

**Technology Transfer and Strategic Health Sovereignty:
Advancing Europe's Approach to Health and Life Science Innovation**

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Abstract:

Europe's health and life-science innovation policy is being reshaped by geopolitical tensions, recurrent supply-chain disruptions, technological change and intensified competition for manufacturing, resources, data infrastructure, translational capacity and talent. This paper conceptualizes strategic health sovereignty as a governance approach that preserves scientific openness and strategic cooperation while building capabilities and reducing structural vulnerabilities in critical medicines and health technologies. Drawing on recent European Union (EU) initiatives, this paper examines how Europe can strengthen competitiveness, product adoption and access by better aligning three policy levers: (1) incentives and protections, (2) simplified regulatory frameworks, and (3) increased focus on technology transfer and scale-up capacity. Emphasizing the urgent need for improvements in the European innovation ecosystem, this paper stresses the importance of better integrated innovation pipelines. It further stresses that a competitive European health and life-science innovation ecosystem needs a visionary investment culture, which in turn requires predictable incentives, regulation and translation mechanisms.

I. INTRODUCTION

European health and life-science innovation, and the recent policy initiatives seeking to regulate and promote it, face severe challenges. On the one hand, recent data suggest that Europe still has an exceptional scientific base, leading universities and hospitals, sophisticated regulatory institutions, and well-established pharmaceutical, biotechnology, and medical-technology industries. For example, the broader life-science sectors, including agriculture and food production, accounted for approximately 9.4% of the European Union's (EU) gross

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domestic product (GDP) and 29 million jobs in 2022, while business expenditure on research and development rose from €26.6 billion in 2012 to €46.6 billion in 2022.¹

On the other hand, scientific strength does not consistently translate into successful scale-ups or manufacturing capacity.² As part of its competitiveness agenda, the Commission published its Strategy for European Life Sciences on July 2, 2025, which acknowledges that “[t]he EU faces fierce competition at global level from other economies such as the US and China, with a growing innovation gap and an alarming failure to translate innovation into products or services. Innovative companies struggle to scale up in Europe.”³ These concerns were also emphasized in the earlier Letta and Draghi Reports.⁴ Proceeding from different institutional perspectives, both reports identify Single Market fragmentation, weak commercialization and scale-up conditions, insufficiently integrated capital and knowledge markets, and regulatory complexity as mutually reinforcing constraints on Europe’s ability to convert scientific excellence into globally competitive industrial capabilities.⁵

Several indicators give substance to these concerns. A Joint Research Centre analysis of internationally oriented biotechnology patent families found that the EU’s global share fell from 22.6% in 2001 to 18.3% in 2020, while the United States retained a much larger share and China gained ground.⁶ Other indicators concern later stages of product development.

According to the Commission’s December 2025 proposal for a European Biotech Act, the European Economic Area’s share of commercially sponsored clinical trials declined from 22% in 2013 to 12% in 2023, whereas China’s share increased from 5% to 18%. The proposal also reports that U.S. biopharmaceutical start-ups attracted approximately €219 billion in relevant

¹ Jesús Lasarte-López, Hugo González-Hermoso, and Robert M’barek, *The Life Sciences Sectors in the EU: Drivers of Economic Growth and Innovation*, JRC142396 (European Commission, 2025), 2–5, <https://publications.jrc.ec.europa.eu/repository/handle/JRC142396>.

² Christopher Robin Lowe, Timo Minssen, and Claire Skentelbery, *Emerging Biotechnologies in Europe: Foresight for Policy*, ed. Pierre-Mathieu Pélissier, JRC139415 (Publications Office of the European Union, 2024), 6–7, <https://doi.org/10.2760/4814109>.

³ European Commission, *Choose Europe for Life Sciences: A Strategy to Position the EU as the World’s Most Attractive Place for Life Sciences by 2030*, COM (2025) 525 final, 5 (July 2, 2025), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0525>.

⁴ Enrico Letta, *Much More than a Market: Speed, Security, Solidarity* (April 2024), 7–8, 19–20, 50–51, <https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf>; Mario Draghi, *The Future of European Competitiveness*, pt. A, *A Competitiveness Strategy for Europe* (September 2024), 29–36, https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en.

⁵ Letta, *Much More than a Market*, 7–8, 19–20, 50–51; Draghi, *Future of European Competitiveness*, pt. A, 29–36.

⁶ Nicola Grassano et al., *Exploring the Global Landscape of Biotech Innovation: Preliminary Insights from Patent Analysis*, JRC137266 (Publications Office of the European Union, 2024), 7–8, <https://doi.org/10.2760/567451>. Patent-family counts indicate inventive activity and international patenting strategy, not independently clinical value, commercial success, or patient benefit.

venture capital between 2015 and June 2025, compared with €25 billion in the EU.⁷ Although these indicators measure different activities and rely on different methodologies, together they raise a central question: Does Europe's relative weakness lie in generating knowledge or in converting it into clinical, industrial, and public-health capabilities?

Recent geopolitical disruptions, trade wars, climate change, and biological threats add to the magnitude and urgency of the concern, as these factors increasingly affect the health and life sciences sectors. The COVID-19 pandemic exposed shortages of essential products and limited visibility over complex supply chains.⁸ Indeed, medicine shortages have become a recurrent problem, with record levels reported in 2023 and 2024,⁹ making them a priority in European policymaking.¹⁰ This is reflected in the Council's September 2026 first-reading position on the much-debated European pharmaceutical package,¹¹ and the May 2026 provisional agreement on the Critical Medicines Act.¹²

Similar dependencies arise in the digital layer of health innovation, including reliance on external providers of cloud services, computing capacity, software and advanced artificial intelligence (AI) models. Interdependence, however, is not itself evidence of vulnerability: the United States remains a major scientific and commercial partner, while China is simultaneously a research partner, supplier and increasingly important competitor. Security concerns arise more specifically where dependence is concentrated, alternatives are unavailable within an acceptable period, or an external actor controls a technological, infrastructural or supply-chain choke point capable of restricting access to a critical resource or service.¹³

⁷ Proposal for a Regulation Establishing a Framework of Measures for Strengthening the Union's Biotechnology and Biomanufacturing Sectors, Particularly in the Area of Health (European Biotech Act), COM (2025) 1022 final/2, explanatory memorandum at 2–3 (Dec. 16, 2025), <https://data.consilium.europa.eu/doc/document/ST-16945-2025-INIT/en/pdf>. These are Commission-reported figures drawn from external studies, including the European Federation of Pharmaceutical Industries and Associations and the Vlaams Instituut voor Biotechnologie.

⁸ Sonu Bhaskar et al., "At the Epicenter of COVID-19—the Tragic Failure of the Global Supply Chain for Medical Supplies," *Frontiers in Public Health* 8 (2020): 562882, <https://doi.org/10.3389/fpubh.2020.562882>.

⁹ European Court of Auditors, *Critical Shortages of Medicines: EU Measures Were of Added Value, but Structural Problems Remain*, Special Report 19/2025 (2025), 4, 50–51, <https://www.eca.europa.eu/en/publications/sr-2025-19>.

¹⁰ As of October 14, 2026, the Council had adopted its first-reading positions on the pharmaceutical package; Parliament's second reading remained outstanding. The Critical Medicines Act also awaited formal adoption. See European Parliament, Legislative Observatory, procedures 2023/0131(COD), 2023/0132(COD), and 2025/0102(COD) (accessed October 14, 2026).

¹¹ Council of the European Union, "Pharma Package": Council Adopts New Rules for a Fairer and More Competitive EU Pharmaceutical Sector," September 28, 2026, <https://www.consilium.europa.eu/en/press/press-releases/2026/09/28/pharma-package-council-adopts-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/>.

¹² Council of the European Union, "Critical Medicines Act: Council and Parliament Reach Provisional Deal," May 12, 2026, updated June 30, 2026, <https://www.consilium.europa.eu/en/press/press-releases/2026/05/12/critical-medicines-act-council-and-parliament-reach-provisional-deal/>.

