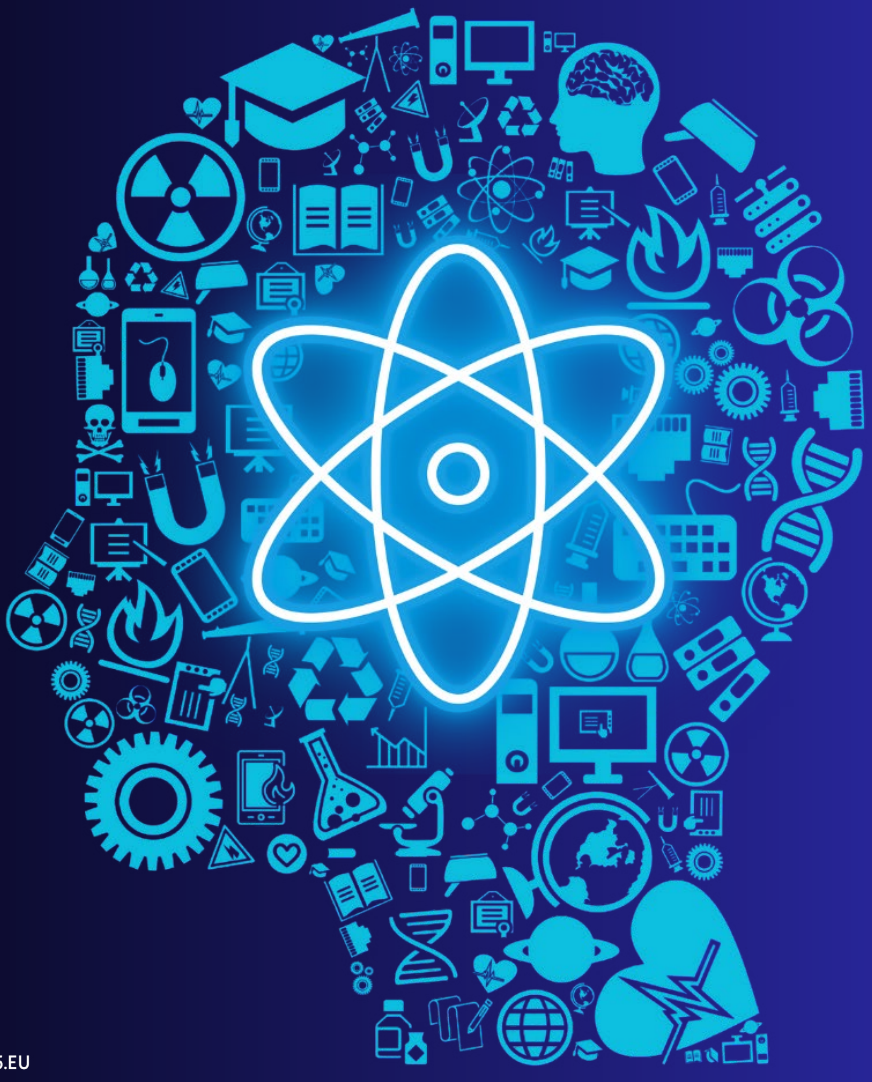
LifeScience 4EU



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The Kraków Agenda for Europe's Life Sciences

Recommendations for Actions in Research and Innovation
for Health and Quality of Life in the EU

Rapporteur: Paweł Świeboda[1]

This report draws on the proceedings of the ***LifeSciences4EU conference,*** *organised under the auspices of the Polish Presidency in the Council of the EU on 15-16 May 2025 in Kraków. The event brought together senior executives from European institutions, scientists, industry leaders, entrepreneurs and experts. The conference was organised by Klaster LifeScience Kraków*[2] *and chaired by its CEO Kazimierz Murzyn.*

It reviewed the state of health in Europe and identified prerequisites for aligning stakeholders for collaborative success. It also identified barriers to progress and explored how research and innovation can leverage technology to strengthen the EU competitiveness in life sciences. Finally, it discussed the path forward for the European health systems.

Findings of the conference have contributed to the European Life Sciences Strategy, complementing the input received from stakeholders as part of the Call for Evidence announced by the European Commission in April 2025.

1. Rapporteur of the conference. Founder and Director of NeuroCentury; Senior Fellow, European Policy Centre; Senior Fellow, Centre for Future Generations.
2. Speakers' contributions to the conference have been reflected in the report. The sole responsibility for the content remains with the author.

Speakers at the conference included: Magdalena Bem-Andrzejewska (National Centre for Research and Development), Jan Beger (GE HealthCare), Alexis Biton (Genopole), Niklas Blomberg (Innovative Health Initiative), Dana Burduja (European Investment Bank), Magda Chlebus (EFPIA), Emer Cooke (European Medicines Agency), Montse Daban (BioCAT, CEBR), Elina Drakvik (Sitra), Monika Frenzel (French National Research Agency), Liesbet Geris (VPH Institute), Tomasz Dylą g (European Commission), Marco Greco (European Patients' Forum), Thomas Grub (Transform Alliance / Medac), Nick Guldemond (Leiden University Medical Centre), Natalia Haraszkiewicz-Birkemeier (European Commission), Karolina Jarosińska (ExecMind), Adam Jarubas (European Parliament), Bożena Kamińska-Kaczmarek (Nencki Institute), Marcin Kautsch (Procure4Health), Albert King (REHEAL), Małgorzata Kośla (PACS2 Research Foundation), Magda Krakowiak (EIT Health), Magdalena Kulczycka (BioForum), Marc Lange (EHTEL), Jeremy Launders (BIOTON), Dominik Lipka (SyVento BioTech), Robert Ługowski (CliniNote), Maciej Malawski (Sano), Maciej Małecki (Jagiellonian University), Thierry Marchal (Avicenna Alliance), Ramon Maspons (AQuAS), Nathalie Moll (EFPIA), Christopher Morton (Elem Biotech), Kazimierz Murzyn (Klaster LifeScience Kraków), Irene Norstedt (European Commission), Piotr Nowak (Poznań Institute of Technology), Martine Pergent (Transform Alliance), Angelo Pezzullo (Università Cattolica del Sacro Cuore), Jaanus Pikani (Scanbalt), Przemysław Pilaszek (FiLeClo), Paweł Przewięźlikowski (Ryvu Therapeutics), Krzysztof Pyrć (Foundation for Polish Science), Jacob Ravn (Aalborg University Hospital), Bogusław Sieczkowski (Selvita), Claire Skentelbery (EuropaBIO), Andrew Smith (ELIXIR), Klaudia Szklarczyk-Smolana (Intelliseq), Monika Ślęzak (Łukasiewicz Research Network), Paweł Świeboda (NeuroCentury, EPC, CFG), Margrietha H. Vink (Erasmus University, Rotterdam), Wendy Rayner (REHEAL), Marta Winiarska (BioInMed), Lucyna Woźniak (Medical University of Łódź), Mariusz Mą sior (Consonance), Rafał Olszanecki (UJ), Andrzej Ryś (European Commission), Tomasz Nocuń (FamiCordTx), Stamatiki Kritas (Council for European Bioregions)

Executive Summary

Few sectors are as vital to economic growth and competitiveness – while also addressing urgent societal challenges – as the life sciences sector. It is also one with an impressive number of recent breakthroughs, which translate directly into improved prospects for prevention, diagnosis and treatment of different disorders. In Europe, the life sciences sector performs well, as reflected in the latest trade statistics, but faces several vulnerabilities and headwinds, both from the inside and on the outside. They include a fragmented regulatory landscape and often inconsistent implementation of the legislative framework – arguably, the single most pressing issue for the EU to address. Distributed nature of the European innovation ecosystem is an asset, drawing on the different strengths of Europe's regions, but also makes reaching the relevant scale more challenging. The speed with which Europe acts can also be an issue, as the EU's funding schemes take prolonged time from ideation to execution.

Reassuringly, there is an emerging sense of purpose in Europe to reinvigorate the continent's life sciences sector and make it world-leading by 2030. The LifeSciences4EU conference in Kraków on 15-16 May 2025 reiterated this conviction and contributed a range of tangible solutions which can help advance the sector's resurgence. A key underlying assumption must be stronger research funding, given the extent to which global competition is centred on this field. A Single Market 2.0. approach is needed, particularly in the domain of clinical trials, with a fully-fledged streamlining and modernisation of existing framework to put emphasis on enabling innovation. A single market for data is of essence, given data's foundational role in life sciences. Collaboration is the jewel in the crown of the EU's life sciences sector but needs to be further incentivised to bridge the gap between discovery and real-world application. Partnerships, patient inclusion and greater philanthropic engagement are all needed, with innovation hubs and clusters serving as the bridges between research excellence and real-world impact.

A new funding paradigm should emerge, bringing forward dedicated investment vehicles, such as a European Life Science Investment Fund, tailored to the needs of life sciences and with public and private sectors co-investing together. Shifting the balance towards breakthrough innovation would require stronger derisking mechanisms, critical to support innovative solutions. Europe's benefit of scale can be successfully harnessed by more effective multi-country clinical trials, enabling participation from diverse populations. There is also scope for rethinking clinical trial execution with AI, rethinking how trial data is captured, structured, and reused – at the source.

All these actions need to be seamlessly coordinated across the entire spectrum of enablers, generating a systemic change in approach to health and wellbeing. The value of transformative solutions depends entirely on how they are integrated into the broader healthcare system. In parallel, trust in science needs to be consolidated across society. This is a defining opportunity for Europe to elevate life sciences as a key force for innovation, resilience, and long-term prosperity.

1. Foundational Role of the Life Sciences Sector

The life sciences[3] sector represents **a cornerstone of European excellence**, leveraging the continent's strong scientific foundation to drive innovation across areas such as health, food, forestry, energy or biosecurity. It plays a critical role in the development of the next generation medical technologies, which are essential for safeguarding the health and security of Europe's citizens.

The field is undergoing remarkable change, witnessing **breakthroughs unimaginable just a few years ago**. From advances in cancer treatment and disease-modifying therapies for Multiple Sclerosis, to cures for hepatitis C, improved management of cardiovascular diseases, and new approaches to obesity, the progress made over the past two to three decades has been extraordinary.

