation of medical supplies and medicines in combat to biosensors, DNA-based diagnostics, and the potential development of biological weapons. Synthetic biology is specifically highlighted by NATO as having a "disruptive, revolutionary impact within the next 20 years, in both civilian and military domains » (NATO, 2025). The European Parliament has similarly emphasized that "AI systems and quantum computing can also increase the risk of biological threats" and stressed that "the ethical use of AI, bioinformatics and synthetic biology is crucial for building trust."[2]

A recent analysis of industrial policy as a national security strategy in China, the US and Europe (Hauge et.al., 2025) highlights their distinct approaches: the US adopted an explicitly hawkish stance, deploying extensive controls and subsidies to maintain technological supremacy and counter China's rise. China has pursued technological self-sufficiency and a growing presence in international trade through long-term industrial planning while increasingly privileging security considerations over pure

[2] See European Parliament Report adopted 10 July 2025, on the Future of the EU biotechnology and biomanufacturing sector: leveraging research, boosting innovation and enhancing competitiveness, by Hildegard Bentele MEP: *" AI systems and quantum computing…can also increase the risk of biological threats…the ethical use of AI, bioinformatics and synthetic biology is crucial for building trust and for society at large to benefit from these technologies"* https://www.europarl.europa.eu/doceo/document/TA-10-2025-0165_EN.html

economic growth. The EU has charted a more restrained course, balancing autonomy with openness while strengthening its economic security apparatus. These distinct approaches are also reflected in the characteristics of policies for the biopharma/biotech sector in these three geographies.

China's long game in biotech leadership: doing R&D faster and cheaper

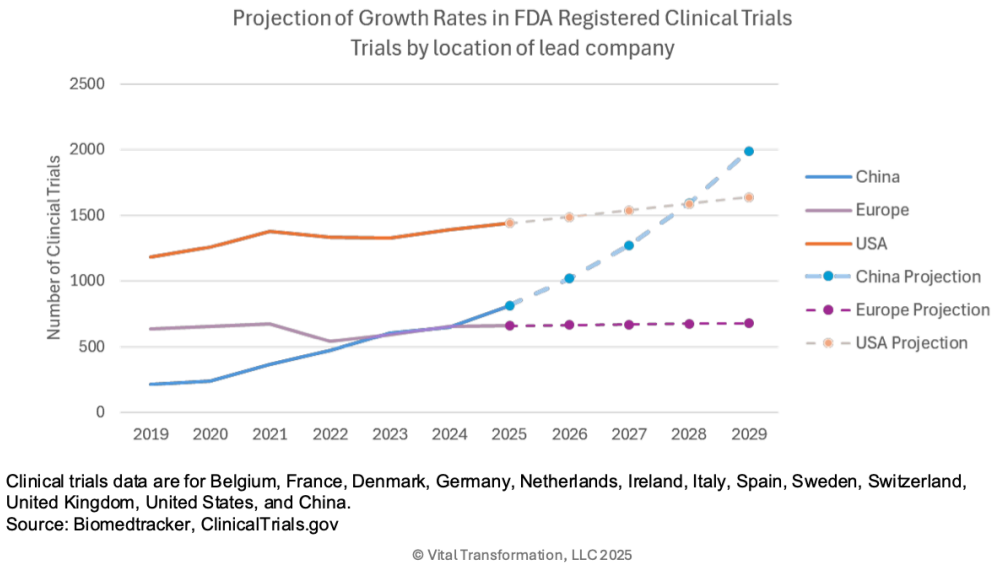
China has made biotechnology a national priority, moving from APIs/generics to innovative biopharma through industrial policy and financial support, talent, attracting FDI, IP and technology transfer. Its support for biotech/biopharma is long-standing,[3] explicitly prioritising biotechnology as a strategic sector in its 14th Five-Year Plan (2021–2025). DNA sequencing, gene editing and synthetic biology are considered "strategic edge" technologies, requiring stronger "national bio-security risk controls" (US Department of Defense, 2024). Public funding for research has totalled at least CNY 20 billion (EUR 2.6 billion) in 2023 and national independence in biotech is a stated objective of its economic security policies (Groenewegen-Lau & Brown, 2025). The 'Made In China 2025' Strategy (MIC25, launched in 2015) set ambitious targets for Chinese firms to gain international regulatory approvals. China's strategy is paying off. China's biotech rise is reshaping global development speed, cost structures, and market dynamics. A timely headline in the Wall Street Journal in late 2024 called it industry's "own DeepSeek moment" when US-headquartered Summit Therapeutics announced performance results for a cancer immunotherapy with a Chinese partner (Wainer, 2025).

As of 2023, 29% of all global trials involved a Chinese site (Groenewegen-Lau, 2025). According to one recent study, China produced a total of 16.612 trials, almost double US registrations by 2023 (Lee 2025[4]). China's growing contribution to global clinical trials is in large part due to single-country trials conducted in China by Chinese companies, at a per patient trial cost that is less than that in the US. Trial costs are a key issue, resulting from increasing studies complexity and recruitment challenges, among others (Beaney 2025). Chinese manufacturers have also started conducting clinical trials in the US, and recent data on the number of FDA-registered clinical trials by Chinese firms shows that they have increased nearly four-fold since 2018 (Schulthess & Bowen, 2025). China's strong ecosystem of contract research and manufacturing organisations offers a cost-effective end-to-end alternative to other locations (Groenewegen-Lau & Brown, 2025) in addition to a combination of population size and hospital specialisation, which enables faster patient enrolment (Plackett, 2025).

[3] Speaking before the Chinese Academy of Sciences and the Chinese Academy of Engineering in May 2018, Xi Jinping identified biotechnology as a "frontier field" in which China must excel, highlighting the need to "achieve major breakthroughs" in several biotechnology-related fields, including synthetic biology, stem cell research, gene editing, brain science, and regenerative medicine (as reported in Singleton, C. (2025).

[4] China experienced rapid growth in clinical trials, surpassing both Japan and the US in total trials and randomized controlled trials (RCTs). By 2023, China led with 16,612 total trials (7798 RCTs), while the US registered 9100 (4619 RCTs).

Figure 1: China-based companies currently launch more FDA-registered clinical trials than those based in Europe and will overtake the US in 2028 at the current trend

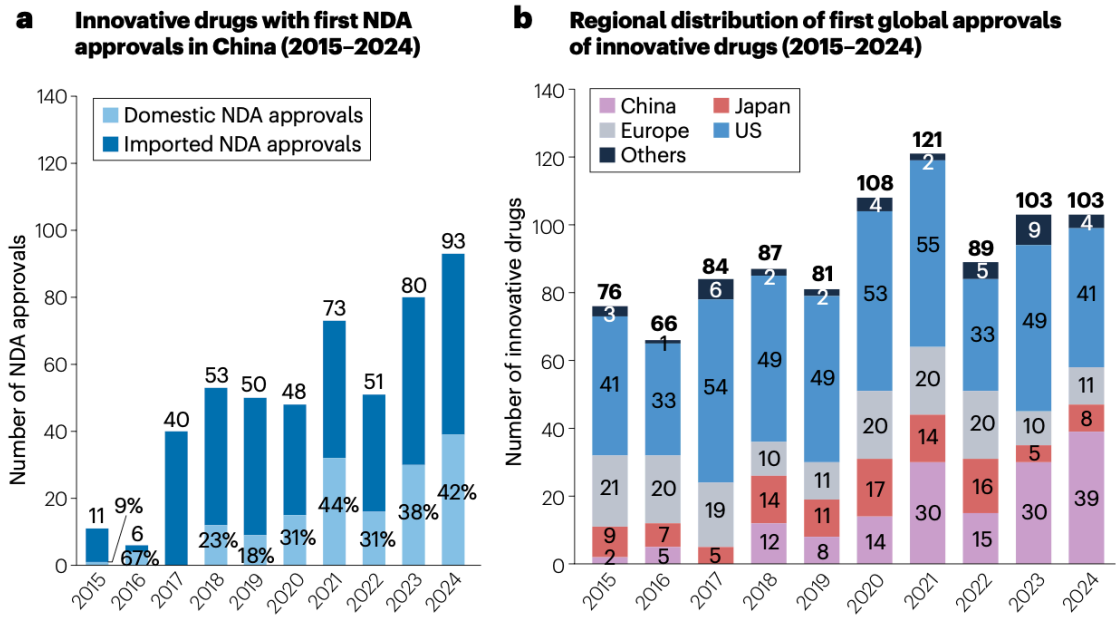


Source: Vital Transformation, 2025, page 28.

At the same time, China's companies still have limited commercial infrastructure, hampering genuine global reach. Out-licensing to Western pharmaceutical companies has surged, with a rising share of first-/best-in-class assets (esp. in oncology and metabolic diseases) (Jefferies, Stifel, GlobalData, 2025), partly driven to address global reach, and fuelled by pharma's decreasing R&D productivity and ensuing cost pressures.[5] Around 28–33% of large-pharma in-licensed innovative assets in 2024–25 was sourced from Chinese biotechs through licensing and other types of agreements (Gormley, 2025), a trend that is reaching record levels with China comprising 18% of licensing deals globally for multinational companies (Temple-West, 2025). China is also strengthening its fusion of AI and biotech (MERICS, 2024). Domestic AI drug-discovery companies and data-rich digital health platforms are expanding.

[5] "*Since 1950, the number of new drugs approved per $1 billion in R&D has halved roughly every nine years. By 2019–22, Deloitte estimates R&D returns for top pharma had fallen below the cost of capital, meaning each additional dollar invested was destroying, not creating, value.* https://www.ladanuzhna.xyz/writing/trillion-dollar-biotechs?s=03

Figure 2: China's growing role in global pharmaceutical innovation



Source: Nature Reviews Drug Discovery 24, 738-739 (2025), p. 738 - *Regional distribution of first global approvals of innovative drugs from 2015–2024. First global approval refers to the initial regulatory authorization of an innovative drug in any market worldwide. Analysed regions include the United States (regulated by the FDA), Europe (EMA member states), Japan (PMDA), mainland China (NMPA) and other regions.*

As highlighted in a Rhodium report assessing MIC25 (Boullenois, 2025), China selectively integrated foreign expertise into sectors where it could complement domestic capabilities. Access to China's market was exchanged for technology and process know-how, accelerating technological development by diffusing technological know-how throughout the broader Chinese economy, including to domestic Chinese competitors. China also created "reverse dependencies" where the world increasingly relies on China-based production and appear well-positioned to make significant advances in several high-tech sectors, including biotech and medical devices.