¹³ European Commission and High Representative, *European Economic Security Strategy*, JOIN (2023) 20 final, 2–7 (June 20, 2023), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023JC0020>; *Strengthening*

Developing appropriate responses to these challenges will most likely require combining European capacity-building and diversification with strategic collaboration among reliable international partners.

This setting raises a series of connected questions at the interface of incentives, regulatory policy-making, technology transfer/scale-up, and adoption/access – which capabilities must Europe retain, develop or be able to access reliably if it is to convert scientific excellence into “biosolutions” or health outcomes? What is the role of intellectual property, regulatory protection and public funding in encouraging innovation while supporting translation, manufacturing and availability? Can regulatory procedures be made more predictable and proportionate without weakening evidence, safety, fundamental rights or public trust? Which forms of strategic collaboration can strengthen European capability without creating new choke points or exclusive dependencies? Finally, what institutional arrangements are needed to move knowledge, data, technology and know-how from research into production, adoption and patient access?

This paper examines these questions through a law-and-governance analysis of the emerging European policy architecture. It considers selected measures, rather than comprehensively assessing competition law, procurement, pricing or reimbursement, and does not empirically evaluate their effects. Section II clarifies health and life-science sovereignty in the EU’s multilevel and digitally dependent legal order. Section III considers incentives, knowledge and control; Section IV examines regulatory pathways; and Section V analyzes technology transfer as the institutional connection between research and deployable capability. Section VI concludes.

II. HEALTH AND LIFE SCIENCE SOVEREIGNTY IN THE DIGITAL & AI AGE

Discussing “sovereignty” in the European context requires attention to the EU’s peculiarities. Firstly, EU frameworks include both national and supranational mandates and competences that govern regional and national sovereign systems. Its powers are conferred by the Treaties and distributed across several legal bases and with varying levels of government approaches. Member States retain key competences and are for instance responsible for organizing and delivering health services. The EU therefore does not represent a unitary health system.

EU Economic Security, JOIN (2025) 977 final, 1–7 (December 3, 2025), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025JC0977>.

Equally, internal-market harmonization, research policy, industrial policy, competition law, trade, data regulation and crisis preparedness give the Union substantial supranational authority over the conditions under which health technologies are developed, manufactured and supplied.¹⁴ European health sovereignty therefore cannot sensibly be discussed by assuming exclusive jurisdiction exercised by a single public authority. It is better understood as a challenge of coordinating capacity within a multilevel legal and institutional system, with Member States that may even compete with one another within the EU.

Sovereignty therefore does not imply autarky from other regions or countries, such as the U.S. or China, nor does resilience require complete self-sufficiency. Dependency becomes a sovereignty concern when it affects a socially important function and creates a material vulnerability—for example because supply is highly concentrated, substitutes are unavailable, switching would take too long or the loss of specialized knowledge would be difficult to reverse.¹⁵ International collaboration is necessary and attempts to localize every activity or resource could decrease capabilities and increase costs, fragment research populations and create new concentrations of risk.

The digital dimension of sovereignty must likewise be incorporated into this assessment. The question is not whether every dataset, model or cloud service is European, but whether European actors possess sufficient understanding, lawful access, operational security, bargaining power and alternatives to avoid unacceptable dependence. Data localization is inadequate where control of software, interfaces or technical administration remains concentrated elsewhere. Interoperability, cybersecurity, auditability, portability and credible exit options may contribute more to resilience than nationality alone. Strategic collaboration similarly strengthens sovereignty when it diversifies sources, pools expertise or creates reciprocal capacity, but not when it produces an irreplaceable choke point.¹⁶

Novo Nordisk’s collaborations with OpenAI, Amazon Web Services, and Anthropic provide a good example of this tension. The September 2026 Anthropic announcement envisages testing Claude Science in selected research and development workflows and using frontier models for software development. It describes data governance and human oversight but does

¹⁴ Consolidated Version of the Treaty on the Functioning of the European Union (TFEU) arts. 3(1)(b), 3(1)(e), 4(2)(a), 4(2)(k), 6(a), 16, 114, 168, 173, 179–190, 207, 2016 O.J. (C 202) 47, especially art. 168(7).

¹⁵ Jakob Edler et al., “Technology Sovereignty as an Emerging Frame for Innovation Policy: Defining Rationales, Ends and Means,” *Research Policy* 52, no. 6 (2023): 104765, secs. 2–4, <https://doi.org/10.1016/j.respol.2023.104765>; European Commission and High Representative, *European Economic Security Strategy*, 5–10; *Strengthening EU Economic Security*, 5–7.

¹⁶ European Commission and High Representative, *European Economic Security Strategy*, 5–10; *Strengthening EU Economic Security*, 5–7, 11–12; Regulation (EU) 2023/2854, arts. 23, 25, 30, 2023 O.J. (L, 2023/2854).

not disclose the detailed allocations of right or arrangements for changing providers.¹⁷ Access to frontier AI capabilities may accelerate research while creating dependence on externally controlled models, infrastructure and expertise. Such arrangements require careful attention to contractual rights over data and outputs, protection of confidential information, operational security and the options available if a provider changes its terms or withdraws.¹⁸ The relevant question is whether the collaboration expands European capabilities while preserving the practical ability to continue development. In other words, the relevant objective should be to preserve the knowledge, institutional competence and practical alternatives required to make and implement strategic choices under changing conditions.¹⁹

Against this background, European health and life-science sovereignty may perhaps be best understood as the capacity of the EU, as well as European countries, to identify health priorities; generate, understand and govern relevant knowledge and technologies; translate them into clinical and industrial applications; and secure reliable production, procurement, adoption and access.

This capability-based conception also clarifies the relationship between sovereignty and innovation incentives. If sovereignty depends on practical capacity, what conduct does European law reward, who will assume the relevant risks, and who controls the assets needed to continue development?

Section III examines these questions through intellectual property rights, regulatory protection, and public funding. Their contribution to sovereignty depends on the regulatory pathways and capacity for technology transfer considered in Sections IV and V.

¹⁷ Novo Nordisk, “Novo and Anthropic Will Collaborate to Advance Drug Discovery with Claude,” September 16, 2026, <https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=916768>; Novo Nordisk, “Novo Nordisk and AWS Enter Strategic Partnership to Accelerate Drug Discovery through AI,” August 10, 2026, <https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=916594>; Novo Nordisk, “Novo Nordisk and OpenAI Partner to Transform How Medicines Are Discovered and Delivered,” April 14, 2026, <https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=916532>.

¹⁸ These risks extend to biotechnology: today’s AI collaborator may become tomorrow’s competitor as its scientific capabilities expand. This possibility warrants contractual and technical safeguards for intellectual property and trade secrets, including protected processing environments. However, such safeguards do not necessarily prevent a provider’s independent expansion into competing activities. See Jeffrey Dastin and Michael Erman, “Anthropic Quietly Sets Up Biology Lab as It Ramps AI Drug Program,” *Reuters*, September 18, 2026, <https://www.reuters.com/world/anthropic-quietly-sets-up-biology-lab-it-ramps-ai-drug-program-2026-09-18/>.

¹⁹ Edler et al., “Technology Sovereignty,” secs. 3–4; European Commission, *Trade Policy Review: An Open, Sustainable and Assertive Trade Policy*, COM (2021) 66 final, 4–10 (February 18, 2021), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0066>.