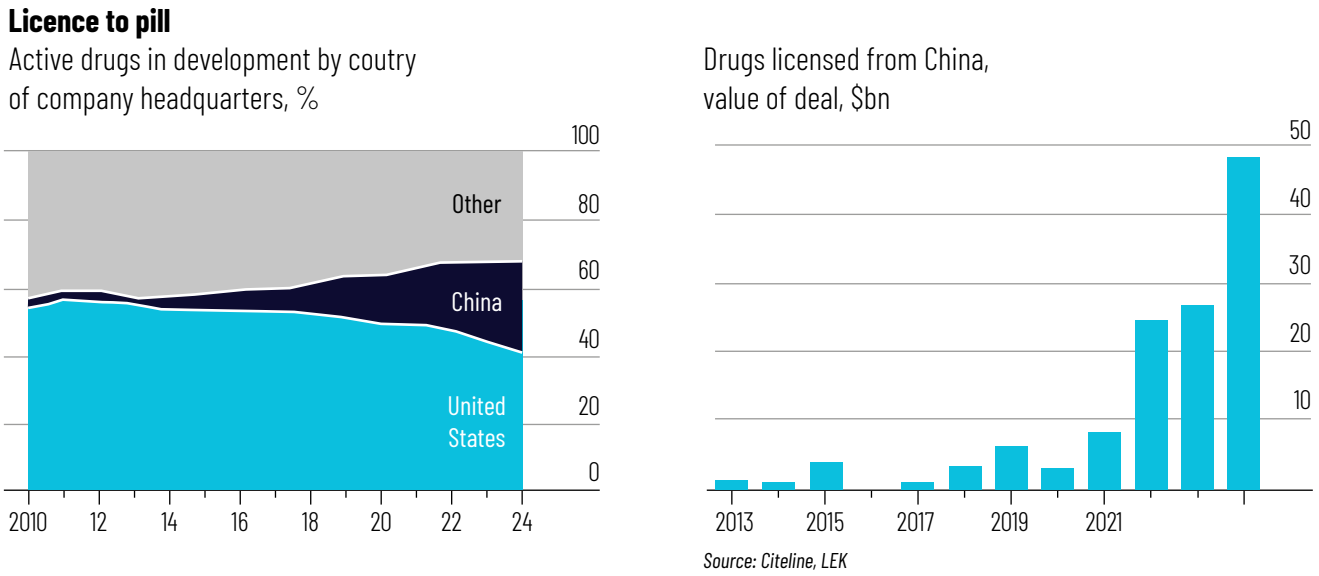
The life sciences sector is also **a crucial part of the European economy**, making a sizable contribution to the overall growth and employment. It employs about 29 million people, generating about 10% of the EU's GDP (2022 data)[4]. The EU's medicinal and pharmaceutical industries maintain a strong global presence, recently achieving a record trade surplus of EUR 193.6 billion[5]. This sector represents the largest area of technological strength where Europe continues to compete successfully with the United States and China, as measured by the significant representation among the top 100 globally capitalised companies. In addition, research-based pharmaceutical companies reinvest a higher percentage of their revenue into research and development than any other industry[6].

Europe's assets include an impressive scientific community eager to come up with next breakthroughs[7]; scientific freedom; diversity, equity and inclusion; stable investment conditions in Research and Innovation (R&I); world's largest international research programme with a seven-year horizon; world class research infrastructure; culture of collaboration; and the newly launched programme to attract talent to Europe[8].

Despite its strengths, the innovative potential of the European life sciences sector is constrained by **several internal rigidities and external headwinds**. As highlighted in the recent Mario Draghi report, they include relatively low Research and Development (R&D) investment, a complex and fragmented regulatory environment, lengthy clinical trial processes, slower approval timelines for new medicines and medical devices, and fragmented health data systems[9]. **These trends are a cause for concern.** The EU is less successful than other regions in bringing innovations to the market, supporting start-ups and scale-ups, and profiting from life sciences R&D.

As a result, between 2015 and 2023, the EU's global market share in medical devices declined from 39% to 26%, while the US share increased from 42% to 47%[10]. In addition, European biotechs have access to only around 20% of the financing available to their US counterparts[11]. Europe's share of global clinical trials has also dropped significantly, from 25.6% to 19.3% over the past decade[12]. **China is emerging as the top global innovation engine in biopharma, putting pressure on Europe and the US** (See Figure 1). In 2023 alone, China approved a record 48 first-in-class therapies, underpinned by substantial investments through mega-funds, sweeping regulatory reforms, and aggressive global talent recruitment strategies .

Figure 1. China's growing innovation potential



Source: The Economist, 16 February 2025

Source: Citeline, LEK

More broadly, **healthcare systems across Europe face growing pressures** due to rising costs associated with more advanced and specialised care, alongside significant demographic shifts such as aging populations and the growing burden of chronic diseases. These challenges underscore an urgent need to accelerate the integration of medical innovations into clinical practice to ensure the consistent availability of high-quality, effective treatments. Strengthening the ability of health systems to adopt and scale innovations will be essential to maintaining both sustainability and equitable access to care.

Innovation in Europe is distributed, which is both a blessing and a curse. It is a blessing because Europe can more easily harness ideas and creativity from its incredible resource base. It is a curse since it is more difficult to align, reach the benefit of scale and overcome the intrinsic tendency towards fragmentation. In practice, this means that apart from several major players with global significance, there are numerous second tier biotech clusters emerging in the different European countries.

More than at any point in the past, **time is of essence in life sciences**. However, the European funding mechanisms rarely allow for rapid take-up of ideas. It often takes 3-4 years from the moment an idea is born to the time when an innovator can start working on a project with EU funding. Important Projects of Common European Interest (IPCEI), the scheme allowing for state aid for selected projects, take a long time as well. As an example, the PANACEA-NOVO project[14], part of the IPCEI Med4Cure initiative focused on advancing and supporting innovations in the healthcare sector, has taken 3.5-4 years since the initial EU-wide decision to start preparations, with the Polish authorities still not having released the funds enabling the start of the project. Such long funding cycles drain innovation momentum.

In some areas the EU can act faster: the EIB can generally invest within 6-9 months, once the European Commission confirms the strategic direction and upon the condition that the relevant ecosystem is in place. Often, **an investor's mindset needs to be adopted across the life sciences sector** to make sure tangible opportunities are not missed.

One of the key takeaways of the Draghi report is that **excellent science is a fundamental building block of competitiveness**. One cannot attract sufficient investment inflows without a strong science base. Another of last year's flagship reports, "Safer Together. Strengthening Europe's Civilian and Military Preparedness and Readiness" (Niinistö Report) includes substantial provisions on health, recognising it as a central pillar of preparedness. One of its key conclusions is that this endeavour cannot succeed without fully mobilising the capacities and resources of the private sector.

2. Vision: Where Europe Aims to be in 2030?

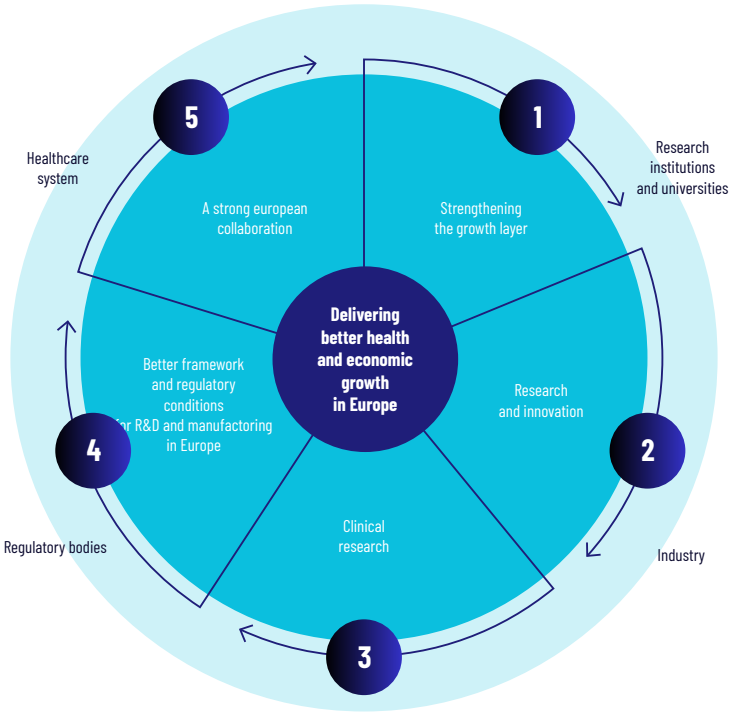
By 2030, Europe needs to be in the position to execute a revival of a thriving life sciences industry, supported by greater alignment in Member States' approaches. To achieve this, it is essential to address the current challenges through a holistic strategy that strengthens the entire life sciences ecosystem – from early-stage innovation and clinical research to manufacturing. The recently concluded Call for Evidence for the Life Sciences Strategy underscored the urgent need for enhanced strategic coherence across the numerous ongoing and planned initiatives at the EU level[15].

The EU has made significant progress in building **a supportive ecosystem for rare diseases**, arguably advancing further in this area than in any other health domain. This achievement is reflected in the establishment of the European Reference Networks, the active engagement of patient communities, and the integration of Research Infrastructures. This example should now be emulated in other domains.

Achieving the effect of scale in health research requires strong interdisciplinary and cross-border collaboration. No single discipline or country can deliver transformative results on its own. Building large data pools, establishing broad patient cohorts, and conducting major clinical trials all necessitate a pan-European approach. Importantly, the **challenge of crossing borders should be reframed as a competitive advantage[16]:** if Europe can master effective collaboration among its own Member States, it will be well-positioned to engage with global partners and lead international efforts. In addition, several Advanced Therapy Medicinal Products are only available in some countries, not because of spending constraints or because the health technology assessment does not work, but due to the fact that special treatments can only be accessed in designated hospitals. This points to the need for a stronger cross-border healthcare component.

Finally, more dialogues with citizens are needed about what science brings to everyday life. Exploring opportunities and risks of scientific discovery in an open fashion can ensure that a societal pull factor is created, in addition to the industrial push side.

Figure 2: The European Life Sciences Ecosystem



Source: Recommendations for a European Life Science Strategy, Danish Life Science Council

The Life Science sector in the EU consists of a full range of actors, from large and established companies with the resources to develop new medicines, to start-ups and SMEs, which face significant hurdles in accessing venture capital.

3. Key Drivers of Innovation: Overcoming Barriers and Building Competitive Strengths

Amid intensifying global competition, it is crucial for Europe to establish **world-class framework conditions** in the life sciences sector to stimulate, support, and sustain an innovative ecosystem involving all key stakeholders. For this, a parallel track is needed: addressing existing structural issues – such as regulatory fragmentation – while also harnessing the transformative potential of medical technologies, digital health, and breakthroughs in biopharmaceuticals. Meeting this challenge requires coordinated efforts to modernise policy and regulatory frameworks.

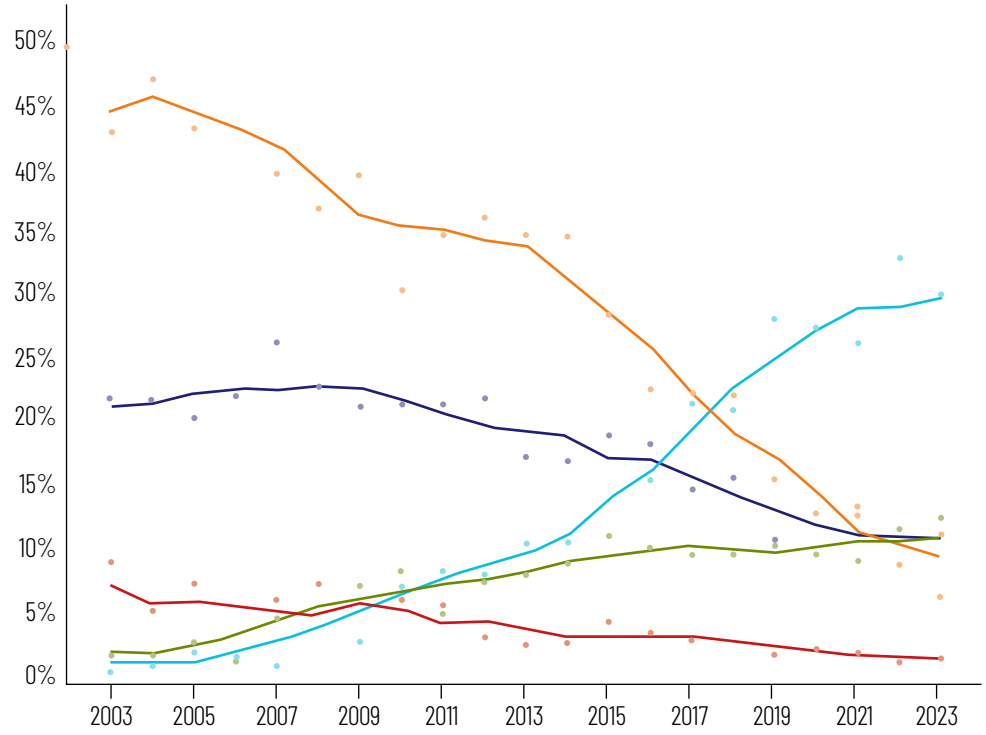
The life sciences sector is diverse, spanning from globally competitive pharmaceutical companies to a vibrant ecosystem of start-ups and small and medium-sized enterprises (SMEs). Smaller biotech companies are often more effective than large pharma in ensuring knowledge transfer from academia. The continued success of these actors depends on access to capital, supportive infrastructure, and an enabling environment that fosters innovation at every stage of development. We can call them **drivers or enablers** of European health innovation: the transversal levers that cut across several life science domains.