China's trajectory in technological leadership could accelerate in the coming years, pointing to a structural shift. China accounts for approximately one-third of the global clinical trial pipeline. In novel therapies that could define future standard treatments, Chinese companies are leading in areas such as ADCs (antibody-drug conjugates) and BsAb/TCE or are becoming significant emerging players in fields like siRNA (small interfering RNA) and PROTAC (proteolysis-targeting chimeras), according to a Goldman Sachs analysis (Zitong Finance, 2025). The trend is shifting from importing foreign innovations to licensing out, and according to the latest estimates, could account for 35% of approvals by the US FDA by 2040, up from the current 5% (Morgan Stanley, 2025).

Biotechnology is also relevant to China's *Military-Civil Fusion* strategy, which promotes the use of dual-use technology and collaboration between the military and civilian sectors. Its aim is to achieve a transformation of China from a "biotech power" to a "biotech superpower" (US State Department, 2020). Reports by the US State Department[6] argue that China is calling for a whole-of-nation effort and

[6] The Military-Civil Fusion Strategy was formally elevated to a national development strategy in 2015 and emphasized in the 13th Five-Year Plan (2016–2020) and subsequent plans. Under this plan, the PRC seeks to develop the People's Liberation Army into a "world class military" by 2049. According to the US Department of Defense, "the PRC's Military-Civil Fusion strategy supports the modernization goals of the People's Liberation Army (PLA) by ensuring it can acquire advanced technologies and expertise developed by PRC companies,

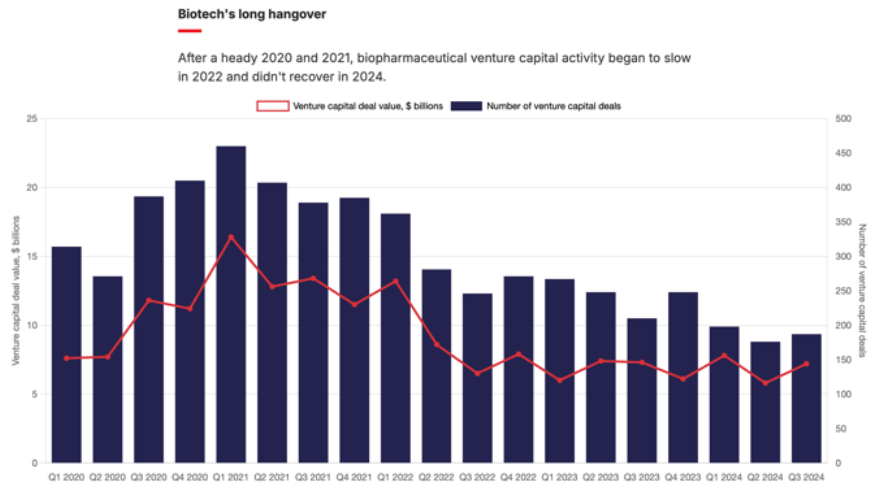
mobilises biotech for dual-use purposes, from gene editing to biomanufacturing, with implications for the next "Revolution in Military Affairs" (US International Security Advisory Board, 2024). More recently, the US' National Commission on Emerging Biotechnologies (NSCEB) argues that China is investing heavily in technologies such as gene editing for military applications (NSCEB, 2025a). Chinese biotech leadership is increasingly portrayed as a national security concern for the US.

The US: contradictory policies on biotech and biopharma

The US remains a global powerhouse in biotech and biopharma and retains its leading role in this field (Kasianov, 2024) sustained by structural strengths through its investor structure and depth of capital markets, world-leading clusters, translational biology, and leadership in AI applications.

Recent developments present a more complex picture though, with contradicting policy signals. Delays in FDA approvals, uncertainty around drug pricing reforms and most-favoured-nation (MFN) pricing (White House 2025c) are raising concerns over longer-term competitiveness, jobs, and tax revenues and are forcing companies to adapt their value strategies, given the longer-term impact on the US' biopharma/biotech ecosystem (Temple-West & Kuchler, 2025). Cuts and threats of cuts in funding bodies (such as ARPA-H, NIH etc), and of various programs in science and basic research, a proposal that the federal government take 50% of universities' patent royalties on inventions arising from federally funded research (Allen, 2025), are all initiatives at risk of weakening the US' scientific base and leadership, and arguably a strategic mistake, given China continues to execute a long-term, state-backed industrial strategy focused on research, development, and technological self-sufficiency (Ostertag 2025).

Figure 3: Biotech's long hangover



Source: PitchBook, quoted in: Walrath, R. (2024). Chemical & Engineering News (), "Navigating the financing doldrums in 2024, December 8, retrieved from online article: https://cen.acs.org/pharmaceuticals/drug-development/Navigating-financing-doldrums-2024/102/i38

universities, and research programs that appear to be civilian entities." (quoted from: https://www.defense.gov/News/Releases/Release/Article/3661985/dod-releases-list-of-peoples-republic-of-china-prc-military-companies-in-accord/); also quoted in the : "The PRC's 13th and 14th FYPs call for the mechanization, informationization, and intelligentization of key civilian and military technologies, including AI; quantum information; brain science; biotechnology; clinical medicine; deep space, deep sea, and deep earth technology; and integrated circuits".

In a field that has already experienced a more difficult period in the past years due to the underlying macro-economic context, these developments are starting to show their impact in terms of number of IPOs and difficulties to raise capital (Temple-West, 2025a). Investor concerns over the pricing environment are compounded by import tariffs on pharmaceuticals and the Section 232 national security investigation of pharmaceuticals and imports of pharmaceutical ingredients (US Federal Register, 2025a).

These pressures undermine the same innovation ecosystem that the US simultaneously seeks to strengthen through national security and industrial policy. Biotech has long been linked to national security throughout past US administrations (US International Security Advisory Board, 2024), building on defence-related funding for innovation and capacity-building. The US' DARPA (Defense Advanced Research Projects Agency) has funded platform technologies like mRNA (BioCentury Staff, 2013) and synthetic biology, in addition to the Biodefense and Emerging Infectious Diseases programs at NIH and BARDA (Biomedical Advanced Research and Development Authority). In 2022, Biden's Executive Order on Biotechnology and Biomanufacturing highlighted biotech's dual economic and security role, while the (not passed) Biosecure Act brought into focus a growing concern over security aspects of biotech. It aimed at restricting federal agencies from contracting with or funding "biotechnology companies of concern," and to protect sensitive genomic and health data.

This national security framing is intensifying. The National Security Policy Memorandum's (NSMP) "America First Investment Policy" (The White House, 2025a) of 21 February 2025 sets out its intention to enact policies to strengthen domestic industry and a stronger inbound and outbound investment control framework. It suggests that greater attention should be brought to biotech, especially where sensitive technologies and personal health data are involved.[7] It indicates that the US Outbound Investment Security Program (OISP) should include more investment types and expand its scope to include biotechnology and that transactions that are currently notifiable may become prohibited.

Highlighting the close integration of military and civilian dimensions of biotech in China, the report by the bipartisan NSCEB argues that the US government's approach in biotech has been "piecemeal and uncoordinated". Biotech is described as the next "battlefield" of this competition (NSCEB, 2025a). The report highlights the need for leadership in the AI-biotechnology convergence and calls for investment of $15b over the next five years. Interestingly, a delegation from the NSCEB has met with the European Commission end 2023, calling for continued US-EU dialogue and collaboration (NSCEB, 2025b).

Possible scenarios in the geopolitics of biopharma

With biotech's dual-use nature and systemic technology aspects through its links with data, AI, and synthetic biology, political attention towards the sector is growing. The Belfer Center Index (Belfer Center, 2025) argues that given that China has the most immediate opportunity to overtake the US in biotech, this could quickly shift the global balance of power if trends continue unchanged.[8] The possible scenarios that could unfold are:

[7] The Memorandum states that a review could "*consider new or expanded restrictions on United States outbound investment in the PRC in sectors such as semiconductors, artificial intelligence, quantum, biotechnology, hypersonics, aerospace, advanced manufacturing, directed energy, and other areas implicated by the PRC's national Military-Civil Fusion strategy.*"

[8] For example, according to the 'Critical and Emerging Technologies Index' of June 2025, published by the Harvard Kennedy School Belfer Center for Science and International Affairs, *"China has the most immediate opportunity to overtake the United States in biotechnology; the narrow US-China gap suggests that future developments could quickly shift the global balance of power. The United States and China perform similarly in biotechnology overall, with China's strengths underpinned by its human capital. The United States excels in security, genetic engineering, vaccine research, and agricultural technology, bolstered by private-sector innovation and public-private partnerships.*

Managed rivalry: this would largely be a continuation of the current trajectory. The US continues efforts to reshore pharmaceutical R&D and manufacturing via tariffs and the MFN threat (PhRMA, 2025) and tightens controls where it seeks risks. FDI in China and the licensing trend that is currently dominating relations between US/Western biopharma multinationals and Chinese biotechs will continue largely unencumbered. China continues its path of technological autonomy while seeking global reach.

Key proof points (at the time of writing): The Department of Justice's "Bulk Sensitive Data" rule (US Department of Justice, 2025) is in force (effective Apr 8, 2025) and explicitly restricts bulk genomic and health data transfers to "countries of concern," with additional due diligence/audit obligations. In June 2025, the FDA moved to halt/review certain new clinical trials that would involve sending living cells of US citizens to China and other 'hostile' countries for genetic engineering and subsequent infusion back into US patients. This would impact companies developing cell and gene therapies and that rely on China-based CDMO's and push them to shift to third party manufacturing towards other countries.[9] NIH has paused issuing awards that include foreign subawards pending a new structure and blocked controlled-access data to institutions in countries of concern (effective Apr 4, 2025). While the FDA is showing more openness to approving more drugs without US clinical trial participants (CDER's drug trials snapshot report), it has maintained a more guarded position on China-only trials. On the other hand, China is deepening its path to global expansion, nudging clinical trials and equipment supply chains while maintaining strict data export laws.

Acceleration of chokepoints as leverage: the US would introduce tighter outbound investment controls beyond today's scope (currently semiconductors, AI and quantum tech) to parts of the biopharma stack, for example more extensive blocks on transfers of genomic data and leaning more on the List of Entities of concern, which prohibits US firms and institutions from doing business with Chinese entities listed without prior approval by the US government. The indirect effect would include a shift to locations other than China for development and manufacturing. This scenario would also entail stricter scrutiny on licensing deals with Chinese biotech companies, driving more development to non-China locations.