III. INCENTIVES, PROTECTION & CONTROL

Consider first the following scenario: a health technology is patented in Germany, trained on Danish health data, financed by Horizon Europe, licensed to a company in the United States, and manufactured in Singapore. Can it still be considered European? The question is useful for visualizing the substantial limits of equating sovereignty with ownership. Europe remains a scientific power, and although it may supply the data, public funding and formal legal rights, it is less successful at converting research into products that are manufactured at scale within Europe and ultimately reach patients.²⁰ Its incentive system should therefore be judged not only by whether it *generates* an invention, but by whether it carries that invention through commercial translation, scale-up, manufacture, and adoption. No single instrument, incentive or reward - whether a push or pull mechanism - can perform all of those jobs. Instead, a bundle of them - including public grants, intellectual property rights, regulatory protections, growth capital, infrastructure, procurement, and market access - must be considered together.²¹

A. Patents and regulatory protection

Patents remain the bundle's core. In exchange for an enabling disclosure, they protect inventions that are new, inventive, and industrially applicable; their term runs for twenty years from filing.²² Supplementary protection certificates (SPCs) can then partly compensate medicinal products for patent term consumed by regulatory review.²³ Regulatory data and market protection add another layer, delaying a follow-on applicant's reliance on the originator's preclinical and clinical dossier and, in turn, delaying market entry. Current EU law follows an eight-plus-two structure, with a possible additional year for a qualifying new indication (8+2+1).²⁴ The pending pharmaceutical reform seeks to recalibrate that bargain.

²⁰ European Commission, *Choose Europe for Life Sciences*, sec. 1; Draghi, *Future of European Competitiveness*, pt. A, 6–7.

²¹ Daniel J. Hemel and Lisa Larrimore Ouellette, “Beyond the Patents–Prizes Debate,” *Texas Law Review* 92 (2013): 333–58; Amy Kapczynski and Talha Syed, “The Continuum of Excludability and the Limits of Patents,” *Yale Law Journal* 122 (2013): 1938–49.

²² Convention on the Grant of European Patents arts. 52, 54, 56, 57, 63, 83, Oct. 5, 1973, 1065 U.N.T.S. 199, as revised Nov. 29, 2000.

²³ Regulation (EC) No. 469/2009, arts. 3, 13, 2009 O.J. (L 152) 1 (supplementary protection certificates for medicinal products).

²⁴ Directive 2001/83/EC, art. 10(1), 2001 O.J. (L 311) 67; Regulation (EC) No. 726/2004, art. 14(11), 2004 O.J. (L 136) 1.

Under the Council’s September 2026 first-reading position, the baseline would be eight years of data protection and one year of market protection. A further year would reward medicines addressing unmet medical need or medicines containing new active substances that meet specified evidence and development conditions.²⁵ For the latter, comparative clinical trials must be combined either with efficacy trials in more than one Member State or with EU filing before, or within ninety days of, the first corresponding application outside the Union. Where comparative trials are justified as impossible or inappropriate, both the multi-Member-State trial and timely-filing conditions would be required. Part of the current two-year period of market protection would thus become a conditional reward. The trial-location criterion seeks to anchor clinical research and trial networks in Europe, while timely filing seeks to prevent the Union from becoming a secondary market for innovative medicines. Comparative trials reward evidence capable of demonstrating a medicine’s added value against existing care.

That said, the attempted territorial pull of these conditions should not be overstated. A medicine may qualify by combining comparative trials with timely EU filing, without conducting trials in several Member States; nor does the extension require European scale-up or manufacturing. What it may nevertheless achieve is to link exclusivity more closely to European clinical development and regulatory priority.

B. Control over the technology bundle

Even this, however, reaches only the reward attached to the authorized *product*. The capacity to develop, manufacture, and supply that product rests on a much wider technology bundle. A modern therapeutic or diagnostic may depend on curated research and clinical datasets; increasingly, source code, model architecture, and trained weights; trial protocols and regulatory correspondence; cell lines and process parameters; quality-control systems and supplier relationships; and the tacit knowledge and judgment of scientists and operators.²⁶

²⁵ Council Position at First Reading on a Directive on the Union Code Relating to Medicinal Products for Human Use, Council Doc. ST 7106/2/26 REV 2, arts. 83–85 (Sept. 28, 2026), <https://data.consilium.europa.eu/doc/document/ST-7106-2026-REV-2/en/pdf>. Article 84(2) separately provides for a further year for a qualifying new therapeutic indication; article 84(3) limits cumulative market protection.

²⁶ Regulation (EU) 2025/327, arts. 51–52, 2025 O.J. (L, 2025/327); Directive 2009/24/EC, art. 1, 2009 O.J. (L 111) 16; Regulation (EU) 2024/1689, art. 53 & annex XI, 2024 O.J. (L, 2024/1689); Directive (EU) 2016/943, art. 2(1), 2016 O.J. (L 157) 1; European Medicines Agency, *ICH Guideline Q10 on Pharmaceutical Quality System*, EMA/CHMP/ICH/214732/2007 (September 2015), secs. 1.2, 1.6.1, 3.1.2; World Health Organization, *WHO Guidelines on Technology Transfer in Pharmaceutical Manufacturing*, Technical Report Series 1044, annex 4 (2022), secs. 1.4–1.7, 5.12 & app. 1, <https://www.who.int/publications/m/item/trs1044-annex4>.

These elements are not all protected in the same way. Some are subject to formal intellectual property or regulatory rights; some are controlled principally through secrecy and contract; others are embodied in organizations, facilities, and people. Patents, copyright, database rights, regulatory data protection, data protection law, trade secret law, and contractual restrictions may also overlap within the same technology. Formal title to one component does not, thus, determine who can obtain regulatory approval, reproduce the process at industrial scale, or maintain supply. While Europe may own or fund patented results, the data, supplier relationships, capital or any other elements of the above-described bundle may be controlled elsewhere.

For present purposes, *control* means the practical ability to assemble those elements and move a technology from invention to reliable supply. For that to happen, Europe need not own every input or locate every activity within its borders, but it needs to build the capacity to combine or adapt these outputs, transfer them, and avoid dependence on a single external actor or location.

C. Supporting research, translation, and scale-up

Going back to the incentives backbone, its rationale should be framed accordingly: which activity is Europe seeking to induce? Who will perform it, and where? Which missing asset or capability presently prevents it? The answer changes with the stage of development and, when connecting incentives to availability and access, it is useful to consider what the public is - metaphorically and practically - buying at each stage.

At discovery and early development, the central need is risk-tolerant funding and room for cumulative inquiry. Horizon Europe is an example of an intervention before an authorized product can earn a return from exclusivity. Beneficiaries generally own the results they generate, must use their best efforts to exploit them, and must disseminate them as soon as possible subject to legitimate constraints. Research data are to be “as open as possible, as closed as necessary.”²⁷ When the grant agreement so provides, the Commission or funding body may object to a transfer or exclusive license to an entity in a non-associated third country if it is not aligned with Union interests. Where this right applies, advance notification allows the funding authority to object before the transfer or exclusive license takes effect. This safeguards the

²⁷ Regulation (EU) 2021/695, arts. 14, 38–40, 2021 O.J. (L 170) 1.

Union's interests in publicly funded results but does not itself provide the expertise or infrastructure needed to develop them.²⁸

At commercial translation and European scale-up, the often-missing elements are patient capital (which must tolerate long development periods and substantial risk of failure), regulatory capability (teams must be able to convert a scientific result into an approvable development program), and production capacity (including pilot lines, good manufacturing practice (GMP)-ready equipment, process validation, quality systems, etc.). The Strategic Technologies for Europe Platform (STEP) is an existing policy framework that seeks to address obstacles to European biotechnology scale-up by directing existing Union programs toward the development, manufacture, and value chains of critical technologies, including biotechnology.²⁹ The European Innovation Council (EIC) STEP Scale Up scheme supplies part of the capital, offering €10–30 million investments intended to catalyze rounds of €50–150 million or more.³⁰ Yet an applicant must already have a non-binding equity pre-commitment from a single qualified investor covering at least 20 percent of the target round. Thus, while the scheme is helpful to an investment-ready firm, it does not solve the earlier gap smaller - or less experienced market participants face.³¹

The proposed European Biotech Act similarly targets the assets that exclusivity cannot supply. It would add a strategic-project framework that reaches production sites, pilot and demonstration infrastructure, GMP-capable development accelerators, and centers combining manufacturing, regulatory science and clinical expertise.³² Lastly, the 2026 Technology Transfer Block Exemption Regulation and Guidelines provide a competition-law safe harbor for qualifying bilateral licenses (and certain risk-sharing assignments) of patents, know-how, software copyright, and other specified technology rights for production. Subject to its other conditions, the exemption applies where the parties' combined market share does not exceed 20 percent if they compete, or each party's share does not exceed 30 percent if they do not. Hardcore restrictions exclude the agreement from the exemption, while specified excluded obligations require individual assessment.³³ In that way, the Regulation can reduce competition-law uncertainty.