3.1. Research and Development: Foundational Role in the Innovation Ecosystem

Research is central to developing the innovative therapeutic approaches needed to enhance Europe's healthcare systems. It drives the discovery of new treatments, enables faster responses to emerging health threats, and supports the growth of sustainable, high-value industries. Beyond improving individual health outcomes, R&D in the life sciences underpins broader societal goals – enhancing health system efficiency, fostering technological leadership, and reinforcing Europe's strategic autonomy in critical medical technologies.

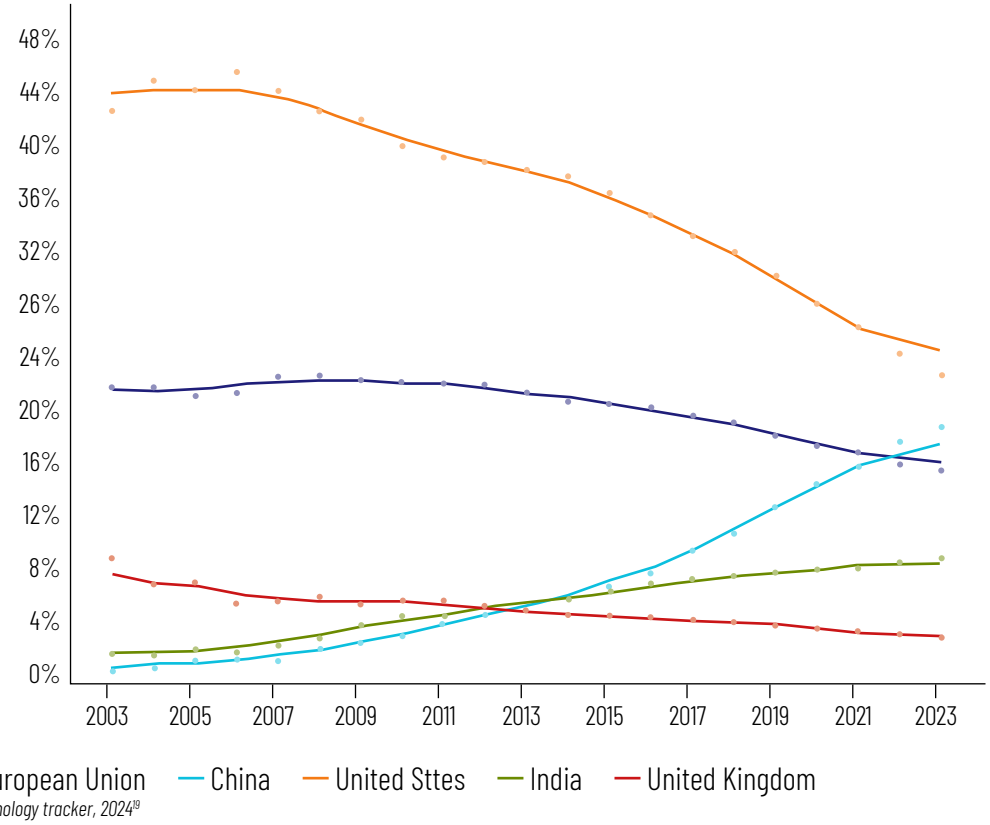
Global competition is increasingly centred on research. Over the past two decades, Europe has lost approximately 25% of its share of global R&D investment to other regions[17]. While it retains a strong overall position, its trajectory in several key areas shows signs of decline vis-à-vis major competitors, as illustrated by trends in research output (See Figure 3 and 4). Given that R&D investment cycles can span up to 30 years, this situation calls for rapid and strategic action to safeguard Europe's long-term competitiveness.

Figure 3. EU research performance in novel antibiotics and antivirals (highly cited papers)



Source: ASPI Critical Technology tracker, 2024[18]

Figure 4. EU research performance in novel antibiotics and antivirals (cumulative publications)



Source: ASPI Critical Technology tracker, 2024[19]

3.2. Regulatory Framework: Enabler of Innovation

Regulation affects numerous domains of the life sciences sector in a very profound way, whether it is biotechnology, biological therapies, cell and tissue therapies or regenerative medicine. These areas are **frequently subject to overlapping regulatory frameworks**, including emerging legislation on Artificial Intelligence, which is increasingly relevant in the context of digital health and data-driven research.

There is a persistent perception that Europe does not function as a fully integrated Single Market, particularly in the domain of clinical trials. **This necessitates a Single Market 2.0. approach in life sciences**, orchestrating game-changing progress in ecosystem design and implementation of a single rulebook. **The life sciences industry is not seeking deregulation, but rather the streamlining and modernisation of existing frameworks** to enable innovation within a predictable and supportive environment.

Tackling regulatory fragmentation must become a central goal of Europe's policy action. One major barrier is the absence of a fully implemented single authorisation process for clinical trials across the EU. Additional fragmentation arises from varying approaches to ethical reviews in the different Member States, with countries often competing rather than collaborating, thereby increasing complexity. Despite the existence of legislative frameworks such as the Clinical Trials Regulation and the Health Technology Assessment Regulation, implementation remains inconsistent. Greater mutual understanding of national imperatives is needed.

Conducting clinical trials across multiple EU countries entails navigating a complex patchwork of national requirements, resulting in delays and increased costs. The time to start trials remains a critical bottleneck. Achieving excellence in multi-country trials will require Europe to match the speed and agility of the world's most innovative regions. Similarly, Europe's health technology assessment (HTA) landscape remains highly fragmented. Under the EU HTA Regulation, only joint clinical assessments are conducted at the EU level – leaving all other components of the process to individual Member States. As a result, industry stakeholders continue to face 27 separate sets of requirements, undermining efficiency and delaying access to innovation across the continent.

In addition, **small companies need to be better supported in their compliance journey**. The more integrated the permitting system is, the better for SMEs who do not have ample resources to spend on legal and procedural advice. The European Commission has just created the EU Biotech and Biomanufacturing Hub, which provides a one-stop platform, available through the EU's "Your Europe" portal. Its aim is to help biotech start-ups and SMEs navigate through EU funding mechanisms, R&D support and scaling infrastructure, intellectual property guidance, regulatory compliance and approvals.

However, **the knowledge about its services has not yet been propagated across the ecosystem**. The criticism has also been that it does not bring any new elements but only links what has already been available.

Very often, the challenge lies in **varying interpretation of regulatory provisions** by the Member States. This is crucial, given that there is a lack of a properly functioning EU Single Market in the area of health, and primary competences remain with the Member States. Medical Devices Regulation (MDR) and In Vitro Medical Devices Regulation (IVDR) have introduced significant regulatory hurdles, hindering patients' access to innovative medical technologies, as well as innovation in the EU. This compares negatively to the approaches in the United States, where a breakthrough designation enables an intensive and close dialogue with the regulator, followed by market access. In addition, the UK has recently introduced a similar approach by means of the

Innovative Devices Access Pathway (IDAP), which aims to accelerate the introduction of transformative medical devices into the National Health Service by providing **an integrated and enhanced regulatory and access pathway for developers**. The IDAP pilot phase has selected eight technologies to receive tailored regulatory and access support, focusing on devices that address unmet clinical needs.

Oftentimes, **there is insufficient knowledge of the European ecosystem and the EU regulatory space**. This is why the European Medicines Agency (EMA) has placed a significant emphasis on helping various actors anticipate regulatory challenges when moving from the innovation to the patient. Investing in ensuring that the early steps are taken in accordance with the regulatory framework, saves a lot of time at the end of the market authorisation process[20]. The EMA has created several channels for early engagement which enable an open discussion about the requirements of the EU legislation.

The EMA sees its role as that of an enabler of innovation, facilitating the translation of scientific advances from bench to bedside. Central to this is **early engagement with innovators**, allowing the Agency to provide guidance and align regulatory pathways for emerging ideas. The Agency makes an extra effort to understand the challenges of transition from startup to scaleup phase. Cutting edge innovation often requires tailormade solutions. The EMA offers portfolio and technology meetings, all with the objective of providing the best possible advice on what is needed to register a product[21]. It works with health technology assessment bodies and payers to ensure that its efforts in the regulatory space also serve the objectives of the latter.

The **Agency's Innovation Task Force** is a multidisciplinary platform which provides preparatory dialogue and orientation in innovative methods, technologies and medicines. This is space for informal dialogue with opinion leaders, a brainstorming on innovation, particularly in those areas where there is no existing guidance. There are new products which emerge through the Innovation Task Force, whether in cell and gene therapy, or in emerging digital technologies, organ-on-a-chip, new drug delivery systems.

Intellectual Property Protection

As emphasised in the Draghi report, Intellectual Property Rights (IPR) are foundational to driving medical innovation. Robust IPR frameworks incentivise the development of novel therapies by offering innovators the legal certainty and market exclusivity needed to invest in high-risk, high-cost research. In the life sciences sector, where the pathway from discovery to product can take over a decade and cost billions, **IPR plays a critical role in enabling return on investment and fostering continued scientific progress.** In this context, the EU must maintain a coherent, predictable, and enforceable IPR framework. This includes not only core patent protection but also complementary mechanisms such as regulatory data protection, market exclusivity for orphan drugs, and Supplementary Protection Certificates (SPCs), which extend protection to account for long development timelines. A strong IPR environment does more than attract private investment. It also ensures that the value created by EU-based research is retained within Europe, fuelling the growth of domestic SMEs and anchoring global innovators in the European ecosystem.

3.3. Translating Research into Innovation: Role of Collaboration

Building a resilient European science and research base, along with a more innovation-friendly regulatory framework, is a critical foundation, but the next step is ensuring the effective translation of fundamental research into innovation and entrepreneurship. Achieving this requires **stronger collaboration between industry, academia and healthcare systems** to bridge the gap between discovery and real-world application. Metabolic research is a good example of a success story in the field. Progress has only been possible because of dynamic interplay of partnership, collaboration and competition among three key players: patients, the pharmaceutical industry and academia[22]. One clear example is the evolution of continuous glucose monitoring (CGM). In the 1990s, patient organisations actively demanded access to real-time glucose monitoring, particularly given the severe consequences of hyperglycaemia experienced by children. The persistent advocacy exerted pressure that ultimately led to the development and global market adoption of CGM systems, now a cornerstone of the treatment of millions of people living with diabetes. This example shows that **patients must be involved at every stage of the drug development process, from trial design to implementation**. Data sharing is also critical: numerous research projects based on large-scale data have been made possible only through open, trust-based partnerships with the pharmaceutical sector.