*Key proof points (at the time of writing)***:** A Senate amendment filed on 31 July 2025 to the FY 2026 NDAA (National Defense Authorization Act) (S. 2296) sought to insert a new iteration of Biosecure Act-type language, reflecting congressional intent to extent national security frameworks into biopharma. This has now been passed by Senate but still needs to clear the House of Representatives. With a scope extending to any federally funded or contracted work and based on a list of companies of concern (including those that are linked to the Chinese military), it is set to have repercussions for US pharmaceutical companies' choice of partners/suppliers. In addition, and according to the New York Times, the Trump administration was considering introducing major restrictions on medicines from China by imposing more scrutiny on licensing deals for experimental drugs with Chinese biotech companies (Copeland & Robbins, 2025). The FDA announced a new priority voucher program that proposes to substantially shorten FDA review timelines, however specifying that this is "for companies aligned with critical US national health priorities" (likely to include pandemic-related drugs and

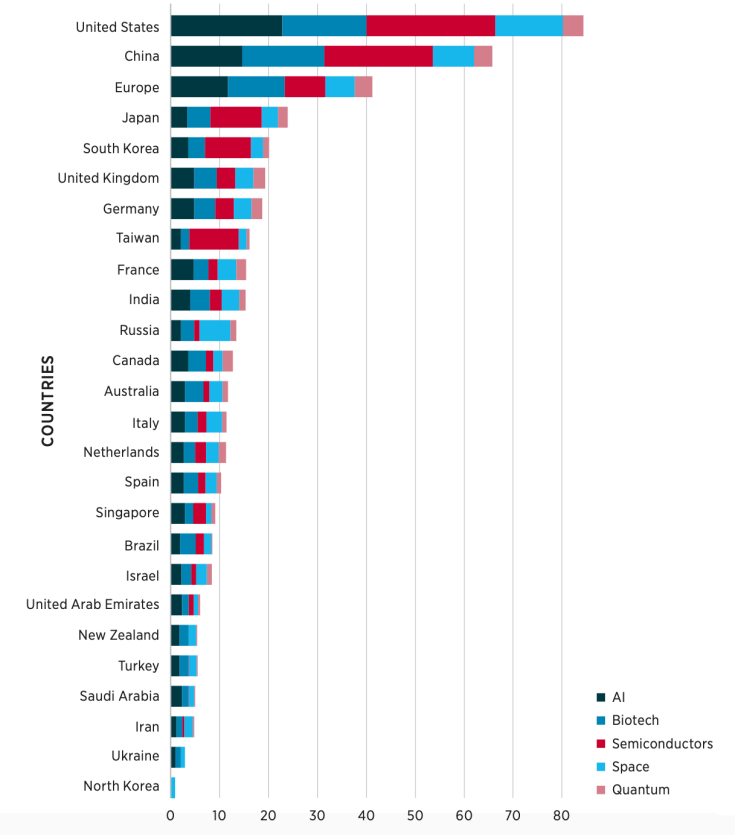
China has dominance in pharmaceutical production through extensive, large-scale public investments and state-backed manufacturing." See also: https://www.economist.com/graphic-detail/2025/06/06/who-is-ahead-in-the-global-tech-race.

[9] As highlighted in the FDA's press release: *"The integrity of our biomedical research enterprise is paramount. We are taking action to protect patients, restore public trust, and safeguard US biomedical leadership."* In: FDA. "FDA Halts New Clinical Trials That Export Americans' Cells to Foreign Labs in Hostile Countries for Genetic Engineering". Press Release. June 18, 2025.

vaccines, critical supply chain gaps, advanced therapies etc.). While this does not explicitly exclude Chinese-origin (or any foreign-origin) drugs, policy developments might make prioritization of a Chinese-origin drug more unlikely. China could respond by further prioritizing domestic IP, tightening localisation rules and local production preferences in procurement, tighten export controls on jointly developed technology and local data storage/processing rules.

These developments are reshaping the dynamics of capital flows, investment decisions impacting location of clinical trials and manufacturing, and supply chain derisking. Europe still retains an important position in biotech, which makes an economic security lens all the more important.

Figure 4: Country scores across critical and emerging technology sectors



Source: Belfer Center: Critical and Emerging Technologies Index, June 2025, p. 9.

II. Europe's economic security strategy

The European Commission has identified economic security as a priority in response to the strategic vulnerabilities exposed by COVID 19 and the war in Ukraine. The EU's Economic Security Strategy, adopted in June 2023 (European Commission, 2023a), establishes a comprehensive policy framework on three pillars: promoting competitiveness, protecting economic security and partnering with third countries. This strategy expands the definition of "security" beyond purely defence-related considerations to encompass supply chain weaponization and the risk of economic coercion more broadly (European Commission, 2023b).

The Commission's approach reflects a fundamental shift in European thinking. In her Political Guidelines for 2024–2029, Commission President Ursula von der Leyen emphasized that *"the Commission will prioritise advancing Europe's economic security and economic statecraft. This means boosting our competitiveness at home and investing in research capacity for strategic and dual-use technologies that are essential for our economy and security."* (Von der Leyen, 2024).

This commitment has intensified. In June 2025, addressing the G7 in a strongly worded speech, the Commission President called out China's "pattern of dominance, dependency and blackmail", while reiterating Europe's policy of de-risking (von der Leyen, 2025). Her reference to a "shared stake in economic security" with third countries reflects the growing importance of economic security also in the EU's external and trade policy. This commitment has gained further prominence through both the Polish and Danish EU presidencies in 2025, which have made economic security a key priority.

The challenge lies in translating strategic intent into operational policy in critical sectors. Implementation of export controls by China impacting Europe demonstrates the difficult choices it faces in a US-China escalation, and its margin for action faced with US pressure to align to its security-driven policies. The then US Deputy Secretary of the Treasury, Michael Faulkender, was explicit in April 2025: *"We are engaging with countries across the globe and urging them to implement strong regimes to address national security risks. As we evolve and strengthen our own system, we need to make sure allies and partners are not becoming vectors—even unwittingly—for the risks we are working to keep out of the United States"* (US Department of the Treasury, 2025).

However, as the Center for European Policy Analysis notes, *"the two sides have found it difficult to align their export controls and investment screening efforts."* (Hamilton 2025). Language in the EU-US joint statement on trade of 21 August merely alludes to complementary actions to address non-market policies of third parties, cooperating on inbound and outbound investment reviews and export controls, as well as duty evasion, but there will be no automatic alignment of EU economic security norms with those of the United States.

Europe's implementation of an economic security framework lacks coherence, while the framework itself is still evolving. As Gehrke and Ringhof noted in 2023, Europe has tools such as investment screening, export controls and safeguards for research cooperation, but they "add up to less than the sum of their parts" (Gehrke & Ringhof, 2023). This still resonates. It is a point of weakness and is leaving Europe without the scale of US or Chinese strategies, despite the fact that calls to think more strategically in terms of 'spheres of influence' and closer solidarity are becoming more urgent (Kayali, 2025).

The EU's push for a more coherent approach is rendered more difficult by fragmented competencies and national implementation at different speeds (Lockhart, 2025). Some Member States are intent on integrating economic security considerations in their national strategies, but at the same time are reluctant to prioritise the economic security *of Europe* over national interests (Lockhart, 2024). Assessment of dependencies on China and the US remain inconsistent with the different levels of understanding of the challenges (Seman & Julienne, 2025).

In biopharma, Europe has no time to lose. Europe's framework must address how geopolitical friction manifests through chokepoints in value chains, how they evolve, and it must take timely and

proportionate measures to anticipate and address them along the economic security strategy's three pillars of protect, promote and partner.

III. The urgency of an EU economic security strategy in biopharma

Biopharma is already caught up in today's "techno-nationalism", where technology is fused with state power, with policies that link a country's technological capabilities and self-sufficiency to its state security, economic prosperity, and social stability (Capri, 2024). Pharmaceuticals are not exempt, as the US Section 232 investigation and more anecdotal threats to leverage drug pricing in transatlantic trade[10] show.

In biopharmaceuticals, US policy toward China is constraining the EU's options. China has expressed concern that the EU might adopt provisions similar to those in the UK-US "Economic Prosperity Deal", which ties preferential pharmaceutical tariffs to "supply chain security" and ownership criteria, which can be considered implicit references to excluding Chinese firms.[11] Though the text itself avoids naming China, the linkage to Section 232 national security investigations makes the target clear. The US is pushing the EU toward alignment; China is pushing back.

Europe's economic security concerns should extend beyond China, however, as the US' current state-capitalist policy itself can present structural risks to Europe's sector, with demands for substantial US investment a condition for market access. This creates asymmetric dependencies: European firms face pressure to align with US security frameworks while also having to meet US investment thresholds, a dynamic that could constrain European strategic autonomy in the sector (Hindelang & Stein, 2025).

This, coupled with the push for speed and cost-efficiency in drug development and the boom of licensing deals with Chinese companies, is creating an investment and innovation flow that is at risk of weakening Europe's position in attracting capital and trial activity.[12] Europe's challenges in life sciences, including biopharma, are now well recognised by member states.[13] Europe sees falling shares of global R&D pipelines (proportion falling from 31% in 2007 to 23% in 2022) (Tan et.al., 2025). Fragmentation, limited venture capital depth, and delayed access compared to the US and China have impacted Europe's attractiveness for trials (in terms of share of total global trials) and launches of new medicines in Europe as a first-launch region. Without action though, Europe risks becoming a hedge against current uncertainty rather than a first-choice hub for launches and trials.

Member States must overcome their narrow 'money-in, money-out" mindset and commit to systemic coordination. Information on exposures and opportunity costs created through delayed

[10]: *"We're working very hard right now to get the other countries to lift up their prices a little bit, and to get the drug companies to put it to them. And if they don't, the drug companies will have a lot of problems…And if the countries don't, and as an example, if it's Europe, I'll say, 'That's okay. You no longer are allowed to sell cars in America. You no longer are allowed to have Mercedes, BMW, Volkswagen or any of the other many cars.' And they will say, 'Oh, I love the idea of lower drug prices for America.'"* President Trump, July 22, 2025, quoted in https://www.foxbusiness.com/politics/trump-says-he-may-use-trade-force-countries-pharma-companies-buy-his-most-favored-nation-provision

[11] Bloomberg and FT, see also quote by Joerg Wuttke, former president of the EU Chamber of Commerce in China: *"China is clearly worried that the EU will accept the same wording as the UK did on export controls", "They are pushing the EU not to do this, and the US is pushing the EU to do it."*

[12] According to figures quoted in Reuters, *"The total cost of licensing agreements, including low upfront payments and subsequent larger payouts, averaged $84.8 billion in the US, compared with $31.3 billion in China over the past five years"*, see: Roy, S. and Sneha S K: US pharma bets big on China to snap up potential blockbuster drugs, June 16, 2025, Reuters

[13] The key challenges are clearly laid out in the recent Council Conclusions on *"A call for action on life sciences for the Union's competitiveness"*, 30 September 2025.

implementation of EU legislation in capital flows, data, trials and supply chains must be shared; spillover effects of national incentives tracked; and institutional design optimized to avoid the 'weakest link' problem in coordination across Member States. Success requires clear metrics: time-to-first-patient compared to US/China, regulatory performance, EU share of pivotal trials, and reduction in single-source dependencies. Measurements of beneficial spill-over effect from the Recovery and Resilience Facility show that investment in one member states and cooperation can yield significant cross-border benefits that multiply initial investment over the longer term. Measurable indicators based on this methodology must be developed for biopharma and made more visible, guide policy and sustain political will.