²⁸ Regulation (EU) 2021/695, art. 40(4).

²⁹ Regulation (EU) 2024/795, arts. 2(1)–(3), 3(1), 2024 O.J. (L, 2024/795).

³⁰ European Commission, *European Innovation Council Work Programme 2026*, C (2026) 4080 (June 17, 2026), sec. VI, 104–8, https://eic.ec.europa.eu/eic-funding-opportunities/eic-2026-work-programme_en.

³¹ European Commission, *European Innovation Council Work Programme 2026*, 106.

³² European Biotech Act Proposal, COM (2025) 1022 final/2, arts. 3–6.

³³ Commission Regulation (EU) 2026/877, arts. 1–5, 2026 O.J. (L, 2026/877); Guidelines on the Application of Article 101 TFEU to Technology Transfer Agreements, 2026 O.J. (C, C/2026/2323).

D. Reliable supply and antimicrobial incentives

Reliable supply requires still another policy mix - especially for mature, off-patent, and generic medicines whose main problems are low margins, concentrated supply chains, and underinvestment in manufacturing capacity. Under the May 2026 provisional agreement on the Critical Medicines Act, strategic projects could create, expand, or modernize manufacturing capacity. Member State support would carry Union-market supply obligations, while Union support could be conditioned on availability under the relevant funding instrument. Procurement would apply resilience criteria, including diversification and reliable delivery.³⁴ Where an assessment finds high dependence on one or a few third countries, specified procurement mechanisms would favor Union manufacturing, subject to international commitments and stated exceptions. Cooperation with third countries would remain another route to diversified supply. These tools address the failure to maintain redundant, validated capacity.

Finally, socially valuable but commercially weak innovation may justify a targeted reward. The Council's first-reading position on the pharmaceutical package would create a transferable data exclusivity voucher for a qualifying priority antimicrobial.³⁵ It would add twelve months of regulatory data protection to one centrally authorized medicine and could be transferred once. Eligibility would require, among other things, a significant clinical benefit with respect to antimicrobial resistance, capacity to supply expected Union needs, disclosure of direct research support, and timely filing with the European Medicines Agency. If used for another product, that product could not have exceeded €490 million in annual gross Union sales in any of its first four post-authorization years, a ceiling intended to limit the spillover to health budgets. The voucher may mobilize private capital, but it is a cross-product subsidy: it finances one antimicrobial by postponing follow-on reliance on another medicine's dossier. The resulting cost is thus borne by delayed competition elsewhere.

IV. EVOLVING EU REGULATORY FRAMEWORKS

³⁴ Council of the European Union, Final Compromise Text on the Critical Medicines Act, Council Doc. ST 11059/26, annex, arts. 5, 15–16, 18 & 27 (June 30, 2026), <https://data.consilium.europa.eu/doc/document/ST-11059-2026-INIT/en/pdf>. The agreement awaits formal adoption.

³⁵ Council Position at First Reading on a Regulation Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use, Council Doc. ST 7105/2/26 REV 2, arts. 41–44 (Sept. 28, 2026), <https://data.consilium.europa.eu/doc/document/ST-7105-2026-REV-2/en/pdf>.

On January 29, 2025, the Commission released its competitiveness agenda, an effort to ‘regain competitiveness and secure sustainable prosperity.’³⁶ Recognizing that Europe has failed to keep pace with other big economies, “due to a persistent gap in productivity growth,” the agenda seeks to confront “longstanding barriers and structural weaknesses that hold it back.”³⁷ Taking into account the findings of the Draghi Report, the agenda revolves around three main areas of action: security, decarbonization, and innovation, as well as five horizontal enablers which together should boost competitiveness.³⁸ One such enabler is simplification of regulatory frameworks.³⁹ And, indeed, this is especially important in the life sciences.

The Commission’s Life Sciences Strategy observes that:

“Life science innovators must sometimes also navigate complex regulatory frameworks. Innovators are often faced with the need to follow both EU legislation and national legislation, which are not sufficiently innovation-friendly, future-proof and lack clear paths to access markets. The risks of losing competitiveness to other regions are especially high in areas such as medical devices and clinical research. This requires Member States and the Commission to join forces.”⁴⁰

While the strategy proposes several ways to address these concerns, adjusting the regulatory framework to foster innovation remains an overarching goal. In this section, we discuss recent regulatory adjustments based on a three-stage approach that aligns with the traditional life sciences development phases: (1) research and development; (2) certification and product regulation, and (3) market access and uptake. We then consider whether simplification alone can boost innovation in Europe.

A. Research and development

To spur research and development in the life sciences, the Commission’s main focus consists of, *inter alia*, strengthening cooperation, optimizing the use of resources, relying on

³⁶ European Commission, “An EU Compass to Regain Competitiveness and Secure Sustainable Prosperity,” January 29, 2025, https://ec.europa.eu/commission/presscorner/detail/en/ip_25_339.

³⁷ European Commission, “An EU Compass.”

³⁸ The other enablers are reducing Single Market barriers, financing competitiveness, promoting skills and quality jobs, and coordinating EU and national policies. European Commission, “An EU Compass.”

³⁹ European Commission, “An EU Compass.”

⁴⁰ European Commission, *Choose Europe for Life Sciences*, sec. 1.

AI and data, as well as adjusting regulatory frameworks and building (digital) infrastructure that is more conducive to innovation.⁴¹ It has therefore (unsurprisingly) made several suggestions to amend applicable regulatory frameworks.

Alongside the funding and infrastructure measures discussed in Section III, the proposed European Biotech Act addresses uncertainty about regulatory pathways. Noting that ‘[f]ragmentation and the complexity of the EU regulatory framework are factors that make the EU less attractive for translating cutting-edge research and innovation into marketable products’,⁴² the proposal contains several interventions to boost innovation. These include assistance in identifying regulatory pathways from the EU Health Biotechnology Support Network,⁴³ a measure which is especially important for small and medium-sized enterprises that may lack in-house regulatory support, and the creation of an EU regulatory status repository.⁴⁴

The proposal would also allow the Commission to establish regulatory sandboxes for novel health biotechnology products that cannot appropriately be accommodated in other relevant sandboxes and face difficulty identifying a suitable regulatory procedure.⁴⁵ Regulatory sandboxes first emerged in the financial technology space, allowing developers to test their products under regulatory supervision, with any derogations limited to those permitted by the applicable legal framework.⁴⁶ Regulatory sandboxes have since been introduced in several other sectors, including for AI and data protection,⁴⁷ and are now proposed for pharmaceuticals⁴⁸ and biotechnology as a tool to enable research and development. Importantly, the Act would also facilitate cross-framework coordination among authorities who are active in sandboxes but who focus on different regulatory frameworks.⁴⁹

⁴¹ European Commission, *Choose Europe for Life Sciences*, secs. 2–3.

⁴² European Biotech Act Proposal, COM (2025) 1022 final/2, explanatory memorandum at 3.

⁴³ European Biotech Act Proposal, COM (2025) 1022 final/2, art. 34.

⁴⁴ European Biotech Act Proposal, COM (2025) 1022 final/2, art. 35.

⁴⁵ European Biotech Act Proposal, COM (2025) 1022 final/2, art. 40(1)–(2). Article 40(1) excludes products likely to fall within the health legislation listed in article 39(1)–(2).