Patient inclusion and participatory research can make an enormous difference. However, it also requires developing a different level of trust. This has been clear in the IHI project RADAR-AD where a system of monitoring people at home was developed to predict an early onset of dementia. The reason for this project achieving its results lies in patient organisations, especially Alzheimer's Europe and their national centres, being deeply involved not only as advisory bodies, but also in developing data collection solutions. **Public-private partnerships are an excellent framework to provide transparency and trust.**

In pursuit of collaboration, greater philanthropic engagement is needed. Foundations allow for tapping into different communities with their respective strengths. This makes it easier to set up national screening programmes, develop European master protocols, or create clinical trial networks. Philanthropic funding is important, but so is mobilising the skills and capabilities of the people involved.

Trust is needed across the ecosystem, including between academia and industry. They often have similar goals and aim to move in the same direction but do not communicate sufficiently well. Collaboration is often best nourished in **clusters or innovation hubs** which exemplify the enabling conditions necessary for sustained innovation. These ecosystems combine supportive regulatory frameworks, targeted and risk-tolerant financing instruments, and a deep talent pool cultivated through strong linkages with world class research universities.

Figure 5. Comparison between Kendall Square (Boston) and Leuven (Belgium)

Kendall Square, Boston (USA)	Leuven (Belgium)
Often called "the most innovative square mile on the planet," Kendall Square exemplifies how co-location of top-tier research universities, such as MIT and Harvard, industry leaders (e.g. Novartis, Biogen, Moderna), and venture capital can create a powerful life sciences ecosystem. Strategic public and private investment, proximity to hospitals and regulators, and a culture of entrepreneurial risk-taking have enabled rapid translation of research into scalable companies. The area hosts over 500 biotech firms and has been central to breakthrough developments in mRNA, genomics, and neurotechnology.	Anchored at KU Leuven, one of Europe's top research universities, and supported by VIB, Flemish Institute for Biotechnology, UZ Leuven hospital, and IMEC (Research and Technology Organisation with excellence in semiconductor and life sciences), the region has cultivated a strong biomedical and digital health cluster. Startups like reMYND and ONTOFORCE, alongside strategic EU and regional investments, help Leuven translate cutting-edge research into commercially viable technologies. It also benefits from Belgium's favourable tax structure for IP and R&D.
Key enablers include strong public-private partnerships, early-stage risk-tolerant capital, world-class universities and teaching hospitals, integrated infrastructure and high talent density.	**Key enablers** include academic-industry co-location, high public R&D intensity, cross-disciplinary institutions (biotech, data, microelectronics), proximity to EU-level initiatives.

Pharmaceutical alliances with biotech SMEs are increasingly common, especially in drug discovery and early-stage R&D, licencing agreements and co-development deals, incubator and accelerator programmes[23]. **Public-private partnerships**, such as those under the Innovative Health Initiative (IHI) and Horizon Europe, bring large firms, SMEs, and academia together to pursue jointly defined projects. Cluster-based collaboration is emerging in regions like BioValley (France/Germany/Switzerland), Medicon Valley (Denmark/Sweden), or Kraków with the Klaster LifeScience Kraków.

Support for translation comes from organisations such as EIT Health, whose ecosystem comprises 120+ healthcare and life science innovation stakeholders, from business to research, education, health care providers, insurers, patient groups, and others. This diverse community actively collaborates via EIT Health's strategic pan-European and global connecting platform - and its associated programmes and initiatives - to support the effective translation of fundamental research to market to address unmet patient and societal resiliency needs. Over the past decade, it has supported over 3200 start-ups through its programmes and helped them to directly raise more than EUR 2 bln, with close to 500 thousand patients and citizens benefitting from the supported innovations, and over 50 thousand students and professionals trained.

3.4. Funding Innovation: Focus on Derisking

Attracting a sufficient volume of funding to **the life sciences sector requires strong derisking mechanisms for investors in innovative solutions**. As highlighted in the Draghi report, access to venture capital is essential for start-ups and SMEs to be able to scale. Europe continues to lag the US in this regard. To reverse this trend and retain high-growth companies in Europe, it is essential to establish **an enabling framework for the private capital market**. This should include market-driven initiatives and stronger partnerships with private investors to enhance access to venture financing and support the long-term growth of the European life sciences sector.

The European Investment Bank (EIB) plays a leading role in financing life science innovation through **blended finance instruments** that serve two core purposes: de-risking early-stage investments, absorbing early-stage risk, and working alongside the European Commission to implement certain policy priorities. By combining its own resources with EU budgetary instruments, the EIB helps to bridge the funding gap that often hampers the translation of research into commercially viable solutions. The approach enables the EIB to **crowd in private capital by improving the risk-return profile for other investors**, thereby stimulating greater overall investment in the sector.

In parallel, the EIB provides **technical assistance and advisory services** to life sciences companies – supporting them in business model development, strategic growth planning, and crucially, in navigating complex regulatory pathways. This hands-on engagement is particularly valued by early-stage and scaling biotech and medtech firms, which often lack internal regulatory expertise.

Currently, the EIB has a robust portfolio of European life science companies, offering not only financing, but also strategic support as they move towards commercial scale-up. Beyond direct investments, the Bank has the capacity to establish **dedicated investment vehicles** – such as thematic capture funds focused on specific areas of unmet medical need – and co-invest with private industry in structured financial models tailored to the life sciences domain.

3.5. Multi-Country Clinical Trials: Achieving the Effect of Scale

Conduct and efficiency of clinical trials is an important dimension of competitiveness in life sciences. Testing new treatments, interventions and diagnostic tools to determine their safety and effectiveness is a crucial component of ensuring early patient access to the most effective and safe treatments. Europe faces several **persistent challenges in clinical trials**, which hinder its ability to fully capitalise on its scientific strengths. These challenges include fragmentation across languages, regulatory environments, and healthcare systems, making multi-country trials complex and resource-intensive; high-operational costs and administrative burden, often deterring companies from launching trials in the region; cross-border complexity and compliance overhead, which reduce efficiency and scalability of trials; limited integration of real-world data (RWD) due to inconsistent data standards; lack of interoperability, and siloed health information systems; inefficient patient recruitment and feasibility processes, which delay trial initiation and impact the representativeness of study populations.

Accelerating Clinical Trials in the EU (ACT EU) Initiative[24] aims to transform the EU into a competitive centre for innovative clinical research. The initiative is run together by the European Commission, the European Medicines Agency and the Heads of Medicines Agencies. It aims to transform how clinical trials are initiated, designed and conducted. The Initiative builds on the Clinical Trials Regulation and Clinical Trials Information System's launch on 31 January 2022.

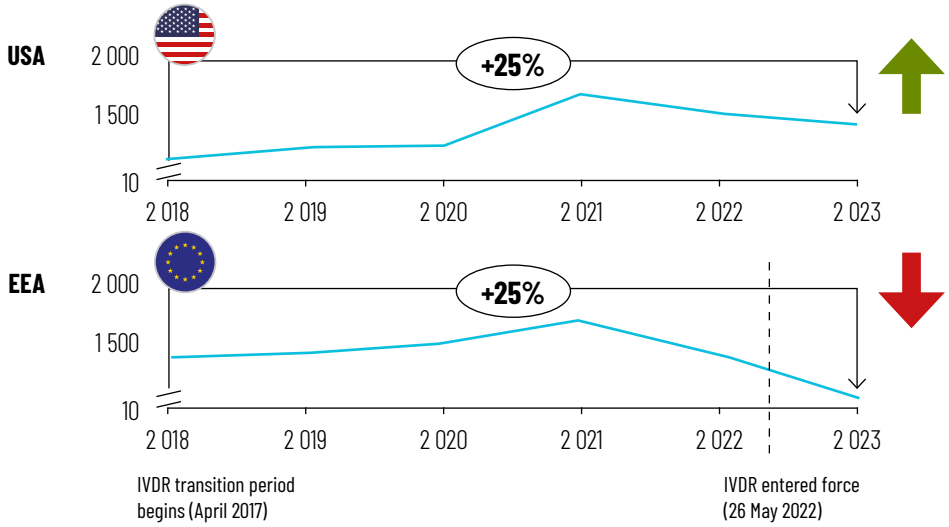
The method of platform trials was significantly advanced during the COVID-19 pandemic, enabling continuous testing of multiple interventions over a longer duration. When part of clinical practice, they can offer a dynamic and cost-effective approach to evaluating both new and existing interventions. Their adaptive design allows for the simultaneous assessment

of multiple treatments or processes withing a single, lasting trial structure. This makes them particularly effective not only in identifying high-value innovations but also in facilitating the evidence-based removal of low-value care, improving resource allocation across healthcare systems.

In parallel, **multi-country clinical trials are vital for advancing medical research**. By enabling participation from diverse genomic, biological, ethnic, and socio-cultural populations, these trials enhance scientific validity and promote greater equity in access to innovation. They also expedite patient recruitment and ensure that findings are more generalisable across populations. Increasing the number of multi-country trials within the EU can help distribute the benefits of a strong European life sciences ecosystem more evenly across Member States.

Importantly, there is **a well-established correlation between hosting clinical trials and timely access to new treatments**, underscoring the strategic importance of promoting trial activity across the Union. Despite this, conducting multi-country clinical trials in Europe remains burdensome and challenging due to regulatory fragmentation and insufficient coordination. This results in outflow of the clinical trial pipeline to other regions.

Figure 6: Total number of clinical trial initiations in oncology, 2018-2023.



Source: IQVIA

3.6. Accessibility of Data: Towards a Step-Change

Access to and interoperability of health data across EU Member States is a cornerstone of timely, accurate, and personalised diagnostics. While most EU Member States acknowledge the value of health data for research and innovation, the speed and implementation diverge considerably across countries. Some countries have made only incremental progress in data infrastructure or governance, while others have developed more ambitious, structured frameworks to support secure and scalable data access. For example, **Germany's DiGA framework**, which enables certified digital health applications to be prescribed and reimbursed, has created **a clear legal and reimbursement pathway for digital tools, backed by clinical data.** Similarly, **Finland's Findata** provides a centralised and legally mandated process for secondary use of health data. It has reduced administrative burden, improved transparency, and ensured equitable access for public and private stakeholders, while maintaining strong data protection safeguards. **In the UK, the NHS England Trusted Research Environments initiative** is notable for its commitment to privacy-preserving analytics and standardisation. The intiative allows approved researchers to work within a secure infrastructure without removing data, offering a scalable model for responsible, federated data access.

Successful implementation of the European Health Data Space (EHDS) has the potential to transform health systems by enabling cross-border data use for research, innovation, and regulatory decision-making. **Engaging the life sciences industry as a strategic partner in the rollout of the EHDS will be essential to maximise its impact.** Prioritising industry participation can significantly accelerate the development of new medicines, optimise clinical trial design, and support real-world evidence generation – ultimately fostering a more competitive and innovation driven European health ecosystem.

3.7. Human Resources: Winning the Talent Race

Attracting top talent in life sciences requires the creation of world-class research and technology ecosystems that serve as dynamic hubs of knowledge and innovation. These environments not only foster breakthrough discoveries but also help achieve global leadership in science. To support workforce mobility and retain expertise, it is essential to offer **flexible career pathways and smoother transitions between academia, start-ups, and established industry players**. Equally important is sustained investment in upskilling and reskilling, ensuring that Europe's talent base remains aligned with the pace of scientific and technological advancement.

The EU is devoting significantly **more attention to attracting and retaining top talent**, as evidenced by President von der Leyen's "Choose Europe" initiative with a EUR 500 mln package for 2025-2027. As part of the latter, the European Commission is launching a new Maria Skłodowska-Curie Action "Choose Europe for Science" pilot[25], which will offer more support and opportunities for early-career researchers. It also offers targeted support to researchers affected by war and displacement.