Without action, Europe faces more dependence with further decline in global trial share and less launches, slowing access to innovation for Europe's patients, and its external dependencies in sensitive assets (such as genomic data, biopharma manufacturing inputs, CDMO capacity) will rise; it will see reduced leverage in global norm-setting in areas such as AIxBiotech and synthetic biology, areas in which China will seek an expansion of influence.

Europe should carve out its own path of "indispensability",[14] leveraging both its leadership in nascent enabling domains, such as quantum research and safeguarding its position in areas such as vaccines and biomanufacturing. It must nourish its ecosystem of biotech startups and scale-ups, while ensuring they scale in Europe rather than migrating to more supportive ecosystems. The France-Germany Economic Agenda's emphasis on economic security is an encouraging signal (Franco-German Economic Agenda, 2025).

Europe's ecosystem issues, China's rapid capability build, and the volatility of US policy justify an EU biopharmaceutical economic-security lens beyond reactive measures. Europe's challenge is not a lack of assets or talent, but a lack of coherence and political will to coordinate efforts at the speed and scale that match the systemic approaches of the US and China. Member States must rapidly align behind the five-priority framework. Current US uncertainty creates a strategic window that will not last.

The strategic dependency problem in biotech/biopharma: biotechnology occupies a central position within the EU's Economic Security Strategy as one of four critical technology areas identified for highest priority assessment, alongside advanced semiconductors, artificial intelligence, and quantum technologies (Council of the European Union, 2024). The European Commission selected biotechnology based on three criteria: its enabling and transformative nature across multiple sectors, the significant risk of military-civil fusion inherent in dual-use applications, and the potential for misuse in human rights violations through surveillance and control technologies. The Commission has initiated collective risk assessments for biotechnology, recognizing it as highly likely to present the most sensitive and immediate risks related to technology security and technology leakage.

This security lens should be broadened beyond traditional security concerns to encompass four key areas where biopharma faces strategic vulnerabilities: capital flows, data infrastructure, clinical trials, and development and manufacturing inputs. Each represents potential chokepoints that could be leveraged in geopolitical competition.

[14] See remarks made by Sabine Weyand, Director-General for Trade and Economic Security at the Forum Alpbach: *"Interdependence is no longer perceived as a win-win. Dependencies are used instrumentally…What we need is indispensability," … "Europe must become irreplaceable in global supply chains – so that our dependencies cannot be turned against us."* Quoted in: Deconinck, C.: What negotiations? Top EU trade official admits caving in to Trump, August 27, 2025, Brussels Signal.

1. Capital flows

US uncertainties and financing climate: funding for biotechs has trended into fewer, larger rounds, with partnering and structured finance (Senior, 2023). Companies and investors are rebalancing toward assets with clearer paths to market and taking more value via licensing. The potential of an MFN-style pricing approach in the US is adding to policy uncertainties, geopolitical pressures and macro-economic stress, heightening investor risk-aversion. If MFN pricing is realised in the US, it would cap pharma revenues. This is likely to contribute to further accelerating licensing partnerships with Chinese biotech firms and the growth of clinical trials in China (Schuthess & Bowen, 2025). It could also push companies to adjust launch sequencing or suspend EU launches if low net prices risk anchoring US MFN references (a possible scenario given learnings from international reference pricing).

China's biopharma ascent is reshaping investment flows: Chinese biotechs benefited from several reforms that fast-tracked IPO approvals, allowed pre-revenue biotechs to trade publicly and facilitated early-stage investor exists, leading to a surge in funding. Licensing has become a leading channel through which Chinese innovation is embedded in Western pipelines, moving beyond fast-followers into next-generation modalities, with a growing share of first-in-class candidates.[15] The Wall Street Journal is reporting that 31% of US biopharma licensing deals in 2024 involved Chinese assets driven especially by high-value cancer therapies (antibody-drug conjugates and bispecifics).[i] In parallel, Chinese biotech shares have risen in consequence, driven by the oncology licensing momentum and faster development timelines (Sandlund et. al., 2025).

In-China-for-China policies' impact: companies' "in-China-for-China" policies will become more complex, as geopolitical tensions, regulatory divergence (e.g. data, cybersecurity, export controls), and local protectionism increase, with the US and China pulling in opposing directions: China incentivising/mandating for localisation through procurement, US pulling for disengagement. Multinationals establish China-specific regulatory and trial pathways, navigate data localization rules and access China's vast market (Capri, 2023), often involving technology transfer for local manufacturing (Sidley, 2024). Analysts see these as responses to structural localisation pressures. The trend is toward a more decoupled structure, a strategy which the European Chamber of Commerce in China describes as 'siloing', i.e. a form of decoupling of a company's operations in China from the rest of the group. Alicia Garcia-Herrero et al. argue that European companies are 'siloing' their operations, structuring China as a semi-autonomous hub for sourcing and patents, in order to be able to compete locally (Garcia-Herrero et al., 2025). This introduces heightened strategic complexity and global fragmentation. The result is a higher cost of capital for fully global programs.

Globalisation of innovation "made in China": faster patient recruitment and post-2017 NMPA reforms have accelerated timelines in China, and enabled speed in the pipeline for out-licensing and launches beyond Asia. At the same time, domestic price controls and reimbursement caps in China limit profits, forcing Chinese companies to seek access to overseas markets, approvals from leading regulatory agencies notably EMA/FDA, and investors.[ii] With China's presence in clinical trials expanding in global trials, analysts anticipate that Chinese companies will increasingly launch their own drugs outside of Asia, with the Chinese government implicitly supporting a model where early

[15] Since 2022, Chinese biotech firms have launched 639 first-in-class drug candidates—a 360% jump from 137 between 2018–2021, far exceeding growth rates in the US/EU/Japan: Fierce Biotech: In their July 14, 2025 article *"China biotechs 'reshaping' US biopharma as outlicensing deals rise 11%: Jefferies report,"* they write:"Since 2022, China biotechs have developed **639 first-in-class drug candidates, a staggering 360% increase from 137 candidates from 2018 to 2021.", and FiercePharma: Making Sense of China's R&D ascent

R&D is funded domestically,[16] and later stages are financed via foreign licensing. China will need to be able to sustain a 'homegrown research-to-global commercialization' trajectory to help pay for more research, which would not only make drugs more affordable in China, but across the globe (Dreyer, 2025).

Chokepoint risks in capital flows:

The push for speed and cost-efficiency in drug development and the boom of licensing deals with Chinese companies is creating an investment and innovation flow that is at risk of weakening Europe's position in attracting capital and trial activity.[17] Even the signal of a US pricing policy based on most-favoured-nation (MFN) principles has repercussions for Europe, where access delays (EFPIA, 2025) already weigh on launch choices. Companies may increasingly deprioritize or postpone EU launches, not just in smaller, lower-priced markets but potentially also in big Member States. Absent strong incentives and faster uptake of innovation, Europe risks being seen merely as a hedge against US unpredictability rather than a primary market.

Capital is also vulnerable to deliberate policy interventions. MFN pricing in the US, tariff volatility, or procurement restrictions inspired by the Biosecure Act would limit federal reliance on China-linked vendors, reverberating through global sourcing strategies and shifting investor valuations. The new Outbound Investment Security Program, effective from January 2025, formally targets semiconductors, quantum, and AI, but not biotech. Even so, the "America First Investment Policy" memorandum (The White House, 2025a) indicated a potential expansion to include biotechnology (Paul Weiss, 2025). In late April, then Deputy Treasury Secretary Michael Faulkender underscored this direction (US Department of Treasury), stressing that investors must understand their counterparties and the purpose of their investments. He framed the program as a way to ensure that US businesses thrive without undermining national security. If biotech is pulled into scope, the first to be targeted are likely to be synthetic biology, already under dual-use scrutiny, together with genetic data flows and other strategically sensitive domains.

China's biopharma sector sits at the heart of this tension. It is more globally integrated but increasingly exposed to potential US outbound-investment controls, EU FDI screening, and scrutiny of Chinese CDMOs. Its trajectory is not one of automatic dominance but of interdependence: its rise is real, yet its sustainability depends on continued access to foreign markets, capital, and regulatory recognition.

Europe, in contrast, struggles with structural chokepoints of its own. Fragmentation, slower access to markets, and weaker venture financing are key pressure points for European companies. Capital flows where speed and cost converge and where talent, capacity, and new modalities cluster. The risk for Europe and for any region unable to combine rapid development and fast access with competitive pricing is that capital and the pivotal nodes of the biopharma value chain will continue to migrate elsewhere. An additional risk factor, given recent developments, is the combination of Europe's dependence on pharmaceutical exports (contributing to an EU trade surplus of €193.6 billion in 2024 -

[16] See recent OECD figures: *At 8.7%, growth in R&D expenditure in China continued to surpass that of the OECD area, the United States (1.7%) and the European Union (1.6%) in 2023.*

[17] According to figures quoted in Reuters, *"The total cost of licensing agreements, including low upfront payments and subsequent larger payouts, averaged $84.8 billion in the US, compared with $31.3 billion in China over the past five years"*, see: Roy, S. and Sneha S K: US pharma bets big on China to snap up potential blockbuster drugs, June 16, 2025, Reuters

Eurostat figures), the biotech sector's reliance on US capital,[18] and the current challenging financing context, with Q1 showing a 64% decline in overall funding compared to Q1 2024 (Shorthouse, 2025). This asymmetry holds potential for chokepoints if US capital retrenches.

2. Data and digital infrastructure

AI and quantum tech as gamechangers in biopharma: quantum technologies can play a role in accelerating drug discovery where handling vast datasets benefits from quantum-enhanced optimization. AI is already central to biopharma and the capacity to accelerate drug discovery. Gen AI is by some estimates (McKinsey 2024) expected to unlock $60–110b in annual value across the pharmaceutical industry value chain. Increasingly, national strategies to support the biopharma sector are integrating AI infrastructure, computational power, data and talent. There are growing investments in biotech by major Silicon Valley actors on the US side, with venture-capital investment in US-based AI drug discovery firms, and on the Chinese side, tech companies such Tencent, Baidu, Alibaba, and ByteDance are backing biotech startups. These developments are indicative of the dynamic relationship between AI and biotech, spanning areas such as cloud-based genomic data analysis, gene synthesis, easing access to drug discovery capabilities, with a recent case in point being CRISPR-GPT (Qu et al., 2025), an early-stage system that integrates CRISPR-based gene editing with large language models like GPT to automate genetic edits.