⁴⁶ Mathieu Guerriaud, “‘Regulatory Sandboxes’ Could Solve the Regulatory Problems Encountered in Europe and Arising from Innovation in Biological Medicinal Products,” *Pharmaceutical Medicine* 38, no. 1 (2024): 19–23, <https://doi.org/10.1007/s40290-023-00507-6>. See also Financial Conduct Authority, *Regulatory Sandbox* (November 2015), 2–3, 8–9, <https://www.fca.org.uk/publication/research/regulatory-sandbox.pdf>.

⁴⁷ Norwegian Data Protection Authority, “Regulatory Privacy Sandbox,” accessed October 14, 2026, <https://www.datatilsynet.no/en/regulations-and-tools/sandbox-for-artificial-intelligence/>; Information Commissioner’s Office, “Regulatory Sandbox,” accessed October 14, 2026, <https://ico.org.uk/for-organisations/advice-and-services/regulatory-sandbox/>.

⁴⁸ Council Position on the Medicinal Products Regulation, Council Doc. ST 7105/26 REV 2, arts. 116–118.

⁴⁹ European Biotech Act Proposal, COM (2025) 1022 final/2, art. 39.

The Biotech Act further proposes to amend the EU Clinical Trials Regulation.⁵⁰ While the latter already sought to increasingly harmonize clinical trial rules by, for instance, introducing an authorization procedure where actors need only submit a single submission in the EU portal Clinical Trials Information System,⁵¹ greater harmonization was, according to the Commission, necessary to expedite the approval of clinical trial applications.⁵² Under the new rules, the approval timeline should reduce from 106 to 75 days, and from 75 to 47 days if no additional information is requested.⁵³ To achieve this goal, and to further streamline the entire clinical trial process, the Biotech Act would introduce a single core dossier, allowing sponsors to rely on said dossier when running multiple parallel or sequential trials for the same investigational medicinal product.⁵⁴ Moreover, one Member State would be responsible for verifying the dossier and ensuring its completeness and suitability.⁵⁵ The proposal would also set conditions for the use of AI in clinical trials.

The EU has also enacted other legislation with the aim of spurring innovation by making health data more available. The European Health Data Space (EHDS) entered into force in March 2025, but its principal primary- and secondary-use requirements will apply in stages from 2029 and 2031; participation by third countries and international organizations in HealthData@EU is deferred until 2035.⁵⁶ The EHDS enables greater cross-border sharing of primary data, allowing a patient in one EU member state to access their prescriptions in another, and lays the basis for secondary data sharing by providing for national health data access bodies and HealthData@EU, a cross-border infrastructure for secondary use. Under the EHDS framework, users can identify datasets in HealthData@EU before applying for a permit from the relevant national health data access body. Data will be accessible through a secure processing environment, with access provided by the health data access body or, under the simplified procedure, a designated trusted health data holder.⁵⁷ This framework can expand research opportunities, although its practical value will depend on implementation and the usability of the available data.

⁵⁰ Regulation (EU) No. 536/2014, 2014 O.J. (L 158) 1 (clinical trials).

⁵¹ Regulation (EU) No. 536/2014, arts. 5(1), 80; Żaneta Zemła-Pacud and Gabriela Lenarczyk, “Clinical Trial Data Transparency in the EU: Is the New Clinical Trials Regulation a Game-Changer?” *IIC—International Review of Intellectual Property and Competition Law* 54 (2023): 732–63, <https://doi.org/10.1007/s40319-023-01329-4>.

⁵² European Biotech Act Proposal, COM (2025) 1022 final/2, explanatory memorandum at 3–4, 27–28.

⁵³ European Biotech Act Proposal, COM (2025) 1022 final/2, explanatory memorandum at 27.

⁵⁴ European Biotech Act Proposal, COM (2025) 1022 final/2, art. 58(24) (inserting arts. 27a–27c into Regulation (EU) No 536/2014), at 146–48.

⁵⁵ European Biotech Act Proposal, COM (2025) 1022 final/2, art. 58(24), proposed arts. 27a(2)–(3), 27b(3)–(4), 27e.

⁵⁶ Regulation (EU) 2025/327, art. 105, 2025 O.J. (L, 2025/327) (European Health Data Space).

⁵⁷ Regulation (EU) 2025/327, recital 77, arts. 67–68, 72–73, 75 & 77–79.

The EU's wider simplification program will also affect life science innovation. On November 19, 2025, the Commission presented the Digital Omnibus package, addressing the AI Act and the broader digital framework, including the General Data Protection Regulation (GDPR).⁵⁸ Its AI component has since become Regulation (EU) 2026/1744, which entered into force on July 27, 2026, and, among other changes, postponed the application of the AI Act's high-risk-system rules.⁵⁹ The broader Digital Omnibus proposal, including its GDPR amendments, remains under negotiation. For life sciences, these initiatives raise a common question: whether reducing compliance burdens will make the combined requirements for data use and health technologies easier to navigate while preserving effective safeguards.

B. Certification and product regulation

On December 16, 2025, the Commission published a proposal for a regulation to simplify the rules on medical devices and *in vitro* diagnostic devices.⁶⁰ Medical devices range from medical apps, and implantable devices to wheelchairs, whereas *in vitro* diagnostic devices include influenza or COVID-19 tests. Such devices are subject to the Medical Device Regulation (MDR),⁶¹ and the In Vitro Diagnostic Medical Devices Regulation (IVDR),⁶² both of which put in place stricter requirements relating, *inter alia*, to the clinical evidence needed to demonstrate regulatory compliance requirements compared to earlier EU Directives. However, the stricter requirements, coupled with the notified bodies' limited capacity, as well as 'insufficient preparedness of the manufacturers posed the risk of supply shortages and disappearance of critical devices from the market', leading to an extended transition period.⁶³ This was, the Commission recognized, a short-term solution, which 'could not solve the underlying structural problems in the implementation of the MDR and IVDR' that in turn

⁵⁸ Proposal for a Regulation as Regards the Simplification of the Digital Legislative Framework (Digital Omnibus), COM (2025) 837 final (Nov. 19, 2025); Henry Pearce, "Between Simplification and Stagnation: The EU Digital Omnibus and the Future of Data Protection Law," *Cambridge Yearbook of European Legal Studies* (2026): 1–10, <https://doi.org/10.1017/cel.2026.10035>.

⁵⁹ Regulation (EU) 2026/1744 of the European Parliament and of the Council (Digital Omnibus on AI), arts. 1(40), 4, 2026 O.J. (L, 2026/1744), <https://eur-lex.europa.eu/eli/reg/2026/1744/oj/eng>. For the broader proposal's continuing legislative status, see European Parliament, Legislative Observatory, procedure 2025/0360(COD), [https://oeil.europarl.europa.eu/oeil/en/procedure-file?reference=2025/0360\(COD\)](https://oeil.europarl.europa.eu/oeil/en/procedure-file?reference=2025/0360(COD)) (accessed October 14, 2026).

⁶⁰ Proposal for a Regulation Amending Regulations (EU) 2017/745 and (EU) 2017/746 as Regards Simplifying and Reducing the Burden of the Rules on Medical Devices and In Vitro Diagnostic Medical Devices, COM (2025) 1023 final (Dec. 16, 2025).

⁶¹ Regulation (EU) 2017/745, 2017 O.J. (L 117) 1 (medical devices).

⁶² Regulation (EU) 2017/746, 2017 O.J. (L 117) 176 (in vitro diagnostic medical devices).

⁶³ Medical Devices Simplification Proposal, COM (2025) 1023 final, explanatory memorandum at 2.

affected innovation.⁶⁴ The proposed regulatory simplification is intended to provide a longer-term response.