3.8. Enabling Technologies: Revolutionising Entire Cycle of Innovation

Emerging technologies such as **artificial intelligence (AI) and quantum play an increasingly important role** in the discovery of new medicines, clinical trials, diagnostic and therapeutic approaches and the manufacturing processes. Some of the new cancer vaccines are building personalised treatments based on large AI models. Investment in the development of these technologies is crucial, as is a well-designed framework for responsible use.

Support for AI adoption in life sciences is currently envisaged through initiatives such as GenAI4E" and investments in digital infrastructure. In addition, the European Medicines Agency has a workplan to facilitate the development and use of responsible and beneficial AI. Building trust in technology is of essence, which is especially relevant with regard to algorithmic decision-making. The latter needs to be placed under sufficiently strong professional or democratic control. This is one of the most significant areas of the interplay between science and the regulatory landscape.

4. Action: Next Steps for Driving Change

Delivering a radical improvement in the prospects for the European life sciences sector requires actions across a range of areas, from scaling innovation to securing sustainable funding and driving real-world implementation. Instead of isolated initiatives that may be useful in addressing selected problems, what is needed is **coordinated and determined action across the entire spectrum of enablers** based on a thorough understanding of the differences between the healthcare systems in Europe.

A systemic change is needed across the board. This is illustrated by the untapped potential of prevention and the continuously marginal role it plays in most of the health systems. Given that 70 percent of the chronic disease burden is preventable, a significant opportunity exists to improve population health outcomes, enhance productivity, and ultimately increase societal well-being. However, the current health systems are underutilising this potential. Today's preventive efforts are largely confined to vaccination, surveillance, and screening. Despite the promise of personalised prevention, the stratified and siloed health systems, as currently structured, are unlikely to deliver the full benefits. Prevention will need to be integrated more deeply into care models, ensuring that innovation in prevention is reflected in the implementation capacity.

Transformative solutions are emerging. As one example, pharmacogenomics offers the potential to tailor treatments to individual patients based on their genetic profiles. By identifying how different doses of a medication interact with specific genomic markers, pharmacogenomics can significantly improve the treatment outcomes and minimise adverse effects. It also holds the promise of transforming clinical decision-making, potentially replacing more generalised approaches with precision-guided interventions. However, to fully realise its potential, this field requires sustained support and investment.

While new devices or molecules are often introduced as advancements, **their value depends entirely on how they are integrated into the broader healthcare system**. If not properly embedded within clinical pathways, such innovations risk increasing system costs without delivering proportional benefits, ultimately exacerbating financial pressures on already strained healthcare budgets. **The success of innovation is not just about scientific breakthroughs, but about system-level integration**, equitable access, and real-world impact.

4.1. From Ideas to Impact: Towards an Integrated Ecosystem for Innovation

Europe needs a cohesive and well-integrated ecosystem, supported at both national and European levels, where **high-potential R&D projects can be seamlessly connected to shared infrastructure and expertise**. Stronger infrastructure means a more effective backbone of Europe's biotech and life sciences ecosystem. While start-ups and mid-sized companies are critical drivers of innovation in areas such as drug discovery and development, they cannot build or maintain essential infrastructure, such as preclinical Contract Research Organisations, pre-GMP and pilot GMP facilities, or clinical manufacturing platforms, on their own. These components are capital-intensive, technically complex, and require long-term investment.

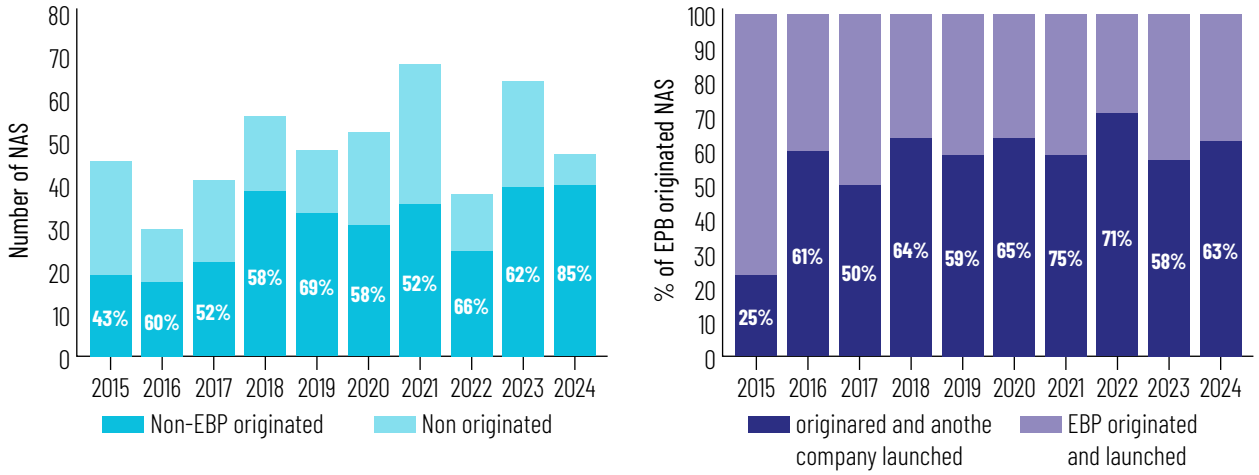
To remain competitive with the United States and China, Europe must be willing to fund high-risk, early-stage biomanufacturing projects that serve as enablers of innovation across the product life cycle. **A holistic view of the full development pipeline** – from discovery to commercialisation – is vital, ensuring that Europe's innovative capacity is matched by the infrastructure and policy frameworks needed to to achieve the effect of scale. As one example of challenges along the innovation trajectory, in the study of the Barcelona-based AI Observatory in Health, only 20 AI-driven developments out of 170 being monitored are currently implemented at scale. The gap between technological maturity and actual deployment highlights the **need for effective integration strategies and real-time monitoring of innovation pipelines** to offer targeted support mechanisms.

As a result, ecosystem support needs to go all the way from the lab to manufacturing. This means **end-to-end development pathways** for strategically important therapies. Although Europe remains a major supplier of active pharmaceutical ingredients (APIs) for innovative medicines, gaps remain in modern manufacturing infrastructure, especially in areas such as mRNA and oligonucleotide production. The COVID-19 pandemic served as a stark reminder: although the BioNTech-Pfizer vaccine was developed in Europe, the first doses went to the United States, owing to its stronger production and distribution capabilities. This underscores a pressing need for the EU to strengthen its biomanufacturing capacity and incentivise modernisation.

To make this a reality, the next EU Multiannual Financial Framework should include sustainable funding mechanisms for the operational capacity of shared research and manufacturing infrastructure, as well as for its scaling and expansion. This requires **moving beyond traditional grant-based models towards hybrid approaches** that combine public investment with service-based revenue models and long-term institutional support.

Speed is of essence, but speed needs to be measured by the time it takes for an innovation to reach the patient. Progress in this field is possible, as demonstrated by the significant strides made by Spain in reducing the time between EMA approval and national reimbursement decisions[26].

Figure 7. Emerging biopharma companies originated 85% of new drugs in 2024 and originated-and-launched 63% of them



4.2. High and Breakthrough-oriented R&D Spending

Given the continued need for scientific breakthroughs, including **in areas like antimicrobial resistance, where the EU can be uniquely positioned to lead**, a sizeable R&D funding commitment, including in the future framework programme is a prerequisite of improving the prospects of Europe's life sciences sector. In the current Horizon Europe programme, the Health Cluster (Cluster 1), which encompasses life sciences, medical research, and health innovation has been allocated approximately EUR 8.25 billion over the seven-year period. In addition, life sciences research receive support through other Horizon Europe components, such as the European Research Council grants, Marie Skłodowska-Curie Actions, and various European partnerships. In order to keep up with the global R&D trends, **a doubling of the current effort would be required**.

In addition, the call for greater flexibility in funding, highlighted in the Heitor report[27], is particularly pertinent to the life sciences sector. This entails **a shift toward more impact-driven funding calls** that are less prescriptive and more responsive to evolving scientific and technological developments. **An enabling environment that fosters risk-taking and agility in funding mechanisms** is essential to ensure timely responses to emerging challenges and opportunities. Moreover, funding structures must be designed to support interdisciplinary and cross-sectoral research, a necessity in the life sciences where progress relies on collaboration across diverse scientific domains. Increased investment in high-risk, high-reward research is also crucial to analyse breakthroughs with the potential to transform healthcare and other life science-related sectors.

While simplification is essential, harmonisation across all funding instruments is not always desirable. **R&D programmes need to be fit for purpose** given that the research process does not follow the one-size-fits-all logic. Specific tools might be needed for different parts of the R&D value chain, whether it is discovery, early development or late development.

In the scoping of R&D, all health solutions need to be covered that result in better outcomes for the patients or increase efficiency of the healthcare systems. **Gaps need to be identified where the EU does not perform sufficiently well, as is the case in advanced therapies.**

Research expenditure needs to be part of a fully connected and integrated funding system from the outset. This means **close coordination and bridging of research, development, innovation, and implementation**. Existing and emerging partnerships, such as the European Partnership for Personalised Medicine, seek to ensure that from the very beginning, starting with the design and funding of research projects, there is a clear pathway toward clinical application and system-wide adoption. Embedding this continuity early on is critical to translating scientific breakthroughs into real-world impact for patients and health systems. Researchers should be supported not only in conducting high-quality science but also in ensuring that their work has real-world relevance and impact. This includes integration of implementation research considerations from the outset and fostering **a culture that values innovation pathways as part of the research lifecycle**.

Public-private partnerships (PPPs) play a critical role in bridging the gap between early-stage research and large-scale deployment by combining strengths of public research institutions with the resources, agility, and market access of industry. They go a long way towards supporting the connection between research and real-world healthcare impact. **Sustained EU-level commitment to PPPs** will not only promote faster innovation cycles but also help align research priorities with societal needs, enhance cross-sector knowledge transfer, and reinforce Europe's competitiveness.

4.3. Collaboration Schemes and Innovation Hubs as Drivers of Change

Life sciences flourish in collaboration and benefit from targeted support through the formula of world-class innovation hubs. They are optimal settings to facilitate transfer of publicly funded research to market given their experience in technology transfer mechanisms and creation of shared innovation spaces. There are already prominent examples of such hubs in Europe - the BioValley in France, GoCo Health Innovation City in Sweden, Leiden Bio Science Park[28], the CRISPR cluster in Vilnius or the Kraków LifeScience Cluster. Others, such as a major innovation hub for life science and quantum technology in central Copenhagen, are being developed. EU funds, including Horizon Europe and the future framework programme, should support core enablers of such hubs. Partnerships and collaborative research initiatives in the EU have proven highly effective in connecting life science hubs across Europe. Strengthening and integrating these connections by **bringing together the various clusters in the European innovation network** would significantly enhance the impact and cohesion of the continent's life sciences landscape.

Mechanisms that promote collaboration and avoid duplication of effort include **data spaces and European Research Infrastructures (RIs)**, which play an important role in facilitating cross-border and interdisciplinary collaboration by providing access to cutting-edge technologies, standardised services, high-quality data and interoperable platforms across Europe and internationally. The RIs are a single-entry point for industry to access data and expertise. They should further **develop their service offering and enable on-demand sample and data collections** to become more responsive to industry needs and accelerate R&D processes.