Importance of health and genomic data as a competitive asset: health and genomic data is an essential 'currency' in biopharmaceuticals. Countries with access to large and diverse data have a strategic advantage, particularly when large datasets are analysed with significant computing power (Capri, 2024). In the US, availability of large datasets is driving accelerated integration of analytics in biotech. China is actively collecting and analyzing large amounts of genomic and health data to develop predictive algorithms aimed at understanding diseases and facilitating drug discovery (US Office of the Director of National Intelligence, 2021). This is also a potential strength of Europe but conditional on how the EHDS is implemented.

AI and quantum tech capacities and health/genomic data are strategic assets: AI is shifting competitive advantage to novel target insights. China disposes of massive datasets, a pool of returning scientific talent, AI/automation investment (such as Insilico's "robotic lab" in Suzhou) and state funding through the Five-Year Plan's priority on AI-drug discovery, and low-cost pre-clinical infrastructure. This is accelerating its position as a significant challenger to the US' lead. Recent deals reflect an increased trend towards embedding China's AI-discovery capacities. But this is also raising concerns that Western firms may become dependent on targets derived from Chinese companies. For the US, this could mean greater pressure to secure proprietary datasets and talent. For China, it could accelerate its discovery despite lagging in some later-stage commercialization.

Security concerns: collection of genetic data by Chinese entities raised growing concerns in the US (for example the collection of vast amounts of genetic information in its China National GeneBank (Burgis, 2025; US Government Accountability Office, GAO-25-107377[19]). In an opinion piece published in May

[18] *There is a gap between US capital invested in Europe and European capital invested in the US in biotech. While not in the EU, The UK BioIndustry Association's finance reports show the share of US investors participating in UK/European biotech rounds in 2024 accounted for around 26% of the investor base supporting UK biotech (UK Biotech Financing Report, 2025, BIA)*

[19] US Government Accountability Office, GAO-25-107377, published: Apr 30, 2025: the Office of the Director of National Intelligence (ODNI), *"issued public warnings in 2021 and 2022 on the economic, intelligence, privacy, and military risks of Americans' genomic information being collected by foreign governments, noting China as having the motivation and capability to collect such information"*

2024, former and current MEPs expressed their strong concerns that genetic data "could be utilised for purposes which starkly contrast with the EU's values and security interests," urging vigilance on how genetic and health data is shared, and greater awareness about the security risks of working with Chinese state-linked genomics companies (Lexmann et al., 2024). More recently, the UK Biobank, which holds data from 500,000 volunteers, granted access to researchers in China, raising serious alarm from intelligence services like MI5, citing the risks of anonymized data being reidentified or leveraged for strategic gains (Burgis, 2025).

Chokepoint risks in data and digital infrastructure

Genomic and health data are increasingly seen as strategic assets in biopharma competition. Large, diverse datasets accelerate drug discovery, power AI-driven target identification, and are key for personalized medicine.

China has explicitly linked genomic data to its biotech/biopharma ambitions, using national programs and partnerships to collect and analyze vast datasets. The growing scope of its export-control systems and data-security laws can impair foreign firms' ability to access jointly developed innovations or retrieve research done within China (Merics, 2024). China's Human Genetic Resources (HGR) rules, reinforced by the Personal Information Protection Law (PIPL), impose strict approval requirements on the collection and export of human genetic material. While 2025 guidance clarified some workflows, most cross-border projects still face lengthy reviews. These barriers slow multi-country studies and make joint analysis outside China harder. The ripple effects are visible elsewhere. Some European funders have paused new joint programs with NSFC due to China's data-export rules, citing legal and compliance uncertainty; the move may slow collaborative research in sensitive health and environmental fields (Silver, 2025).

The US frames genomic information as a national security concern. The US' executive order 14117[20] restricts transfers of bulk genomic and other health data to "countries of concern" (Hengesbaugh, 2025) with only narrow exemptions. Because no blanket safe harbour exists for corporate groups, US firms with R&D units in China face an additional compliance risk. Arguably, such measures would not only prevent leakage but also force companies to rethink their evidence-generation strategies and to strengthen US tech leadership, given that several congressional reports and security strategies highlighted the importance of access to valuable datasets for the development of AI capabilities.

Europe's vulnerabilities lie in infrastructure and governance. As highlighted in the recently published EU AI in Science Strategy, the EU's global share of AI computational capacity is less than 5% and major tech actors are moving in fast on AI in science, including in biopharma. Cloud and high-performance computing remain dependent on US providers, meaning that genomic and clinical trial data is stored or processed through US-controlled platforms, thereby subjecting them to US laws and potential restrictions. In addition, a multitude of EU rules, GDPR, MDR/IVDR, the AI Act, and the European Health Data Space, create complex layers that slow data use. GDPR's impact on investment flows is particularly instructive: US-led venture investment in EU data-heavy startups fell by about 21% and amounts fell by around 13% vs comparable US deals, with an adjustment over time through more US-EU syndication (Jia et al., 2025). Although not biotech-specific, it illustrates how heavy regulatory frameworks can dissuade capital and add to data hurdles.

[20] Access to US sensitive personal data, published in the Federal Register (codified at 28 C.F.R. Part 202)

3. Clinical Trials

China's rapid rise as a key hub for clinical trials with a rising share of 'first-in-class' candidates[21] is the result of systemic reforms: rapid patient recruitment timelines for clinical trials, harmonised regulatory pathways, notably after the reforms of China's regulatory agency NMPA in the mid-2000s under which drug trial standards have been harmonized with international standards, enabling more licensing deals, an integrated CRO base and digital integration.

Europe has a solid regulatory architecture but exiting legislation is not evenly implemented across the EU. The EU's Clinical Trials Regulation (CTR) is a real opportunity for more streamlined processes that would benefit companies of all sizes but is not yet delivering consistent speed across Member States. Time-to-first-patient influences decisions on the location for pivotal trials and first launch location. In a study commissioned by EFPIA, IQVIA data indicates Europe's declining global share is "influenced by longer trial timelines," with *site start-up* and *recruitment* slower than in the US and China across oncology, rare disease and infectious disease areas. While China has grown number trials in cell and gene therapies (CGT), for example, the cost of developing and manufacturing CGT's has impacted the ability to initiate new trials in Europe (Beaney 2025b). If Europe fails to improve its performance in these areas, it risks seeing a further erosion of the number of clinical trials across Member States, which would weaken its strength in science overall, patients would wait longer, and investment would be directed toward jurisdictions that offer faster recruitment and clearer post-approval uptake.

Chokepoint risks in clinical trials:

While the US' FDA is showing more openness to approving drugs without US clinical trial participants (as per FDA CDER's drug trials snapshot report, 2024), it has maintained a more guarded position on "China-only" pivotal evidence, intend to not approve drugs solely tested in China. The FDA demands that additional trials be conducted "in a population applicable to the US" (Baxter 2025). This has led to increasing investment by Chinese companies in multi-country clinical trials. In June 2025, the FDA announced that it would not approve new clinical trials that would involve sending living cells of US citizens to China and other 'hostile' countries for genetic engineering and subsequent infusion back into US patients. This would primarily impact companies developing cell and gene therapies and those relying on China-based CDMO's and would require shifting to third party manufacturing towards other countries.

One area which for now remains anecdotal is the impact of the licensing of assets generated in China on maintaining a level-playing field of competition. Scott Gottlieb, former head of the FDA, argues that Chinese firms in most cases "piggyback on Western innovations by scouring US patents, zeroing in on biological targets that are initially uncovered in American labs" while being able to move more quickly through early-stage clinical trials stages due to fewer regulations in China (Gottlieb, 2025). In recent

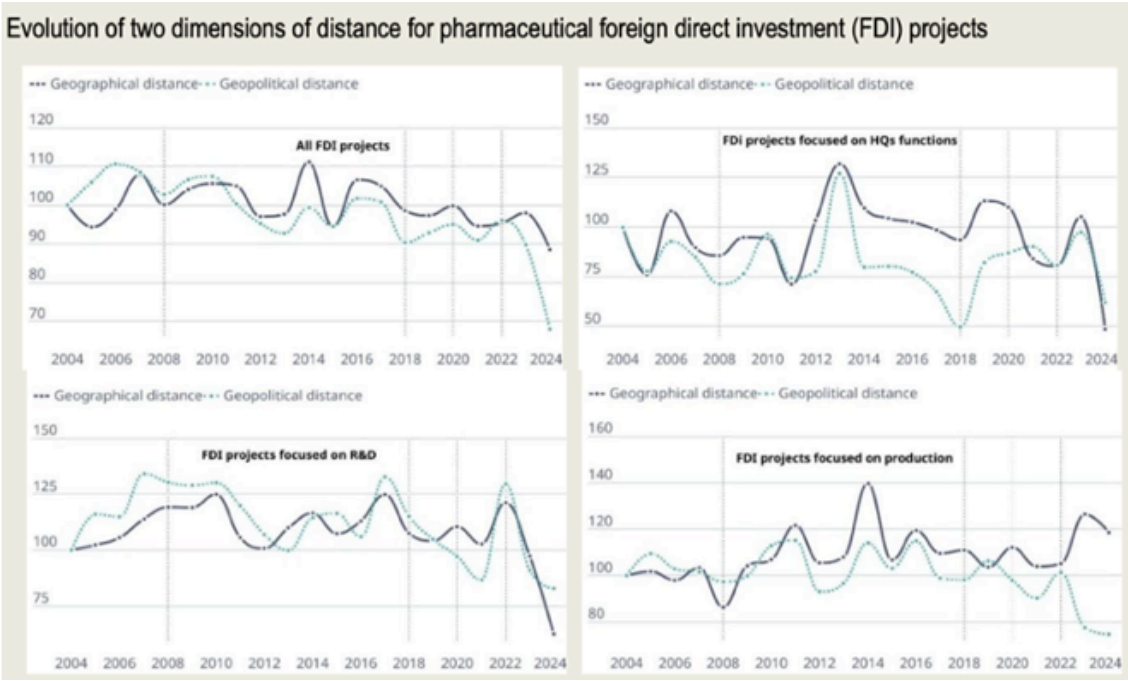
[21] Since 2022, Chinese biotech firms have launched 639 first-in-class drug candidates—a 360% jump from 137 between 2018–2021, far exceeding growth rates in the US/EU/Japan, see for example Fierce Biotech's July 14, 2025 article *"China biotechs 'reshaping' US biopharma as outlicensing deals rise 11%: Jefferies report": "Since 2022, China biotechs have developed 639 first-in-class drug candidates, a staggering 360% increase from 137 candidates from 2018 to 2021."* (https://www.fiercebiotech.com/biotech/china-biotechs-reshaping-us-biopharma-outlicensing-deals-rise-11-jefferies-report); also: Ellison, A., Kansteiner, F.: Making sense of China's R&D ascent, 25 July 2025, Fierce Pharma podcast

reporting in The New York Times, this is seen by some US investors as a real issue, with a potential introduction of tighter scrutiny of licensing agreements with Chinese biotechs reportedly under consideration (Coppeland & Robbins, 2025). For many investors, China's rise calls for greater US investment in biotech, much improved policies and regulatory reforms to better compete with China, rather than more control (Dunn & Whitlock, 2025). Untangling the complex relations between US and Chinese companies through a push to curb the ability to conclude licensing agreements would come at a cost to companies and harm to patients, as has been highlighted by industry associations and companies (Liu, 2024).