Recognizing that several medical device requirements are ‘disproportionate to the actual risks posed by the devices, which results in unnecessarily high costs and burdens’,⁶⁵ the proposal would revise risk classification rules, including those for software, replace the five-year limit on certificate validity with periodic reviews proportionate to the device’s risk class, and permit broader use of evidence, including non-clinical evidence such as modeling results where justified, to demonstrate conformity. It would also move the MDR and IVDR from Section A to Section B of Annex I to the AI Act, thereby limiting which AI Act provisions would apply directly to the relevant high-risk device systems.⁶⁶

C. Market access and uptake

Health technology assessment (HTA) informs decisions about the use, pricing and reimbursement of health technologies and is distinct from regulatory authorization. The HTA Regulation phases in joint clinical assessments for medicines and selected medical devices; national bodies must give due consideration to the resulting reports when conducting their own assessments. Put simply, the health technology assessment compares new health technologies against existing ones to determine their added value (if any). National HTA bodies conduct their own health technology assessments, but the EU has introduced the Regulation on Health Technology Assessment which applies from January 2025.⁶⁷

Although national bodies will still conduct national health technology assessments, the Regulation on Health Technology Assessment introduces a joint clinical assessment requirement for new medicines and certain medical devices, which national bodies shall take into account when completing their own assessments.⁶⁸ As Johns et al state, ‘[t]he political ambition of the JCA framework is to improve access to medicines by harmonizing transparent HTA criteria at the EU level, standardizing the methodology used to assess the clinical benefit

⁶⁴ Medical Devices Simplification Proposal, COM (2025) 1023 final, explanatory memorandum at 2.

⁶⁵ Medical Devices Simplification Proposal, COM (2025) 1023 final, explanatory memorandum at 2-3.

⁶⁶ Medical Devices Simplification Proposal, COM (2025) 1023 final, arts. 1–2, 4 & annex I; Sofia Palmieri and Henrik Nolte, “Simplification or Back to Square One? The Future of EU Medical AI Regulation,” *Bill of Health*, March 5, 2026, <https://petrieflom.law.harvard.edu/2026/03/05/simplification-or-back-to-square-one-the-future-of-eu-medical-ai-regulation/>.

⁶⁷ Regulation (EU) 2021/2282, arts. 7, 36, 2021 O.J. (L 458) 1 (health technology assessment).

⁶⁸ Regulation (EU) 2021/2282, arts. 7, 13; see also arts. 10(3), 10(6), 13(1)(d) (early access, discontinued assessments, and requests for clarification).

of a health technology compared to its best available alternative’.⁶⁹ National HTA bodies retain responsibility for contextual assessment and non-clinical dimensions, including economic evaluation, but generally may not require developers to resubmit evidence already supplied for the joint clinical assessment. Reducing duplication at EU level therefore addresses one part of the route to patient access, rather than eliminating the subsequent national decisions.

D. Simplification equals more innovation?

The EU is clearly - and quickly - attempting to simplify its regulatory laws in hopes that it will boost innovation.⁷⁰ But simplification does not automatically mean more innovation. Regulation is just one piece in the innovation puzzle. It must be viewed against other ways of incentivizing innovation, as was previously discussed. And a balance must, nonetheless, be struck. On the one hand, there is a need to ensure that products are developed safely and securely and that citizens’ fundamental rights are respected; while on the other hand, regulators cannot impose so many requirements on actors that they are discouraged from inventing in the first place, or from inventing in Europe. That would leave Europe significantly worse off.

Europe’s overlapping regulatory frameworks remain difficult to navigate, especially for small and medium-sized enterprises. Medical-device classification and the AI Act’s high-risk test perform different functions: under Article 6(1) of the AI Act, the relevant product or safety component must also require third-party conformity assessment. Ordinary class I devices are therefore not automatically high-risk AI systems.⁷¹ Where both regimes apply, developers nevertheless need a coherent route through their combined obligations. Cross-regulatory sandboxes can help, but their lessons must also inform guidance available to developers outside them.

Regulators should therefore produce coordinated guidance explaining how their regimes interact, including where apparently similar concepts serve different purposes. Informed

⁶⁹ Adam Johns et al., “EU Joint Clinical Assessment: A Framework for Optimising Use with Cost-Effectiveness Decision-Making,” *Journal of Market Access & Health Policy* 13, no. 4 (2025): 52, sec. 1, <https://doi.org/10.3390/jmahp13040052>.

⁷⁰ Rory O’Neill and Claudia Chiappa, “Várhelyi Races to Deliver ‘Major Overhaul’ of EU Health Laws in 2025,” *Politico*, July 2, 2025, <https://www.politico.eu/article/oliver-varhelyi-eu-health-laws-eu-life-sciences-strategy/>; Philippe Aghion, Antonin Bergeaud, and John Van Reenen, “The Impact of Regulation on Innovation,” *American Economic Review* 113, no. 11 (2023): 2894–2936, <https://doi.org/10.1257/aer.20210107> (studying French employment-regulation thresholds, rather than health-product regulation).

⁷¹ Regulation (EU) 2024/1689, art. 6(1); Medical Device Coordination Group, *FAQ on Interplay between the Medical Devices and In Vitro Diagnostic Medical Devices Regulations and the Artificial Intelligence Act*, MDCG 2025-6 (June 2025), 5–6, https://health.ec.europa.eu/document/download/b78a17d7-e3cd-4943-851d-e02a2f22bbb4_en?filename=mdcg_2025-6_en.pdf.

consent to participate in a clinical trial, for example, is distinct from consent as a legal basis for processing personal data under the GDPR. Guidance should clarify the relationship between these requirements rather than imply that one necessarily satisfies the other.⁷²

Simplification should also prompt reflection on how regulation works. The Organisation for Economic Co-operation and Development (OECD) recommends more outcome-focused approaches and supervised experimentation, trials, and testing.⁷³ These approaches can help regulators learn from innovation while preserving public-interest safeguards.⁷⁴ They could complement the mission-oriented intellectual property and technology transfer arrangements discussed in Sections III and V.

For example, regulatory sandboxes and in-house development of AI-driven medical devices raise questions both about enabling experimentation and about creating credible pathways from a confined setting to safe validation and broader deployment.⁷⁵

V. BUILDING BRIDGES ACROSS THE VALLEY OF DEATH: THE IMPORTANCE OF PROMOTING TECHNOLOGY TRANSFER

The preceding analysis showed why strategic health sovereignty cannot be secured through legal rights or regulatory reform alone. Incentives influence which risks private and public actors are willing to assume, while well-calibrated regulation can make the path from experimentation to authorization more predictable and procedurally feasible. Neither, however, ensures that the knowledge, data, finance, infrastructure and organizational competence required at successive stages of development will actually come together. Technology transfer is where these earlier policy choices acquire practical effect—or fail to do so. This is where the rubber hits the road.

A. What technology transfer entails

⁷² European Data Protection Board, *Opinion 3/2019 Concerning the Questions and Answers on the Interplay between the Clinical Trials Regulation and the General Data Protection Regulation* (January 23, 2019), paras. 15–17; for critical discussion, see Kärt Pormeister, “The Logical Fallacies of the Legal Bases for Data Processing in and beyond Clinical Trials,” *International Data Privacy Law* 12, no. 2 (2022): 132–42, <https://doi.org/10.1093/idpl/ipac003>.

⁷³ OECD, *Recommendation of the Council for Agile Regulatory Governance to Harness Innovation*, OECD/LEGAL/0464 (October 6, 2021), <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0464>.

⁷⁴ OECD, *Recommendation for Agile Regulatory Governance*, preamble & secs. IV-V.

⁷⁵ Sofia Palmieri, Timo Minssen, and I. Glenn Cohen, “When Hospitals Build Their Own AI: A Comparison of the EU and US Regulatory Framework,” *BMJ Digital Health & AI* 2, no. 1 (2026): e000105, <https://doi.org/10.1136/bmjdh-2026-000105>.

The cross-border development scenario in Section III captures the difficulty. The decisive issue is whether the circulation of knowledge strengthens European capabilities or leaves indispensable stages of development under the control of actors that cannot readily be replaced. European actors need sufficient knowledge, bargaining power, alternatives and capacity to absorb and adapt the technology, while the arrangement must also offer mutual benefits to participating partners.