The European Life Sciences Strategy should promote **the role of RIs in sustaining data resources over the long-term**. It should also reflect on the impact of the current global disruptions on data flows, calling on Member States to invest more thoroughly in their data infrastructures and for this investment to be connected across countries effectively. Data infrastructures should also be connected better with projects and programmes that are generating the data.

Innovation does not happen in isolation but across teams, sectors, companies and countries. **Collaboration can take many forms[29]**, and include:

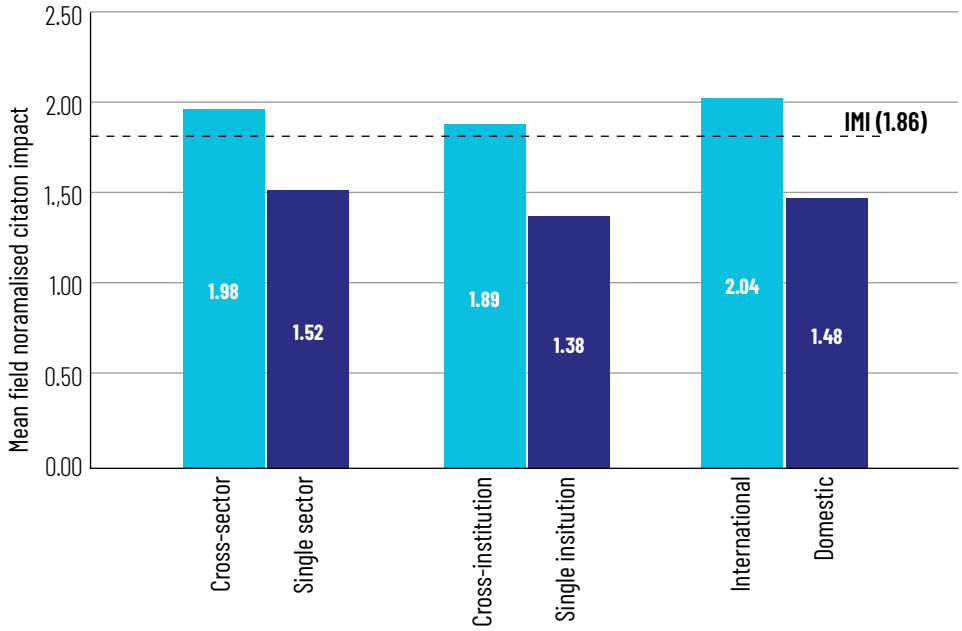
- typical **project-based collaborations** like those funded by the Innovative Health Initiative, where industry and academia work together to solve real world challenges,
- new models of **PPPs like OpenTargets[30]**, aimed at delivering pre-competitive insights for systematic drug target selection and based on the collaboration of industry and academia around open platforms for target validation data,
- **Data-centred projects**, exemplified by ELIXIR's collaboration with DeepMind, which developed the AlfaFold model to solve 3D protein structure by training their LLM on the publicly available data through the Protein Data Bank.

There is also a growing tendency of software companies in Europe to anchor their entire business model on **ingesting data from public repositories**, repurposing and mixing with proprietary data from pharma companies to develop new knowledge.

To optimise collaboration, one needs to **connect not only the organisations but also the capabilities they bring from different dimensions:** research, regulation, civil society, patient or industry. If we look at the medical technology sector, industry partners, such as those involved in Innovative Health Initiative projects, have unparalleled engineering capabilities. Pursuing advanced imaging or advanced radiotherapy is not possible without the expertise and technological capabilities of industry. Scientific excellence and collaboration with industry should not be viewed as opposing forces but mutually reinforcing ones. Evidence from the IHI shows that research papers involving cross-sectorial, cross-institutional or international collaboration are

significantly more cited than the those produced within a single institution or country[31]. This demonstrates that collaboration drives greater scientific and innovation impact.

Figure 8. Numbers of single sector and collaborative publications in IMI2 (H20202) projects to date (SpringerNature)



Source: IHI (presentation of Niklas Blomberg, Executive Director of IHI, at the LifeSciences4EU conference.

For the ability to collaborate to be turned into a true competitive advantage of Europe, bottlenecks need to be addressed. Some of the challenges in collaborating have to do with the fact that universities and hospitals are often seen as reactive. Solving this question should be part of the DNA of the forthcoming European Life Sciences Strategy.

4.4. Unlocking Innovation Through Enabling Regulation

Europe's regulatory framework must evolve into a **true enabler of innovation**. Today, it is not sufficiently designed for innovation. The current level of complexity, divergent implementation across Member States, and the relatively slow pace of approvals and market authorisations present substantial obstacles. Regulatory authorities should be equipped with adequate resources to provide sustained support to developers throughout the innovation cycle. Furthermore, the integration of digital tools and AI should be accelerated to simplify processes, reduce administrative burden, and move toward a more streamlined and cohesive European regulatory system.

Simplification, an important political objective for the current European Commission, **can make a substantial difference in the area of life sciences**, removing barriers to innovation. Similarly, consistency across regulatory frameworks is needed, with numerous barriers that could be removed through relatively straightforward legislative adjustments, many of which have already been submitted for consideration. Given the evolving nature of the regulation affecting the life sciences sector, a more extensive recourse to AI sandboxes is needed, to enable the testing and validation of emerging approaches.

In addition, interpretation of existing regulatory frameworks, particularly as they apply to emerging technologies, is a challenge. When developing tools based on machine learning or other advanced algorithms, innovators often face uncertainty in how regulatory standards should be applied, underscoring the **need for clearer, more adaptive guidance from authorities**. Regulatory rules need to be **future proof** as well. The ongoing revision of the pharma legislation is needed since the previous package was agreed 20 years ago, but the new framework needs to remain relevant for a considerable time.

In this context, a recurring concern among the stakeholders is the slow pace of legislative and regulatory action in the EU. **The timelines associated with EU-level initiatives**, such as the proposed Biotech Act, with legislation expected no earlier than 2026 and full impact possibly not felt until 2029, **are widely viewed as insufficient to meet the urgency of today's innovation and health system challenges**. While necessary steps like public consultations and impact assessments are crucial for inclusive and evidence-based policymaking, there is growing pressure to **accelerate pathways from proposal to implementation**.

Rolling out the Health Technology Assessment (HTA) Regulation, Clinical Trial Regulation (CTR), and the European Health Data Space (EHDS) demands urgency, and careful coordination. **Success hinges on meaningful dialogue with those responsible for implementation:** payers in the case of HTA, and hospitals for clinical trials. A more focused approach would help streamline efforts, especially as innovation spans both small molecules and advanced therapies, which should be seen as complementary rather competing paradigms.

To achieve more immediate progress in enabling innovation, **action is needed on the basis of coalitions of the willing** - Member States and institutions - ready to act faster within the boundaries of existing legislation, to pilot new solutions and deliver early results. The EU HTA Regulation, which entered into force in January 2025, includes **a provision for voluntary collaboration** among Member States. This provision offers a strategic opportunity to go beyond the mandatory Joint Clinical Assessments and create a more integrated and harmonised HTA landscape across Europe. Voluntary collaboration can serve as a platform for Member States to jointly address systemic challenges, such as divergent methodologies, inconsistent evidence requirements, and varying timelines, that currently hinder efficient market access for innovative health technologies. By working together, national HTA bodies can align their approaches, share best practices, and co-develop tools that enhance the predictability and quality of assessments.

Ongoing reviews and updates of the regulatory framework have to clarify inconsistencies, overlaps, and contradictions between different aspects of the legislation. The forthcoming revision of the MDR and IVDR regulations is **an opportunity not to be missed to increase predictability, proportionate surveillance and promote innovation**. In order to do so, there is merit in designing a patient-centric central governance structure to set a strategy and take decisions for the entire medical technology sector in the EU and take responsibility for the functioning of the European market for all medical technologies[32].

In addition, the **current mandatory re-certification process should be removed** for medical devices every five years across all risk classes. A higher level of transparency and predictability for companies in the certification process is needed, as well as a streamlined procedure for innovative medical devices in the EU. The certification process concerning product updates should also be reviewed. While the current efforts by the European Commission to clarify existing regulation in implementing acts will be helpful, they do not remove the need for an overhaul of the existing legislation. Similarly, the work of the Medical Device Coordination Group on developing guidance and launching a pilot project in Q4 of 2025 on **accelerated assessment of breakthrough innovative devices** is important but will need to be followed by regulatory changes.

There should also be **streamlining of the regulatory process for combination products**. Combination products now account for up to 25% of the pharmaceutical pipeline, while the EU regulatory system remains fragmented with separate authorities for pharmaceuticals, medical devices, and diagnostics. This points to the need for a more effective coordination across authorities involved in certifying combination products, shortening the time-to-market. Roles and responsibilities of notified bodies, national health authorities and the European Medicines Agency should be clarified, and a "one-product" approach for combination products established, with a designated authority support.

The EU should also **recognise and support platform technologies**, such as mRNA, as foundational assets. While the US FDA has already classified mRNA as a platform technology – enabling faster and more flexible development pathways – the EU has yet to adopt a similar regulatory stance. Its lack may be impeding the acceleration of advanced therapeutic development in Europe. There is some recognition of platform technology master files in the proposed EU pharmaceutical legislation, but it is currently limited to Chemistry, Manufacturing and Controls (CMC) and quality-related aspects. This narrow application does not reflect the full strategic potential of platform technologies across the entire product life cycle, from early development through the regulatory approval and commercial deployment, particularly in fast-moving fields like mRNA, gene therapy, and synthetic biology.

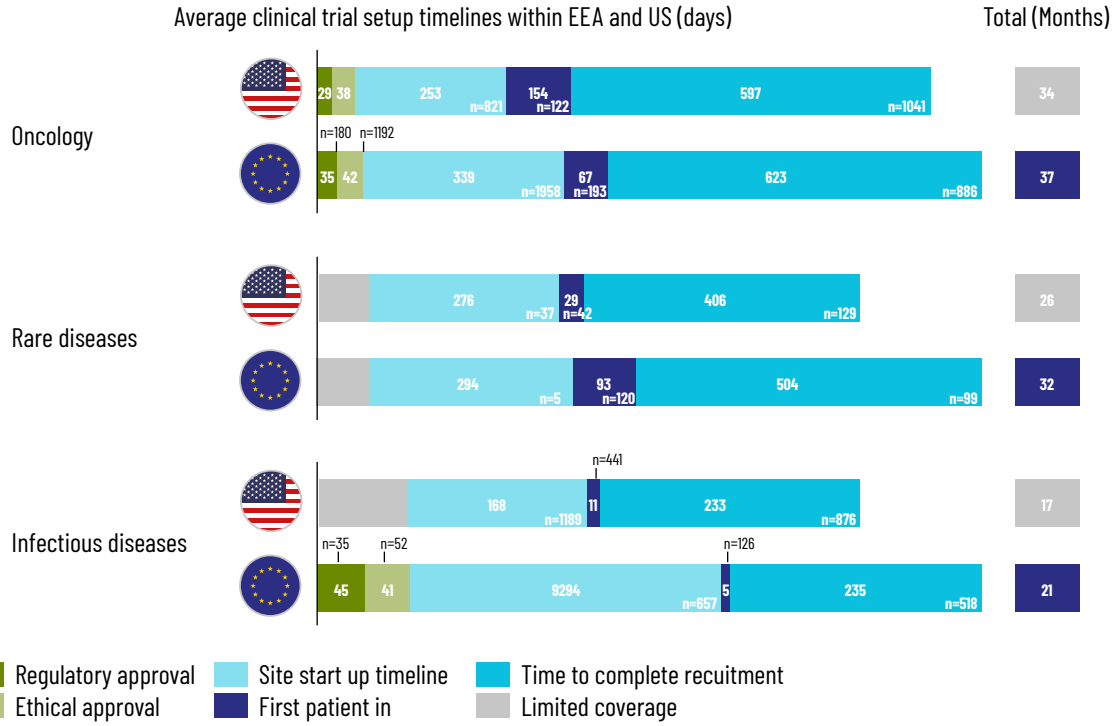
A **predictable and enforceable IP system remains the backbone of innovation**, offering legal certainty and encouraging investment. This principle remains vital as Europe reviews its IP framework. While the recent compromise on the Pharmaceutical Package upholds the 8-year base for regulatory data protection, it does shorten market protection to one year, introduces modulated exclusivity tied to access and supply obligations, and expands the Bolar exemption to include HTA and pricing & reimbursement activities. To maintain confidence in its IP system, Europe must ensure innovators that rewards such as the Supplementary Protection Certificates, patents, RDP, and market exclusivity can be reliably enforced at the Member State level.