4. Development and manufacturing inputs

COVID 19 highlighted dependencies along the full supply chain at different stages of drug production. With rising geopolitical tensions, companies face the risk of more expensive dual infrastructures and a qualification burden while being constrained in dual sourcing due to highly specialised supply chains.

Figure 5: Evolution of geopolitical distance as a factor for FDI decisions



Source: OECD (2025). OECD Supply Chain Resilience Review, p. 34.

FDI trends are increasingly filtered through geopolitical factors. Financing, sourcing and location strategies are complex decisions, with de-risking strategies balancing different risks (not only geopolitical), costs, supply chain resilience and strategic advantage. Data from the OECD on FDI for the pharma sector (OECD 2025) shows that while the geography of sourcing evolves only slowly due to the multitude of considerations that factor into companies' strategies, geopolitical distance (i.e. the institutional and political alignment between countries) is trending downwards for FDI, meaning companies are more sensitive to less geopolitically exposed locations. The recent uptick of FDI in China based on announced projects (and likely taking a more "siloed" structure) (Irwin-Hunt, 2025) should not distract from this more substantial medium-term trend, which shows a "friendshoring"/reshoring effect for HQ/R&D location choices. An obvious recent development is the successive announcements

by multinational pharmaceutical companies of investment in the US. Recent figures surveying 38 tariff-related Investor Signals targeting the US identified between November 2024 to July 2025 identified 36 that stated they were considering investment in production and manufacturing in the US in response to the tariffs, and of these, 21.8% are in the life science cluster (Lewis 2025).

Dual-sourcing will also be impacted as geopolitical frictions increase its need: as OECD data highlights, moving "one segment" of the supply chain is just pushing the risk associated with foreign supply upstream (OECD, 2025). Dual sourcing is not always feasible and for high-tech biopharma processes where very specialised inputs are needed working with two suppliers is often more a source of risk than a solution, as two suppliers will not deliver the exact same inputs and small differences can have a high impact on quality. In this case, firms prefer to build long-term relationships with suppliers they trust. Biopharma companies rely on a small number of highly specialized points in the biopharma chain, such as single-use systems (bags, filters), chromatography resins, typically capital-intensive specialised equipment, such as bioreactors, sequencers, cytometers, and mass spectrometers, other types of inputs, such as critical enzymes/reagents, LNP lipids and plasmid DNA for mRNA/ATMP production, and concentrated CDMO capacity for biologics and viral vectors. Building true redundancy with these specifications is a resource-intensive task as it requires second vendors with equivalent specifications, material qualification, extractables/leachables studies for single-use, method bridging, process re-optimisation, stability etc. A lot of this runs on regulatory time to have a fully qualified second source, not only operational time. For biologics and ATMPs, small differences in raw materials or disposables can shift critical quality attributes.

Europe is still in a strong position on biomanufacturing and on a number of specialised inputs, for example in certain bioprocessing equipment, and strong in-house capacity (e.g. in France, Belgium, Germany, Ireland).

Chokepoint risks in development and manufacturing inputs:

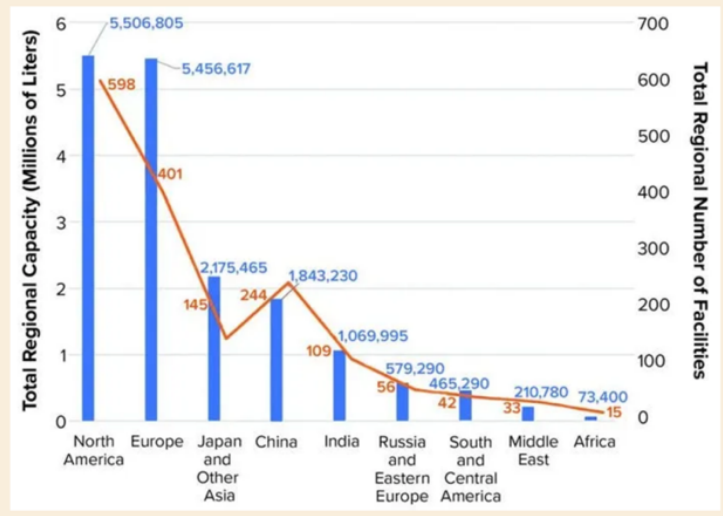
The US considers biomanufacturing critical and highlighted its importance as an "effective security umbrella" in its 2025 Fact Sheet on National and Economic Security, stressing the need for the US to develop new manufacturing technologies in "bio-manufacturing" (alongside batteries and microelectronics) to support defence needs and reshore capacity (The White House, 2025b). Developments in the area of generics are an indicator of more localization incentives; for example, in recent FDA programs where companies must be tested and manufactured in the US to be eligible for speedier reviews (Manalac, 2025). However, the biopharma sector depends on a complex and global network of inputs and equipment which would make similar frameworks difficult to implement in practice.

That said, the implications of US tariffs in the field of pharmaceuticals will impact on sourcing, compliance readiness and cost structures in supply chains and manufacturing. In a recent opinion piece in The Washington Times, White House advisor Peter Navarro argues that US national security and economic sovereignty are being undermined by overdependence on "foreign adversaries" for pharmaceuticals and medical supply chains. Restoring domestic pharma manufacturing capacity must be a strategic priority, including tariffs or restrictions on overseas providers and federal procurement policies favouring US producers (Navarro 2025).

Dependence on a small set of providers is a possible chokepoint, where export controls or licence changes can interrupt access. Illustrative is the placing of US company Illumina on the Unreliable

Entity List (February 2025), and the subsequent ban in March by China immediately after additional 10% tariffs on Chinese goods by the US. In January 2025, the US Commerce Department's BIS (Bureau of Industry and Security) issued an interim final rule adding export controls on certain equipment, arguing these tools generate high-content biological data that can feed AI-enabled biodesign (US Department of Commerce, Bureau of Industry and Security, 2025). These items require license requirements to destinations of concern (e.g., China, Russia, others) on national-security grounds (risk of AI-enabled biological design) (Sandler, Travis & Rosenberg, 2025).

Figure 6: Global biomanufacturing capacity by region in 2021 (measured in total biocapacity volume)



Source: BioProcess International, retrieved from: https://www.bioprocessintl.com/economics/total-global-capacity-finally-shows-improved-productivity

Europe is a major exporter of pharmaceuticals and vaccines yet relies on external suppliers for certain biomanufacturing inputs (for example, certain reagents, biologics components, sequencing and analytical equipment, etc.). While these dependencies do not currently undermine Europe's strengths, they could become strategic chokepoints if subjected to export controls or emergency allocation regimes. The context is volatile. As an illustration, Chinese import tariffs and access concerns because of rising tensions with the U.S. have pushed Chinese pharmaceutical companies with R&D activities to seek locally made reagents. Reagents are substances added to a biological sample to cause a chemical reaction or to test for the presence of other substances. China's reagent market for lab and diagnostic use has been to some extent supplied by imports, but is now being gradually replaced by local operators, one of whom reported that since April more than 90% of its customers have discussed replacing imported products. At the same time, Western suppliers are also intending to localize production in China. While this is not yet indicative of a chokepoint, it is an illustration of the shifts in localisation of investment and supply chains, triggered by geopolitically motivated policies, leading to greater concentration over time of upstream inputs into biopharmaceutical development and manufacturing (Silver 2025).

IV. Recommendations for a European framework for economic security in biotech/biopharma

As established, Europe's economic security framework suffers from fragmentation and uneven implementation. In biopharma specifically, the framework faces additional challenges. Export controls and dual-use rules are governed by a common EU framework but implemented by 27 national authorities. This ensures rules-based decisions but makes coordination essential. Rapid developments in biotech combined with AI are challenging existing frameworks and technology assessments for the emerging technologies' potential harmful use. Addressing them coherently through updates to EU dual-use control lists and carefully calibrated national measures will be important, as set out in the April 2025 Council Recommendation on coordination of national control lists (Council of the European Union, 2025).

Biotech and biopharma require bespoke governance given the sector's dual-use character, EU-national competence complexity, and relevance for patient access and health systems. As framed in the Draghi Report and in anticipation of a future EU Biotech Act, clear consensus is emerging that Europe's investment landscape, fragmentation, and slow implementation of EU legislation are core challenges. The seven recommendations below address these gaps while building on existing instruments.

1. Establish greater risk assessment capacity

Use "technology foresight" as a systematic exercise for identifying emerging, disruptive and/or critical technologies, and to anticipate their potential future impact.[22] The European Commission, with input from industry and investors, should increase its own understanding of the rapidly changing business models in biotech, the frontier technologies that drive these changes and, in combination with the risk assessment exercise in biotech that has started within the framework of its Economic Security Strategy, it should identify what new dependencies are emerging that will impact Europe's economic security in biotech. For example, Europe must understand the implications of an increasing divestment of Europe's clinical research capacities from China, and other types of current strengths vs. emerging dependencies and their implications for R&D and biomanufacturing, for example in AI-biodesign software, DNA synthesis screening, enzyme/reagent supply chains, clinical-data brokers, and high-spec instruments.

Establish a regular and voluntary public–private risk dialogue that can anticipate and map dependencies and ensure that actions taken are proportionate to the risk assessed. Such a capacity should be managed at an EU level, drawing on insights from HERA, EMA, the Joint Research Centre and national ministries from the 27 Member States and the broader biopharma industrial ecosystem (larger size companies and SMEs, CROs, CDMOs). Importantly, it also needs to connect to work on digital and technological sovereignty. Developments such as a rise in single-source exposure for a critical input could trigger relevant measures (regulatory, through partnering with third countries etc). Part of this dialogue should also assess how EU legislation can positively impact economic security objectives or undermine them. It should develop, where possible, de-risking incentives that support companies' efforts to diversify sources of biological inputs (e.g., enzymes, reagents, cultures), and facilitate secure access to raw material. It should resource member-states' capacities so trade/economic/national-security skills sit together (link to FDI, export-control, research-security,

[22] As described in: Technology Foresight, European Commission, 12 September 2025 (https://knowledge4policy.ec.europa.eu/tech-foresight_en)

cybersecurity). Such an approach would also facilitate the EU's ability to identify areas for retaliatory measures where these may be needed. Industry expertise is essential and often missing in deliberations on geopolitical trends and should be consulted before measures are taken. Rigorous processes for preserving confidentiality of information shared is a key pre-condition to any meaningful dialogue though.