The Commission's Startup and Scaleup Strategy identifies a "double valley of death": first, between publicly supported research and commercial application and, second, between early company formation and expansion at scale.⁷⁶ Improving the framework and processes for technology transfer therefore bears directly on whether European research generates productive firms, manufacturing capability and patient benefit within Europe, as well as on whether Europe remains an attractive location for international investment and strategic collaboration.

In health and life sciences, translation involves a succession of difficult transitions—from discovery to proof of concept, clinical validation, regulatory approval, industrial production and, ultimately, adoption. Failure may occur whenever responsibility for the next stage is unclear or the necessary expertise, evidence, capital or infrastructure is unavailable.⁷⁷ Technology transfer should consequently be understood as the process through which an innovation reaches the bedside or market and becomes usable and scalable by the innovator, another organization or in another operational setting.

The subject of transfer is the practical capacity to continue development, which may depend on research materials, data, software, regulatory knowledge, validated processes and the tacit judgment of experienced personnel. As the World Health Organization's (WHO) guidance on pharmaceutical manufacturing emphasizes, successful transfer requires a receiving organization to consistently reproduce a process within the applicable quality system; the delivery of documents alone will seldom suffice.⁷⁸

B. Private-to-private and public-private technology transfer: both are necessary

⁷⁶ European Commission, *The EU Startup and Scaleup Strategy: Choose Europe to Start and Scale*, COM (2025) 270 final, sec. 1 & fig. 1 (May 28, 2025), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0270>.

⁷⁷ Marcus C. Parrish et al., "Surviving in the Valley of Death: Opportunities and Challenges in Translating Academic Drug Discoveries," *Annual Review of Pharmacology and Toxicology* 59 (2019): 405–21, <https://doi.org/10.1146/annurev-pharmtox-010818-021625>; World Health Organization, *Guidelines on Technology Transfer*.

⁷⁸ World Health Organization, *Guidelines on Technology Transfer*, secs. 1.4–1.7.

Technology transfers are not principally a movement from universities into industry. Such transactions are important, but a large part of the transfer on which European capacity depends occurs between private undertakings: when a start-up licenses a platform to an established pharmaceutical company, when a developer works with a contract manufacturer, when production is transferred between sites, or when specialized know-how passes through a supply chain. These private-to-private transfers often determine whether a promising technology can leave the laboratory, survive clinical development and become a reliably manufactured product. A European strategy concerned only with university patent licensing would therefore miss much of the process through which industrial competence is accumulated—or lost. Policy must also support European firms' ability to absorb technologies, enter strategic alliances, and retain economically significant development and production functions as their products mature.

Private commercialization remains the backbone of that process. Firms and investors provide the risk capital, management capacity, regulatory experience and manufacturing discipline required to sustain development over long periods of uncertainty. The relevant public-policy question is then how to create an ecosystem in which private investment can build on excellent science and move successfully between development stages. This requires attention to the interfaces between firms, universities, hospitals, investors, regulators and health systems. Each contributes something that the others cannot readily reproduce, and translation becomes more effective when scientific, clinical, regulatory and commercial considerations meet early enough to shape the development program.⁷⁹

Within this ecosystem, universities should not be regarded simply as suppliers of inventions to business. Their public mission includes independent inquiry, education, critical expertise and the pursuit of research whose social importance may not yet be reflected in commercial demand. Academic hospitals add clinical knowledge, patient relationships and highly specialized facilities. These institutions may preserve fields of expertise during periods when private investment is unavailable and may carry research forward where market incentives remain structurally weak. Public-sector research has, moreover, made a substantial

⁷⁹ OECD, *Public-Private Partnerships in Biomedical Research and Health Innovation for Alzheimer's Disease and Other Dementias*, Science, Technology and Industry Policy Papers, no. 20 (OECD Publishing, 2015), <https://doi.org/10.1787/5js36rc8wwbt-en>; SiRM, L.E.K. Consulting, and RAND Europe, *The Financial Ecosystem of Pharmaceutical R&D: An Evidence Base to Inform Further Dialogue* (2022), https://www.rand.org/pubs/external_publications/EP68954.html.

contribution to the discovery of medicines and vaccines.⁸⁰ In areas such as drug repurposing⁸¹, antimicrobial development and advanced-therapy development⁸², they may also play a more active role in carrying research toward clinical use. The relevant objective is therefore not to subordinate universities to commercial priorities, but to enable them to cooperate with private and public partners while preserving academic freedom, research access and the broader public value generated by taxpayer-funded research.⁸³

That balance is difficult to achieve in practice. Academic incentives continue to reward publication and research income more readily than the patient work of translation, while many university technology-transfer offices operate with limited specialist capacity and uneven access to investors and industrial partners. Digitalization has made the task still more demanding.⁸⁴ A biomedical project may now combine patents with health data, software, trained models, biological materials and confidential know-how, each governed by different legal and institutional arrangements. Premature disclosure may compromise patentability, yet an excessive focus on exclusivity may restrict follow-on research or alternative applications. Effective transfer therefore requires early coordination of publication, intellectual property, data governance and regulatory strategies, rather than negotiating a license only after the underlying research has been completed.⁸⁵

The involvement of public resources also calls for a more substantive conception of risks and success. Licensing revenue can be relevant to institutional sustainability, but it is an incomplete measure of whether publicly supported knowledge has been valorized. A more convincing assessment asks whether the technology progresses, whether useful capability is created, and whether the resulting product or service becomes available to society. In that

⁸⁰ Ashley J. Stevens et al., “Role of Global Public Sector Research in Discovering New Drugs and Vaccines,” *Journal of Technology Transfer* 49 (2024): 857–67, <https://doi.org/10.1007/s10961-023-10007-z>; Barry Bozeman, Heather Rimes, and Jan Youtie, “The Evolving State-of-the-Art in Technology Transfer Research: Revisiting the Contingent Effectiveness Model,” *Research Policy* 44, no. 1 (2015): 34–49, <https://doi.org/10.1016/j.respol.2014.06.008>.

⁸¹ Johnathon Liddicoat et al., “New Government Drug Repurposing Programs: Opportunities and Uncertainties,” *Science Translational Medicine* 16, no. 753 (2024): eadl0998, <https://doi.org/10.1126/scitranslmed.adl0998>.

⁸² Christoph Priesner and Martin Hildebrandt, “Advanced Therapy Medicinal Products and the Changing Role of Academia,” *Transfusion Medicine and Hemotherapy* 49, no. 3 (2022): 158–62, <https://doi.org/10.1159/000524392>.

⁸³ Cf. Priesner and Hildebrandt, “Advanced Therapy Medicinal Products,” 158–62.

⁸⁴ OECD, *The Digitalisation of Science, Technology and Innovation: Key Developments and Policies* (OECD Publishing, 2020), <https://doi.org/10.1787/b9e4a2c0-en>.