4.5. Modernisation of the Approach to Clinical Trials

The greatest opportunity for advancing medicine development in Europe lies in establishing **a robust and modern clinical trials ecosystem that facilitates efficient multi-country trials**. This would represent a critical milestone in realising the full potential of the EU Clinical Trials Regulation (CTR), fostering simplification, flexibility, and cross-border collaboration in medical research. To achieve this goal, harmonised dossier reviews by National Competent Authorities and Ethics Committees across Member States should be ensured.

In 2021, the EMA launched the **Accelerating Clinical Trials in the EU initiative**, which brings together the Commission, the EMA, and all the national competence authorities in the Member States, to examine how the infrastructure for clinical trials can be improved, including decentralised trials, adaptive trials and digital solutions. The goal is to enable better, faster and smarter clinical trials, in a joint effort with healthcare professionals, industry regulator, regulators, academia and Member States.

Figure 9. Longer trial timelines in the EU



Source: Clinical Trial Repository, presented in IQVIA / EFPIA-VE, "Assessing the Clinical Trial Ecosystem in Europe", August 2024.

As part of **the new European Medicines Agency's network strategy to 2028**, the intention is to transform the clinical trial ecosystem and engage in a **substantial initiative on driving digitalisation from an organisational perspective**. The EMA has made substantial efforts to harness real world data, launching DARWIN EU® as a federated data network which enables access such data from the health systems. This helps to complement the regulatory decisions on medicines. The agency uses Artificial Intelligence and big data analytics to help improve its decision making on processes.

To remain globally competitive and better serve patients, **clinical trials in Europe must become faster to initiate, more seamlessly integrated with healthcare delivery, and consistently driven by real-time data**. Regulatory processes need to be streamlined, with harmonised ethics approvals, and digital infrastructures that allow for continuous data flow between clinical care and research environments. Trials must also be designed for cross-border accessibility and scalability, enabling wider patient participation and accelerating the generation of evidence across diverse populations. Embedding trials within routine care settings, supported by interoperable data systems and adaptive trial designs, will be key to reducing startup times, lowering operational costs, and improving the relevance and impact of trial outcomes.

Conditions should also be put in place for **embedding of platform trials** across the Member States. Their funding should also be ensured through the future Framework Programme.

The potential for **enhanced collaboration among the able and willing Member States should also encompass the implementation of the EU Clinical Trials Regulation**, which includes provisions for voluntary coordination. Under this provision, Member States have the option to rely on a joint assessment of clinical trial applications in Part I assessment phase, which covers scientific and technical aspects. The legal framework, allowing one Member State to act as a Reporting Member State,

whose conclusions can be adopted by others, remains underutilised. In practice, many countries still carry out separate reviews, leading to unnecessary duplication and delays. **A more European approach requires not only researcher collaboration, but also institutional trust and regulatory coordination**. Enabling and incentivising Member States to fully embrace existing flexibilities could significantly accelerate clinical trial approvals, reduce administrative burden, and improve access to innovation across the EU.

One of the most concrete opportunities for accelerating innovation in Europe lies in the **streamlined approval of clinical trials**. Under the CTR, it is already legally possible to conduct single, harmonised approvals across Member States. This regulatory framework allows sponsors to submit a single application for multi-country trials, with coordinated assessment procedures between national authorities. Yet in practice, fragmentation persists, often due to inconsistent implementation, procedural delays, and a lack of political or institutional will to fully leverage the available tools. As was pointedly noted during the LifeSciences4EU conference, *"**We can do single approvals across Europe if we want – so can we please want it?**"*. This underlines that mindset and incentives should support what the legislation already enables. **A shared ambition to act as one in Europe needs to become an operational practice.**

In the words of another contributor to the Kraków conference, "*if it takes us ten years before we see the effects, it is too slow*". In a rapidly evolving innovation landscape, Europe cannot afford to wait a decade for regulatory changes to translate into real-world impact.

4.6. Making Life Sciences Data Actionable at Scale

Data is the foundation for innovation in life sciences. The establishment of the European Health Data Space, the first common data space to enter into force, is a forward-looking and ambitious project which brings the promise of radically improved access to data for research and healthcare. It enables **the creation of a single market for data** and data-driven innovation. The concept of the EHDS envisages the establishment of an infrastructure to enable the sharing of large, anonymised health data sets for the purposes of research, innovation and policymaking by the national Health Data Access Bodies[33]. The EHDS Pilot Project has now presented all its deliverables with recommendations and analyses aimed at enhancing data interoperability, ensuring regulatory compliance, and establishing foundational frameworks for the European Health Data Space[34]. In the next phase, the EHDS could serve as a foundation for leveraging AI to support and enhance healthcare across the EU.

Diagnostic tools developed using harmonised regional datasets can be validated and then envisage **integration of new data sources, via the EHDS, to assess and enable their broader applicability**. Such an approach is particularly relevant in the context of personalised medicine, where the quality and diversity of integrated datasets, encompassing factors like age, sex, and genomic background, are critical to ensuring clinical relevance and equity.

Integrating multi-omics data, including genomic, proteomic, metabolomic, and environmental information, **represents one of the most complex yet promising challenges in the transition towards personalised prevention**. The approach remains technically and conceptually demanding, but holds transformative potential for more effective, targeted interventions. The boundaries between prevention and treatment are often blurred, highlighting the need for more integrated lifecycle-based approaches.

More emphasis is needed on **promoting effective data management practices**. A recent Innovative Medicine Initiative (IMI; precursor to Innovative Health Initiative) eTRIKS project (European Translational Information and Knowledge Manageement Services) provided tools and guidelines that SMEs could adopt to enhance data quality and interoperability in their respective projects. The subsequent European Health Data & Evidence Network (EHDEN), also funded under IMI, aimed to harmonise health data across the EU by mapping it to the Observational Medical Outcomes Partnership (OMOP Common Data Model. EHDEN certified SMEs in data curation and quality assessment. They were then trained to standardise and curate diverse healthcare datasets. The result is a large cohort of companies with a uniform methodology that can now work as contractors under the Darwin system. The life sciences industry should be actively engaged in the implementation of this approach, supporting efforts to **standardise existing data sources and elaborating a common data model**[35]. In parallel, realising the potential of common data spaces, progress needs to be achieved at the grassroots level, through implementation within the hospital environment[36].

CLINNOVA is an example of cross-border collaboration involving France, Germany, Switzerland, and Luxembourg, whose goal is to unlock the potential of precision medicine through data federation, standardisation, and interoperability. The initiative develops AI algorithms to improve health outcomes and utilises federated learning to develop more accurate models of disease progression and validate digital biomarkers. CLINNOVA has implemented a federated learning proof of concept for MS segmentation of MRI images[37]. Emphasis is placed on data quality to develop AI algorithms for personalised treatment and translational research, highlighting the importance of standardised and interoperable data in refining clinical endpoints.
See: https://www.clinnova.eu/en/

4.7. Rethinking Clinical Trial Execution with AI

According to ACT-EU, Europe's clinical research ecosystem faces **two persistent and interconnected challenges affecting clinical trial execution:** chronically low patient enrollment rates and inefficient, fragmented, and often manual data workflows. These issues delay innovation, increase costs, and place additional strain on healthcare professionals already working under pressure. Removing these roadblocks is particularly critical for the development of cross-border clinical trials and studies requiring complex datasets, including those in personalized medicine.

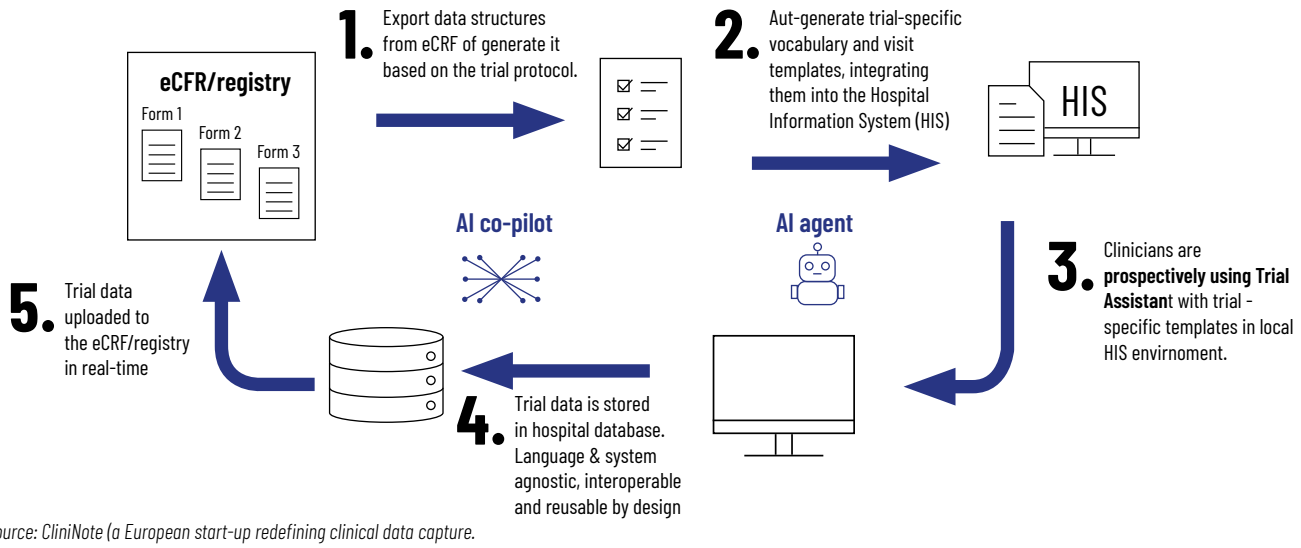
At the LifeSciences4EU conference, CliniNote introduced the ACRE AI initiative as a direct response to these systemic challenges. ACRE AI (Advancing Clinical Research in Europe with AI-powered Data Framework) addresses key bottlenecks by **rethinking how trial data is captured, structured, and reused-at the source.** Grounded in digital transformation, clinician empowerment, and real-world interoperability, the initiative proposes a modular, AI-enabled approach that reduces manual workload, enhances data quality, and ultimately helps more patients access clinical trial opportunities faster.

The framework is aligned with the ambitions of ACT-EU and the emerging European Health Data Space (EHDS). It seeks to address key bottlenecks in trial activation and execution by:

- Standardizing clinical documentation and data while improving interoperability across countries, languages, and systems by creating an additional layer of co-pilots and AI agents on top of the existing infrastructure;
- Automating patient-trial matching with AI agents that can reason over both structured and unstructured data (retrospective approach);
- Facilitating clinician- and patient- assisted recruitment through embedded tools used during medical interviews (as part of a prospective on-site approach);
- Improving data quality, minimizing queries, and enhancing risk monitoring via real-time data management and reporting.