Develop a biotech risk dashboard: monitoring capital flows, data flows, supply chain vulnerabilities, and trial chokepoints. Track cost of capital trends in early-stage versus late-stage rounds, IPO window status, EIB/EIC disbursement pace, risks from ongoing policy developments (MFN/tariff investigations), licensing patterns by modality and geography, ratio of out-licensing versus internal global launches for EU-origin assets, and impact of external reference pricing concerns on EU launches.

2. Strengthen Innovation Capacity and integrate Dual-Use

Europe's innovation system remains strong in science but lags in translation and scale. The EU's 2025 report "A comparative analysis of public R&I funding in the EU, US, and China" finds that Europe's public R&D funding is fragmented, indicating a need for better coordination and simplification. The US and China invest more on later R&D stages, aligning means with objectives (European Commission, 2025b). There is broad consensus across different stakeholder communities that this is a major issue for the EU, and one that will weaken its global position on strategic technologies if left unaddressed.

Current policy proposals – such as the Competitiveness Compass, the proposals for the next MFF (and within that, the European Competitiveness Fund and a stronger EIC – European Innovation Council), the Strategy for European Life Sciences, the Medifence initiative – offer building blocks for policies that can serve Europe's scientific excellence and innovation objectives while also strengthening Europe's economic security. Economic Security must not be limited to *de-risking*. It should shape, and not just follow, tech frontiers in strategic sectors. Areas for action should be:

Make Europe "indispensable" in a few frontier areas: the EU should identify areas in which it retains leadership for specialised inputs for biopharma development and biomanufacturing, and on frontier modalities on which Europe can carve out an advantage, for example in mRNA. Europe's evolving health-data infrastructure can advance Europe's unique selling points in running clinical trials, and underpin leadership in personalised medicine, and the recent Franco-German paper highlighting the need for an "Executive Dialogue for AI in Industry" to initiate joint R&D projects on sovereign AI, including in health could indicate greater political momentum to advance innovation in this field (Franco-German Economic Group, 2025).

Leverage dual-use as a driver for innovation*:* the EU is moving towards a more comprehensive dual-use (civilian-defence) approach in health security, linking civilian and defence preparedness. Commission proposals related to Horizon Europe, the EIC and the European Competitiveness Fund would enable more dual-use related R&I. As highlighted by Commissioner for Research Ekaterina Zaharieva, "we cannot miss out on the potential of research and innovation to make Europeans safer." (Greenacre, 2025). Evidence from the US' DARPA shows that dual-use R&I can boost the productivity and economic return of public research by exploiting civilian-defence synergies through shared infrastructure and knowledge flows, crowding in private co-investment, reducing duplication and accelerating speed to market (Expert Group on the Economic and Societal Impact of R&I, 2025). Europe should step up efforts in biopharma and health security, connecting dual-use biotech and medical-countermeasures (MCM) research to investment vehicles such as HERA Invest to integrate civil-military

R&I on vaccines, diagnostics and biosensors for CBRN threats. These efforts will be reinforced by the EU Strategy for Life Sciences and the Medifence initiative (European Commission 2025a). HERA is already responsible for supply-chain vulnerability assessments and MCM procurement and could play a greater role to coordinate priorities and advance pull mechanisms for dual-use health innovation.

A European pathway for lifescience start-up to scale-up transition and simplification: about 80 percent of the projected "blockbusters", i.e. assets that achieve over €1 billion in peak-year sales for the next five years, are currently in the portfolios of first-time and recent launchers. They are developing breakthroughs in new modalities that may revolutionize care for patients with limited treatment options (Harputlugil et al., 2024). Europe should make sure that there is a clear roadmap for biotech start-ups and scale ups within the various recent initiatives: in a future European 'Innovation Act' (streamline innovation policies, access to capital and funding across the EU), the EU's start-up and scale-up strategy, the planned 28th regime (eliminate cross-border legal and regulatory barriers), the Biotech Act. Europe should support this roadmap through the proposed MFF and simplified access to capital through the EIC Accelerator and the Competitiveness Fund. Support action to clinical trials, as well as to biotech clusters strengthening the translational infrastructure and collaborative frameworks between industry and academia, should be an integral part of such a roadmap to ensure joined-up incentives and actions. Healthcare system decision-makers must be included to ensure there is also rapid innovation uptake, i.e. a dynamic demand and launches in Europe at competitive speed.

3. Secure Data Infrastructure and AI-Biotech Synergies

Treat health/genomic data and computing power as strategic infrastructure: the European Health Data Space (EHDS) can contribute to leveraging Europe's health data wealth. However, as highlighted in the Draghi Report, the EHDS is not yet delivering the data access needed for AI-enabled research and evidence generation. Industry concerns over insufficient guarantees and protections with regards to IP and business sensitive data must be addressed while broad opt-outs and divergent national add-ons must be avoided (EFPIA, 2024). The EU's GDPR, the AI Act and the EHDS set the EU's framework for health data but their coexistence creates complexity and costs for business. A harmonised system across 27 Member States should enable interoperability of systems and data standards, and be adequately resourced (skills, capacity-building, data quality etc). Networks and collaboration between universities, industry/start-ups, and healthcare systems can make a strong contribution in that effort through large-scale, cross-border use cases.

Build capacity for healthcare-specific AI and quantum tech where Europe can gain competitive advantage. With a proposed €20 bn AI gigafactories push, part of the effort should focus on health/biotech moonshots (training, simulation, discovery), pairing it with regulatory sandboxes, and target grants at AI-biotech translational projects (Shah-Neville, 2025). Europe needs scale and focus in health AI and offer a competitive regulatory framework, building on EMA's workplan and 2023 reflection paper (EMA 2023), maximising the use of EMA's DARWIN EU for data and real-world evidence. Similarly, countries such as Denmark, with a strong focus on quantum tech, can bring in leadership and build partnerships with other hubs across Europe. The synergies between biotech and AI are recognised in the Franco-German economic agenda, setting out a political priority for Europe.

4. Make it simpler

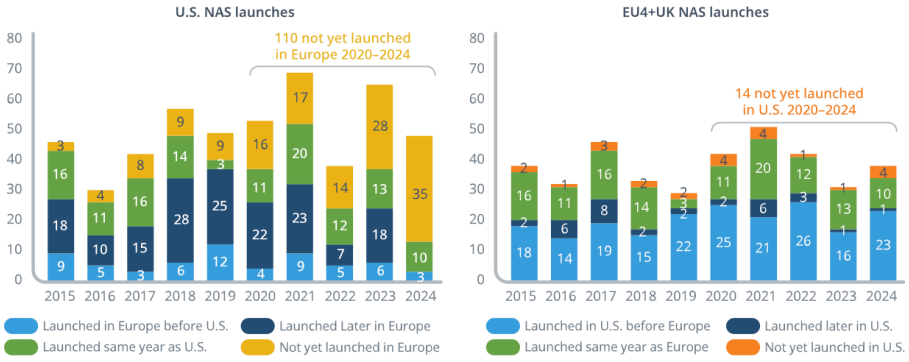
IMF data shows that deepening the single market is the most powerful tool to boost investment, innovation, and productivity and that acting jointly will decrease duplication (International Monetary

Fund, 2025). A summary of a recent panel at BIO 2025 in Boston (Nelson 2025) highlights what it comes down to for investors: Europe has significant strengths but hubs are too disparate, capital is not being deployed and maximised, and regulatory processes must be made simpler and more streamlined.

The EU's Clinical Trials Regulation harmonises trial authorisation and oversight across EU/EEA countries, via a single portal and coordinated assessment, so multi-country studies can operate as one EU market. The EU should address the key areas where fragmentation of the single market due to a lack of thorough national implementation is impacting choices by the biopharma sector and risk future vulnerability, notably in relation to China. Support should tackle national bottlenecks, leverage novel patient-centric trial designs and enable broader use of hybrid/decentralised formats where appropriate. The Biotech Act should make bold proposals for improvement, but monitoring performance for example of recruitment times and number of multi-country trials is key.

Assess market access fragmentation as a growing risk factor: Europe experiences continued access delays and a widening asymmetry between the EU and US in terms of access. Today, 40% of medicines approved by the US FDA are not launched in Europe.[23] Access to new drugs in the EU's 27 national markets remains a protracted issue. However, access and pricing dynamics in Europe will inevitably be impacted by the shifting geopolitical dynamics.

Figure 7: NAS launches in the US and the EU4+UK, 2015-2024



Source: IQVIA Institute, Jan 2025.
Notes: NAS Launch dates reflect the availability of a medicine in the relevant geography regardless of reimbursement status. Launch dates in EU4+UK reflect the earliest of the five countries. U.S. NAS launches compared to their status in Europe. EU4+UK NAS launches compared to their status in the U.S. Information in most recent periods can be restated later and may change.
Report: Global Trends in R&D 2025: Progress in Recapturing Momentum in Biopharma Innovation. IQVIA Institute for Human Data Science, March 2025.

Source: Global Trends in R&D, IQVIA Institute, March 2025.

The EU's 'Strategy for European Life Sciences' highlights the "fierce competition on the global scene from other economies such as the US and China." Chinese biopharmaceutical companies are not yet able to match western firms for regulatory and commercial heft with most still relying on partnerships for global reach. However, a shift in this dynamic may just be a matter of time, as they are expanding onto international markets. Several analysts and industry observers believe that Chinese biopharma firms will be able to move from heavy reliance on licensing/partnerships to a model with stronger independent global launches outside of Asia, with the Chinese government implicitly supporting a

[23] *Based on IQVIA data in 'Global Trends in R&D', IQVIA Institute, March 2025: In the past five years there have been 110 (40%) US NAS launches that have not yet been launched in the key European markets, while only 14 (7%) drugs launched in Europe failed to be launched in the US.*

model whereby early R&D is funded domestically (OECD[24]) and later stages are financed via licensing with western firms.

Europe needs to plan for this trajectory and must ensure its own sector remains competitive. An additional complication is the threat of MFN pricing in the US (White House 2025c). The policy's intent alone influences strategic behaviour, given its impact on pharma revenues and compels companies to seek price increases elsewhere. It is also likely to contribute to further licensing partnerships with Chinese biotech firms and the growth of clinical trials in China (unless US measures put a significant curb on this). If efforts in Europe to address existing gaps lag, companies may deprioritize or delay EU launches, especially in smaller or lower-priced markets. Chinese biopharma firms could claim larger European market share, particularly where affordability is a competitive advantage. It is interesting to note that two out of the currently nine compounds under review by the HTA Regulation's Joint Clinical Assessment process are co-developed/from a Chinese company.[25]

The current uncertainty surrounding the US' investment climate is raising hope that there will be increased interest of biotechs and investors for Europe beyond just being a hedge against the US' current unpredictability. It would require much stronger signals from Europe.