⁸⁵ Markus Perkmann et al., “Academic Engagement and Commercialisation: A Review of the Literature on University–Industry Relations,” *Research Policy* 42, no. 2 (2013): 423–42, <https://doi.org/10.1016/j.respol.2012.09.007>; Richard Jensen and Marie Thursby, “Proofs and Prototypes for Sale: The Licensing of University Inventions,” *American Economic Review* 91, no. 1 (2001): 240–59, <https://doi.org/10.1257/aer.91.1.240>; Commission Recommendation (EU) 2023/499, pts. 3, 22–23, 29, 2023 O.J. (L 69) 75.

regard, exclusivity may remain necessary to attract private capital, particularly where clinical development is lengthy and costly. It can nevertheless be accompanied by development milestones, reserved research rights and proportionate provisions for rights to revert where a project is abandoned. Where public support is substantial, carefully tailored commitments concerning availability or continuity of supply may also be justified. The EU's knowledge valorization framework increasingly reflects this ecosystem-oriented approach, treating valorization as the creation of economic and social value rather than as a one-way transfer of publicly generated intellectual property.⁸⁶

Public participation becomes especially important where the social value of innovation is not matched by an adequate commercial return. Antimicrobial resistance is the clearest example: stewardship appropriately limits the use of new antibiotics, but in doing so also constrains the sales on which conventional pharmaceutical investment depends. Academic research, clinical networks, public funding and credible pull incentives may therefore be required to bring projects to a stage at which private development becomes viable.⁸⁷

Advanced therapies present a different but related case. Universities and academic hospitals frequently originate these technologies and may maintain specialist clinical or GMP capabilities, including certain forms of preparation under the hospital exemption.⁸⁸ Yet wider and more consistent access will ordinarily require industrial partners capable of financing confirmatory studies, standardizing production and maintaining supply at scale. Universities, private undertakings and public-private partnerships are thus not competing substitutes. Their complementary roles allow socially important research to continue while retaining a credible route to commercial development and patient access.⁸⁹

Place-based initiatives may help these relationships develop more effectively. Innovation District Copenhagen is instructive because its ambition extends beyond conventional university

⁸⁶ Council Recommendation (EU) 2022/2415, 2022 O.J. (L 317) 141 (knowledge valorization); Commission Recommendation (EU) 2023/499, 2023 O.J. (L 69) 75 (intellectual-asset management); Commission Recommendation (EU) 2024/774, 2024 O.J. (L, 2024/774) (industry-academia co-creation).

⁸⁷ European Commission, *Reform of the Pharmaceutical Legislation and Measures Addressing Antimicrobial Resistance*, COM (2023) 190 final, sec. 6 (April 26, 2023), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023DC0190>. Council Recommendation on Stepping Up EU Actions to Combat Antimicrobial Resistance in a One Health Approach, 2023 O.J. (C 220) 1; World Health Organization, *Analysis of Antibacterial Agents in Clinical and Preclinical Development: Overview and Analysis 2025* (2025), <https://www.who.int/publications/i/item/9789240113091>. Andrea Morales Caceres et al., "Using the International Pandemic Instrument to Revitalize the Innovation Ecosystem for Antimicrobial R&D," *Journal of Law, Medicine & Ethics* 50, suppl. 2 (2022): 49–51, <https://doi.org/10.1017/jme.2022.79>.

⁸⁸ Regulation (EC) No. 1394/2007, art. 28(2), 2007 O.J. (L 324) 121 (inserting art. 3(7) into Directive 2001/83/EC).

⁸⁹ Priesner and Hildebrandt, "Advanced Therapy Medicinal Products," 158–62; Council Regulation (EU) 2021/2085, arts. 115–25, 2021 O.J. (L 427) 17 (Innovative Health Initiative).

technology transfer. It brings together public authorities, universities, hospitals, companies, investors, foundations and innovation organizations in an area containing substantial life-science and quantum capabilities. Its potential lies not simply in geographical concentration, but in reducing the institutional distance between research, clinical validation, entrepreneurship, finance and specialized facilities.⁹⁰ Co-location will achieve little, however, unless it is supported by skilled intermediaries, workable contracting practices and genuine access to infrastructure and capital. Innovation-district research accordingly cautions against treating property development as a substitute for ecosystem governance.⁹¹ Copenhagen's longer-term significance should be judged by whether it enables technologies and companies to progress, attract follow-on investment and develop lasting clinical and industrial capabilities.

Regional ecosystems must, in turn, connect to European finance and infrastructure. The EIC's Transition, Accelerator and STEP Scale Up instruments seek to support different stages of this trajectory, while the Scaleup Europe Fund responds to the continuing shortage of large growth-financing rounds.⁹² Funding instruments will nevertheless be effective only if their interfaces are well designed. Later-stage capital may be deterred by uncertainty concerning background rights, inadequate evidence planning or a manufacturing process that cannot be reproduced beyond the originating laboratory. European research infrastructures can help overcome such discontinuities by providing firms and public researchers with access to translational, clinical and technical capabilities that would be prohibitively expensive to maintain independently. Their contribution depends less on their formal existence than on sustainable funding, professional operation and access arrangements that work across borders and for smaller enterprises.

The same consideration applies with particular force to data and AI. For example, data do not move in the ways that patents do: their translational value depends on provenance, quality, interoperability and a lawful basis for continued access and use. An AI-enabled technology

⁹⁰ Danish Ministry of Industry, Business and Financial Affairs, *Vision Plan for Innovation District Copenhagen* (September 2025), <https://www.em.dk/Media/639051215347600960/Vision%20plan%20for%20Innovation%20District%20Copenhagen%20-%20English.pdf>; Innovation District Copenhagen, "Our Organisation," accessed October 12, 2026, <https://innovationdistrictcopenhagen.com/about-us/our-organisation/>.

⁹¹ Sara Lawrence, Michael Hogan, and Elizabeth Brown, *Planning for an Innovation District: Questions for Practitioners to Consider*, RTI Press Occasional Paper OP-0059-1902 (RTI Press, 2019), 10–13, <https://doi.org/10.3768/rtipress.2018.op.0059.1902>.

⁹² European Commission, *European Innovation Council Work Programme 2026*, secs. III, V–VI; "Scaleup Europe Fund to Start Making Investments," August 4, 2026, https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/scaleup-europe-fund-start-making-investments-2026-08-04_en; *A European Strategy on Research and Technology Infrastructures*, COM (2025) 497 final/2, [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0497R\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0497R(01)).

may be practically inseparable from the computing environment in which it was trained, the software needed to update it and the expertise required to validate its outputs. A transfer that conveys an algorithm while leaving the recipient dependent on an irreplaceable provider for essential cloud or model functions may create formal control without genuine technological capacity. The EHDS may improve the conditions for lawful secondary use, but its contribution to translation will depend on implementation, data quality and institutional competence.⁹³ Likewise, the proposed European Biotech Act's development accelerators and advanced-therapy centers can strengthen translation only if they connect data, regulatory science and manufacturing expertise in facilities that are genuinely accessible across the Union.⁹⁴

Technology transfer thus connects the forms of control examined in Section III with the regulatory pathways considered in Section IV. It is the process through which knowledge becomes reproducible capability and produces public benefit. Private commercialization, public research, shared infrastructure and collaboration must work together if European actors are to absorb, develop and scale important technologies while sustaining strategic international partnerships.

VI. CONCLUDING REMARKS

Strategic health sovereignty depends on Europe's capacity to make and implement choices concerning important health technologies. This requires sufficient knowledge, infrastructure, expertise and alternatives to sustain international cooperation and respond when a critical relationship or supply chain is disrupted.

Incentives and regulatory reform can improve the conditions for innovation, but their contribution depends on the effective orchestration of measures and connections to development finance, translational expertise, manufacturing, adoption, and the scaling of technologies. European and national authorities should therefore coordinate support across these stages, while developers, investors and research institutions address the evidence, rights and infrastructure needed for the next transition.

⁹³ Jens Declerck et al., "Health Data Quality Skill Gaps and Training Needs among European Health Data Stakeholders: Cross-Sectional Survey," *Journal of Medical Internet Research* 28 (2026): e86878, <https://doi.org/10.2196/86878>.

⁹⁴ European Biotech Act Proposal, COM (2025) 1022 final/2, arts. 4–6 & 33; European Innovation Council and SMEs Executive Agency, "EMA and EISMEA Partnership Helps Europe's Health Innovators Accelerate the Journey from Discovery to Patients," July 15, 2026, https://eic.ec.europa.eu/news/ema-and-eisMEA-partnership-helps-europes-health-innovators-accelerate-journey-discovery-patients-2026-07-15_en.

Universities, hospitals and public research organizations have a complementary public role: pursuing independent inquiry, maintaining expertise and advancing socially important fields in which commercial incentives are weak or premature. Public–private partnerships can connect these strengths with the resources needed for further development and patient access.

A strategy built on coherence, openness and collaboration should be judged by its results: whether technologies progress, firms scale, critical capabilities remain available, dependencies become manageable, and patients obtain meaningful access.