By enabling faster, more inclusive, and more efficient clinical trials, ACRE AI has the potential to significantly enhance Europe's competitiveness in life sciences innovation - a key objective of the European Life Sciences Strategy.

Figure 10. AI-supported Clinical Trial Data Framework (ACRE AI)



Source: CliniNote (a European start-up redefining clinical data capture.

4.8. The New Funding Paradigm

The path from discovery to impact is not a short sprint but a complex, multi-stakeholder journey that requires coordinated scientific, regulatory, and commercial expertise. **Funding is a critical enabler throughout the process.** A major barrier to progress is the misalignment between how public funding is structured and what innovation requires. Too often, early-phase public investments are designed with the primary goal of producing publications, rather than generating exploitable, translational data. To address this, there is a pressing need to **rethink funding models and coordinate actions of the different funders longitudinally**, giving them access to trusted third parties with deep domain knowledge, and providing mechanisms to review, monitor, and evaluate projects based not only on academic outputs but also on their exploitation potential. This shift is essential to ensure that promising therapies, such as gene and cell therapies, progress beyond the lab and ultimately reach patients.

EU funding needs to incorporate **a greater component of risk-taking**. The margin needs to be greater for testing new scientific hypotheses, not only moving along established pathways. This means **shifting the balance further towards breakthrough innovation**. In addition, flexibility needs to be greater for adjustments when the environment changes. This is crucial for greater participation in EU-funding schemes on the part of the business actors, given that reacting to market shifts is of crucial importance from their perspective.

Addressing the funding gap needs to be achieved by a range of initiatives covering all aspects of the funding cycle. **Life Sciences should become one of the pillars of the envisaged new EU Competitiveness Fund**, pulling together different budgetary envelopes to create a one-stop-shop, ensuring continuity of funding and overcoming the enormous complexity of

funding instruments, while not dismantling the specificity of the different tools, which is needed to support developments in a tailor-made fashion. The Competitiveness Fund should build connectivity between the different programmes, and fund more milestones, rather than aim to do everything in one single effort.

The way EU-level funding is channelled and implemented across Member States should be better harmonised. Today, in numerous programmes, funding is distributed through national agencies, each with its own set of mechanisms, and administrative processes. This fragmentation creates inconsistencies, inefficiencies, and barriers, particularly for start-ups, SMEs, and research institutions trying to navigate multiple national systems. To address this, there is a clear need for greater alignment across the funding pipeline, from EU-level allocation to national disbursement.

One of the persistent barriers to innovation, particularly in Central and Eastern European context, is **the narrow and rigid interpretation of funding eligibility criteria**. At the LifeSciences4EU conference, stakeholders expressed concern that public authorities often require revenue-matching thresholds (e.g. 30% of project costs), which can be disproportionately burdensome for startups and mid-sized companies. It is these smaller companies that often lead the early development of first-in-class and best-in-class small molecules, which later reach patients through collaboration with larger pharmaceutical firms. A technology-driven funding approach, rather than a goal-driven, patient-oriented framework, can lead to systemic blind spots. For example, some promising drug candidates may be excluded from national or EU-level support simply because they are not labelled as "biotechnology" in the narrowest sense. The guiding objective for policymakers should be **funding solutions that improve patient outcomes in a technology-agnostic way**.

There is ample ground for **simplification of funding schemes**. Although the European Commission has invested in making the 2025 Horizon Europe Work Programme more accessible and user-friendly, with wider use of simplified cost options, such as lump sum grants, and removing unnecessary financial reporting requirements for beneficiaries, a significant further effort would be needed to make a real difference.

In addition, a new **European Life Science Investment Fund (ELSIF**), is needed, which would be in the position to **attract institutional investors and carry out direct co-investments in life science companies alongside venture capital funds**. By co-investing with trusted VC partners, the fund would allocate more capital to promising companies beyond the capacity of single VC funds alone, while leveraging their expertise and deal flow. Investing alongside experienced VC firms offers a layer of diligence and validation, making the syndication safer for public or institutional investors. It would result in stronger scale-up financing, improved capital efficiency. The ELSIF should incorporate **a late-stage venture fund to address the need for scaling**. This would help to accelerate the growth of life science-companies and make it easier to retain them in Europe.

EIT Health is actively supporting the later-stage scaling of companies in Europe, including through its **Venture Centre of Excellence (VCoE) strategic industry-VC co-investment programme** co-designed and operated with the European Investment Fund (EIF). This programme has supported over 160 start-ups to fundraise more than EUR 5bn in their latest fundraising rounds, including many in Series B, C and beyond. Moving forward, this initiative could be scaled to support further SMEs at later stages, gathering together the necessary financial resources and key actors to address their scale-up needs[38].

Apart from innovative project funding, **demand-based pathways to commercial revenue are equally important**. Pricing and reimbursement systems remain the primary mechanism for market access. The EU needs to reflect on new payment models, to ensure emerging solutions are available to the patient. In addition, innovation procurement plays an important role.

Innovation procurement tools, such as pre-commercial procurement (PCP and public procurement of innovative solutions (PPI), hold significant potential to drive forward new technologies and services. However, these instruments are often underutilised due to their complexity and the limited number of actors currently equipped to apply them. Expanding the use of these tools will require dedicated capacity building and better alignment between innovation policy and procurement practice.

EIT Health operates several initiatives supporting the early procurement and pre-procurement of innovation, including the HIPSS and Add4Kids programmes ensuring that the principal buyers of innovation — deploying it in turn at scale and equitably across population groups — are able to validate new ways of accessing innovation quickly, safely, and efficiently[39].

Finally, to effective support Europe's start-ups and small biotech companies, there is a growing need for **more innovative and diverse partnering mechanisms**. Traditional funding models, such as institutional joint undertakings, may not always provide the speed, flexibility, or accessibility required by early-stage innovators. For this reason, Europe should expand its toolkit to include new forms of partnership models that enable collaboration across sectors, regions, and company sizes, facilitating faster matchmaking, supporting cross-border consortia, and enabling more dynamic public-private-philanthropic partnerships.

4.9. Towards a Global Hub for Talent

Attracting and retaining talent is a cornerstone of any successful health innovation ecosystem. This requires strategic coordination between government, academia, and industry. Given the intense global competition, **technology may paradoxically prove to be the easier part of the life sciences revival in Europe than harnessing the brain capital**. Boosting the competences and skills of people working in life sciences is a strategic long-term prerequisite.

Successful talent retention cases highlight the importance of comprehensive approaches. In Ireland, for example, companies were literally built on the doorsteps of universities. This proximity of industrial facilities to university campuses enabled **seamless transitions from education to employment**. Similarly, Singapore has built a reputation for actively attracting companies by providing robust administrative, regulatory, and workforce support, effectively "rolling out the red carpet" for business and innovation.

Making Europe an attractive destination for talent in the area of life sciences is a function of successful action in building a strong pro-innovation ecosystem. Nevertheless, **dedicated upskilling and reskilling support is also needed to build capacity, especially in the emerging areas such as AI, genAI, genomics and deep tech**. A number of EU-supported initiatives and networks offer comprehensive training, research, and innovation opportunities, including EU-LIFE Alliance, a consortium of leading life science research centres, which offers PhD and postdoctoral training programmes and develops training resources, or Life Science Academy for Startups, which supports early-stage life science startups in Denmark, Sweden, and Norway.

Developing a strategic learning partnership would go a long way towards scaling up existing efforts. This could take form of a coordinated, pan-European effort, styled after the successful European Battery Alliance Academy, a gateway to all the educational European training providers to "stay on top and ahead of the e-mobility innovation curve".

In the area of digital skills and training, **greater support is needed for initiatives that enable trainers to scale life sciences and digital education across Europe**. While face-to-face instruction remains valuable, particularly for hands-on or clinically oriented learning, expanding access through high-quality online courses and digital learning platforms is essential for broader reach. EU-level investment should prioritise scalable, interoperable training models that ensure consistent skill development across Member States, support workforce mobility, and respond to the evolving demands of the life sciences and digital health sectors.

4. From Vision to Reality: Driving Life Sciences Innovation in a Complex Ecosystem

The European life sciences sector faces **a once-in-a-lifetime opportunity** to strengthen its role as a driver of innovation and a pivotal area of growth in the European economy. Its success in transforming health outcomes is a function of how it will succeed in this effort. Past achievements are a good starting point but will not suffice in the face of growing international competition and worrisome internal trends.

Innovation is no longer a good-to-have but a must-have. It is the only way of addressing the challenge of chronic and age-related diseases that the EU can easily find overwhelming without a significant effort at increasing its innovative potential. **Building trust with citizens** has never been more critical. The rise in vaccine hesitancy underscores the urgent need for sustained evidence-based dialogue with the public. Many citizens are not in a position to fully engage with or understand scientific information, partly due to disinvestment in education systems. This means that **innovation in the life sciences sector has to be pursued in conjunction with society**.

Some changes must be of institutional nature. The calls for the establishment of an EU Office for Life Sciences[40] or a European Life Science Council[41], bringing together representatives from key European institutions, authorities, academia, patient organisations, and industry, underline the need for strategic coordination and cohesion. Regular monitoring of the competitiveness of the European life sciences industry through a tracker of key sector-specific indicators would be most helpful.

There is also an **important task of implementation of innovation in healthcare**. One needs to find an efficient way to work with the cash-stripped healthcare systems, which are coming under increasing pressure, to ensure that innovations are rolled out in practice[42].

Given the multiple pressures and vulnerabilities as well as geopolitical tensions, **the European Life Science Strategy needs to be integrated with the EU's efforts to ensure the security and resilience of its supply chains in critical sectors**, which include healthcare, medicines, and medical technologies. A strong European life sciences sector is one that can consolidate Europe's strategic autonomy and economic security, and drive competitiveness. In addition, the strategy needs to be **designed as a process** to enable learning and continuous adjustments, and to remain in sync with the exponential pace of technology development. A learning mindset and supportive structures are necessary.

In this way, a **trajectory towards lasting global leadership** can emerge. From stronger academic-industry-healthcare collaboration, de-risking mechanisms for private investments, reducing market fragmentation, and addressing the talent gap through upskilling and reskilling, **the question is not which actions to pursue but how to execute them all at once** in a coordinated and meaningful fashion.

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The debate on the future of the EU Life Sciences sector will continue under the Danish EU Presidency, including as part of **"TOGETHER4HEALTH. Achieving sustainability in health care and beyond"** conference of the Danish EU presidency, which will take place in Aalborg, 16-18 September 2025.

The conference will focus on the transformation and integration of the healthcare systems and sectors. It will examine how the demographic challenges are impacting healthcare. The focus will be placed on how cross-institutional collaboration can drive the development of prevention, diagnosis and treatment solutions. Themes such as new investment and funding instruments, technologies, sustainability, equality, innovation, procurement, and prevention will be explored. The conference will gather stakeholders from the entire healthcare ecosystem, including policy makers and government representatives, public health and regulatory authorities, universities, research organisations, healthcare professionals and practitioners, industry, investors, patient organisations and civil society.

In addition, the Copenhagen Life Science Summit, a two-day high-level conference, will take place 8-9 October, as part of Denmark's EU presidency 2025. It will be an opportunity for representatives of the European life sciences sector to exchange insights on the European Life Science Strategy. The event will explore ways of consolidating Europe's position as a leading life science region.

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