Enable innovation-friendly procurement that rewards reliability, not just price: the Commission's plans to revise public procurement rules and the European Innovation Act to "foster the broader use of innovation procurement across the Union" are an opportunity to value criteria linked to resilience/quality, not price alone, that can help keep pivotal activity in Europe. More generally, governments should use purchasing power to connect budgets with strategic innovation, lowering barriers for SMEs and start-ups. Net prices should be kept confidential (to avoid ERP/MFN spillovers). The goal is faster launch-to-access and attracting pivotal trial and manufacturing to Europe. While criteria that value production steps done in Europe are being debated in the context of the proposal for a Critical Medicines Act, it is interesting to note that under the proposed European Competitiveness Fund, EU funding may be made conditional on locating manufacturing, processing or other essential stages of the value chain within the Union, particularly in areas of strategic dependence and where this links with resilience and security objectives. Tailored approaches for innovative biopharmaceuticals could be considered, looking at relevant criteria, but would need to be compatible with dual sourcing constraints. The single market should act as a pull for investment, not a regulatory disincentive.

Unify Europe's R&I potential and create clusters that work from bottom up: Fragmented R&I ecosystems are part of Europe's structural barriers. Countries with leading and well-resourced biotech clusters such as Spain, Denmark, and France should build on recent discussions between Member States on the need to scale up critical technologies through public-private cooperation and aligning funding with ERC, EIC and cohesion funds, as has been kicked off with the Danish Presidency. Efforts should be driven from bottom up, leveraging the wealth of creativity and expertise across Europe (Verbeeck, 2025).

Copy learnings from national biotech/biopharma strategies: assess the gaps that biotech startups would need support in – whether that is sector guidance for biotech on the EU legislative frameworks

[24] *See recent OECD figures: At 8.7%, growth in R&D expenditure in China continued to surpass that of the OECD area, the United States (1.7%) and the European Union (1.6%) in 2023.*

[25] *The full list of all compounds currently under review can be viewed here: https://health.ec.europa.eu/latest-updates/updated-list-ongoing-joint-clinical-assessments-2025-09-02_en*

and their complex overlaps (eg AI Act, GDPR etc); invest in skills and data/digital infrastructure so SMEs can actually adopt AI, provide SME-specific guidance. The EU's 2024 Biotech Strategy has launched a Biotech Hub, which should function as a one-stop signposting service that directs companies to funding, regulatory guidance, IP and networks**,** and this should be part of the guidance given to start ups. It should bring in the service providers to clinical trials, such as CROs.

5. Secure Supply Chains and support Europe's excellence in biomanufacturing

Map supply chains and identify areas in which substitutes for materials may be needed (single-use systems, resins, enzymes/reagents, lipids, sterile primary packaging), similarly for key equipment (bioreactors, high-parameter cytometers, advanced LC/MS, sequencers), and execution capacity (EU CDMOs across biologics, ATMPs and sterile fill-finish). Develop protocols for preparedness in case of supply chain issues, based on HERA work to date. This should also feed into FDI rules and guidance, critical biomanufacturing sites, genomic/clinical data repositories that feed R&D, and manufacturers of specialist inputs, so cases with real security relevance are prioritised.

Secure Europe's advantages, advance modular manufacturing, and track CDMO capacity (reduce dependency): the EU should retain and build its biomanufacturing capacities. Several pharmaceutical companies have strong in-house capacity in Europe, while CDMOs are an essential part in the biopharma value chain, and a key partner for biopharma companies to give them flexibility and enabling back-up solutions in case of development or manufacturing pressures. HERA's work to date on "ever warm" reserve capacity within the framework of EU-FAB, and in mapping of manufacturing gaps and needs is another area of activity that could be expanded beyond a preparedness context. This with an objective of building a strong expertise and skills base in Europe for high tech modular, rapidly adaptable, biomanufacturing infrastructure.

Competition from China has been increasing since the second half of the 2000's, following the regulatory changes to open China's market for contract development and manufacturing organizations (CDMOs) and with Chinese CMOs rapidly growing into global leaders. Following Beijing's recent pledge to accelerate biomanufacturing, China's capacity in this sector is set to grow further (Shen, 2025). At the same time, countries like South Korea, already a strong contender for biomanufacturing, continue to invest in the sector. This is putting the European CDMO sector under significant pressure. Capacity must be measured. The Commission should benchmark EU CDMO capacity growth annually by modality and unit operation (microbial and mammalian drug substance, viral vectors, plasmid DNA, LNP, fill-finish), publish lead times and utilisation ranges, and identify where a marginal public euro would buy the most de-bottlenecking. This provides an objective basis for targeted support—grants, guarantees, procurement offtake or accelerated permitting—where Europe can realistically hold or gain share.

Role of the EU FDI screening remains open: the EU foreign direct investment (FDI) screening is a hybrid system: the Commission coordinates under Regulation (EU) 2019/452, but screening decisions sit with Member States (White & Case, 2025). The 24 January 2024 revision proposal would ensure every Member State has a mechanism, extending anti-circumvention to EU-based subsidiaries of non-EU owners, and setting a *minimum* sectoral scope that (in the Commission's proposal) explicitly includes the Union list of critical medicines. The Council's June 2025 mandate, however, proposes narrowing that minimum to military and dual-use goods, so whether critical medicines remain in the EU-wide floor is still under discussion (at time of writing; Van Bael & Bellis 2025). FDI is mentioned in

the Draghi Report, with a call for tougher screening where this represents a potential security threat and a "geopolitical rival" of the EU.

6. The international dimension: partnering with third countries

No country can manage these challenges successfully alone. The Belfer Center's Critical and Emerging Technologies Index highlights the importance of collaborative partnerships, even for the US. While powerful, it does not have full supremacy (Belfer Center, 2025). Europe can offer predictability and stability in its agreements with third countries and develop a coherent multilateral economic security approach to biopharmaceuticals that aligns with Europe's strategic interests, and complements measures to promote the sector within the EU (Crebo-Rediker, 2025). The EU's efforts at building partnerships to strengthen global health security and Europe's own health resilience, are an essential complement to these efforts.

- **Form Innovation Partnerships and partner up on economic security in biotech**: scientific collaboration risks being fractured by geopolitical considerations. While continued engagement with major powers like China and the US remains essential, albeit requiring substantially deeper alignment on standards and reciprocity than currently exists, particularly with China, the EU should prioritize forming biotech alliances with third countries with strong biopharma footprints and/or active biopharma industrial strategies, such as the UK, Switzerland, Japan, Canada, South Korea, and Australia on clinical trials, manufacturing resilience, promoting harmonized biotech standards and mutual recognition of regulatory frameworks.
- **Resilient Supply Chains**: the need for a coordinated EU approach to securing supply chains is by now well recognised (for example in the proposed critical medicines act, and HERA). More focus is needed on biopharma-specific issues around biological inputs (e.g., enzymes, reagents, cultures etc), secure access to raw materials and other aspects.
- **Standards:** standardisation is key in global tech competition and plays a central role in shaping industrial ecosystems, global trade and interoperability, innovation flows (Ferreira Gomes et al., 2025)**.** The EU should take a leading role in multilateral norm-setting in biotech, particularly in areas like synthetic biology and the AI-biotech nexus, where international standards can serve both moral and economic security goals. It will be increasingly important to align national R&D efforts with norms and values shared by allies and partners to encourage progress and the ethical use of scientific breakthroughs.
- **Global Bioethics Leadership**: coordinate EU-level ethical guidelines for biotech research and development and explore scope for developing a governance framework with other international partners. Given the fast-paced developments in both AI and Biotech, combined with the significant ethical considerations that arise in their application require international rules and standards, there may be scope for a governance framework on AI and biotech.

7. Deploy economic security instruments judiciously

Economic security instruments should be applied with clarity, coordination and speed, calibrated to actual risk through systematic screening in biopharma rather than generic concerns.

Research security is directly relevant to biotech and will need an end-to-end approach, especially in particularly sensitive areas such as synthetic biology and gene editing. The Council Recommendation explicitly links research security to export controls, IP protection, and data rules. Guidance for universities, labs, and hospitals, that can draw on existing tools such as Germany's BAFA "Export

Control & Academia" manual, as well as already existing initiatives between research institutes and universities from different Member States, will be important to turn high-level principles into practice. Addressing fragmented approaches and existing gaps in countries will be essential.

FDI screening's role is still under discussion. The EU foreign direct investment screening operates as a hybrid system: the Commission coordinates under Regulation (EU) 2019/452, but screening decisions sit with Member States (White & Case, 2025). The January 2024 revision proposal would ensure every Member State has a mechanism, extending anti-circumvention to EU-based subsidiaries of non-EU owners, and setting minimum sectoral scope. The Commission's proposal explicitly includes the Union list of critical medicines. However, the Council's June 2025 mandate proposes narrowing that minimum to military and dual-use goods, so whether critical medicines remain in the EU-wide floor is still under discussion (Van Bael & Bellis, 2025). The Draghi Report calls for tougher screening where security threats and "geopolitical rivals" are involved.

On the Commission side, it is to be hoped that coordinating leadership and efficient governance will bring together the many different initiatives and focus them where it really matters, whether through the Lifescience Strategy, the various AI-related initiatives, the planned Competitiveness Fund, or the scaling up of HERA's activities, to name just a few that are related to Europe's biopharma economic security.

But it is the strategic vision and belief in Europe's strengths by national governments that is essential if an economic security strategy is to be more than the sum of its parts. While it will need to be set within the EU's expected economic security doctrine, an economic security-based industrial strategy for biopharma requires a comprehensive approach and an alignment on what Europe's strengths should be in order to build on its position as a globally competitive hub.

The 'promote' element of European strategy is essential given Europe's market access delays and widening competitiveness gaps. Current US state-driven policies demonstrate clearly how market size can become leverage for an entire sector in today's geopolitical context. Europe must become more responsive to biopharma's innovation cycle and the dynamic efficiencies created through the value of innovation and the subsequent genericization. The dialogue of the private sector with healthcare system actors and decision-makers from payer bodies is essential as today's pressures, including geopolitical, also impact Europe's healthcare system resilience.

The essential precondition is a deeper understanding of interdependencies, alignment of objectives, and the strong political will to back them with means to act jointly and at scale, including through resilience-building measures and policy coordination. As one European investor summarized at BIO Boston 2025: "I think it's going to get worse with Asia and China coming on board because they really have the amount of people, drive, ambition, and they want to do it so quickly. They have that sense of urgency that Europe is still really lacking" (Nelson 2025).

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